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consent to medical care

PROTECTION OF LIFE SERIES

STUDY PAPER

Canada

CONSENT TO MEDICAL CARE

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A Study Paper prepared for the
Law Reform Commission of Canada

by

Margaret A. Somerville

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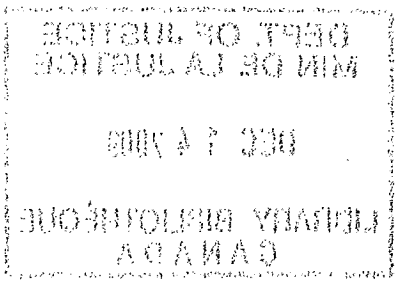

Notice

The following Study Paper is part of a series of research undertaken by the Law Reform Commission of Canada on protection of life issues.

The author is Professor Margaret Somerville from the Faculty of Law of McGill University. She attempts to clarify the difficult problem of consent to medical acts.

The opinions expressed in this Study Paper are entirely those of the author and do not necessarily represent the views of the Commission or of the Commissioners. The Law Reform Commission of Canada would welcome however any reaction, criticism or comments from the reader. They should be addressed to:

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Introduction

Consent is a legal concept and a factual reality. It has many areas of operation and many purposes, but in the medical situation it has the primary functions of regulating risk-taking and controlling invasion of privacy. The way in which this regulation and control is effectuated in any particular medical circumstances, will be determined firstly by which principles of the legal concept of consent are applicable and by their substantive content, and secondly by the reality of the factual presence of consent. This paper seeks to analyze the legal and factual basis on which consent rests, for the purpose of establishing a comprehensive picture of the doctrine's operation in the medical relationship.

Consent is a fundamental concept in both criminal and private law, and in Common Law and Civil Law legal systems. Thus it is necessary to explore each of these dimensions to assess accurately its sphere of influence in Canadian Law. This means that it is impossible to conduct a comprehensive analysis of the doctrine and, at the same time, respect the traditional division of legislative powers under the *British North America Act.*[1] In other words some matters which are purely of provincial jurisdiction must be considered if the total concept of consent is to be developed as an analytical tool. That this development is necessary at a Federal level, for instance for criminal law purposes, can be demonstrated by a fundamental example: without consent, except in a justified situation of emergency, every medical operation would be an assault. Thus consent is an essential part of the criminal law. Although, from a Federal jurisdictional point of view, it would be desirable to approach an analysis of consent through the criminal law, most of the doctrine and case-law relevant to the doctrine's application in the medical relationship is found in the private law sphere. For this reason the plan of this study is to first examine consent as part of the private law medical relationship, and then to assess the role of the criminal law in controlling this relationship particularly the part that the doctrine of consent plays in such control.

As well as crossing federal-provincial jurisdictional barriers, the concept of consent may be treated comparatively in the more traditional comparative law sense of this term. This is a particularly fruitful exercise as consent is a concept subject to recent and still developing evolution, especially in the medical relationship, in Canada and in other jurisdictions which are comparable with Canada.

Consequently, the materials which will be used in this study are comparative in more than one sense and are gathered in Civil Law from Quebec and France, and in Common Law from Common Law Canada, England, the United States of America and Australia.

CHAPTER I

Fundamental Principles Underlying Consent

A. RIGHT OF SELF-DETERMINATION

The right of self-determination expresses the principle, or value choice, of autonomy of the person. Mill[2] espoused this principle when he reasoned that one is only justified in intervening with the liberty of another for self-protection as did Devlin[3] to the extent that he claimed each must be allowed to pursue his or her own way. Other authors[4] put forward self-determination as one of the basic principles of a democratic society and this is expressed in the belief that the values of democracy are individualism, freedom and personal dignity[5] Freund[6] sees the individual as having a qualified right of free choice and self assertion[7] and Capron[8] regards a competent person as needing the law's protection of his interest in being able to choose. Fried envisages as the "ideal good", a social union of "autonomous person[s]" in which "each person's individual self-respect and sense of integrity are fostered and reinforced by the conditions of mutual cooperation in which the value and integrity of others is simultaneously affirmed".[9] Applied to the medical relationship between doctor and patient, this postulates a complex balance between personal autonomy and the limits of this right in respect to one's own, or the use of, another's body.

Some sociologists have suggested[10] that the reason that autonomy has heavy value-weight in a society, for instance the American one, is cultural. American society has high regard for an active, rationally based, mastery of life, and for any achievement that blends individualism with a humanitarian sense of social responsibility. Hence, in American society, it is an accepted and acceptable

notion that one may exercise one's autonomy to become, for example, a volunteer subject of medical research.

The commentators referred to so far, are all from Common Law jurisdictions. One finds, on examining the writings of Civil Law jurists, that the principle of self-determination is also present, but not so much at the apex of the pyramid of values. Decocq[11] expresses respect of autonomy as an influencing, but not overriding, value in any decision. Kornprobst[12] sees the value as even more subordinate to other principles.

In a book on socialist law relating to the person, Nizalovsky[13] compares the approach of the Civil and Common Law systems to the principle of autonomy. He finds a wider prohibition on self-mutilation in Civil Law and, to some extent, a contrast in Common Law as expressed by the latter's belief that each man is master of his own body. The former view may be seen as an expression of paternalism, which is the opposite of self-determination. In a paternalistic approach the motive is to do good to the individual, which, negatively stated, is also to prevent harm to him. The motive behind self-determination is the right *per se* and, outside of seeing the right itself as a benefit, encompasses neither motives of good nor harm regarding the individual. The motive behind any limitation to the latter principle may be seen, consistently with the principle itself, as that of preventing harm to society, not to the individual as such.

This right to self determination may, to some extent, depend for its existence on whether one has an open or closed legal system. In an open legal system all that which is not prohibited, is permitted, which accords with a principle of self-determination, subject to some limitations. In a closed legal system all that which is not permitted, is prohibited and, thus, the right of autonomy is not *sui generis*, but given by law, and, at least to that extent loses some of its own internal, autonomous characteristics.[14] It is also, at least theoretically, more limited in its external operation, as any novel situation will cause prohibitions rather than permissions to arise.

Although differing in theory in their approach to the autonomy value, it is more difficult to assess how far apart the Civil and Common Law are in practice regarding this principle. The right to self-determination has been reaffirmed in many cases at Common Law. Perhaps the most famous and often quoted rendition, is that of Mr. J. Cardozo in *Schloendorff v. N.Y. Hospital*,[15] that: "Every human being of adult years and sound mind has a right to determine

what shall be done with his own body.'' Prosser supports this view: ''It is a fundamental principle of the common law that *volenti non fit injuria*—to one who is willing no wrong is done. The attitude of the Courts has not, in general, been one of paternalism. Where no public interest is contravened, they have left the individual to work out his own destiny and are not concerned with protecting him from his own folly in permitting others to do him harm''.[16] So do such commentators as Skegg,[17] who concludes that the Common Law places great importance on the individual's interest in deciding for himself what is done to his own body.

There may, however, be reason to question the true extent of the principle, as it is only probable, and not certain, that the Common Law will uphold the right of a fully competent adult to refuse treatment.[18] Spece[19] states that human autonomy is the value which is presumed to exist in establishing a right *against* treatment and in the fact that this can be waived to allow treatment.[20] But the operation of this right is not absolute according to Fleming,[21] who initially justified a doctor acting in an emergency without the consent of the patient, or his relatives where applicable, on the basis that ''the law place[s] a higher value on the preservation of life than on the inviolability of the human body''.[22] Interestingly, Fleming has altered this justification in a very recent edition of his work, to one based on ''the humanitarian duty of the medical profession''.[23] This is not inconsistent with the previous justification, but probably some inference of doubt as to the validity of the former must be drawn from its omission.

The previous discussion raises the question, what is the relationship between autonomy and inviolability? Autonomy allows the will of the person to dominate, and the factual result arising from the application of this principle coincides with that of inviolability when the expression of will is to protect self-integrity. Inviolability, on the other hand, may have two contents of meaning. It may connote that one is not justified in treating another without his consent, but is justified in doing so with it, in which case it is merely a particular application of the autonomy principle; or it may indicate a principle that protects a person's physical and mental integrity against non-beneficial acts by the person himself, or others, when it is a preservation of life value.

Consequently, under a principle of autonomy, which includes inviolability in the first sense discussed, one could properly allow a personally non-beneficial act which would be prohibited under a

ruling doctrine of inviolability in the second sense. Fleming, in the earlier statement quoted, is using the principle of inviolability in the first sense, and therefore sees a conflict between touching without consent, which this principle prohibits, and saving life when the unconsented to touching is necessary to this end. It is preferable, I submit, to define the principle of inviolability in the second way, which is how many Civil Law jurists see it,[24] and as having the purpose of preserving life, health and well-being. The first sense of the principle of inviolability is not lost, but would still be, and perhaps even more effectively implemented under the doctrine of autonomy. Such an approach leads to a clearer analysis especially in areas where values conflict and thus must be hierarchized, as it separates the preservation of life value from the autonomy one. In using the terms as defined, Fleming is in reality saying that the Common Law ranks preservation of life above *autonomy* and one could add, that one of the values supporting this preservation is inviolability.

This proposition needs further investigation however, as Fleming makes it clear that both the earlier and later justifications he has proposed for medical interventions without the consent of the person involved, refer to a conflict of the values of autonomy and preservation of life in a situation where the person is factually unable to consent, that is, when there is no possibility of exercising personal autonomy. In this case, no matter how it is justified, preservation of life overrides a strict application of the doctrine of autonomy[25] and this result also coincides with the aim of the principle of inviolability. But what is the position if the patient refuses necessary treatment? In the previous edition of his text, Fleming had replied that the policy of life preservation "may be so strong as to justify medical treatment . . . even *against* the wishes of the patient in order to save his life . . . ".[26] This has been amended in the latest edition to read that "[i]t is extremely doubtful . . . whether our law would permit such an intervention, even to save life, against the declared wishes of a mentally competent adult or guardian of a minor".[27] Thus when a person is capable of consenting and refuses to do so, the conflict between the values of self-determination and preservation of life becomes overt, and the most accurate statement one can make with respect to the law is that it is far from clear which value a Common Law Court will support as prevailing.[28]

Kornprobst[29] states the Civil Law approach when he argues that one can treat without consent, on the basis that the health of the individual is a social good and it is a crime against society to refuse

such treatment. Further (he argues), the doctor's "right to cure" gives him the right to act without consent. These statements bring into focus the relationship between self-determination and consent. The latter of these two concepts will be analyzed later in this paper.[30] This relationship exists because consent is the legal mechanism by which the principle of autonomy is implemented and respected and, to the extent that consent is not required, autonomy is not the dominant value. The question which arises with regard to autonomy is, are there any limits to the type of procedures to which one may consent or which one may refuse. This is to be distinguished from the question of how, having established the limits if any, one effectively consents.

It is in the area of determining to what procedures one may consent, rather than which one may refuse, that limitations to the principle of autonomy appear most obviously to be recognized at Common Law. It can be argued that any such limitation is not an exception to the rule of self-determination. Rather the limitation on the right falls within the autonomy principle itself, as formulated by Mill,[31] if it is justified on the basis that it is necessary for the "self-protection" of society. Here one can see that the difference between the Civil and Common Law is one of degree, rather than kind as the same justification is being used. Kornprobst[32] for example supports imposing necessary but refused treatment on the basis of social good. The Common Law will arguably not impose treatment, but, one step removed and like the Civil Law, refuses to allow consent to procedures it sees as harmful to the collectivity.[33] The strongest example of this principle is the rule that one cannot consent to a criminal offence.

In Civil Law jurisdictions, apart from specific legislative provision, the breadth of the right to consent to bodily interference is, *prima facie*, limited to personally therapeutic interventions,[34] although justifications may arise under the doctrine of necessity. For example, until recently, when legislation on living-donor, organ transplants was introduced by the French Parliament,[35] operations on such donors were justified on the basis of "l'état de nécessité" of the recipient.[36] The right to consent is broader at Common Law in that non-therapeutic medical intervention is not *per se* illegal, and is consented to and carried out regularly, but the legal limits are unclear.[37]

In summary all relevant jurisdictions recognize a principle of autonomy or self-determination, the limits of which depend on public

policy, and which are most strongly expressed in the criminal law. Traditionally these limits are wider at Common than Civil Law but in practice, except for the prohibition of non-therapeutic medical experimentation in France, the actual limits may not be very different. Further, one must recognize that what those limits are, at any time, is a reflection, basically, of the culture in which they exist[38] and hence they are not static.

Finally one should note a value which may be confused with self-determination, and which is highlighted by Bereano,[39] who makes the point that "*participation* in decision-making" is a value in itself. However this is a different value from self-determination if it envisages shared, rather than sole decision-making authority regarding oneself. The difference arises if one intends by the words "decision-making" to mean *decision result* in the sense that some form of majority will prevail, rather than the *decision-making process* which is consistent with a policy of self-determination, which requires information input from other sources.

B. RIGHT TO INVIOLABILITY

As already discussed[40] this is a principle related to autonomy, and in the Civil Law to some extent governs aspects seen under the doctrine of autonomy in Common Law. But most importantly, regardless of jurisdiction, this is one of the most fundamental principles underlying the criminal law.

From the discussion on autonomy I suggest one may conclude that the Common Law envisages this right as having schizophrenic attributes. It is possible to either employ it as a positive, self-protective institution or to use it in a negative, self-destructive way. Further it appears that the Common Law generally assumes that a person will act in his own "best interests" and that this will usually be self-protective viewed subjectively, and ideally objectively as well. Consequently the right to inviolability of the body should be seen as falling within the positive aspect of autonomy and as limited to the extent that the negative "anti-life-preserving" aspects of autonomy are validly exercised and take precedence.

The Civil Law is less inclined to leave to chance the decision to act in a self-protective way and has a well developed doctrine of inviolability of the human body, which arises from a basic moral

presupposition of respect for human life. Laget[41] refers to this as the "most fundamental rule" and Jonas[42] as the "primary rule" needing no justification but rather exceptions to which must be justified. Mayrand[43] takes a similar approach when he says that the principle is not absolute, but can be derogated from in the interest of higher values—for example for reasons of love or altruism and, naturally, in recognized self-interest such as therapeutic surgery. Decocq regards "le caractère sacré de la vie humaine" as giving rise to this right and duty of inviolability, which he describes as "le respect de la personne humaine".[44] It is worth noting that Decocq recognizes "le respect de la volonté humaine",[45] that is the right to autonomy, but only in so far as it applies to support life.

The same view is expressed by Mayrand when he says: "C'est précisément dans le principe de l'inviolabilité de la personne que puise la justification d'une intervention imposée. L'inviolabilité de la personne a pour but sa protection; or, les droits doivent êtres exercés dans le sens de leur finalité. Ce serait fausser le droit à l'intégrité corporelle d'un malade que de lui permettre de l'invoquer pour faire échec à ce qui peut conserver sa vie et, par la même, son intégrité essentielle".[46] In order to complete the picture, one must acknowledge that the matter is not fully settled in Civil Law. For instance Savatier *et al* seem to consider the person's will as dominant and that the inviolability principle supports this when they say "le premier attribut juridique de chaque personne est l'intangibilité de son intégrité corporelle et des principes de sa vie. Il n'y peut être touché, même par le médecin, qu'avec son consentement".[47]

Thus one may debate whether the purpose of the inviolability principle is to preserve autonomy, in which case it parallels the common law self-determination value, or to preserve life and health when this aim will justify overriding a patient's will which is to the contrary. In the former case the principle, consistently with the aim it is designated as serving, will be absolute; on the same reasoning, in the latter case, it will be only relative. This distinction allows one to support the view that the principle of inviolability does apply at Common Law but under an autonomy preserving rationale, whereas at Civil Law it applies in its life and health preserving capacity.

Nerson[48] approaches these principles of autonomy and inviolability from a slightly different and instructive aspect. He sees the "valorisation" of the body as arising from an "inspiration individualiste" and underlining "la necessité de protégé l'intégrité physique de l'individu".[49] In classical Civil Law the body was

neglected, but modern Civil Law has developed obligations of security, ''dans une jurisprudence enfin consciente de la nécessité de protéger les personnes''.[50] Now the problem is how far one can derogate from this principle for such purposes as non-therapeutic experimentation, living-donor organ transplantation, or euthanasia, for, as Nerson says, ''le principe d'inviolabilité n'assume pas seulement la défense du corps contre les atteintes des tiers, mais aussi contre le pouvoir de disposition de l'individu lui-même; des restrictions sont apportées à l'autonomie de la volonté: l'inviolabilité a pour conséquence l'indisponibilité du corps humain''.[51] In order to assess the current situation one must balance this statement against the fact that there has been ''[un] recul du principe de l'indisponibilité du corps''.[52] The problem that now faces each jurisdiction is to work out the limits to which this recoil ought to be allowed to extend, which is regulated through the doctrine of consent and its operation in criminal and private law.

CHAPTER II

The Doctrine of ''Informed'' Consent

''Informed'' consent is a private law doctrine which has become so significant to any discussion of consent that it must be investigated first.

The content of the doctrine of ''informed'' consent can be seen within three main overlapping areas: capacity or competence, information or knowledge, and voluntariness. In the first part of this section capacity will not be in issue, as I will deal initially only with the ''normal, capable, adult subject'' with respect to whom a presumption of both legal and factual capacity operates. Information and voluntariness, on the other hand, are both relevant considerations with respect to such persons and will be examined.

''Informed'' consent is probably the single most discussed topic in medical law, to such an extent that at times, it seems to overshadow everything else. This is dangerous, as it engenders a feeling that, provided one ensures that ''informed'' consent is obtained, the situation is legally and ethically acceptable. Such may not be the case and I prefer to see ''informed'' consent as a necessary, but insufficient protection of the normal adult subject, operating within a framework of protections.

The two platforms from which one often views ''informed'' consent are informing and consenting, and I will look at these first. Then one must study the effects of mistake, deception, coercion, or duress, on the validity of the consent. Such a comprehensive enquiry

covers all the positive and negative aspects of the requirements of information and voluntariness. Additionally, under the duty to inform the patient, I will examine the duty to hand over medical records, which is a duty to inform, but not for the purposes of ''informed'' consent. Then, in the following section, I will examine the relationship between consent and the increasingly recognized right to privacy.

A. INFORMING THE PATIENT

1. The duty to inform the patient or research subject for the purpose of obtaining ''informed'' consent[52a]

This duty is related to assessment of risk. This is so because assessment of risk defines some of the factual content of the information which must be imparted and, in the therapeutic situation, may affect the extent of the duty to inform. The duty to inform the patient is also part of the fiduciary duty of a doctor, that is, part of the doctor's special duty of care and trustworthiness.[53] Outside a fiduciary relationship, although there are obligations not to misrepresent or deceive, there may be no positive obligation to disclose, and a person's consent to an act is usually valid when he knows the nature of the act, although he may be ignorant as to its consequences.[54] The fiduciary relationship changes this situation through its *uberrimae fidei* effect, which imposes a duty on the doctor to ensure that the patient is informed to a much wider extent than just with respect to information relating to the nature of the act, in default of which any consent given is inoperative.[55]

There are two major points to be taken into account in formulating the duty to inform the patient. Firstly the conduct which is legally required to fulfill the duty to inform must always be assessed *in relation to the circumstances* in which it is applicable and, therefore, according to whether the situation is non-therapeutic or therapeutic. In the latter case, the degree of need of the patient for the treatment, the probable effect of the information on the patient's state of health, the magnitude of the harm threatened by the medical intervention, and the chance of the harm occurring, are all relevant factors affecting the standard applicable to the duty to disclose. These variables are related, so that the greater the patient's medical need, the more the chance the information will harm his health, the less the magnitude and likelihood of occurrence of the risk, the more

justification the doctor has in not fulfilling his duty to otherwise fully disclose the nature and possible consequences of the intervention.[56]

Secondly, I suggest, that in order to decide the content of the duty to obtain "informed" consent in any particular situation, it is relevant to ascertain the purpose one seeks to achieve by requiring it.

One may explain the purpose of "informed" consent from many viewpoints which are discussed in detail later.[57] But from the aspect of disclosure, there is a need for information in consent in order to respect non-physical aspects of persons—their thought-process and therefore their humanness.[58] Generally authors[59] describe the right being protected by consent, which is but one aspect of the total purpose consent may serve, as the right of the patient to decide for himself what should happen to him, that is the protection of his integrity or inviolability, and autonomy.[60] As proposed before,[61] these aims are not always mutually compatible, and in defining the duty to inform, one may as in other areas have to choose between them. Although autonomy mandates full disclosure and understanding before consent is given, this could in fact be harmful to a patient's state of health. Disclosure could threaten the physical or mental well-being of the patient, that is it may, arguably, not respect his right to inviolability whereas non-disclosure could be construed as a threat to his autonomy. In these circumstances both the Civil and Common Law allow an exception to the duty to inform, often called a "therapeutic privilege".[62] It is obvious when one understands the justification for this exception that it could only apply to an intervention for the therapeutic benefit of the patient, and not for instance to non-therapeutic medical experimentation. This is undisputed in the literature.[63]

This is a specific example, but in general biomedical research on persons is one of the medical situations in which the consent issue is brought most sharply into focus. Therefore it is fruitful to examine biomedical research in relation to the duty to inform the patient.

Slater v. Baker,[64] the earliest recorded Common Law case which makes mention of experimentation in medicine, actually proposed as the purpose of requiring disclosure to the patient, "so the patient can take courage". It is interesting to ponder how applicable today such a reason for requiring the patient to be informed might be. After all, in knowing more we know that we know less of the total that could be known, and although the increase in knowledge means less risk from disease, at the same time it creates iatrogenic risk.

Paradoxically, it also means that it may be harder for a patient to "take courage" in the face of what he knows, or is told, is unknown.

On examining codes and guidelines as well as some subordinate legislation relevant to human medical experimentation, one finds frequent and consistent reference to a duty to inform the patient. The Nuremberg Code requires "full knowledge";[65] the United Kingdom Medical Research Council insists on "adequate explanation";[66] the United Kingdom Royal College of Physicians calls for a "full explanation";[67] the American Medical Association requires "disclosure . . . a reasonable explanation . . . and an offer to answer any inquiries";[68] the Declaration of Helsinki says that the subject must be "adequately informed . . . ";[69] the Medical Research Council of Canada states that "accurate and complete information" should be given;[69a] the United States F.D.A. regulations require that the researcher "inform" the patient;[70] that country's D.H.E.W. regulations specify that the research subject's "informed consent" be obtained, which is defined *inter alia* as "a fair explanation . . . a description . . . a disclosure . . . an offer to answer any enquiries . . . and an instruction . . . ";[71] and "La Charte du Malade Hospitalisé" of France, states patients must be given "les information sur leur état qui leur sont accessibles".[72]

The documents cited here are relatively modern and demonstrate that in all jurisdictions, even the ones that show early recognition of this duty to inform a patient, there has been recent evolution of either the duty itself where it was not previously acknowledged, or its content where it was. This reflects a change in attitude which can be gauged by realizing that the Hippocratic Oath, the most universal medical ethical guide until recently, had no such requirement.[73] As late as 1957, a Quebec commentator wrote that a doctor could presume consent to ordinary medical treatments and there was no need for him to give information to the patient unless asked for it.[74] Boucher *et al*,[75] also speaking of the situation in Québec in this respect, cite a case, *Brunelle v. Sirois*,[76] which states that in this jurisdiction a tendency to give more information to the patient can be traced during the 1960s. Similarly, Boyer Chammard and Monzein, writing of France, note that the necessity for a clear consent, including a duty to inform, only developed in the 1950s in that country.[77]

It seems that the duty to inform a patient was recognized earlier and developed more strongly in Common Law.[78] Although this phenomenom is undoubtedly just one expression of a complex of

sociological factors, which includes the community's perception of the role of a physician, it is possibly related to the dominance of the autonomy principle in those jurisdictions in combination with a less forceful approach to the inviolability of the body rule with respect to non-therapeutic interventions. This approach was premised on a philosophy that the person was his own best protector and clearly, in order to be this, he needed to be properly and adequately informed, especially in the medical situation where there is a knowledge and competence gap creating inequality.

The question now is what is the extent or scope and depth or content of the duty to inform or, asked another way, what is the standard applied to determine whether a doctor has fulfilled this duty?

Firstly there is a fundamental choice which must be made between seeing the obligation as honoured by giving the required information to the patient, and on the other hand requiring that the informant ensure either objective or subjective comprehension by the patient.[79] The latter is obviously the most demanding and difficult criterion, but it alone fully maintains the concept that consent involves understanding. That the patient is understanding of the information required to be given to him under the doctrine of "informed" consent is necessary for a legally valid consent, appears to be more and more accepted,[80] and is strongly recognized throughout two recent Canadian cases, *Kelly v. Hazlett*[81] and *Reibl v. Hughes*.[82] In the former case the patient's apparent consent was held to be vitiated specifically because the plaintiff did not understand the risks and the doctor knew this.[83] In the latter case the doctor was held liable in battery and in negligence, the Court stating, with respect to liability in battery, that "a physician [has] a strict duty to explain to his patient, in language which the patient can *understand*, the essential nature and quality of the treatment he is to undergo";[84] and, in relation to negligence liability, that the doctor must "take sufficient care to convey to the plaintiff and *assure* that the plaintiff *understood* the gravity, nature and extent of risks specifically attendant on the [procedure]".[85]

The most frequent argument against a requirement of understanding by the patient is that it is impossible to attain with non-medical persons. In this respect Garnham[86] makes a worthwhile distinction when he says that there is a difference between requiring understanding of technical details and comprehension of possible medical and social consequences. The latter should be required in

relation to all medical interventions, but in certain cases it may be crucial to legal and ethical validity. The point is that if, for instance in a non-therapeutic research intervention, a person does not understand the possible risks of what he is undertaking, he is not a volunteer. As a consequence, unless there is some other justification applicable to the intervention, one has moved outside any altruistic rationale and moral justification based on this, for allowing experimentation to take place. Thus it seems comprehension should normally be required as an element of the duty to inform and be mandatory when the situation is non-therapeutic, which is to propose a governing concept of ''informed and understanding'' consent.[87]

It is, however, legally difficult to monitor a totally subjective requirement of comprehension by the patient. An intermediate position has been suggested by Capron, that ''the physician could be held responsible for taking reasonable steps to ascertain whether the information presented has been understood . . . '',[88] that is a test of ''apparent subjective understanding'' by the patient of the information required to be given to him.

Thus in setting a standard to which the physician must adhere in relation to understanding by the patient of the information he is given, one has the choice between requiring: actual subjective understanding; apparent subjective understanding; and objective understanding, that is, the ''reasonable patient'' would have understood, whether or not the particual patient did.

If one chooses ''apparent subjective understanding'' as the standard, a similar standard should equally be applied to govern which information should be withheld. When in other words it may be a breach of duty to give the patient certain information. This occurs if the doctor knew, or ought to have known if he had taken reasonable steps to find out, that disclosure of the information would harm *that patient*.[89] Further, it is worth considering here whether there is at least a difference in nuance between a doctor's duty to withhold information and his doing so pursuant to a claim of ''therapeutic privilege''. ''Therapeutic privilege'' is not a wide doctrine and probably only applies when to disclose the information would cause recognized physical or mental harm to the patient.[90] Yet it possibly applies as a justification for non-disclosure more extensively than only when the doctor would have breached his duty of care, or committed fault, by making a disclosure. Clearly, however, there is a central core where both concepts are coexistant.

The important points to underline are that the doctrine of "therapeutic privilege" applies where its conditions precedent are fulfilled, within the "pure" therapy situation, that it never applies in non-therapeutic interventions,[91] and only rarely, if ever, does it apply in therapeutic research;[92] nor could a doctor breach his duty of non-disclosure to the patient or research subject by informing him of a risk or consequence of a medical experiment.

One must now examine the extent of the duty to inform, that is the range of factors which must be disclosed, and how in any particular situation this is to be assessed. The most frequently formulated general tests are described in terms of materiality or relevancy: that is either the factors must be disclosed which are subjectively material[93] or relevant[94] to that patient in deciding whether to participate in that procedure;[95] or objectively, the doctor must disclose what a reasonable patient in those circumstances would want to know.[96] This approach, whether the subjective or objective standard is used, marks a change from the extent of the necessary disclosure being determined by the medical profession, or according to medical custom, to assessment by lay standards. In the United States of America, the most noteworthy case demonstrating this change is *Canterbury v. Spence*.[97] Such a development, if it has occurred in other Common Law jurisdictions, is not documented as yet in their reported cases and this is clearly an unsettled area of law in all jurisdictions.

It is necessary to consider, however, whether this last statement needs modification in relation to the jurisdiction of Ontario, in view of the two recent cases on consent to medical interventions mentioned previously. These are interesting but complicated with regard to who sets the standard for the content of the disclosure. In the earlier one, *Kelly v. Hazlett*,[98] Mr. J. Morden, in specifying tests to determine what information must be disclosed by a doctor to avoid liability, firstly in assult and battery, or secondly in negligence, says that the former requires disclosure of "the basic nature and character of the operation"[99] and the latter of "collateral risks",[100] with only the latter being "determined with the assistance of expert medical evidence on what would be the proper scope of disclosure".[101] In regard to setting the standard of disclosure for this latter class of risks, any analogy to the American case-law, which holds that the content of "the duty is based upon the notion of what a reasonable patient might be expected to wish to hear in order to make up his mind",[102] was expressly rejected. It seems, however, that a "lay" standard would apply to disclosure of risks in the former class, as a

necessary implication from the fact that expert evidence is not needed with respect to these.

The difficulty thus becomes one of characterizing any particular risk within the suggested division, in advance, in order to determine whose standard applies, the patient's or the reasonable patient's[103] on the one hand, or the doctor's on the other. This proposed division may cause problems in prospective interpretation of the conduct required by law of the medical profession with respect to disclosure;[104] it could also, rather arbitrarily, alter liability through its effect, which the Judge recognizes, on "matters [such] as the incidence of the onus of proof, causation, the importance of expert medical evidence, the significance of medical judgement, proof of damage and, most important of course, the substantive basis upon which liability may be found",[105] which are "more than . . . matter[s] of mere academic interest".[106]

Likewise there is controversy in the Civil Law as to what must be disclosed to a patient[107]. The generally accepted formula in France appears to be that the information must be "simple, approximative, intelligible et loyale".[108] Vidal and Carlotti[109] say this means the patient must be told the essential elements which are determinative of his choice. Mazeaud and Tunc[110] note that "il suffit de lui donner une idée raisonnable de la situation et de lui permettre de porter un jugement raisonnable." These statements are consistent with, and expositive or determinative of, the general attitude of French jurisprudence towards the duty of the doctor to inform the patient. This appears to be less stringent in scope, content and application than in either Quebec or Common Law North America.[111] This assessment of the French law must be balanced, however, against the emphasis in Civil Law on the patient understanding the information which is given[112] which, within the scope of the disclosure required, is a more demanding standard than that often applied at Common Law. This approach may indicate a preference for subjective standards, which is generally true in Civil Law jurisdictions including Quebec, and consequently that the test of relevancy or materiality of what must be disclosed is subjective, rather than objective. This really means fulfillment of the duty is assessed from that particular patient's standpoint and not from that of a reasonable patient, nor from that of his doctor, nor of a reasonable doctor.

Although such a standard is the ideal, it may place an unfair burden on physicians, as well as giving any injured patient the advantage of "hind-sight" in claiming that an undisclosed risk was

material to him, and I suggest the test of disclosure should be based on the standard of what a reasonable patient in those circumstances would consider to be relevant information, with an additional subjective test that if the doctor knew, or ought to have known, that certain other information was considered relevant by a particular patient, than this as well must be disclosed.

These are rather general formulations of the duty to disclose, which are necessary if only to indicate that there are several possible approaches to filling in the content of this duty, which content is continually changing and, further, must be adapted to each set of circumstances. It is possible, however, to formulate a general but not exhaustive substantive standard and to name some more particular instances of the type of information which should be given to a patient. The general rule is that the disclosure must at least include a fair and reasonable explanation of the nature of the procedure and of its risks.

With respect to explaining the nature of the procedure this will usually be accomplished by describing, in general terms comprehensible to the patient, the procedures to be carried out and their inevitable consequences as compared with their risks.

In regard to risks, obviously if these are not known they cannot be disclosed, but usually the very fact that there are unknown risks should be. This is probably the same duty as that formulated by the Court in *Fiorentino v. Wenger*[113] when it held the doctor was in breach in not disclosing specifically that the proposed procedure was novel and unorthodox. Waltz and Scheuneman[114] acknowledge such a duty to reveal that there may be unknown risks, but go even further than this and postualte a duty of "risk discovery" in innovative therapy, which amounts to applying, and complying with, the ethical-scientific principles such as prior animal experimentation, bio-statistical assessment, and "herald" or cooperative trials. In other words disclosure that all risks are not known does not exempt a physician from liability for not disclosing risks which should have been known. It may even be that a certain degree of lack of medical-scientific knowledge of risks may make "informed" consent impossible, although all prior ethical-scientific requirements have been complied with and disclosure made of the fact there are unknown risks. Such was a holding, *inter alia*, of the Court in the *Kaimowitz Case*,[115] in prohibiting a particular experimental psychosurgical procedure.

The most comprehensive statements of the categories of risk that must be disclosed prior to a medical intervention are set out in relation to human medical experimentation in the Regulations of the Department of Health Education and Welfare (D.H.E.W.)[116] and the Food and Drug Administration (F.D.A.)[117] of the United States of America.[117a] But, even these I submit, are still incomplete, at least for the non-therapeutic situation. For example the D.H.E.W. definition, which is the more generally applicable of the two, states that "[t]he basic elements of information . . . include:

> (1) a fair explanation of the procedures to be followed, and their purposes including identification of any procedures which are experimental;
> (2) a description of any attendant discomforts and risks reasonably to be expected;
> (3) a description of any benefits reasonably to be expected;
> (4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;[118]
> (5) an offer to answer any enquiries concerning the procedures; and
> (6) an instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject."

The F.D.A. Regulations,[119] which govern only experiments with "investigational drug[s]", expressly require a patient or subject to be informed that he may be used as a control, if this is, in fact, the case. Such a disclosure requirement, as well as the more specific ones relating to "the nature, expected duration, and prupose of the administration of [the] . . . drug [and] the method and means by which it is to be administered . . . ",[120] are, presumably, included within the requirement of "a fair explanation of the procedures to be followed" of the D.H.E.W. regulations.

Extensions to the D.H.E.W. definition which have been suggested, include a duty to disclose the overall purpose of the research,[121] which would be particularly important if medical research were not restricted to medical purposes.[122] It is possible that some patients or subjects would agree to participate in research having one general purpose but not another, even if both of these are medical: for example a pregnant woman may agree to be a subject of research aimed at improving the well-being of foetuses, but not to the same research if it was designed to advance abortion techniques. It is surely for subjects to decide what purposes they choose to promote by their participation.

Connected with this duty to disclose the general purpose of a medical research undertaking, is a subsidiary one of disclosing the

source of the research funding. This is a safeguard which would be effective in some circumstances, in putting subjects on notice of questions they may want answered before agreeing to participate. Another valuable disclosure for similar reasons of "giving notice", is that suggested by the World Health Organization[123] in relation to the conduct of drug trials, which is that additional renumeration of investigators for conducting research be disclosed to subjects.

I would suggest that it is not sufficient to disclose that alternative therapies are possible, but that the doctor must indicate that he will at least make his best efforts to see that these are made available to the patient, and further, that if one of the treatments is experimental and the patient decides to refuse this now, he would retain the option to consent to it at a future time.[124] Such provisions mitigate against any coercion that the patient may feel if he imagines that a refusal of experimental treatment will leave him without any, or adequate, treatment, or close off his options permanently. That is, not only a right to rescind consent must be given, but also a right to rescind a refusal of consent should be considered.

Other recommendations[125] in relation to disclosure of information to medical research subjects are that it should include: the reason for selecting that person as a subject and a note that the potential subject can decide not to participate without prejudice; promises of confidentiality, of compensation, or of non-compensation if this is applicable,[126] and that additional costs to the subject due to his participation will be met.

The way in which required information is delivered to a patient is important from several aspects. These include avoiding coercion and aiding understanding by the patient, not only understanding of the content of the information, but also of his rights in the particular situation, especially those rights not referred to expressly. This means not only speaking to the patient in his own language, but the words selected within the language used must be simple and clear, without mandatory overtones whether overt or subtle, and invitatory, that is expressing that the person has the right to make a decision whether to submit to treatment or not.[127] In the medical research context, but equally applicable in the "pure" therapy situation, Hershey and Miller[128] suggest that this approach can be implemented by referring to the patient's rights in the second person and the researcher's duties in the first person, for example: "You are completely free to withdraw at any time from the experiment", and "if you have any questions, we expect you to ask us", to achieve the

maximum personal impact of the respective rights and duties involved.

Thus there are more problems involved in giving the patient information than just deciding what must be said. It is also a question of how, where, and by whom the information is to be given if disclosure of information, a procedure designed to protect the patient or subject, is not itself to be used as a coercive tool.

As to how and where the information should be given, Martin *et al*[129] suggest that the disclosure process, as well as the consent which may eventuate from it, must be viewed within a "social context". This means one must take account of possible coercive elements in the setting, such as peer group influence or, to repeat, even such simple factors as the tone of the language used to communicate the information and whether this is framed as an invitation, or gives an impression that consent is presumed.[130] The form and style that a disclosure takes are of even further significance as there is evidence[131] that overwhelming a patient with information may decrease his degree of comprehension. In this respect probably the generally applicable ideal is simple, comprehensive language, presented both orally and in writing, with provision of adequate opportunity for questioning by the patient. At least in the non-therapeutic research situation and possibly where appropriate in other instances, there should be a mandatory delay between presentation of the information and obtaining of consent. Gray,[132] after a very detailed empirical study on consent in the therapeutic medical research situation, concluded that the place where the information was delivered was important to the degree of comprehension by the patient, and it affected his decision whether or not to participate in a medical experiment. For example, a patient who has been admitted to hospital may feel less able at that time to refuse to participate in an experiment than he would have if he had been asked one month prior to admission.

As to who should do the informing there are several factors to be balanced: there is a danger of leaving a patient uninformed when the duty to obtain consent is delegated to a subordinate;[133] on the other hand, the more dissimilar a subject is from the physician in terms of education, race, status and economic position, the more likely is the subject to be unaware of the nature and purpose of the medical procedure.[134] Barber *et al*[135] suggest that physicians, especially when conducting research, use mechanisms which protect them from emotional involvement with subjects by limiting their contact with

them, and one of these is having a nurse or intern obtain consent. To overcome this situation it should at least be mandatory for a physician to personally satisfy himself that ''informed'' consent has been obtained. Ideally this should involve some personal interaction between him and the patient, which will act as a protective mechanism for that patient. This may be enforced legally by seeing such an obligation as part of the physician's non-delegable duty to ensure informed consent is obtained, even if this obtaining is carried out vicariously.[136] *Who* gives the information to the patient is seen by Slovenko[137] as *the crucial factor* in determining the voluntariness of consent, and he suggests that other ''health professionals'' should ''dilute'' the relationship with, and information given by, the patient's own physician.

There is a further comment to be made here and this is that the duty to inform the patient is not fulfilled once and for all, but is a continuing one throughout the procedure[138] and even possibly after it is complete, as patients should be warned if adverse reactions become apparent later. Perhaps the most important application of this continuing duty is if new parameters of risk are discovered after consent was obtained but before the procedure is completed. This is especially true if such a development occurs during a controlled trial, as this adds to the problem of deciding when it becomes unethical to continue such a trial. The additional modification required in such circumstances is that it would certainly be unethical to do so without further disclosure and consent.

Finally I would like to briefly mention some corrective mechanisms and safeguards which may be worth using to enhance the protection afforded by the doctrine of ''informed'' consent.

Firstly, as a legal mechanism, one can insist that the patient is not able to waive the right to be informed, at least in a non-therapeutic situation. Then, with respect to imposing legal liability on a doctor for non-disclosure a lenient test of causality should be accepted,[139] such that the failure to disclose need not relate directly to the injury which eventuated. In this respect the approach of the Civil Law, as outlined by Giesen, seems a desirable one. He says that ''[s]elon les jurisprudences française et allemande, prouver un lien de causalité entre l'intervention pratiquée sans le consentement éclairé du malade et le préjudice causé suffit à établir la responsabilité du médecin. Contrairement à la pratique juridique suivie en Grande-Bretagne, les tribunaux ne cherchent pas à savoir si le malade, à supposer qu'il ait été convenablement informé, aurait ou

non refusé de donner son consentement''.[140] The adoption of such an approach would lighten the burden of the patient in proving causation and really means that liability is imposed for loss of a chance to refuse to participate in treatment, an opportunity which would have existed if the required disclosure had been made.[141]

Lombard *et al*[142] compare the effect in French and American Law of a failure of the doctor to inform the patient. In French law, he says, this amounts to ''dol''—fraud—which means the contract is ''nul'' due to a failure of consent. However, failing to inform the patient is not actionable *per se*, but only if the doctor is at fault in making a decision which has untoward consequences, when he is liable for damages caused by this fault, which is aggravated by the fact that he took the decision alone.[143] In comparison, in the United States of America, if the doctor does not properly inform the patient, he is liable for all resulting complications even those caused without fault.[144]

Less legal corrective mechanisms and safeguards for consent, but ones which may enter into proof of the validity of the informing, are a two part consent form,[145] in which the first part gives the information and the second part is a questionnaire subsequently administered to test the degree of comprehension. This is especially important in medical research where only those subjects displaying a sufficient level of understanding may then participate as subjects.

Again in relation to medical research, Hershey and Miller, and Gray, suggest methods which are not directly related to assessing the understanding of the required information by any particular subject, in order to test the validity of the informing. Hershey and Miller[146] believe that a certain percentage of refusals should be anticipated if the risk is properly explained and that the researcher should be required to keep a record of these refusals. Gray[147] suggests one should examine the decision factors considered by the persons who agree to become subjects, in order to assess the validity of their consent, to the extent that this depends on the information given and understood. If, for example, it is an objectively risky study and no subject reports considering risk, or if there is no benefit to the subjects but no reasons of altruism are given, then there is at least evidence that the subjects have not been informed, or have not comprehended the minimally required amount of information for ''informed'' consent.

Any such review of consent should obviously be carried out by a disinterested party and, in fact, this shows another safeguard applicable here, which is peer or committee review of the validity of the consent. At one stage this was even specifically provided for in some D.H.E.W. Regulations,[148] which established special "consent committees" as well as general review boards which also had a duty to determine the validity of the consent given by research subjects.

Rather than just reviewing the consent given, it would also be possible to require participation of an independent third party or parties in the consent process, even including a review committee itself where this was otherwise involved in the situation "to make the consent decision more genuine".[149] In relation to medical treatment carrying any significant risk this is probably the most practical and worthwhile safeguard and such a third party could be a relative of the patient, or someone of his choosing, or a nurse, or medical social worker. As well as helping to ensure proper disclosure by the doctor and comprehension by the patient, such a procedure overcomes any criticism that the doctor rather than the patient made the decision to operate.

To summarize what I see to be a desirable approach to the informing of patients:

(1) all material or relevant risks must be disclosed as well as other factors related to the treatment which could influence the patient's decision to participate, that is, the disclosure must be complete, accurate and not too complicated;[150]
(2) the test of materiality of information should be objective *vis à vis* a "reasonable patient", with the proviso that this test becomes subjective to the extent that the physician knew, or ought to have known, that additional information which would not have been relevant to the "reasonable patient" was in fact material to this particular patient or subject in his decision-making;
(3) the test of required comprehension of the disclosure should be "apparent subjective", that is the doctor must take reasonable steps in relation to the particular patient to ensure that he understood and that objectively, or apparently, he did;
(4) care should be taken that the informing process is not coercive, and possibly in some circumstances an estimation should be made by a "disinterested" outside party in this respect and with respect to the effectiveness of the informing process;
(5) in non-therapeutic experimentation there can be no mitigation of these standards and no waiver of the right to be informed is allowed;

(6) in the therapeutic situation waiver, ''therapeutic privilege'', and a duty not to inform, may all apply depending on the circumstances, but generally there should be a presumption that they are inapplicable, with the burden of proof to the contrary on the person alleging this, and with the rebuttal of the presumption only being upheld when the circumstances clearly indicate it.

2. The duty to inform the patient of his medical record or of experimental results

The other matter which I wish to deal with here, is also a duty to inform the patient, but in contrast with the duty to obtain ''informed'' consent, is more in the nature of an *ex post facto*, or performance of the contract duty, rather than a formation of the agreement or ''consensus'' obtaining obligation. This may be described as the right of the patient to his medical records or to the results of any experiment carried out on him, and a corresponding duty to inform the patient when he chooses to exercise this right, or when it would be detrimental to him not to be informed.[151] The duty is framed in this way because an overriding duty to disclose may be detrimental to the patient. For example, some authors think it is unethical to inform a person of an untreatable prognosis,[152] which I submit is an acceptable approach to the extent that the person does not seek the information.

In many jurisdictions there has been debate[153] regarding the right of a patient to his own medical records, and whatever the decision reached in the normal therapeutic situation, I propose that at least all experimental subjects must be given this right, whether the experimentation was therapeutic or non-therapeutic. There may be some difficulties with such a right. For example the French *Code de la Santé publique*[154] states that a patient may not be told ''la nature des produits essayés, les essais eux-mêmes et leurs résultats.'' In the United States of America the F.D.A. had relied on their argued exemption from the disclosure requirements of the *Freedom of Information Act*[155] to withhold all drug trial results, although the basis for this practice was upset by a court decision[156] holding such information to be generally disclosable pursuant to the Act.[157]

It is a separate question whether restrictions on disclosure would be, or should be, applied against a patient, or a research subject who helped generate results as opposed to an ''outsider'' who seeks the same information. One difference is that in the latter case problems

of consent and questions of privacy and confidentiality may be involved. There are also other reasons which may require disclosure of research results to a patient or subject where this would not be required in relation to a non-subject. For instance, the subject's participation may be regarded as identifying him with the research and earning him some "quasi-proprietary" interest in the results, at least to the extent that he needs these for his own health care. While dealing with this topic, it is worth mentioning that the fact that a person participated in research should be entered on his medical record and, possibly, should be recorded in some central data bank as a means of protecting "ex-subjects" of research from risk.

Another way in which a distinction may be made with respect to the rights of subjects and non-subjects to research results, is by differentiating between rights and duties. For instance the *Freedom of Information Act*[157a] in the United States deals with *rights* to disclosure, but it says nothing of an independent *duty* of the researcher to disclose the results to the patient.

I submit that, except where a doctrine of "therapeutic privilege" would apply, a patient should have at least a right to examine his medical file if he so desires. Further, the subject of an experiment should have a right to know the experimental results related to his participation. For such a subject this right is a corollary to that of confidentiality, as the latter means he has a right *not* to have such results disclosed, except to the extent that he consents to this. If it can be anticipated that having knowledge of his medical record, or experimental results, may harm a patient or research subject, the situation can sometimes be dealt with by a prior agreement that the information need not be disclosed, except where it would harm the patient not to disclose it. Such non-disclosure could always be legally challenged and the burden would then be on the physician, as it is in "therapeutic privilege", to prove that the withholding of information was justified. A legislative example of such a scheme is found in the *Loi sur les services de santé et les services sociaux*[158] of Quebec. This provides that a person

> to whom an establishment refuses access to his record or refuses to give written or verbal communication of it may, on summary motion, apply to a judge of the Superior Court, Provincial Court, Court of Sessions or Social Welfare Court or to the Commission, to obtain access to or communication of it, as the case may be.
>
> The judge shall order establishment (sic) to give such . . . [person] access to his record, or communication of it, as the case may be, unless he is of opinion that it would be seriously prejudicial to the health of such . . . [person] to examine his record.[159]

It may be that in certain circumstances this suggested duty of *ex post facto* disclosure is even more intense, for example when a randomized controlled trial, either double or single blind, has been carried out and the patient has consented to a certain amount of initial non-disclosure. In such cases there may be a duty to inform the participants after the trial has finished of what they actually took or had done to them, again with a restrictively applied exception that this is not necessary where such disclosure may harm the patient. This is a difficult matter to assess here, as some persons may be psychologically upset on learning, for example, that they exhibited profound side-effects when taking lactose tablets.

B. OBTAINING CONSENT OF THE PATIENT OR RESEARCH SUBJECT

1. What is the purpose of consent?

It has been emphasized that one must look at the principles underlying rules which have evolved to regulate the medical relationship, and enunciate the purpose these rules are designed to achieve if one is to judge whether the rules are necessary, or effective, or whether some better system can be evolved. Nowhere is such an approach more needed than in the elucidation of the nature of consent, and in the controversial area of the necessity or otherwise of obtaining it, and in determining what minimum quality of consent suffices as at least the legally, if not ethically, acceptable entity.

What is the purpose of requiring consent? This would appear to be a simple question which is often answered by saying that it is to protect the autonomy and integrity of the individual. But the numerous responses given in the literature are much more subtle in their distinctions than this straightforward, but not very instructive, reply as to how or when the aim is achieved, and some responses may even constitute a departure from this answer. Certainly it is an enlightening exercise to examine some of the opinions and reasons given for requiring consent. Not the least of these is that in dealing with patients unable to consent, one cannot dispense with or substitute for the usual requirement of consent unless one knows why consent is required in the "normal" case. Only then can one tell whether this purpose can be achieved in other ways.

Firstly there seem to be some presumptions underlying the requirement of consent. Gustafson[160] describes these as a moral assumption that a person has a right to determine his own destiny and a philosophical judgement that he is capable of doing so. In the context of medical experimentation, these presumptions are expressed by Beecher[161] as a belief that the researcher has no right to choose martyrs and that society will not tolerate the domination of subjects by researchers, and that it is the function of the "myth" of "informed" consent, to ensure that this is not occurring.

The presumptions underlying consent are given more specific content by Brody,[162] who says that consent used to be seen as necessary in order to establish a patient's interest in a procedure, and that its ability to do this depended on a presumption that the person would act in his own self-interest and for his therapeutic benefit, that is self-protectively. However there has been a change from consent being seen as only promoting this interest in self-protection to its function also including protection of an interest in self-determination.[163] This change eliminates the need for the presumption of self-protection as, if a truly free and informed consent is obtained, whether the results of the procedure to which consent has been given are good or bad for the person in the sense of helping or harming his physical or mental integrity, there is no doubt that at least in his original decision he is being self-determinative. With such a change other presumptions are introduced which relate to the assumption that it is possible to obtain adequate consent and that the right to self-determination is an overriding good, which is to restate and support Gustafson's conclusions referred to above.

In contrast to the presumptions underlying consent there are also some important presumptions as to the nature of consent itself. Jonas,[164] for instance, describes consent as not being a permission but a willing, and Crépeau explains consent as a matter of judgment and will.[165] These statements imply the necessity for some positive element in the concept and purpose of consent, rather than seeing its function simply as a neutralizing of liability which would otherwise be present. In this respect it is interesting to look at the old Common Law pleading of consent which reaches back to Bracton,[166] and which was by way of the term "leave and licence".[167] The defence of consent had to be raised under the general issue, not as a matter of special pleading, which meant it was *not* regarded as a "justification" to be pleaded by the defendant by way of "confession and avoidance",[168] but rather as an allegation that if consent of the plaintiff were present, then the necessary and sufficient elements of a

cause of action in assult or battery for instance, were absent.[168a] I suggest that these words ''leave and licence'' have a much stronger connotation than a mere waiver of legal rights by the plaintiff, as a waiver effect would be more consistent with regarding consent as a justification. Rather they import a notion of positiveness, of intention and willing by the plaintiff with respect to the act perpetrated by the defendant so that the defendant, relying on consent as a defence, admits the act but avoids a cause of action. Thus liability is avoided by the defendant's proving the positive right given to him by the plaintiff to carry out that act.[169]

This leads to, and is consistent with, the purpose which some authors see in consent of transferring power. Paquin[170] says the doctor only has the power given to him by the patient and for this reason needs consent. Annas and Glantz[171] say that consent has been developed to give the patient more power and to equalize the doctor-patient relationship. It is obvious that these authors are starting from opposite presumptions: the former that the patient has the power, which is usually legally and morally true,[172] and the latter that the doctor has the power, which is often more factually realistic.

Shannon[173] also sees the role of ''informed'' consent as related to power, but as part of a more complex structure. He argues that medical researchers, for example, need a wider loyalty or value base than purely self-interest or scientific interest[174] and that therefore they must view membership of a profession as ''a way of integrating the [professional] individual and society''[175] and of ''specifying social obligations and responsibilities''[176] for them. These two factors together will force the professional ''to perceive the research subject as a fellow citizen'',[177] which will *weaken the power of the professional over the subject*. This is the same function that ''informed'' consent plays in the structure. It does this by informing the researcher that he cannot just do what he wishes, and helps the subject to learn that he has rights which must be respected.[178]

Other writers also state that the purpose of consent is to maximize respect for the person,[179] or more specifically to ensure that the patient's interests are considered and respected,[180] or promoted.[181] At the least, such respect requires involving the patient in decision-making which affects him, and may even demand that society's views in this regard are taken into account as well. Consent is one method of promoting this respect for the person, either by setting rules as to what is recognized as a valid consent by an individual or, with respect to direct societal control in the decision-

making, by specifying acts to which one may or may not consent. Recognition that respect for the person must be ensured, whether as a function of consent or in other ways, is essential to recognizing persons as being of moral worth[182] or, in negative terms, to avoid "tampering with human beings, getting at them, shaping them against their will[183] [which] . . . is . . . a denial of that in man which makes them men and their values ultimate".[184]

How effective consent is in achieving this aim will depend to some extent on the degree to which consent is seen as having *only* a symbolic function of maintaining respect for the individual. In relation to medical research, where respect for the person is most important and often most threatened, Freund[185] has argued the worth of the symbolic function of consent. He notes that by symbolizing respect for the individual it forces the researcher to rethink and articulate the experiment in these terms, and has "a valuable reflexive effect on the enterprise itself".[186] That is, apart from raising sensitivity to the subject's rights, consent may promote a medical purpose by having a salutory effect on the actual medical techniques and procedures used. Such a symbolic effect is good, but it is more disturbing to see the defence lawyers in the *Kaimowitz Case*[187] arguing that consent is not necessary because it serves *only* a symbolic function[188]—a different content of meaning and effect than that foreseen by Freund.

In another group of purposes attributed to consent, one finds Calabresi[189] seeing it function as the minimum requirement in striking a balance between present individual lives and future lives in general, and as reducing the directness of the decision to use the former to benefit the latter. This is in accord with his general theory[190] that there is conflict between society's role as protector of the individual, and society's role in deciding when to sacrifice the individual for the common good. Calabresi believes the decision in the latter case must be made indirectly in order to preserve the appearance of the first "protector" role of society, but that the decision, when made, must reflect society's values. Thus to the extent that society allows an individual to consent to medical interventions, by not characterizing such a decision as contrary to "public policy" or "public order and good morals", it allows the individual "via" the mechanism of consent to implement its own latent policy decisions.

Childress,[191] in a related argument, and speaking of medical research, sees consent as decreasing the sacrificiality otherwise

involved in this activity.[192] This somewhat negatively phrased purpose of consent can be compared with the positive ones of only suffering chosen risks,[193] or of generally protecting the patient.[194] Within this latter purpose some authors advocate that consent should be seen as a guideline to help the patient reach total well-being, and not be seen as a goal in itself.[195] The aim here is probably to emphasize that consent is usually a necessary, but not a sufficient condition for ensuring the legitimacy of an intervention.

There is yet another more philosophical and sociological purpose foreseen in consent. Traced in opinions of commentators from various disciplines, this purpose may be termed that of indentification. First of all there is identification of a patient as a person. May[196] says that personhood is a gift each confers on others and that one therefore becomes a person with the help of other members of the community. The consent situation is definitely an inter-personal encounter,[197] the problem being that it may be de-personalized[198] and with this the involved patient may be de-personalized as well. This may be done deliberately, or subconsciously, by a medical researcher, for example, as a self-defence mechanism.[199]

Jonas[200] also speaks of identification, not so much in the sense of seeing the subject as a person, but rather of the strength of that person's connection with the purpose of the proposed intervention. This can be related to the former type of identification because the more strongly the person identifies with the purpose of the research, the more he is participating as a person in contrast to being used as an object. This he sees as the basic principle allowing, or prohibiting, the choice and use of a human subject in medical experimentation. Such identification is achieved, I suggest, by means of the subject's informed and understanding consent to participate in research, research with which he is sufficiently objectively identified.

This same idea of the purpose of consent, that is to identify the patient or subject first as a person and then with the treatment or research undertaken on him, is probably Ramsay's intent when he speaks of consent as showing fidelity,[201] and as demonstrating a common bond between the patient or subject and the physician or researcher, making experimentation for example, a joint venture, a partnership.[202] Further, Parsons[203] describes the same concept in sociological terms when he says consent is a two-way process: of the professional complex to "admit" the research subject to, and of the

subject to accept the status of, membership in the associational collectivity.

Possibly Gray[204] had such an identification-participation idea of consent to medical research in mind when he wrote that the failure to obtain "informed" consent deprives the research subject of an experience, threatens the integrity of the research project as it then becomes inhumane, and is a violation of ethics poisoning the general atmosphere.

A further purpose for obtaining consent may be to achieve certain legal effects connected with, but distinguishable from the fact that, as a matter of law, it may be necessary to have consent. The concept of consent is related to the concept of responsibility and those who consent must bear the consequences of their decision, that is, one function of consent is to shift responsibility and with it liability.[205] It may be, as Edsall[206] argues, that "informed" consent is too easy a hurdle for the medical researcher to clear, especially if legally it has this effect of fully shifting liability. Further, the presence of consent should be inconsistent with that of coercion or duress, concepts which have both factual and legal content. While this is clearly the aim in obtaining consent, care needs to be taken that consent is not a cover for coercion or duress, rather than guaranteeing their absence.

Apart from any disadvantages there may be legal advantages for the patient arising from the fact that consent is required. It may be easier to prove lack of consent than to prove negligence,[207] or to prove the elements of a cause of action based on the former rather than the latter;[208] further, the impossibility of obtaining consent may be used as a total bar by a court,[209] or legislature,[210] to prohibit certain practices.

Within the context of examining the legal purposes related to consent, one should note specifically that consent does not justify medical experimentation or euthanasia, for example. Justification of research on humans, for instance, depends on the inter-relation of multiple factors. The legal effect of consent, in contrast to some extent to the legally implicated purposes which it may serve, is to make conduct potentially defensible which would be actionable without it.[211] However, consent does not act as a sole justification of such conduct. Rather, once adequate consent is shown, justification will depend on other factors outside the realm of consent. In my opinion, the distinction between consent as a sufficient and a

necessary condition is important to keep in mind if consent is to serve its protective function and not be left open to abuse, especially as a cover for practices which would not be justified on the basis of criteria other than consent.

Such a cover role for consent can be seen in some statements of the reasons envisaged as underlying requirements for obtaining consent. The American Heart Association, for example, seems to regard the purpose of consent as being primarily to protect the doctor from legal liability, when the Association regretfully recognizes that it "does not afford absolute protection to the physician".[212] Similarly, when Wolfensberger[213] speaks of consent as being a "release for the researcher", he is seeing its function as being protective of the researcher rather than of the subject. Clearly consent is protective of the doctor or researcher in the sense that normally he is legally and ethically at fault in failing to obtain it. But to describe it in this way is to warp the purpose the concept is designed to promote. It would be the same as my saying that it is protective of myself not to murder people because to do so would subject me to legal liability, and therefore the reason for the law prohibiting murder is to protect me.

I would advocate a strong emphasis on the purpose of consent as being protective of the patient. This may require an express statement as to whether the protection of his rights to autonomy and inviolability are absolute or relative, and in the latter case the terms of this relativity. There should also be strong emphasis on the idea that consent is usually necessary, but not sufficient, to ensure legal and ethical validity. I would also promote a view of consent as a guideline which is *always* applicable, even if the goal is only sometimes, or never, attained.[214]

2. Should consent be defined?

There is one major reason why consent should not be defined, at least in terms of the procedures necessary to attain it, and this is because normally when one has complied with the definition, then legally the defined entity is deemed to exist. It would be possible to legislate a very stringent definition of consent but it is bad policy to enact unattainable legal standards. Rather than raising the level of adherence the effect may be a total disregard of the law.[215]

The United States D.H.E.W. Regulations give a general definition of "informed consent": "the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion".[216] This provision must be seen as outlining the characteristics of "informed" consent and not as implying that if the procedures mandated in the Regulations are followed, such consent is deemed to be achieved. An express statement to this effect is included in other Regulations specifically applicable to mentally disabled subjects: "Nothing in this subpart [which outlines additional procedural protection for such patients when they participate in medical research] shall be construed as indicating that compliance with the procedures set forth herein will necessarily result in a legally effective consent under applicable State or local law to a subject's participation in such an activity."[217] This is to argue that the procedures required by the Regulations are only safeguards attempting to ensure that "informed" consent is obtained and are not definitive as to what fulfills this.

There is a problem in this interpretation however, as the same Regulations require the "Review Board", the ethical review committee, to certify that "*legally* effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this part";[218] and the institution where the research is conducted is "obligated to obtain and document *legally* effective informed consent".[219] If following the specified procedures is not conclusive evidence that "informed" consent is obtained, then as the Human Experimentation Subcommittee of the Research Board of the University of Toronto pointed out to the D.H.E.W., "in Canada 'legal effectiveness' could only be determined after the fact by litigation".[220] An arrangement was therefore negotiated by this University with the D.H.E.W. whereby the certification made was that, "in so far as the review committee could determine, the informed consent was unlikely to be legally ineffective".[221] Perhaps as the D.H.E.W. accepted this, it represents the sense in which the Regulations are intended.

Another reason not to define consent, except as characteristics which are apparent when it is present, is that it must be seen as a continuing requirement, not something which is achieved once and for all when a subject agrees to participate in an experiment. Further, definition of consent may tend to detract from the notion of continuing change in content of the consent, which is also inherent in

this concept. Seeing consent as a continuing process correlates with the continuing duty to inform which has already been discussed[222] and emphasizes the notion that the patient is *free to stop consenting*, which is usually described as freedom to withdraw from the treatment. I suggest that this latter phraseology undesirably implies that a positive act of discontinuance is necessary on the patient's part, rather than seeing consent as the positive act, in the absence of which there is a return to a netural or usually presumed position at any time.[223] This same distinction can be seen in the terminology used to describe why consent is needed. One can say the patient consents to treatment, or consents to waive a right against treatment. There is more emphasis in the second description on the need for continuing consent, as the right is only waived while the consent continues, whereas in the former there is more an impression of having given consent to a particular treatment once and for all, and that subsequent withdrawal depends on a separate right of revocation. The overall result is the same, but the underlying attitudes are not necessarily the same.

One of the difficulties in seeing consent as an on-going process involving the continued participation of all parties,[224] may be caused by legal doctrine on the concept of consent within the areas of obligations, torts, and contract. Especially within the contractual framework, with its requirement of *consensus ad idem*, consent is assessed when and where the "meeting of the minds" of the parties occurs. Now the medical relationship in all jurisdictions is almost always[225] at least partly contractual, and this gives the impression that consent is given once and for all at the time of entering the contract. The problem can be overcome by envisaging that there are *two consents* involved: consent to the contract and consent to the medical care given under the contract; and that the duty to obtain the latter, and the continuing obligation to do so, arises under the contract.[226]

The reason that such a distinction may be important, apart from promoting the idea of the necessity for a continuing consent, is that it liberates this consent to the procedures undertaken on one's person from any restricting contractual doctrines. For example, in Common Law, whether or not there is *consensus ad idem*, that is consent giving rise to a contract, is judged objectively.[227] This may be an unethical standard to apply in assessing consent to a medical intervention. By separating the two consents involved, one can then envisage the contractual consent, if it is present, within its normal context and as governed by the usual rules. Then one can regard the

consent to treatment as a right and duty created by the contract or by law, and in either case as not limited by or dependant on the rules of formation of contract, but as founded rather on rights given under the contract or by law, or even on basic human rights,[228] any of which may be much broader.

Also one can argue that the distinction between ''consent'' and '''informed' consent'' is observed in this division of consent to the contract and consent to the treatment, respectively. Prosser,[229] speaking of the intentional torts such as trespass to the person, for instance assult and battery which are among the most ancient of the Common Law actions, says the consent which was necessary to negate the wrong, was to the defendant's conduct not to its consequences. Such torts were prosecuted under specific writs and it was ''via'' the development of a more general writ, ''an action for trespass on the case'', and under this, allegation of an assumed obligation, *assumpsit*, and subsequent breach, that contract and its consensual doctrine developed.[230] Thus, in the history of the Common Law, tortiously and contractually relevant consent were related. Possibly the former, being more ancient, influenced the latter, and as the tortious rule was that the consent need only have been to the conduct of the defendant actor to be taken into consideration as negating the actionability of his act, this may show the need to develop a ''consent as to consequences'' requirement—''informed'' consent—which may also be founded in tort, or alternatively, on a contractual obligation basis. The advantage of such bifurcation with respect to both the two consents and the two juridical regimes applicable, is to emphasize all the different necessary elements and effects of consent, and would tend to overcome assumptions such as Toole's,[231] that there is *no assault* in prescribing a drug and therefore, he concludes, *consent is not necessary* in undertaking this procedure. It is true that assault and battery does not lie here because any damage caused is indirect and unintentional and therefore it is irrelevant to consider the necessity of consent in the intentional tort context. But to conclude that this means consent is not necessary, that is that consent is only relevant to avoid commission of assult or battery, shows the absolute necessity of adopting the dual analysis suggested.

3. Is consent possible?

In outlining characteristics of ''informed'' consent and suggesting some guidelines and safeguards towards ensuring that it is

obtained, one assumes that it is possible to attain this goal, a supposition which is far from undisputed.[232] Beecher named the doctrine the ''myth'' of ''informed'' consent[233] and warned that one must recognize the problems inherent in it if it is to be used properly. The principle of requiring ''informed'' consent is correct, he says, the difficulty is achieving it. He concludes that the reality envisaged can only be approached and almost never fully attained.[234] Portes[235] is of the same view: ''le consentement 'éclairé' du malade . . . n'est en fait qu'une notion mythique . . . ''. He suggests that ''nous donnons au mot de consentement sa signification habituelle d'acquiescement averti, raisonné, lucide et libre''.[236] Similarly Pellegrino[237] believes consent is never wholly free or wholly informed in an absolute sense and therefore he advocates a change of nomenclature to ''valid consent''. Ingelfinger,[238] on the other hand, describes consent as ''informed but uneducated'', meaning to indicate by this that there is neither adequate understanding, nor total freedom of choice.[239] Vidal and Carlotti[240] also see free and clear consent to treatment as impossible, but regard it as non-essential in protecting the patient. This is because they view a therapeutic aim as the sole justification for a medical intervention, not consent, and the free and clear consent which they argue is needed and is protective is that relating to choice of a doctor, not the treatment he gives.[241]

Some of the views expressed above pre-date the trend towards more emphasis on ''informed'' consent in all jurisdictions, but, to the extent that they still apply, the danger that they represent is that in saying that ''informed'' consent is impossible to obtain, a reaction is engendered that therefore there is no obligation to try to obtain it. Such an obligation is denied by the use of a principle rather like the old Equitable maxim that ''Equity will not order the impossible''.[242] For this reason, I suggest, the desirable attitude is to regard ''informed'' consent as a process rather than an event, in the sense of both needing continued informing and consenting, and of trying to achieve the desired aim. One may visualize consent as a continuum, with the minimum requirement in order to justify a medical intervention on a person depending on a relationship of relevant variables, but on which the aim should be to come as close to the ideal as possible. This moves the discussion to the next consideration: ''is consent always necessary?'' For, at one end of this proposed continuum, there may be a point at which the intervention is justified without any ''informed'' consent being present.

4. Is consent always necessary?

Although this question has been canvassed to some extent within the discussion of rights against treatment and the doctrines of autonomy and inviolability,[243] it merits separate consideration with the slightly different emphasis that is given by approaching it from the viewpoint of the necessity of consent.

There is a distinction made by McCormick[244] which is worth noting here, as it serves as a useful analytical tool. This is the difference between the ethics *of consent*—that is when consent is required—and ethics *in consent*—how the requirement is applied and fulfilled. These are closely related, partly because the ethics applicable to each category depend on the same variables. Hence the discussion so far, which has principally concerned ethics *in* consent, is also relevant to what follows, where the problem focused upon is the ethics *of* consent.

It seems that one can formulate a general rule that consent is always required to a medical intervention on the person, but that some codes, courts and commentators recognize exceptions to this general rule, though the bases and extentions of these exceptions vary.

Firstly, in the therapeutic situation there may be two such exceptions, one of which may be regarded as apparent and not real, since consent is presumed. This occurs in an emergency when the patient is factually unable to consent, and consent may be implied. The very fact that such an implication is made supports an assumption that consent is necessary.[245] Whatever the basis used to justify such an emergency intervention, it is not usually a cause of legal problems in any of the jurisdictions, unless there have been untoward results. Liability in such cases is judged according to ordinary malpractice standards, which may be even less stringent than usual in view of the emergency circumstances in which the doctor acted. The more difficult decision arises when consent is expressly refused by the patient. The question is whether a doctor is justified in overriding this, that is whether consent may be regarded as unnecessary and its refusal may be ignored. In Civil Law jurisdictions the answer to this question in situations posing a serious threat to a person's life or health is more clearly, but not absolutely, yes,[246] than it is in similar circumstances in Common Law[247] jurisdictions.

When one moves into the area of medical experimentation the exceptions to needing consent are narrower and apply, if at all, only in therapeutic experimentation. Such an exception is most clearly applicable when the experiment is the patient's last and only chance to avoid serious morbidity or death, so that the nature of the situation more closely resembles the normal therapeutic one described above. In this situation the same rules as for therapy including exceptions to needing consent, arguably apply.[248]

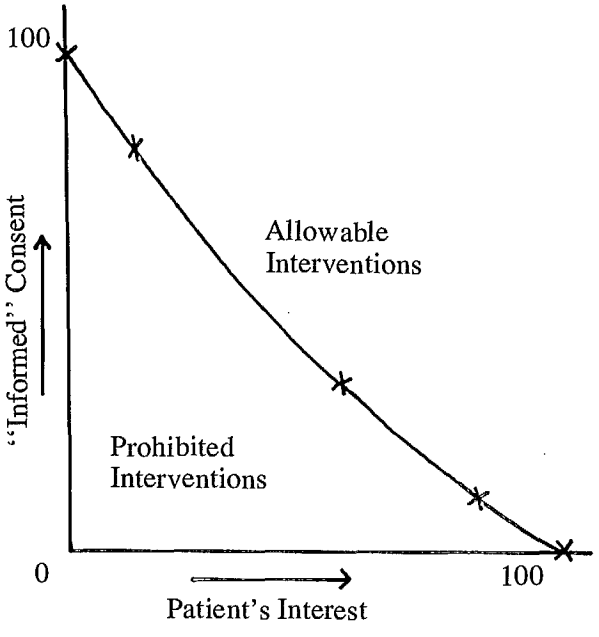
In non-therapeutic medical experimentation some authors say consent is always necessary and others argue for some exceptions. This apparent conflict only arises in a peripheral area where the experimentation does not require any contact with the patient/subject, for example in a retrospective survey using clinical notes, or when it can be argued that the research involves *no* risk (if this is possible since by definition there are always unknown risks in research). However, one can make an undisputed statement about a central core of non-therapeutic research: that in non-therapeutic research this consent is *always* necessary.[249] The exceptions to needing consent which are argued, include large population studies[250] and the use of medical information already obtained about identified individual patients,[251] or of clinical results.[252] It is debatable whether some of these examples are research on the person[253] and that consent may not be needed for this reason. But to argue that one does not need consent to ''no-risk'' experimentation,[254] especially where this is non-therapeutic, or to minor procedures,[255] or that ''modification'' of the consent procedure may be allowed if there is, *inter alia* ''minimal risk'',[256] is another matter and misses the point of consent. Consent is required not just to ensure that a person is not subjected to ''roles'', including that of a research subject, without freely choosing them, but also to ensure that respect for him as a person is maintained. This means that he cannot be used for any purpose without being informed of, and consenting to, this purpose, whether or not the procedure involves risk.[257]

Fried[258] makes a very interesting comment, which is worth considering in relation to whether consent is always necessary in the contexts of both therapeutic and non-therapeutic research. He proposes that one may override a person's express wishes in order to *protect* a third person or the public, and he argues compulsory vaccination is an example of this, but that one cannot compel a person to confer a *benefit* on others. Thus, depending upon where one draws the line between what is protective and what is beneficial, arguably some non-consensual, non-therapeutic experimentation

could be legitimated. One of the difficulties with this distinction is that as protection is a benefit, it may largely be a matter of semantics whether a particular situation is characterized as either protective or beneficial. However the example selected by Fried gives a key to a more restrictive interpretation of his statement. This is that the vaccination procedure envisaged, as well as being protective of the community, is at least of potential and prophylactic benefit to the subject and is therefore not "pure" non-therapeutic research which by definition is *only* for the benefit of *others*. Thus, I submit that *to the extent* that any research procedure is only for this latter purpose, whether the aim is designated as protection or benefit, it cannot be compelled. This statement must be made, however, subject to the proviso that the situation *may* be different where the proposed research subject himself threatens the health of the community[258a] and the research intervention is the least harmful or restrictive alternative available to deal with this threat.

Within the context of exceptions to needing consent to medical experimentation one may consider the situation of "non-subjects" of research, participants from whom consent is never directly sought. These are the persons subjected to television advertising of "over-the-counter" (O.T.C.) or non-prescription drugs, or they may be the "innocent by-stander" suffering effects from research carried out on someone else—for example exposure to radio-activity from a nuclear powered pacemaker inserted for their spouse's heart. There is increasing awareness of the ethical and legal duties owed to these people[259] and it may be that in the future they will have a greater right to be informed, even if their consent is presumed from their subsequent participation in a certain activity.

In conclusion one can summarize the main points about whether consent is always necessary, in the form of a graph, which is for the purpose of general description rather than mathematical exactitude. When the procedure is crucial to the patient's well-being, then the stringency and scope of the criteria for fulfilling the requirement of ''informed'' consent decrease accordingly. Towards one extreme consent may be either presumed or regarded as unnecessary, such as in an emergency situation involving an unconscious patient. But at the other extreme, if there is no therapeutic interest of the patient being promoted by the procedure then in order to ensure that his interests are protected, fully ''informed'' consent must be obtained. If this is impossible then because the procedure may not be carried out without consent, the experiment cannot be conducted. In the intermediate situations whether or not a doctor is justified in going ahead at a certain balance of less than fully ''informed'' consent and less than purely therapeutic interest of the patient is a matter to be judged individually according to *all* the circumstances of each case. It should be kept in mind, that if the patient is unable to fully comprehend, the doctor has an ethical and probably legal duty to decide whether to give or withhold treatment[260] and that this duty cannot be ''passed off'' by an uncomprehending consent or refusal. In other words the doctor has a duty in relation to consent, which obliges him to tread the fine line between disclosure and non-disclosure, and at the same time he has duties other than that relating to obtaining consent; the former duty may be in conflict with the latter. There is a narrow median path by which all duties will be honoured, which must be re-drawn for each fact situation.



5. Is consent sufficient?

This question has already been indirectly canvassed under the purposes of consent[261] and, at a more empirical level, is related to prescribing scientific prerequisites and requirements for the validity of a treatment or of an experiment. The answer is that neither in ethics nor law, is consent a sufficient justification for a medical intervention therapeutic or non-therapeutic, experimental or routine, though it is necessary. This insufficiency can be described in terms of requiring conditions precedent to consent, which may be the scientific validity of a proposed treatment or experiment, or the therapeutic aim,[262] or, that the treatment is justified,[263] or, in non-therapeutic experimentation it might be the superior interest of a third party.[264]

As well as needing such positive conditions to be fulfilled before a doctor may be justified in obtaining consent, there may be a duty not to obtain consent, that is when certain conditions are present, this duty arguably arises. This is probably the negative expression of needing certain conditions precedent to justify obtaining consent, but formulated in terms of a negative duty it is a more forceful statement. Wing,[265] for example, says it is unethical to seek consent to a trial of psychiatric therapy which will harm the patient; Hamburger,[266] speaking of transplant donors, expresses the same idea when he says the doctor has a duty to assess if the decision to donate is reasonable; Cahn[267] says if one argues that the patient can consent to anything, then the doctor is morally bound not to accept certain consents; Capron[268] maintains that the doctor cannot accept a patient's consent to unreasonable risks;[269] and Shannon[270] notes that one element of ''informed'' consent is prudence, which means that even if ''informed'' consent is given it cannot be just mechanically accepted.

This leads to discussion of the valid ''extent of consent'', a phrase that can be used in two ways. One reads that the doctor is limited by the extent of the patient's consent, that is he cannot act outside the area delimited by that consent except in circumstances when he would be justified in acting without consent at all. In other words the patient does not consent to any intervention the doctor chooses but to interventions within certain limits, and beyond these there is no consent.[271] Generally the cases involved here are discussing interventions which went beyond the physical bounds or nature of the intervention to which the patient consented, as opposed to interventions which were within these limits but were performed in a manner to which consent was not given. It is probably only if the

consent were conditional on some particular method not being used, or the method was experimental and there was no express consent to this characteristic, that the methodology alone would take the intervention beyond the extent of the consent. There is in other words a presumption that the content of a patient's consent is impliedly only to standard treatment, anything outside this requiring express delineation to be included in the consent.

The other use and meaning of the phrase ''extent of consent'', seeks to mark out how far a patient can validly consent to an intervention. This is the area of ''public policy'' and ''public order and good morals''. Firstly, all jurisdictions are consistent in holding that a person cannot validly consent, in the sense of exonerating the actor from criminal liability, to an intervention which would amount to a criminal act regardless of consent.[272] Decocq[273] explains the ineffectiveness of consent here in a most presuasive way. He says it is not the consent which is inoperative but the implicit authorization of the law which is missing. Depending on whether one regards a particular legal system as ''closed'' or ''open'' respectively, this observation can be phrased in this way, or, alternatively, that an implicit porhibition of law is present.[274] Nizsalovszky,[275] speaking of Hungarian law, expresses a similar limitation, when he says that consent is limited to an intervention which is socially justified, that is that does not impair society. More philosophically than legally, Lynch[276] writes that one cannot consent to bodily mutilation, as one does not have rights to this extent over one's body.[277] In the same vein, Cahn applies such a principle directly to the problem of the limits of consent in human experimentation, and concludes that ''[e]ven a free consent must have moral limits in a society that honors human dignity, and honoring it, puts a ceiling price on truth''.[278]

6. Must consent be in any particular form?

The answer in law generally is in the negative, unless a particular form is expressly required. Such a requirement is attached to some types of medical procedures in some jursidictions. Lombard *et al*[279] comment that in France consent forms are not in common use, as they are in the United States of America. In the latter jurisdiction such forms are not required under Common Law, unless one argues that their use is customary practice for a ''reasonable'' doctor and that therefore this practice is incorporated by way of the case-law on ''informed'' consent as a necessary element of the standard of medical practice required by law. This, I submit, is most unlikely.

An example of express provisions as to the form of consent may be found in the D.H.E.W. Regulations, which apply only to medical research funded by that body. These require documentation of ''informed'' consent and the details governing this documentation are spelt out at some length. Alternatives are given of full written consent, a witnessed oral presentation plus a written ''short form'', or some approved modification of either of these in certain specified circumstances.[280]

In Quebec written consent is required for hospital care, with separate froms for treatment involving an anaesthetic or surgery[281], and Article 20 of the *Civil Code of the Province of Quebec* requires consent to organ donation or experimentation to be in writing. This provision has been the subject of some academic comment and the better view is probably that the writing required here is a substantive, not a procedural requirement, and that therefore the consent is non-existent legally until expressed in writing.[282]

With regard to consent to experimentation on cadavers, all of the jursidictions discussed have anatomy and autopsy statutes and have proposed or actual legislation on cadaver organ donation which would cover experimental use of tissues[283], and which provide for consent formalities by the person themselves before death or statutorily nominated persons after death, or even imply consent in the absence of provision to the contrary.

There is arguably some danger in requiring formalities, such as writing, with respect to consent. Firstly form, when established, often has a tendency to replace substance. However, provided that the requirement of writing and even the use of a ''pro forma consent form'', is seen as less of a device for informing and more as an adjunct to this, and at best seen as rebuttable evidence of consent, the benefit of additionally using the written form outweighs the risks. The other dangers of requiring written consent relate to revocation. These may be partly avoided by making a very clear distinction between the formalities required for giving and revoking consent. In the latter case, if it is considered desirable to require formalities such as writing, these should only be regarded as evidentiary and not constitutive of legal rights and duties. Revocation of consent is therefore immediately effective in whatever way it is expressed.[284] A danger of requiring written consent which cannot be easily set aside is that the formality itself may act as a coercive influence on the patient or research subject not to change his mind, or to withdraw at a later time.

C. VOLUNTARINESS OR DEFECTS OF CONSENT OF THE PATIENT OR RESEARCH SUBJECT

It is not enough to obtain the consent of the patient. The consent decision must be voluntary, that is, the act of a person who is "so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion".[285] Gray describes this same requirement of voluntariness in another, and probably even more perceptive and instructive way, when he says that it means that the person must be free to refuse to participate,[286] and Cahn labels lack of this freedom the "major malpractice of our era, [which is] 'engineering consent'".[287]

The words used to describe the situations in which consent lacks the required voluntariness are part of common vocabulary but also have technical legal meanings,[288] and within the area of consent to medical interventions, these legal concepts collectively must be taken to cover the widest area possible within their terms. One way in which such an extension could be supported is by comparison between the quality of consent needed to fulfill the consent requirement in the formation of a contract, and that needed for obtaining "informed" consent,[289] the latter being subject to much more demanding standards. Similarly, but inversely, I submit that the lack of voluntariness which will vitiate "informed" consent is of a much lesser degree than that which will constitute a defect in consent to a contract.

In regard to the burden of proof of consent, in Common Law jurisdictions where a relationship is characterized as confidential, or fiduciary, undue influence is presumed to be present.[290] This means that in the medical contract the doctor has the burden of proving the voluntariness of the consent, which burden should be regarded as encompassing both the consent to the contract and consent to the medical procedure that it contemplates.

The same result with respect to burden of proof of consent is probably attained, but more indirectly, in Civil Law. For example in Quebec, Mayrand says "que l'exécution de l'obligation du médecin [here to obtain free and clear consent] étant un fait conforme 'à l'état normal et habituel des choses' la charge d'établir le fait anormal, c'est-à-dire l'inexécution, incombe toujours à celui qui l'allègue" but "la preuve de l'inexécution d'une obligation étant la preuve d'un fait négatif . . . elle se fait très simplement par le témoignage du

demandeur. Le malade ayant affirmé que le médecin ne lui a pas donné l'information requise, il appartient ensuite au médecin de contredire cette preuve.''[291] In France the situation in this regard has been interesting. From 1936 to 1951 the courts held the doctor had the burden of proving that the patient's consent was free and clear,[292] then the *Cour de Cassation*[293] stated that the burden of proving inexecution of the contractual obligation to obtain consent lay with the person alleging this, the patient.[294]

There is much technical, legal discussion on the effect of defects of consent on the consent itself, which it is impossible to canvass here,[295] but this effect can be summarized as two alternatives: either the defect is so serious that it totally negates the presence of consent, that is the consent is null or void *ab initio*, or the defect may make the consent subject to recision or voidable. The further question then asked is whether the absence of consent affects the nature of the allegedly wrongful act; that is whether presence or absence of consent, in some circumstances, is determinative of lawfulness and unlawfulness, respectively, or whether consent is merely a justification for an otherwise unlawful act.[296] Whichever view one takes in answer to either of these two questions, this legal discussion may be distinguished or side-stepped as it relates to consent in the formation of contract, or consent in the areas of tort, or delict, or succession, or consent for criminal law purposes, and may not necessarily be directly applicable here. If one regards the obligation of the physician to obtain consent as one of performance of a contract, then this is breached by failing to obtain adequate and effective consent, and the result is a complete absence of the necessary consent as required by the terms of the contract for which damages may be sought. There is then no need to bring forward all this other complicated legal doctrine unless some remedy or sanction in one of these other areas is desired, when the obligation to obtain consent will not be characterized as contractual, but will be cast in another ''role''.

With regard to the factual determination of when consent is not voluntary, or alternatively when force, fraud, coercion, duress, undue influence, deceit, constraint, mistake or deception are present, the potential situations are unlimited and each case must be determined individually in the light of all the circumstances. One can, however, give examples, which are applicable generally in the form of analogy and cautions. The most pertinent of these cautions is that these coercive factors may be at their most subtle and difficult to detect, and freedom of choice most threatened, in a situation in which

the more powerful party believes he is acting for the benefit of the other.

1. Coercion and duress

Gray[297] gives some examples of subtle pressures to participate, which were disclosed in interviews with subjects of therapeutic experimentation—a labour induction study on women giving birth. He found that the women consented because they feared damage to their relationship with the doctor,[298] that they lacked knowledge of the options open to them, and that the consent of the patient to use of the experimental, labour-inducing drug had not been sought in a *neutral* situation—it was sought after admission to the hospital and after agreement to induction of labour, that is after patients had already committed themselves to undergoing the induction treatment by some technique. It is almost as though the consent were being obtained in increments so that the width of the decision lost its psychological impact. This raises the consideration that perhaps the patient involved in medical research should be considered a ''special subject'' along with prisoners, the mentally retarded and other ''disabled'' or ''disadvantaged'' persons,[299] as some authors believe that he is the most likely of all to suffer coercion.[300]

It is also possible that this coercion does not just arise from the doctor-patient relationship but may be caused by a patient's fear of pain and discomfort, or fear that if he refuses a treatment or does not participate in suggested research, he will receive less attention generally.[301] Exactly where one crosses the line here from unavoidable intrinsic influences on consent, to legally operative extrinsic coercion, is difficult to determine. Bloom outlines three attempts to analyze the nature of coercive pressures on patients. Firstly he quotes Caudill,[302] who found that fellow patients in a mental hospital exerted pressures on new patients to co-operate with the doctors. Goffmann,[303] on the other hand, argues that a power structure is the origin of coercion in the hospital situation. He says the staff-inmate split creates a power differential which causes the patient to ''play the game'' to avoid punishment. The third theory is that of social re-motivations—that patients adopt the attitude or value system of the staff towards their illness and treatment.[304] Whichever of these is true, all show coercive forces acting on patients, as far as consenting to submit to medical treatment or research, and underline the necessity of taking special care to protect patients in this respect. Recognition of such coercive phenomenon probably explains the

reasoning behind what, at first reading, appears to be a somewhat unusual situation in the United Kingdom, where safeguards for healthy volunteers are not so strick as for patients. For example, there is usually review committee approval before carrying out experiments on patients, whereas this is not the practice with research involving normal volunteers.[305]

I wish to note here a rare, but thought-provoking situation, with respect to deciding when consent is coerced. ''Thomas'' was an agressive psychopath, who may have been helped by experimental psychosurgery. Small electrodes were implanted in his brain and when these were stimulated he was ''normal'', at least with respect to his psychopathic tendencies. At such times he consented to psychosurgery, but adamantly refused when his brain was unstimulated.[306] Should one argue here that Thomas was coerced into ''normality'' and therefore his consent was invalid?

There are other examples of coercion involving patients. The doctor might make it a condition precedent to treating the patient at all, that he participate for instance in an experiment[307], or collateral benefits, such as the waiver of hospital fees, might be promised in return for such participation.[308] This, in effect, is a form of payment and raises the whole question of payment as a form of coercion.[309] As Lord Harley said in *Vernon v. Bethell*:[310] ''Necessitous men are not, truly speaking, free men, but, to answer a present exigency, will submit to any terms that the crafty may impose upon them.'' This statement summarizes the coercive aspect of payment, but this is not the only objection to its use, especially in the medical research situation. Many authors argue it epitomizes the ''reification'', the dehumanization,[311] the use, rather than the participation, of the subject in research. Payment may be regarded as emphasizing the fact that in human experimentation, ''[t]he experimental subject does not hazard his physical capacities by using them. Rather, by abstracting his purposes from those in which his body is risked, he makes his body into a separate thing which he sells or gives away so that others may pursue *their* purposes with it''.[312]

The law's attitude to monetary payment ''vis-à-vis'' one's body varies in different jursidictions. The general view in French law is that the body is not able to be an object of sale,[313] and although these statements are often made in the context of the sale of organs or tissue for transplantation, one assumes that the same prohibition applies to medical experimentation on the person where this is otherwise allowed. The matter is not entirely straightforward however, because

some French writers argue that payment in the nature of compensation or indemnity is permitted,[314] and in Common Law jurisdictions, where payment for participating in experimentation is not prohibited *per se*,[315] writers propose that it should be regarded as compensatory in order to avoid a coercive effect.[316] The net result in each legal system with respect to placing "benefits" in the hands of research subjects would thus be the same, although one starts with diametrically opposed general rules on the validity of payment.

In Quebec, Mayrand[317] notes that as in France, the human body cannot be an article of commerce, and also that one can distinguish recompense from commercialization. He says it is not clear whether Article 20 of the *Civil Code of the Province of Quebec*, forbids payment for experimentation,[318] as it certainly does in regard to alienation of non-regenerative tissue. This prohibition could, of course, be directly relevant to some experimental situations. Crépeau[319] proposes a distinction between "sale" and "letting of services" and suggests payment for experimentation may be valid under the latter, although he queries the validity of a policy which makes a distinction allowing payment for experimentation, but not for non-regenerative organ donation.

Where payment to experimental subjects is legally allowed, or more precisely is not prohibited, various suggestions have been made to avoid the coercive effects of such a practice, which are at their strongest where deprived subjects are involved.[320] Cahn[321] says that payment is valid as long as it does not purchase an unwilling consent, which probably means one must determine if there would not be consent without the payment. In this case the apparent voluntariness may be due to the payment, which would therefore be coercive and destructive of the legal validity of the consent. This type of reasoning however leads to a difficulty. One always has reasons for consenting, and these reasons cause one to make a certain decision. It seems that once these reasons are identified they are to be divided into two categories, coercive and non-coercive, although, in the broadest sense, they are all coercive of the decision reached. Thus the criterion for marking-off the boundary between the coercive and non-coercive groups is not a difference in kind between such factors, but a matter of degree, that is some deviation from the normal pressures under which people find themselves. Daube describes such normal pressures as those influences which are "part of the normal burden and dignity of social existence".[322] This is a useful description for identifying coercion because it requires, in order to designate a factor as non-coercive, that persons be in a "normal" situation and allows

one to recognize that the fact that they are not is itself coercive, and may cause other factors normally coercive, to become so.

One may see Freedman's[323] approach to coercion within this framework: his view is that a reward to bring a person up to a standard of living to which he has a right is duress, but a reward above this level is not; that is, he says, it is the *effect* of the payment, the payment not *per se*, which is determinative of coercion. It is true that one is only interested in the coercive force represented by payment, that is with characterizing its effect in this respect, but the problem is that it is here that one has the most difficulty in drawing the line between allowable and prohibited pressure. For instance taking Freedman's criterion of coercion, quite apart from any questions of whether this is broad enough, what is a "normal" economic position of a person? Certainly if one, or one's family, is starving, to offer payment for experimental participation is coercive, but what if one is just poor, or earns less than the average, or wants more than most other people? Perhaps the answer may be that to be consistent with a principle of autonomy, one must judge the situation objectively and determine whether the coercive pressure of the payment arises from extrinsic need, in which case it is duress, or from intrinsic desires, in which case it probably is not.

In relation to payment of medical research subjects there is a further anticoercion recommendation made by Hershey and Miller[324] that payment be made *pro rata* over the participation period, which has the additional and necessary safeguard effect of ensuring that a subject is not coerced into continuing with an experiment just because payment is an all-or-nothing, "lump-sum" event, at the end. In this respect it is interesting to note that the D.H.E.W. Regulations, applicable to research on prisoners, appear to be even more stringent. They provide that "withdrawal from [a] project for medical reasons [must] not result in loss of anticipated remuneration[325] which implies that the subject receives full payment for "part performance" in such circumstances.

The Report of the Committee to Investigate Medical Experiments on Staff Volunteers,[326] referred to above, makes the interesting comment that payment of staff volunteers is desirable for "establishing the voluntary character of the service", that is for demonstrating that it is not an expected obligation of employment, which would be a coercive belief. Thus one has covered the full range from payment being fully and solely coercive to its being needed to rebut coercion[327] and the only general rule which can be formulated with

respect to identifying coercion, is that each situation must be judged according to its own circumstances.

That being said, it is however possible to formulate some safeguards which may be applied to reduce the likelihood of coercion generally, including when this is in the form of payment. The first step is to increase sensitivity to, and recognition of, possible coercive influences. The sources of interference with the power of choice can be drawn together and categorized under these headings: the content of the required disclosure; the relationship of the physician, or others, to the patient; the setting for obtaining ''informed'' consent and the time; the language used; the inducements or compensation in the medical research context. All of these points have already been discussed.

Then consideration should be given to whether consent should be obtained by an independent third party and not the physician, or whether, in some circumstances where ''informed'' consent is particularly suspect, an ethical review committee should participate in the consent obtaining process by patient interview before the committee. It should be noted in this respect that Annas, Glantz and Katz are of the opinion, that '''third person' participation in the consent process is grossly inferior to complete [review committee] participation''.[328] In the medical research context a further protection against coercion is solicitation by general notice rather than by direct approach, or in such a way that initiative to participate is left with the volunteer.[329] The final and ultimate safeguard against duress is to ban the activity in the promotion of which it is likely to occur, or to prohibit participation in such specified activities by any group of particularly susceptible individuals.[330]

A more subtle approach is to set stringent conditions, which will tend to ensure that coercion is avoided, a ''no, unless . . . '' type of regulation. In other words research is prohibited unless certain conditions precedent, chosen for their ability to reduce or eliminate the likelihood of coercion being concurrently present, are fulfilled. Such an approach has been recommended for general application to research involving prisoners in the United States of America.[331] As Hershey and Miller say: ''It is virtually impossible to determine directly whether a decision is based on a 'free power of choice'. Thus, it must be defined by the absence of unacceptable influences and interferences, which is the approach that the D.H.E.W. regulations take.''[332]

2. Mistake and deception

Two possible sources of error affecting consent are first mistake and secondly deception or misrepresentation. The two concepts are not necessarily exclusive, as the latter encompasses the former, and although treated separately by the Common Law, fall under one broad category of error in Civil Law. It is useful however, for the sake of analysis, to distinguish two situations: mistake—where the error is not induced intentionally, nor usually as a direct result of the words or conduct of the party against whom mistake is alleged as a defect of consent; and misrepresentation—where the wrongful belief is induced by the party not in error, either innocently, negligently, or fraudulently. It is important for legal purposes to distinguish these latter categories, as the remedies available will differ according to which is applicable. However, in a broader sense they are all instances of deception, even though in a legal context this word is sometimes used only as a synonym for deliberate concealment or fraud. In the medical context, the word deception may carry the inference that the misrepresentation was intentional and made by the physician for a particular type of purpose, that is to promote some interest other than, or even in addition to the patient's.[333] Further, depending on the circumstances a non-disclosure or concealment may fall within either mistake or misrepresentation, but with respect to a doctor's non-disclosure of information he is under a duty to disclose, it will be the latter.

Firstly, it is necessary to consider the effect of mistake on both the consents relevant to the medical situation, that is consent to the medical contract and consent to medical care.

Mistake, like other defects of consent, may vitiate consent to a contract, including a medical contract. At Common Law, the rules on when mistake has the effect of nullifying consent, and hence the contract to which it was given, are among the most highly technical doctrines to be found in this system.[334] The presence of mistake is, in general, assessed objectively.[335] Whether or not it is operative to void consent going to the formation of a contract, which is the only legal effect mistake may have at Common Law,[336] may depend upon whether the mistake is characterized as unilateral, common or mutual, that is the mistake is only on the part of one party, or the same mistake is shared by both parties, or each party is acting subject to a different mistake respectively.[337]

In comparison, in Civil Law, mistake or error is a wider doctrine[338] and is judged subjectively. But as in the Common Law,

the Civil Law doctrine determining whether or not consent to a contract is vitiated, either through relative or absolute nullity, that is whether the contract is valid, voidable, or void, is complicated. In summary, the determination depends on the concurrent application of two tests: first whether on the one hand the defect of consent is an obstacle to formation of the contract, that is to a *consensus ad idem*, or whether on the other hand there is a "consensus" but it is defective; and secondly whether nullity of the contract would sanction a rule in the public or private interest. In the former cases, respectively, the nullity is absolute, that is the contract is void. In the latter it is relative, that is the contract is voidable and this latter sanction can only be invoked by the person in whose favour such nullity is established.[339]

Without exploring these doctrines in detail, their significance here is that, at Common or Civil Law a patient whose consent to a medical contract was tainted by mistake, could seek to escape the contract. However, by itself, this remedy, even if available, is often only of theoretical significance to an injured patient.

With respect to the effect of mistake by the physician in relation to consent to the medical contract, it is both unlikely that he would be the party in error in regard to the nature or object of the contract, or that he could rely on the patient's mistake to argue that the contract was void[340] or voidable. Therefore his mistake is of little practical relevance within the context of the current discussion.

Mistake affecting the patient's consent to medical care is more significant. The standard I have suggested is that the doctor may rely on the patient's consent as being valid, from the point of view of being informed, when there is "apparent subjective understanding" by the patient of the information required to be disclosed to obtain an "informed" consent.[341] If one applies this standard then the patient's mistake will be irrelevant unless a reasonable doctor would have known, or this doctor in fact knew, that the patient was mistaken. Similarly, when the question is one about the presence of consent for the purpose of the torts of assult and battery, that is consent in its traditional sense as compared with "informed" consent, subjective mistake by the patient will not vitiate consent if, objectively, the patient appeared to be consenting.[342] It will only be vitiated if the consent was induced by fraud and the patient was mistaken as to the nature of the act to which consent was given, and not just as to its consequences.[343]

Where the doctor is the party in error in relation to obtaining the patient's consent to medical care, if for example he inaccurately describes the risks of a certain procedure, the question is one of negligence or malpractice in performance of his duty to disclose or, if the error is intentional, of deception or fraud. In all these cases whether the patient's consent to treatment was valid or not will depend on whether the doctor's mistake, regardless of how or why it occurred, was such as to make the consent ''uninformed'' or even no consent at all.

To turn now to the more troublesome source of error in relation to obtaining ''informed'' consent, namely the use of deception[344] in medicine generally, and in human medical experimentation in particular. Deception raises difficult problems at both legal and ethical levels. In practice the problem is probably discussed most frequently in the context of randomized controlled trials or psychological experimentation.

It is sometimes said however that the most common form of deception in medicine is when medical students represent themselves as qualified doctors or imply that the physical examination they wish to carry out includes some element of patient benefit when this is not the case. Such deception is of course inexcusable and any consent given in these circumstances would be legally defective.

Another example of deception reported in a medical journal[345] which falls outside the area of medical experimentation also raises pertinent questions. A study was carried out on terminally ill patients in which an audiogram was done while they were alive, and after death if they were subject to a post-mortem autopsy[346] the anatomical structure of the ears was compared with the audiogram results. The patients ''of course''[347] were not told the object of the research, but because there was a worry that they would be frightened by being selected if they realized that all selected patients died soon afterwards, therefore the researchers selected at random non-terminally ill patients as well and conducted audiograms on them.[348] How one views such experiments depends on the position one takes with respect to deception. There are basically three possible positions: that deception is never justified; that it is only justified if there is consent to not being informed and the general nature of the withheld information is disclosed; or that it is justified according to various other conditions in certain circumstances.

The legal problems associated with deception involve firstly its effect on ''informed'' consent. When ''knowing consent''[349] is defined to include certain basic elements of information, can one consent to not being informed of these and still say that there is ''informed'' consent? Hershey and Miller[350] say no, but some others are not quite as definite and would allow deception as apparently compatible with effective consent, within limits[351] which limits include disclosing that there has been concealment and obtaining consent to this.[352]

Apart from its effect on ''informed'' consent, deception may be either a tort, or delict, or even a crime in itself. As already stated, for private law purposes one can classify the misrepresentation which gives rise to the deception as fraudulent, negligent or innocent,[353] and remedies that may arise include damages in tort or delict, or nullity of, or the right to rescind the contract if one purports to, or does exist respectively.[354] It is also possible that a misrepresentation amounting to fraud, which requires an intent to deceive or at least a high degree of recklessness as to the truth or falsity of the statement, could be a criminal offence. Or it could be the basis of revocation of a licence to practice medicine on the ground that the fraud constituted unprofessional conduct.[355]

Ethically, deception is objectionable because it is an infringement of human dignity.[356] The objections to the use of deception in any research, which objections may also be applied to medical research and even medicine more generally, have been summarized by Mead.[357] They are: denigrating the subject, with the harm to him compounded by debriefing, as then he must somehow accommodate to the fact that he was deceived; causing the investigator to develop an attitude of contempt for other humans, which may cause insensitivity and delusions of grandeur;[358] and a dual effect on science, in that the experimental results may not be entirely valid due to communication of multisensory subconscious clues as to the deception, with the result that the whole culture of experimentation becomes one in which human dignity is violated rather than respected.

If one is of the view that some deception is allowed, then what are the limiting conditions? In relation to medical research the Canada Council Consultative Group on Ethics[359] attempts to answer exactly this question. The experimenter has the burden of showing the importance of the expected results and that no other methodology which excludes deception is possible. There must be no deception as

to facts which would affect a decision to participate, and the researcher must show that the deception will not result in harm to the subjects. Such harm includes adverse feelings to having been deceived. The subjects must be debriefed after the experiment and told of the reasons why deception was necessary. If such debriefing is impossible then deception cannot be used. I suggest one add to this, where it is possible, requirements of consent to being deceived[360] and some prior disclosure of the general nature of the information concealed.[361] There must also be a requirement that the researcher make a full disclosure after the experiment and obtain the subject's consent to use the information generated, in default of which the information must be destroyed,[362] or given to the subject to use as he wishes. Such a provision makes it less likely that a researcher will conduct an experiment using deception where there is a strong chance of causing an angry reaction by subjects, as such subjects may then withhold consent to using the information. The latter alternative allows for the information to be preserved while still respecting, at least *ex post facto* and to some extent, the subject's right not to be used as a research subject without his consent.

It is worth pointing out here that where "informed" consent is not obtained prior to conducting a medical intervention, the patient's retrospectively operating acquiescence is not an "informed" consent but rather is in the nature of a waiver of any rights of litigation which he may have, or a ratification of the doctor's act. Such a situation may arise not only when deception has been practiced, and hence inadequate information disclosed. It may also arise when the patient is incapable of consent in an emergency situation, or suffering from temporary mental derangement, in which case a subsequent ratification of the treatment given is an alternative legal justification to the defences of necessity or implied consent.

To return to deception, it is possible to see it in an even wider context than that already described. When a relationship gives rise to express or implied expectations which are acknowledged as justified, that is, ratified by the party who must fulfill them, then to deliberately disappoint such expectations is a form of deceit. Fried calls this faithlessness.[363] A physician may be guilty of faithlessness with respect to any type of obligation, including the general one of putting the interests of the patient first. If this occurs the physician can be said to be deceiving the patient in the broad sense defined. The same reasoning applies to the obligation to inform the patient and obtain valid consent, which is often the only obligation regarded as affected by deception. In a sense, in such cases, one has a double

deception, as one has deceived the patient in the wider sense by deceiving him in the more traditionally recognized context of deception, that is with respect to factual information. Rather than being superfluous, Fried's more general analysis and use of the term deception are particularly valuable in this area, as it gives insights in relation to the obligation to inform and shows that the aim must be to cut down, or eliminate, the faithlessness involved in any deception which takes place. This sounds like a contradiction in terms, but, under the full rigour of the conditions I have suggested, it may be that the doctor is not being faithless in deceiving his patient if he places the interests of the latter foremost. In fact, it is possible to view a justified use of the doctrine of "therapeutic privilege" as an example of precisely such a situation.

D. THE RELATIONSHIP OF "INFORMED" CONSENT AND PRIVACY

One can describe this relationship in two essentially reciprocal ways: consent acts to protect privacy,[364] or privacy defines the negative and positive boundaries of consent. In other words privacy is invaded if the limits set by a consent are exceeded, and privacy may protect the right to participate in, or consent to, medical treatment or research.[365] In either case the assumption is that one may not invade privacy without consent, but that consent negates any invasion of this pre-existing right. That is, privacy may be seen as a function of consent and therefore of autonomy.[366] In the first description of privacy given above, the emphasis is more upon the determination of the extent to which the right to privacy is yielded by the consent given, and in the second, on the valid extent of the consent. But unless this difference in approach caused different presumptions to arise, there would be no variation in result in any specified case by using either of the concepts.

There is another relationship which needs to be spelled out here and that is between confidentiality and privacy and consent. Confidentiality may be described as an obligation arising in one person which is founded on another's right of privacy, which right has been suspended by consent to the limited extent of the confidentiality. Thus confidentiality protects rights of privacy by limiting further disclosure, whereas privacy and its consent requirement is the protection against initial disclosure. Ruebhausen and Brim[367] make the distinction in this way: that consent concerns the

conditions under which information is obtained, whereas confidentiality concerns the conditions under which it is used. This is an instructive description, provided that one realizes that whether or not there has been a breach of confidentiality also depends on consent. Usually a patient does not, or should not, just give consent to the giving of the information. Rather, whether the information is given orally or by the act of participating in treatment, it should be consent to giving this information for a specified purpose.[368]

In the ''pure'' therapy situation the purpose for which information is given by the patient may be implied, that is to facilitate his treatment and cure. Any use beyond these limits, for instance using the information for research purposes, would need further express consent. Confidentiality, therefore, limits the use of the information to the purposes expressly or impliedly included within the consent and proscribes any other disclosure. A difference between confidentiality and privacy arises only if one regards an initial unauthorized disclosure as the sole breach of privacy, because something once revealed is no longer private in the strict sense of this term, and then considers further unconsented use or revelation of the same facts as breach of confidentiality. It is a semantic, rather than a real difference as regards both the content of the relevant legal or ethical obligation, and the overall outcome in terms of the ethical or legal validity of making a certain disclosure.

The purpose of a right to privacy is protection of the individual, his human dignity and right to self-determination, especially but not limited to, his psychological integrity, which has been called a right or claim to ''private personality''.[369] The Canada Council Consultative Group on Ethics[370] believe that a right to privacy provides for the deeply felt need of human beings to reveal to others only those aspects of their lives which they wish to reveal. This is a very significant aspect of human freedom and, as such, is often in conflict with society's search for knowledge.[371] More juridically and medically the French jurists[372] see the patient's ''secret'' as his extra-patrimonial property and the purpose of medical secrecy as preserving the integrity of the person, all of which assumes the existence of a right to privacy.

It is not possible, here, to show the history of the development of a legal right to privacy, which Berlin says derives from a conception of freedom only as old as the Renaissance.[373] ''[A]ncient law recognized that a person had a legal right 'to be let alone', so long as he was not interfering with the rights of other individuals or

the public. This idea has been carried into the common law, [which] . . . has both tacitly and expressly recognized the right of an individual to repose and privacy . . . ''[374] There is wide recognition of the applicability of this right in the medical context, in the form of either a right to privacy or secrecy, or as a duty of confidentiality, which is more express in the Civil than Common Law.[375] International documents founding such a general right are the International Covenant on Human Rights[376] and, in the medical context, the Declaration of Geneva[377] which specifically provides that the duty of secrecy survives the death of the patient.

British Columbia, in 1968, was the first Province to enact legislation protecting privacy[378] followed by Manitoba in 1970.[379] In Canada, *The Canadian Human Rights Act*[380] legislates both a principle of ''the privacy of individuals and their right of access to records containing personal information concerning them for any purpose . . . ''[381], and it enacts provisions applicable to the protection of personal information[382] in federal information banks.[383] In an even broader context, Quebec's *Charter of Human Rights and Freedoms*[384] provides that ''[e]very person has a right to respect for his private life''[385] and ''[a]ny unlawful interference with any right or freedom recognized by the[e] Charter entitles the victim to obtain the cessation of such interference and compensation for the moral or material prejudice resulting therefrom''.[386] Further, ''in the case of unlawful and intentional interference, the tribunal may, in addition, condemn the person guilty of it to exemplary damages''.[387] This last provision is especially interesting in relation to medical research, as, in many instances, breach of privacy in that context will be deliberate. With respect to showing that the act breaching privacy was ''unlawful'', probably the Act itself by legislating a right to privacy creates this unlawfulness, at least as a *prima facie* presumption arising from a breach of privacy. Alternatively, unlawfulness may be based on a breach of the *Code of Medical Ethics* of the Professional Corporation of Physicians of Quebec,[388] which has the status of subordinate legislation, and promulgates a duty of confidentiality.[389]

In the United States, Amendments to the Constitution have been interpreted by that country's Supreme Court as conferring a right of privacy on all citizens[390] and the American Medical Association Code[391] expressly recognizes a duty of confidentiality by doctors. Likewise the duty of confidentiality is recognized in the United Kingdom where both the British Medical Association[392] and the

British Medical Research Council[393] state that there is an obligation on the doctor to maintain secrecy.

Remedies for invasion of this right to privacy, or breach of this duty of confidentiality may include an action for breach of contract. In Common Law jurisdictions, the remedies include the possibility of tort actions in defamation,[394] or even perhaps for breach of confidence[395] or of a right to privacy[396] and, where there is a legislated duty of confidentiality, for breach of statutory duty.[397] In Michigan breach of confidence by a doctor is a criminal offence.[398] This can be compared with the situation in France where, as well as being an expressly legislated professional obligation,[399] breach of confidentiality by a doctor is punishable under the *Code pénal* by fine or imprisonment.[400]

One must now consider exceptions[401] to this duty of secrecy. This raises firstly the relationship between privacy and confidentiality on the one hand, and privilege on the other. A doctor has a duty of confidentiality "vis à vis" his patient but this does not necessarily mean that he is privileged from disclosing the information subject to this duty, when ordered to do so by a court of law. The doctor, when he is required to testify, may claim to have a "medical privilege" which allows him to refuse to disclose his patient's secret, but in all jurisdictions there is some doubt as to the existence or extent of such a privilege, although it is recognized in Civil Law doctrine.[402] At Common Law the matter is less certain,[403] but the same result is achieved by some courts through a holding that disclosure by a doctor of information gained in confidence from his patient is against public policy.[404] Some jurisdictions have now legislated the privilege.[405] The purpose of recognizing such a privilege is, as Portes[406] said in a different context, that secrecy is essential for confidence and without confidence medicine is impossible.

It is necessary to point out here that the privilege involved is not the doctor's but the patient's[407] and that therefore, it cannot be set up against the patient. The reason for belabouring this is that sometimes such a privilege is relied upon, in terms of rights of privacy of the doctor, to deny the patient access to his medical records. This I submit should not be allowed, except perhaps within the scope of a narrowly defined "therapeutic privilege".[408] In other words the patient has two mutually consistent rights here, a right to privacy and confidentiality, and a right of access.[409] Any conflict between them arises only when one considers third party access.

Where, in a case before a court, a doctor seeks to rely on privilege any denial of this by way of exception to the patient's right of privacy and the doctor's duty of confidentiality, is based on the state's power to administer justice and is not related to any theory concerning consent. Another such example of an exception to privacy not being related to consent, is when the respect for privacy may harm another[410] or perhaps even the person himself. In these instances one can argue that there should be a mitigation or suspension of the doctor's duty of confidentiality. One example of such a situation would be if veneral disease were diagnosed and the person's partner was unaware of this,[411] or a disease were detected, and it is not in the patient's interest to be told this but others need to know of it in order to care for him.[412]

The Medical Research Council of Great Britain[413] has dealt with the latter case, by providing that, unless *expressly forbidden* by the patient, the research physician should be willing to communicate information of which he gains knowledge to the clinician treating the patient when it is pertinent to the patient's health care. In some cases, such as notification of infectious disease, a duty to disclose is even legislated.[414] A more controversial disclosure without consent, is demonstrated in a United States case[415] where the court ruled that the public's right to be informed how its funds were disbursed, surpassed the privacy issue. The D.H.E.W. were ordered, under the *Freedom of Information Act*,[416] to disclose files on grants given by the National Institute of Mental Health for research on the use of stimulant drugs on children.

Other exceptions to the right of privacy and duty of confidentiality are related to consent, in that where consent is not considered necessary then privacy may be non-consensually invaded; or if consent may be implied then this occurs with only a presumed permission. An example of the former type of exception is that consent may not be needed to epidemiological research provided anonymity is maintained.[417] A possible instance of the latter exception is the generally recognized exception allowed for publication at scientific meetings[418] or in journals, provided, at least in the latter case, that the patient is anonymous and cannot be identified.[419] Express consent is not usually sought for publication.[420] It is not clear whether this exception is based on implied consent as suggested, in which case publication could be expressly prohibited by the patient, or is a non-consensual exception to a right of privacy and duty of confidentiality, in which case it arguably could not be prevented by the patient, is not clear.[421]

Special problems of privacy, particularly relevant in the medical research context, have arisen in recent years with the development of computers and information systems technology in general.[422] Since the "Ellsberg Affair" in the United States, one is particularly aware of the potential for harm that exists in the unauthorized use of psychiatric records. Such systems do not alter the doctor's duty of confidentiality, but may impose additional duties of records' security and care in order to prevent unconsented to link-ups or retrievals.[423] The problems posed are not completely original, only more intense because of the increasing complexity and longevity of data collection and storage.[424] Strict measures of control over access by the government or any person to computer stored medical information have been proposed in the United Kingdom,[425] although evidently not implemented.[426]

Computer technology also causes additional problems in the medical context, apart from just those involved with preventing a breach of confidentiality. One of these is that if a breach occurs the data may not even be correct. For this reason Whalan[427] has suggested that a new writ should be developed on the same principles as *habeas corpus*, which he has called *habeas notae*. It would compel production of a centralized record for inspection by the person concerned and allow for its correction. *The Canadian Human Rights Act*[428] is pertinent in this respect, as it legislates a principle which embodies respect for "the privacy of individuals and their right of access to records containing personal information concerning them for any purpose including the purpose of ensuring accuracy and completeness . . . to the greatest extent consistent with the public interest".[429] In relation to medical records, in particular, Quebec has legislated both a duty of confidentiality (with the exception that a "professional . . . may examine such records for study, teaching or research, with the permission of the director of professional services of the establishment which keeps such records . . . ")[430] and a right of access to them by the patient.[431]

A discussion of information systems raises the consideration of duties regarding shared confidentiality or secrets. This is a problem discussed more often in Civil Law doctrine than in Common Law. Lombard *et al*[432] report that the Cour de Cassation has recognized a doctrine of *secret en commun*, and Boyer Chammard and Monzein[433] note that the Conseil d'Etat regard medical secrets in group medicine as being confided to the group. Kornprobst and Delphin[434] discuss a *secret partagé ou collectif*, the latter term being intended to overcome the objection that a secret is not a secret if it is shared. At

Common Law there is support for the belief that there may be a duty on persons supervised by physicians to observe the same degree of confidentiality as physicians,[435] and Baldwin *et al*[436] suggest that there is a notion of acquiescence by the patient to an "extended confidence", when he discloses to the doctor.

If this is true one must underline the word confidence and I suggest that as with other derogations from a patient's rights, one should place the burden of proof on the doctor to show that the course of action taken in sharing the patient's confidences was justified. In some situations, where it is clear that others will have access to medical information regarding patients, an extended duty of confidentiality has been legislated, binding on all such persons.[437] Further, the recognition of an extended duty of confidentiality is particularly important where approval of a review committee is recommended, or obligatory, before a certain procedure may be carried out.[438] Thus one line of attack against the mandating of such review requirements is that they represent an unjustified interference with the patient's right to privacy, in the sense of his being able to decide for himself and by himself what is done to his own body, and that they may interfere with the confidentiality inherent in the doctor-patient relationship.[439]

Other safeguards of privacy, even if not of confidentiality, may be developed if one sees this right as a function of autonomy and inviolability. That is, the right to privacy may be respected, although information is divulged, as long as one recognizes that that right requires the fulfillment of certain conditions precedent to disclosure. Those safeguards which have been or could be adopted include, as already suggested, the recognition that in situations where privacy is not to be protected by non-use of information, other adequate safeguards such as consent and anonymity, must be employed; that journals should only publish identifiable photographs with the signed permission of the patient;[440] that medical records are regarded as the property of the patient;[441] and with respect to medical information systems, that the systems and the persons responsible for them are required to be licensed; that the persons using the information and the use to which it is put, be approved and recorded; and finally that adequate technical safeguards are required to ensure that information cannot be retrieved and misused.[442] Further, it is recommended that not only must consent to *collection* of patient data be obtained, but also consent to its *preservation,* as both threaten his privacy.[443] Another recommendation is that there should be specific consent to the making of records and to the maximum period for which these

may be maintained before destruction.[444] Finally it is worth noting that a safeguard of privacy which appears to be increasingly used in American jurisdictions in relation to medical research carried out in sensitive areas such as drug and alcohol abuse, is a legislated duty or privilege of confidentiality.[445]

The discussion, so far, has only considered a patient's right to privacy, but it has been suggested that a concept of privacy also applies to physician-researchers[446] and more importantly, to ethical review committees. There may be a need for this in the latter case if the membership of a committee are to feel free to express their true opinions, but this advantage must be balanced against the need for openness and public accountability.[447]

In conclusion one wonders how far pragmatic analysis of the conflict of medical confidentiality and scientific research by Baldwin *et al*[448] represents what should be the approach taken to these privacy problems. The reasons for transfer of medical information, they say, are clinical, administrative and scientific, and the question is not whether the information can be transferred for these purposes, but under what circumstances this should take place. This is a different starting point and hence results in a different emphasis and perhaps a different result, than does reasoning from a primary right of privacy and duty of confidentiality as the general rule, to which, as a matter of legal interpretation, exceptions are to be narrowly construed.

CHAPTER III

How are consent in the medical relationship, and the underlying principles of autonomy, inviolability and privacy affected by ''disability'' of the patient or research subject?

The first point to be made, is that the rights and duties expounded in the ''normal'' patient context apply equally to the group of persons whom I will call collectively ''special patients''. And to the extent to which these rights and duties are unable to apply because of factual or legal disability or incapacity, that disability or incapacity must be regarded as a condition mandating greater protection of the person and not as justifying a derogation from rights which would be recognized with respect to ''normal'' persons. Consistent with this principle, an important general rule may be formulated in regard to medical research involving ''special patients''. The rule is that it should be regarded as a condition precedent to involving any ''special'' patient in non-therapeutic medical research that the information required from the research cannot be obtained from other ''normal'', that is competent, adult, non-institutionalized subjects.

Some of the matters already discussed do not need modification for application to a ''special'' patient, for example the fiduciary duty of the doctor. Or they are easily modified to accommodate the

interests of the ''special'' patient, for instance the juridical basis of the doctor-patient relationship. In the latter case, whether the patient is ''normal'' or ''special'', tort or delict duties of the doctor are equally applicable. With regard to establishing a medical contract, this is not different legally from setting up any other contract for an incompetent,[449] in that account must be taken of both factual and legal incapacity of the patient and of the status of the person able to act on the incompetent's behalf.[450]

The major problem arises with regard to procuring ''informed'' consent, the ''second'' consent which as earlier proposed there is a duty to obtain in order to justify contravening the right to inviolability of the person.[451] The dilemma can be stated interrogatively: in what circumstances is apparent consent not consent because of the disability of the patient, and when can someone, other than the person himself validly allow another, the doctor for instance, to contravene an incompetent's right to inviolability? The answers whether in fact, in law or in ethics are not clear, but there are basic principles from which one can work out some answers.

Firstly it is important in formulating these principles that they be consistent with those derived for the ''normal'' patient. For example, I have stated that a major purpose of requiring ''informed'' consent is to fully extend the application of a principle of respect for the person.[452] With the competent patient this principle is honoured in both the concepts of autonomy and inviolability. But in the case of incompetent patients, because there is no autonomy, it requires a predominance of the inviolability concept, which means protection from harm and respect for his human dignity. This aim is not always easy to achieve even in the ''pure'' therapy situation and it is even more difficult to ensure when medical research on such persons is involved. This does not mean that it is impossible to carry out medical research on ''special'' patients, but rather that special care must be taken to ensure that such experimentation conforms to ethical and legal principles. This requires a close analysis of what is required in the ''normal'' situation, and whether and how these same principles can be honoured with the ''special'' patient, in default of which the research should be prohibited.

With this approach in mind I wish to examine the problems of consent in relation to the various categories of ''special'' patients, with an emphasis on the difficulties encountered in the medical research situation as this demonstrates most clearly the complex of issues involved.

A. CONSENT WITH RESPECT TO THE DYING, INCURABLE OR "DEAD" AS PATIENTS, OR SUBJECTS OF MEDICAL RESEARCH

One of the most difficult areas of consent is that with respect to euthanasia, which I will not deal with specifically here as the subject of euthanasia is being dealt with extensively in another paper in this series. Rather, I will consider consent in more general terms within a medical relationship in which the patient is dying or incurable. The conditions governing consent to euthanasia would be at least as stringent.

The possible coercive effects on consent arising from the dual role of patient and medical research subject have already been considered,[453] but those who are dying or terminally ill may be considered a "special" sub-category. This categorization may alter the situation in two ways: first it may justify very risky therapeutic experimentation, if this is the only hope for the patient,[454] and thus possibly widen the area of operation of the doctrine of "therapeutic privilege"; secondly, respect for the person as a dying human and the effect of dying on the ability to give "informed" consent,[455] may restrict non-therapeutic experimentation which would otherwise be justified with "informed" consent on a non-dying subject. For these reasons the *Netherlands Report*[456] disapproves of experimentation on the dying under any circumstances. Similarly, the *British Medical Journal*[457] recommends that no experimental trials be conducted on the dying in the United Kingdom. Curran[458] advocates that the F.D.A. regulations in the United States be interpreted as not allowing the use of dying subjects in drug trials, unless these hold out a hope of saving the person. As Beecher notes[459] the inadequacy of classifying subjects as a special category entitled "dying", is that because no time period is included everyone is arguably a present member of the class; and further it is unnecessary, unless it is meant to express detachment of the physician-patient bond. If the latter proposition were true, it would lead to the paradox that the healthier the patient the stronger the physician's obligation to him and the sicker the patient the weaker the duty.

There is a matter which has been the subject of legislation and much academic comment which must be at least briefly touched upon here, and this is the determination of a dying patients death. The juridical and ethical regimes applicable to a dead person are based on different principles and have different aims than those relevant to the living person, and they seek to uphold respect for the dead person and

for the feelings of those by whom he was known and loved. After death such respect may not require inviolability, or this right's area of operation may be limited according to different criteria than those applicable to living persons, in that respect for the deceased, or respect for his relatives' sentiments, only requires that his wishes or theirs be obeyed.[460] This is really to recognize an extended principle of autonomy, insofar as the will of the deceased or that of his relatives may be determinative, more than the principle of inviolability *per se*.

The problem which then arises is how to handle the situation where there is no overt threat to autonomy, that is in the absence of express wishes of the deceased or his relatives. In such cases there is a need for presumptions which will operate to determine whether organs may be taken or cadavers used for scientific, or therapeutic purposes. These presumptions are generally classified under two systems, that of ''contracting-in'',[461] where the presumption is that in the absence of the express consent of the deceased before death or of his relatives after death, the deceased's body is inviolable; or ''contracting-out'',[462] where the operative presumption is that all persons consent to the use of their bodies after death, in the absence of their or sometimes as well their relatives' express wishes to the contrary. In general these types of provisions, provided any required express or implied consent is present, are wide enough to allow medical experimentation on the cadaver, such experimentation being within the meaning for example of such provisions as ''therapeutic purposes, medical education or scientific research''.[463]

For the purpose of deciding which principles with respect to consent apply one must now determine when one is dealing with *inter vivos* medical experimentation and when with *post mortem*, which means determining death. As the subject will be dealt with in detail in another paper in this series, it is only necessary to give an outline of the problems involved in this determination here. One issue is that of whether or not a definition of death should be legislated.[464] The difficulty is that death is a biological process, but the law requires an event, a precise point in time beyond which a person is regarded as dead. It is possible to mark this point anywhere along a continuum from permanent loss of the ability to interact with one's surroundings,[465] to whole brain death, or even to cellular death at the other end. It seems that ''brain death'' is becoming more and more recognized as death of the person. But a further consideration is whether this criterion of death should be legislated, and, even if it is, whether it should be recognized as a sufficient criterion of death or

simply as one criterion, the determination of death depending, in any particular circumstances, on the clinical judgment of a doctor or doctors.

One should also be aware that there may be two points in time with legal significance here, and the distinction between them becomes more important if a concept of "brain death" is adopted. The first moment occurs when the doctor is justified in no longer taking extraordinary measures to keep the patient alive, or even perhaps, in discontinuing active treatment. This point will then subsequently be followed by the second, the moment of death. It is only when the person is already dead that it *appears* that the two moments, of withdrawal of artificial support measures and of death, coincide. Further, it is necessary to consider whether the fact that death is being declared for different purposes might call for different safeguards, including variations with respect to consent.[466]

B. CONSENT AND CHILDREN AS PATIENTS OR SUBJECTS OF MEDICAL RESEARCH

Here the problem is one of "informed" consent for reasons of legal, and when younger children are involved sometimes also factual, incapacity. Again this is a much debated topic, but some clear positions can be identified. One matter which can be settled immediately is that, in my view, the dangers of coercion associated with allowing payment for medical experimentation involving children, would never justify any advantages associated with this practice. Consequently, I propose that all payment in money or in kind should be prohibited except where it is genuinely an indemnity, or takes the form of a therapeutic advantage arising directly from the experiment itself.

1. Consent to therapy and therapeutic research

With respect to "pure" therapy or therapeutic research, which by definition is for the benefit of the child, the parent may give "informed" consent.[467] This is so because the parent has both a legal right and duty to care for his child, in default of which, the state under its *parens patriae* power may intervene through its courts to order necessary treatment.[468]

On the same line of argument there seems to be no reason why a minor, who is able to consent to therapy, could not also consent to therapeutic research. The problem then becomes whether, and when, a minor's consent to therapy is effective. This is a much debated question, but one which has been resolved to a certain extent by legislation in some jurisdictions. For example, in Quebec a minor of fourteen years of age or older may consent to "care and treatment required by [his] state of health",[469] as he may in at least one state of Australia.[470] In Ontario,[471] British Columbia[472] and the United Kingdom[473] he may so consent at sixteen years of age. The individual states, of the United States of America display a variety of legislation in this respect, which either generally lowers the age of consent to medical treatment, or does so at least for the purpose of obtaining consent to treat certain specified medical conditions.[474]

In default of legislation, or where there is legislation but a minor is below the age specified for consent, there may still be a problem about whether or not his consent to therapy is effective, except when the legislation *expressly prohibits* consent by a child below a specified age.[475] One difficulty caused by some legislation is that although it does not prohibit consent below a certain age, it may create a presumption that it is meant to cover the field and hence abrogate any previous law and, when, interpreted strictly according to its terms, it may make a certain age of the child a condition precedent to his giving a valid consent. The United Kindom legislation is noteworthy in this respect. It has a saving provision, that the Act does not make ineffective any consent which would otherwise be effective.[476] I suggest that it is preferable to view all the relevant legislation in this way, except where this is impossible because of express statutory direction such as under the Quebec Act. That Act provides that the consent of the person exercising paternal authority is necessary when a minor less than fourteen years of age is involved.[477]

It is at least arguable that apart from, and except where abrogated by statute, at both Civil and Common Law a minor capable of discernment can consent to medical treatment. Here again it is important to make the distinction between consent to the medical contract and consent to medical care. I suggest, that even if the minor lacks capacity with respect to the former, he may have it in regard to the latter consent. This is particularly true if one argues that consent to a contract requires legal and factual capacity, whereas consent to medical care only requires factual capacity. Such an approach may even enable a minor to consent against the wishes of his parents.

Dierkens is of the view that: ''les prescriptions du droit civil en matière de capacité régissent essentiellement . . . l'exercice de droits partrimoniaux. Elles ne sont pas d'application stricte lorsque les droits sur la vie ou le corps sont mis en question. La capacité naturelle, appréciée essentiellement en fonction du degré de maturité, peut prendre alors une importance determinante. C'est ainsi qu'en cas d'absence ou même d'opposition du père, le mineur, qui jouit d'une maturité suffisante, peut, sans aucun doute, autoriser valablement le médicin à prendre les mesures conservatoires indispensables.''[478] Similarly Crépeau,[479] speaking of the law in Quebec prior to the enactment expressly requiring a minor to be at least fourteen years of age to consent to medical treatment,[480] says that an adolescent minor capable of discernment had capacity to consent to a medical intervention and to enter a non-lesionary, that is therapeutically beneficial, medical contract.[481] This was so because ''le droit à l'inviolabilité est un droit extrapatrimonial, personnel, qui ne saurait être exercé que par son titulaire s'il est en mesure de la faire et s'il est doué de discernement''.[482] This is still the applicable policy enshrined in the statutory provision allowing a minor to consent. The difference is that the criteria chosen for its application are a specified age and, presumably, discernment,[483] rather than solely the latter.

In Common Law there is very early authority establishing that a minor can enter a medical contract. Coke[484] states that ''an infant may bind himself for his . . . necessary physic'', and an ancient case, *Dale v. Copping*,[485] held that the necessaries for which a minor can contract include medical services. One must realize here that the fact that the contract was for a ''necessary'' overcame invalidity of the contract even due to lack of consent, not just invalidity due to lack of capacity in the sense of legal status. Hence the minor could be bound to such a contract although incapable of discernment; the basis of his liability was either that being for a necessity the contract *must* have been entered in some way, therefore lack of actual consent was irrelevant or alternatively, consent establishing the existence of a contract may have been implied by legal fiction from the minor's state of necessity. Whatever the basis for this law, its application is conditional on the medical contract being ''necessary'' for the minor.

Where the treatment is not within the above category but is for the benefit of the minor, there is support, including that of Nathan, for the view that if the minor has the intellectual capacity to fully appreciate the nature and consequences of the medical procedure performed for his benefit, then he can give a valid consent.[486] On the other hand, one author sums up the situation at Common Law as

being "not clear if the minor has power to consent [or] whether one must also obtain the consent of the parent".[487]

One must here again make the distinction between the two consents involved, that to the medical contract and that to medical care, in order to understand the authorities and aid analysis. Coke was speaking of consent to the medical contract,[488] Nathan and the other authorities quoted,[489] of consent to a medical intervention, in the sense of consent being necessary though not always sufficient, if an intervention is not to constitute a crime, nor the torts of assault or battery. The vital question with respect to minors is, whose consent in the latter sense is both necessary and sufficient?

In an interesting historical approach Annas, Glantz and Katz survey the early Common Law on minority and conclude that the concept of an age of majority was based on feudal law and custom, and is not related to modern needs.[490] However, even within the limitations of this early law a study of Blackstone[491] shows that minors were not without significant legal capacity, for example with respect to marrying, or making a will disposing of their personal estate. Also, if one looks to minors' consent in the law of torts in general, it is often assumed to be present in non-, or minimal, risk situations, as otherwise every physical social contact would become an assault and battery. Further, where risks are involved, if the minor understands these and voluntarily accepts them, his assumption of risk either for himself or of his conduct to others, is as valid as for an adult.[492]

The question then becomes should any general ability at law of a minor to consent to being touched, or to acceptance of risk, be modified in the medical context. The rationale for allowing the parent to consent for the child, putting aside any prerogative the parent may have arising from his liability for costs incurred as a result of successful or unsuccessful treatment of the child,[493] is that the former is better able to take into account all the interest of the latter, because the latter is incapable of making an educated and rational choice.[494] This argument applies in the case of a minor incapable of discernment, but not necessarily to a mature minor, and hence the "mature minor" exception to needing parental consent has been recognized by various courts. This rationale also explains two other generally recognized exceptions to needing parental consent to therapy on a minor. These are the emergency situation, where what is in the best interest of the minor is obvious, and where an emancipated minor is involved.[495]

Finally one must consider the situation in the Civil or Common Law with respect to resolution of conflicts between a parent and child, which is usually when the parent consents to therapy and the child does not. Implied in discussion of the opposite situation, that is where the child consents and not the parent, a principle may be deduced that it is necessary to recognize the child's wishes and to justify overriding them, especially as the minor approaches maturity.[496] This reflects a more recent approach of the law which has been to realize that attaining maturity is not an overnight event but a process, and should be recognized as such; further, there may be increasing recognition that perhaps a child has a right of veto which arises before he has capacity to consent and which one must justify contravening.[497] Pilpel[498] describes this evolution as a change from seeing children as the property of parents, to recognizing them as persons with rights and, with this, a change from their not being able to consent, to being able to do so by common law (or "droit commun") exception, or pursuant to statutory provision and, as a corollary, with at least some right to refuse treatment.[499]

2. Consent to non-therapeutic research

One now moves to the much more difficult area of consent to non-therapeutic medical research on children. The point just discussed is important here, in that it leads to the conclusion that if the child objects to participating in such research, one is not justified in overriding his wishes.[500] Thus with the mature minor the capacity to consent to beneficial treatment must carry with it an ability to refuse non-beneficial intervention, but whether it also carries the capacity to consent to the latter is a further question.[501] When therapeutic treatment of an immature minor is involved, I have suggested that the parents must be justified in overriding his wishes, but such justification would never be present in the non-therapeutic situation.

In relation to non-therapeutic interventions on minors one is therefore left to deal with the situations of the non-discerning, non-objecting minor and the discerning, consenting minor. The question is whether the parents' "consent" is sufficient and necessary in each case.[502]

There are many lines of philosophical, ethical and legal discussion[503] which can be only briefly outlined here, but all of them have influenced and are influencing the evolving consensus on the

subject. The most interesting and most publicized philosophical argument has been engaged in between Ramsey[504] and McCormick.[505] The former is of the view that children incapable of consent may never be used in non-therapeutic research, whereas the latter believes that this is justified where children ''ought'', as members of the human race, to accept this obligation. Such an obligation would exist when risk, discomfort and pain are minimal and the research is very likely to be useful. In such cases, McCormick argues, parents may give ''proxy'' consent. There are inherent problems in each view: Ramsey's approach is probably not feasible, accepting the current state of research carried out on children;[506] McCormick's view probably has a generally unacceptable logical extension. If one can use children as subjects in situations where they ''ought'' to consent, why apply this rule discriminatorily, that is why not apply it equally to adults who could then be conscripted as experimental subjects within the terms of the ''ought'', in much the same way as is done for military service? It is in avoiding this difficulty that Toulmin's[507] modification of McCormick's formula is useful. He says the stress should be on that to which the child (or other incompetent) could not reasonably object. In practical terms the results are the same, but this avoids imputing an obligation to the child and not to others.

The legal development in this area is best traced in the context of live organ donation by children, which is, of course, non-therapeutic for the donor.

In France, such donations, by any person, child or adult, were, like non-therapeutic medical experimentation, initially considered illegal. However, this was modified by the development of a legal doctrine of a ''state of necessity'', functioning as a justification for the wrong of operating on the donor, when the purpose was to avoid a greater evil, namely the death of the recipient.[508] This doctrine is applicable to minors capable of discernment in exceptional cases,[509] but it is not clear whose consent is necessary and sufficient, the minor's alone, the parents' alone, or both.[510]

In Quebec the situation is governed by legislation. Article 19 of the *Civil Code of the Province of Quebec* enacts a general rule of invioliability, requiring consent for its valid waiver. Article 20, *inter alia*, enables a minor capable of discernment to consent to *inter vivos* organ donation, or to experimentation, one of the conditions being that no serious risk to the minor's health results from this. The Article's original version also called for the consent of both the

person having paternal authority and a judge of the Superior Court. Quite apart from the problem of determining what amounts to a "serious risk" there was another difficulty in interpreting this provision—it was not clear where effective consent arose, either with the minor, or with the parent or judge or all three. This Article has now been amended[511] to provide for the consents of the minor and of the person with parental authority as well as an *authorization* by a judge.

In regard to the effects of the minors and parent's consents under this new provision, in my view the better interpretation is that the minor's consent is constitutive, with the consent of the parents being regarded as enabling or declarative. This view may be supported either on the basis that under the "droit commun" a minor capable of discernment has capacity to consent to a medical intervention,[512] and that Article 20 extends this capacity to non-therapeutic interventions, or that Article 20 grants this capacity *de novo*, provided in either case that its terms and conditions are complied with. Any other interpretation of Article 20 leads to the result that one is taking an organ from, or experimenting on, a minor for another's benefit, without his consent being recognized as the primary although insufficient justification of the intervention. With respect to adults such interventions are not permitted except on the primary basis of the adult's consent and they should not be permitted *on the basis of* a third party's consent with respect to minors. Thus Article 20 legislates "le droit de sacrifier pour autrui"[513] and extends this to discerning minors in certain circumstances. Whether one is justified in contravening the inviolability of a minor on the basis of some justification other than personal consent is a further question and discussed later.[514]

In Common Law jurisdictions the regulation of organ donations by living persons is also instructive regarding consent to non-therapeutic medical interventions on minors. Among the Common Law Provinces of Canada, Ontario,[515] British Columbia,[516] Nova Scotia[517] and Newfoundland[518] have prohibited tissue donation[519] by minors and in doing so, have followed the uniform legislation[520] recommended for adoption in all Common Law provinces of this country.

In England there is no legislation governing donation of organs by living persons, whether child or adult, and the rights of parents to consent to medical interventions on their children, although not questioned in the therapy situation, have only been clearly recog-

nized by the courts in reported decisions in recent years.[521] Some of these cases involved paternity disputes in which blood tests were required and where, consequently, there was an element of non-therapeutic, rather than therapeutic, benefit involved. However in these cases there was no question of the intervention being without benefit to, or contrary to the best interests of the child.[522] There is dicta in these cases that has subsequently been used[523] to ground an argument that a parent may consent in the ''best interests'' of the child, which does not necessarily mean for the child's therapeutic benefit, the latter being the traditional requirement for any consent validating a medical intervention.[524] In my view this is an unfortunate extension[525] in relation to children incapable of discernment, an extension demonstrated in the American courts' reasoning in the minor, or mentally incompetent, organ donor cases.

In *Bonner v. Moran*[526] the court held that a fifteen year old boy could not alone consent to be a donor of skin, but by implication indicated that his parents could have consented.[527] In conformity with a view that parents can consent to non-therapeutic interventions on their children, a Connecticut court, in *Hart v. Brown,*[528] authorized the parents of seven-year-old twins to consent to the donation of a kidney by one to the other. Similarly in *Nathan v. Farinelli*[529] the court characterized its duty not as one of deciding whether or not to allow the operation to take place, but of reviewing the parents' decision. The Court both relied on *Bonner v. Moran* and expressly rejected the psychological benefit test, thus interpreting this case as authority supporting the parents' right to consent in a non-therapeutic situation. In contrast to instances in which immature minors were involved in non-therapeutic procedures, in *Rappeport v. Stott*[530] a Massachusetts court held that a seventeen-year-old girl was intellectually, and therefore legally, capable of consenting to a bone marrow donation. This is an application of the ''mature minor rule'', that is that the consent of such a minor is sufficient.

If one accepts that parents may consent to some non-therapeutic interventions on non-discerning children one must examine the conditions under which the courts have allowed such consent. In this respect a comparison of two cases involving mental incompetents, who are in a directly analogous situation to non-discerning minors as far as capacity to consent is concerned, is instructive. In *Strunk v. Strunk*[531] the court authorized[532] an operation to remove the mentally incompetent donor's kidney for transplatation into his brother. This was done on the basis of the parent's petition and after finding, on very slim grounds, that there would be psychological harm to the

incompetent donor if his brother died, as he would be ''saddened''. The avoidance of this sadness was equated to psychological benefit. In *Re Richardson*[533] on the other hand, the court held that the parents could not consent, nor could the court authorize the organ donation operation on the incompetent, certainly not in this case since they had found no benefit to the donor; and possibly not in any case.

The development of the test of psychological benefit used in these incompetent transplant donor cases, evolved from the courts' difficulty in finding that the requirement of therapeutic benefit to the person on whom a surgical operation was carried out was fulfilled. This requirement was necessary for the legality of an operation at Common Law.[534] This was dealt with by changing the content of the requirement of therapeutic benefit to include not only the traditional element of possibility of physical benefit to the patient, but also psychological benefit, or merely benefit, in the sense that the intervention was in the ''best interests'' of the donor.[535] Thus in instances of non-therapeutic interventions for ''inter-vivos'' organ donation the presence of psychological benefit, or any benefit, to the prospective factually or legally incompetent donor, seemed to be regarded by the courts as a sufficient condition precedent to an incompetent's or minor's consent, where such consent was possible, or to the guardian's or parents' consent, or to the court's authorization.

This modification of ''therapeutic benefit'' to psychological benefit was first developed in three Massachusetts cases, each involving kidney donations between twins,[536] in which psychiatric evidence was given that there would be ''grave emotional impact'' on the donor if not allowed to donate. Avoidance of this trauma was characterized as benefit. However, in all these cases the minors concerned could have been regarded as ''mature'', as two sets of twins were aged fourteen and the other nineteen years. However, it is not clear whether the ''mature minor rule'' applied, assuming that this connotes equivalence to the competent adult situation with respect to consent and does not have special rules of its own. This doubt is caused because with competent adult donors ''informed'' consent has come to be regarded as an alternative to, or substitute for, therapeutic benefit; and yet the courts in the cases under discussion, went out of their way to find psychological benefit to these mature minors. Further, these cases do not answer the question of whether the parents' consent alone is sufficient, either with or without psychological benefit, when a non-discerning minor is involved.[537]

Two cases already mentioned, in which the donor children were seven and six years of age respectively, are of interest in this latter respect. In *Hart v. Brown*[538] there seems to have been an easing of the psychological benefit test, to one of lack of "substantial harm" to the donor and substantial benefit to the recipient, as justification for the non-therapeutic intervention.[539] In *Nathan v. Farinelli*[540] there was an overt weighing of costs and benefits to both children on the basis of what was "fair and reasonable", and the court expressly rejected the psychological benefit test as highly speculative.

These cases and the change in the requirement of therapeutic benefit that they show, are significant when one considers whether parents may consent to non-therapeutic medical interventions on their children. They constitute at least some precedent for saying that parents may consent when the minor is not capable of discernment, when the procedure is not therapeutically beneficial to him, and when, perhaps, it is not even in his best interests. The harm does not outweigh the benefit to the minor in the latter case but rather the justification advanced is that the harm to him is outweighed by the benefit to someone else. In my view this proposition is unacceptable as a general policy, and perhaps even as a particular one. Such precedents must be contained within the strict limits of their facts, that is where a close, identifiable relative is being benefited by the non-therapeutic intervention. This limitation may be achieved by arguing that, at their widest, doctrines of "proxy consent" or "substituted judgment", historically and in these cases as well, have only been applied to assist close relatives in need.[541] However it is disturbing to realize that a strong argument can also be made for expanding the application of the precedent set by these cases only on the basis of this same fact, that they involved close relatives, usually brothers and sisters. This occurs because it can be suggested that if the court allowed parents to consent to a non-therapeutic intervention when they were faced with such a terrible conflict of interest, between choosing the death of one child and maiming another, they would more readily permit this in the non-therapeutic research situation, when such a conflict is not present.[542]

In summary I submit that non-therapeutic medical research involving risk, may not be carried out on minors who have not personally given "informed" consent and, in particular, may not be justified on the basis of "proxy" consent. This position is not the same as saying that any such research is never justified. Such a position should also be generalized I suggest to cover other non-therapeutic or doubtfully therapeutic interventions, such as the

sterilization of mental incompetents, or to controversial techniques such as psychosurgery. Similarly the following discussion of the medical research situation, dealing as it does with many of the issues raised by ''proxy'' consent in relation to such interventions, may also be generalized to those other non-therapeutic or doubtfully therapeutic interventions.

The question then is; short of banning all non-therapeutic medical interventions on children personally incapable of giving ''informed'' consent, when should they be allowed and how should they be regulated? Firstly, to ensure that the consent of parents is not seen to be a justification, in the area normally referred to as ''proxy'' consent, one should end the ''charade of consent''.[543] That is the reality of what is taking place must be stated bluntly so that ''proxy'' consent is not seen as consenting on the child-subject's behalf, but rather as consenting directly to the intervention on the subject. This means dropping the use of the word consent and rather speaking of selection of child-subjects, the child's assent, and the permission of parents.[544] Although such a change may only be in nomenclature and not reflect any difference in reality, it is, I submit, important for the purpose of developing attitudes and sensitivity to the issues involved. The aim is to distinguish ''what a person may do for oneself, [sic] consent, from what one may do on behalf of another, grant permission''.[545]

Then, arguably, ''no risk'' or ''minimal risk'' non-therapeutic interventions,[546] may be allowed with the assent of the child where the child is capable of such assent, and with the permission of the parent. In this case one is not contravening the general rule that parents have no authority in non-therapeutic circumstances and may not purport to consent to infliction of harm on their children.[547] Rather, arguably[547a] their consent is not needed because of the lack, or insignificance, of any harm or risk of harm.[548]

With respect to more than minimal risk, non-therapeutic interventions, the ''mature'' minor, subject to proper safeguards of ethical review by a committee and possibly parental permission in some circumstances, ought to be allowed to give ''informed'' consent. There would also be other conditions precedent to carrying out such interventions, in additon to those normally required. For instance, in relation to medical research, one condition is it must be impossible to carry this out, or conduct it further, on adults. Another is that the studies must be initiated on older children, if this is valid for research purposes, prior to including younger children, even

though the latter are capable of discernment.[549] Or, with regard to other procedures, for example sterilization, this must at least be the least restrictive and least harmful alternative available.

There is, however, a fundamental problem in allowing more than minimal risk, non-therapeutic medical interventions on minors capable of discernment, and this is the problem of identifying when a sufficient level of discernment is present. A child may be considered legally capable of discernment as young as seven years of age, but this may not indicate he has the necessary discernment to consent to medical research, as has been empirically demonstrated by Schwartz.[550] This researcher found, that despite careful and detailed effort, children under eleven years of age were unable to be made aware that they were participating as research subjects. Six of nineteen minors aged eleven to seventeen years had some awareness of the research element involved, and of these six, five suffered acute anxiety. If the results of this study are generally applicable it throws doubt on whether one can, or should, use even ''discerning'' minors as medical research subjects.[551]

Thus it is strongly arguable that parents cannot consent to any non-therapeutic medical intervention involving risk, or more than minimal risk, and that such interventions should never be allowed on minors incapable of giving fully ''informed'' consent at a subjective level.[552] And yet there may be exceptional circumstances where this is justified, for example where all children are threatened by a serious disease and no other type of medical research except that on children offers any prospect for discovering a cure, or where children are afflicted with a fatal disease and while research on the disease does not offer them any potential benefit, it may nevertheless benefit others with the disease in the future. In such cases the emphasis must be on two matters: the truly exceptional nature of allowing the research intervention[552a] and further, that although permission or consent of the parents may be a necessary condition precedent, it does not have the effect, in itself, of making the intervention legally valid.[553]

Rather a system of elaborate safeguards, which include the parents' permission and the child's assent to the extent that he is capable of giving it, must be set up[554] and a further and adequate justification for conducting the research must be found. In the latter example cited above, of non-therapeutic research on a fatal disease from which a child is suffering, it may be that the patient's ''identification'',[555] with future sufferers of the same disease, goes

some way towards this. However a justification such as this must be used with extreme caution and reluctance, or it will open the way to using non-consenting patients incapable of discernment, simply on the basis that there is some connection between a disease from which they suffer and the research. It is only within such a framework of safeguards that one may honour the rule that parents may not consent to any risk of harm or more than a minimal risk of harm being inflicted on their children, while still recognizing that some truly rare situations do exist, where the ethics may mandate the medical intervention being conducted.

3. Institutionalized children

These children deserve special mention and special protection, which means they should never be subjected to non-therapeutic medical interventions or used in non-therapeutic medical research, and exceptional care must be taken in accepting third party permission to any intervention with their physical or mental integrity. In a sense they have a double "disability", that of being children and of being institutionalized and, in the latter respect, are comparable to prisoners.[556] They are too available, too easily coerced, too little protected by someone with the necessary bond of affection and personal commitment. This bond is necessary for even "proxy" consent to serve its proper function, assuming for the moment this is legally adequate and should be treated as effective. This has been legislatively recognized with regard to medical experimentation in Pennsylvania,[557] where non-therapeutic research on juvenile inmates of state and county correctional institutions is banned.

The matter is more difficult with respect to therapeutic medical research or to doubtfully therapeutic interventions. However, here there must be a heavy onus on the physician to show that the intervention is carried out with a geniune therapeutic aim for *that* child, that there have not been coercions applied to either the child or parent,[558] and that there is adequate independent scientific and ethical review of the proposed intervention or research protocol. This includes determining that the procedure is within the definition of therapy.

It is worth noting that in the United States, the National Commission in its draft paper on "Research Involving Children"[559] and in its subsequent "Report and Recommendations"[560] on this topic, does not distinguish between therapeutic and non-therapeutic

medical research for the purpose of deciding what safeguards should apply in a particular research situation. Rather, benefit to the child-subject is one factor taken into account in deciding whether to approve the particular research. Within this wider context special provision is made for children who are wards of the state or institutionalized, in that with some narrow exceptions there is a general prohibition on including them in medical research.[561]

4. "Consent" by the state and its refusal to recognize consent with respect to medical interventions on children

Just as the state can authorize treatment of children against the wishes of the parents, under its *parens patriae* power or specific statutes it can intervene for similar reasons to prevent unjustified treatment to which the parents have consented. It is interesting here to consider whether parents' power over their children as well as the power of the state to intervene, is original or derivative. The more acceptable view is probably that the parents' power is original, but limited by the rights of the child, and that the state's power is derivative, both from the parents' power and the child's rights, either of which it can enforce for proper ends. In the process of maturation, one can then argue there is a progressive handing over of power from parent to child, so that one finally has a competent adult with individual, original rights, which are limited only to the extent specified by law.

The bases on which the state may intervene to authorize or prohibit medical treatment or research may be simply under its general protective power over minors or those unable to protect themselves. Or it could be pursuant to child abuse legislation[562] such as that in California, where it is a misdemeanor to endanger the health of a minor or to subject him to *unjustifiable* mental or physical suffering.[563] Levine[564] suggests that a parent who consents to a child participating in non-therapeutic experimentation may be liable, with the physician, for conspiracy to commit child battery. Hershey and Miller,[565] in a list of possible actions arising from the same circumstances, include first, court determinations that the child is "dependent and neglected", with the possible consequences of parental loss of custody and the child being made a ward of the state. Secondly, they list criminal liability of both the parent and researcher where harm is actually inflicted on the child as part of the study. If

such a situation amounts to child abuse then there may be further liability, since failing to report an incident of child abuse about which one has knowledge, may in itself be an offence, as it is for example in Quebec.[566]

C. CONSENT AND FOETUSES AS PATIENTS OR SUBJECTS OF MEDICAL RESEARCH

The most difficult problem here is consent as it relates to medical research on foetuses. This is not only a controversial topic in itself, but it often involves another ethically polarized area, that of induced abortion.[566a] Therefore some reference to the arguments put forward regarding this practice are necessary to an analysis of consent in relation to medical interventions on foetuses. If one believes abortion to be morally unacceptable, then it is difficult to accept arguments justifying research on aborted foetuses as their availability depends on a moral wrong. It is argued against this that the ethics of abortion are irrelevant, as a utilitarian justification applies, and that as the foetuses have been aborted it is simply wasteful not to use them for research. The problem with this rebuttal is that the act making the foetuses available is a deliberate human intervention, and in my view it is not clear that one can morally apply utilitarian arguments of waste as justification in such a situation. The same type of arguments could be applied to prisoners, and yet we take a different approach, probably because society is seen as having acted to place them in a situation of availability where they may be coerced. Thus we make a distinction between this ''artificially created'' type of availability or coercion and that arising in the ''ordinary course of events'', for example pressure from one's family group. As a result we see persons affected by the former as needing more, rather than less, protection.

Depending on the proposed future of the foetus, it may be included within one or more of the categories of patient or research subject already discussed. Whether it should be governed by the rules suggested for consent to treatment and research on children while still *in utero*, is a matter of debate, and to some extent, relates to one's views on the acceptability of abortion and the basis upon which one justifies and performs it. If one regards the foetus as a person, in fact or law, from conception, or from implantation, or from viability, or from some other arbitrarily determined time, then at that point in time abortion, for many people, becomes unacceptable. But whether or not abortion is acceptable past this point in time, the logical corollary

of recognizing the personhood of the foetus is that from that time, the foetus *in utero* must be treated with respect to consent to medical interventions on it, according to the same rules as an infant child.

With respect to medical research on the foetus *in utero* prior to its personhood being recognized, it is very much a moral value judgment as to what experimentation may be consented to on its behalf. I suggest that for reasons of distributive justice one is not entitled to discriminate between foetuses going to term and those to be aborted. The rule must be that only interventions which would be allowed on a foetus going to term, which interventions are governed by the criteria applicable to treatment or research on non-discerning children, are allowable. There is, however, one modification which must be made because of the physiological unity of the mother and foetus. This is that the mother may consent to therapy for herself, and even to non-therapeutic research directed towards her when the latter involves at most minimal risk for the foetus, and even if it carries more than such risk if it is necessary therapeutic experimentation for the mother.

It is sometimes argued that if one can intervene to kill the foetus by abortion, why not do so in a more socially useful way, by experimentation?[567] One of the answers to this question is that even though the woman may have a right to an abortion, this does not necessarily mean she, or anyone else, has the right to consent to experimentation on the foetus. In other words if one recognizes a right to have an abortion this must be premised on a woman's right which in the circumstances overrides rights of the foetus; when there is no right of the woman being upheld, as in experimenting on the foetus, its rights may not be ignored or waived by consent.

There is also a danger in allowing consent to minimal risk research on foetuses. Although this does not seem very different from the situation with regard to non-discerning children, where it has been suggested that such research may be acceptable, a subtle distinction has been and may be made. This is that the assessment of risk is subjective and with a foetus intended for death by abortion, in comparison, almost any procedure can be considered minimal risk. That is "risks to the foetus-to-be-aborted may be considered minimal in research which would entail more than minimal risk for a foetus-going-to-term".[568]

Assuming that one finds it ethically acceptable to conduct some or all forms of medical research on one or more "categories" of

foetus, that is ''to-be-aborted'', aborted, non-aborted, viable, pre-viable, living or dead, there are still problems of ''informed'' consent. If the foetus is not to be aborted the situation is directly analogous to that governing children incapable of discernment, and the parents may ''consent'' or give permission for treatment or research on the same conditions and in similar circumstances. When abortion is involved the matter is more complicated as there is an objective conflict of interest, and probably not sufficient mutuality of interest, at least between the mother and the child, to allow the consent of the mother on its behalf to be recognized as legally valid. However, in the United States the National Commission and the D.H.E.W. agreed to the contrary, ''that a pregnant woman need not be presumed to lack interest in her fetus even when she has decided to terminate her pregnancy; thus she may validly be asked for consent for research involving the fetus''.[569]

The Peel Report[570] is consistently vague with respect to the consent required for research on the foetus. It speaks of research, presumably therapeutic, on a viable foetus to which ''the parent's consent can normally be inferred'', (*quaere*) and then of ''areas of research which whilst not jeopardizing the helath and welfare of the foetus are not of direct benefit to that particular foetus. In such cases [the members of the Advisory Group] consider that express consent should be obtained from the parent''.[571] The Report then deals with the dead foetus, where if the United Kingdom *Human Tissue Act*[572] applies, the consents required under this must be obtained and if not, there must be ''no known objection on the part of the parent who has had an opportunity to declare any wishes about the disposal of the foetus''.[573] The latter alternative given here, apparently implements the opinion that ''[w]here the separation of the foetus from the mother leads to the termination of its life there is no statutory requirement to obtain the parent's consent for research, but equally there is no statutory power to ignore the parent's wishes''.[574] The provisions regulating consent to research on the pre-viable foetus while still alive, are the same as for the dead foetus.[575] This probably explains the complexity of the terminology used in the passage last cited above, as the words ''dead foetus'' could just as easily have been used if this was all that was intended to be covered within these terms, in comparison to the terminology needed if the provision is meant to extend to the living pre-viable foetus, as this provision, in all likelihood, does. It is also possible that the Advisory Group considered such a pre-viable foetus to be already dead,[576] which raises the difficult but essential distinction between the process of

dying considered medically, and the event of death considered ethically and legally.

Some commentators believe that, as a matter of law, consent to experimentation on the foetus may not be required at all, ''because there is no interest in young foetuses that needs to be protected by the use of consent'',[577] or because the foetus is a tissue specimen removed from the mother and the mother's consent to the abortion surgery covers any dealing with such specimens that the hospital's pathology laboratory deems to be fit and proper.[578] It has also been argued that one does not need the consent of the foetus, and therefore, nor the ''proxy'' consent of the parent, to foetal research, because if this were the case one would also require ''proxy'' consent to abortion on behalf of the foetus.[579] In fact this latter argument shows why ''proxy'' consent to foetal experimentation involving abortion should not be regarded as valid, as it is a protective device for those ''unable to speak for themselves'' and one can never justify using it to achieve the very opposite of its intent''.[580] The conclusion then should not necessarily be that because ''proxy'' consent is not needed to abortion it is therefore not needed to research on the foetus, but perhaps that the research requiring such consent may not be carried out.

In relation to defects of consent with respect to consent to foetal experimentation, coercion in the form of payment can present one of the major problems. The D.H.E.W. Regulations provide that ''no inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of'' research[581], and the Peel Report's ''Recommended Code of Practice'' states there must be ''no monetary exchange for foetuses or foetal material''.[582] This approach, I submit, is an essential safeguard, not only of the foetus, but also of the mother, in order to ensure she is not coerced into decisions she may later regret.

There is one final question to be raised in relation to consent to medical interventions on the foetus, and this is how does consent to such interventions affect the foetus's right to sue if, and when, it becomes legally recognized as a person? Once the foetus is born, and certainly if it is viable, there is now no doubt that in all relevant jurisdictions it has the protection of law and remedies for pre-birth injury available to it.[583] In Civil Law jurisdictions the ''nascituris rule'' seems to apply, which means that any right of the child to sue for damages for personal injury only accrues on viable birth. It is not as clear that this is the case in Common Law. The situation between

various states of the United States of America, differs in that there are some precedents which require the injury to have occurred after viability for recovery of damages, which recovery does not, however, depend on live birth, and other precedents which hold that it does not matter when the injury occurs, but the cause of action only accrues on live birth. The latter is the approach taken in England, Common Law Canada and Australia.[584] Such remedies, provided their necessary conditions precedent were fulfilled, would be applicable in the case of a foetus suffering harm from *in utero* medical interventions, whether later aborted or not, depending on the effect that the consent of the parents has on the child's right to sue. In my view this effect would vary, according to whether the treatment of research was therapeutic or non-therapeutic, and whether the foetus was born as a result of induced abortion or not. In the case of therapy or therapeutic experimentation where abortion was either not involved at all, or was medically indicated as "pure" therapy for the mother, the parents' consent would probably bind the child, who should be taken to have had his right to sue waived on his behalf. As one moves along the continuum to clearly non-therapeutic research on the foetus and "abortion on demand" the parents' consent becomes legally less effective in binding the child, until it is of no effect at all.

D. CONSENT AND MENTAL INCOMPETENTS AS PATIENTS OR SUBJECTS OF MEDICAL RESEARCH

There are two disabilities covered by the term mental incompetency—legal and factual incapacity, either of which may be temporary or permanent.[585] When the latter incapacity is present, the situation is analogous to medical interventions on non-discerning children, with the same "caveat" present about involvement of institutionalized persons in medical research.[586] Neville[587] analyzes the reasons why institutionalization should be a bar to using such persons as research subjects, which really amounts to a delineation of coercive factors which may affect the validity of consent. He says that civilized protections, to ensure that one person does not have undue and inappropriate power over another, are not effective in this situation. He maintains this is so because such protections require a right to dissolve personal relationships and to belong to contrasting groups for support; and they suppose a practiced development of

private judgment and an environment that "does not conspire to subject the individual to the interests of the environment itself".[588]

When mental incompetents are involved in medical interventions, special care is needed in assuming or accepting the concordance of interest of the parent or guardian and the incompetent for the purposes of "proxy" consent, or any granting of permission. With a child one has the promise of life in the future as a fully legally capable person. The lack of this feature with respect to some mental incompetents, may alter judgments made by others concerning them, to the effect that their interests are more likely to be sacrificed. As with children, account must also be taken of the degree of the factual incapacity and assent of the patient sought to the extent that this is possible. This is so even when the intervention is independently justifiable because, for instance, it is therapeutic. Likewise, more weight should be given ethically and legally to such a person's objection to participation than would be to his consent, so that his power of veto is stronger than his ability to consent.[589]

This shows that in determining what is an ethically and legally adequate consent to a medical intervention on a mentally incompetent person, it is necessary to examine both legal and factual incapacity, the former of which may or may not coincide with the latter, and further to recognize that institutionalization is not *necessarily* conclusive of either.[590] Where a person is factually incompetent he is also legally incompetent, but he may have been declared legally incompetent, by a process of law such as commitment or interdiction, and at some later time be factually competent.[591] Traditionally a functional test of competency in relation to managing one's estate was used as the basis for a declaration of legal incompetency, which, as a corollary, was often aimed at protecting the incompetent's property and not his person. Such a declaration, however, was generally regarded as rendering the person subject to it incompetent in all respects. This global effect should be re-examined and a person who is factually competent in regard to medical decision-making should not be deprived of this right. Rather, a person should only be declared to be totally legally incompetent where this is necessary to protect both his person and his property.

Legal processes of commitment or interdiction have the effect of vesting the power to exercise some, or all, of the incompetent's rights in a guardian, tutor, or curator. It follows from the fact that the aim of this process is protection of the incapable person, that if the protector has the right to consent to violation of his ward's bodily integrity, he

can only do so for the benefit of the person under his care.[592] This, I submit, is an even clearer case than when the same arguments are applied to "proxy" consent involving children, because there is absolutely no question of custody coming into play, that is custody in its ancient sense of ownership rather than care. Thus, I propose, a guardian or tutor of a mental incompetent may only consent to therapy or therapeutic research undertaken for the benefit of the incompetent. Apart from lacking legal ability to consent on any other bases, there is a strong policy reason to limit the "proxy" consent to this extent, and that is the otherwise present danger of taking account of social worth in the selection of subjects for risky medical research.[593]

When one examines legal doctrine, it is the unanimous view of Civil Law writers that a tutor or curator of a legally incompetent person may not consent to non-beneficial medical interventions being undertaken on the latter.[594] Kornprobst[595] looks at the various categories of legal incompetents under French law, and says that "petits mentaux" must consent for themselves, whereas for "internés" a relative may do so, while for "interdits" a tutor may consent, and with "prodigues", as the tutor is only appointed to their goods, they retain the right to give personal consent. Thus those who are legally not permitted to consent for themselves are excluded from participating in non-therapeutic medical interventions, as another may not consent to a procedure not for their benefit. With those able to consent for themselves, assuming the proposed non-therapeutic medical intervention is otherwise permissible, it is a question of fact as to whether they have given the necessary "consentement libre et éclairé".

The general regime for mental incompetents is essentially the same in Quebec[596] as that just outlined, but one must take account of the effect of Article 20 of the *Civil Code of the Province of Quebec*. I suggest that in conformity with the general principles of the Civil Law, the desirable interpretation of this Article is that it does not extend to allowing "proxy" consent of the legal representative to non-therapeutic experimentation on, or organ donation by, a factually or legally incompetent person.[597] Further, I submit, the person himself, while subject to a decree of legal incompetency taking away his power to consent to medical interventions, may not consent within Article 20, even though at the time he is factually competent.[598] This, in reality, is to interpret the word "consent" in Article 20, as meaning and requiring for fulfillment, personal consent

given by a person with full legal and factual capacity, except if such person falls within the express provisions covering minors.

In Common Law the matter is not clearly settled as to the extent to which a legal guardian may consent for an incompetent,[599] although one may draw an implication relevant here from the fact that the Common Law Provinces of Canada have prohibited the mentally incompetent as *inter vivos* organ donors,[600] and the Australian Law Reform Commission proposes the same rule.[601] There is again no doubt that the guardian can and must act for the benefit of the incompetent and the problem therefore arises in relation to consent to non-therapeutic medical interventions. The live organ donor transplant cases in the United States of America which involved mentally incompetent donors, and which have already been discussed,[602] are instructive in this regard. They show that a court may or may not feel itself free to authorize, or to validate "proxy" consent to such a non-therapeutic intervention on the incompetent.

Also with respect to use of the doctrine of substituted judgment[603] in relation to such interventions, a further comment should be made here, as this doctrine traditionally has closer legal links with mental incompetency in its strict sense, than with decisions involving non-discerning children and hence may be more readily applied in the former area. This doctrine has been used for one hundred and fifty years to provide for needy dependents from incompetents' estates, but it is another matter to use it as a justification to invade another's bodily integrity, especially when it is much easier to be altruistic on behalf of that other rather than oneself. The *Kaimowitz Case*[604] is a strong precedent that the Court will not recognize "proxy" consent to experimental treatment of doubtful therapeutic value, to say nothing of non-therapeutic interventions on a mental incompetent.

It is necessary now to mention the problem of the sterilization of mentally incompetent persons,[605] which is a non-therapeutic, non-experimental intervention, but which in some circumstances, is arguably in the "best interests" of the person subjected to this procedure. Great care is needed to ensure that the real, but latent, "best interests" taken into account are not in fact those of the community rather than of the mental incompetent. If the former were the case, which should never be, the situation would much more closely resemble that of non-therapeutic medical research. But where such decisions are based solely on the best interests of the mental incompetent, cases[606] determining whether "proxy" consent

to the sterilization procedure is valid may be regarded as special examples of courts' reactions to a unique problem, with no direct application outside the realm of sterilization to other non-therapeutic situations especially as far as doctrines of ''proxy'' consent are concerned.

Another factor which must be taken into account in Common Law jurisdictions is the potential law-making effect of recognized current professional practice. For instance the proposed D.H.E.W. Regulations in the United States of America, limit medical research on institutionalized mentally disabled individuals to that ''related to the etiology, pathogenesis, prevention, diagnosis or treatment of mental disability or the management, training or rehabilitation of the mentally disabled and [which] seeks information which cannot be obtained from subjects who are not institutionalized mentally disabled''.[607] It could be that there Regulations will have a general limiting effect on what is legally acceptable medical research on such persons. This would occur if such Regulations defined the scope of what a guardian may consent to on behalf of a mental incompetent, assuming this may extend somewhere beyond direct therapeutic benefit, or if they outlined the extent and content of acceptable medical practice with respect to such a person.

Some Codes relevant to human experimentation are informative with regard to consent to medical interventions on mentally incompetent persons. The Nuremberg Code[608] does not provide for consent by the legal guardian of an incompetent, although Mishkin[609] reports that Ivy who drafted it had included this, but it was omitted from the Court's judgment in which this Code was first handed down probably because it was irrelevant to the case. Under the Declaration of Helsinki, as with children, the legal guardian can consent to research on his mentally incompetent ward.[610] The United Kingdom Royal College of Physicians Committee on Ethics[611] would permit negligible risk, non-therapeutic experimentation on mental incompetents with the consent of the guardian, giving, as the justification for this approach, the advancement of medicine. In contrast, English ''staff volunteer'' research subjects must be of ''full age and sound mind''.[612] The American Medical Association Guidelines[613] allow the legal representative to consent to non-therapeutic experimentation on a mental incompetent, but only where ''mentally competent adults would not be suitable subjects'' and the circumstances are such that ''an informed and prudent adult would reasonably be expected to volunteer himself or his child as a subject.'' There is an important proviso that ''[n]o person may be used as a subject against his will''.

But notwithstanding this safeguard I query the legitimacy of the previous criteria, as they require that competent adults are not suitable subjects and then that the circumstances are such that they would be expected to volunteer. It is much easier to get someone to agree to participate in unwelcome tasks where this is clearly not possible, than to obtain the same agreement when faced with the reality of participation. Thus, in delimiting the area of acceptable research, mental incompetents may not be protected by this provision to the same extent that ''normal'' adults would be. This provision in the Guidelines is meant to be an objective test of the acceptability of the ''proxy'' consent of the guardian. But I suggest that one also should insist upon subjective acceptability, which requires both criteria couched in terms that demand affinity of interest between the guardian and the incompetent, as well as that the research be subjectively beneficial to the person involved.

The point is that all three elements necessary for valid consent, capacity, voluntariness, and information, are suspect with mental patients and, when doubts are present as to all of them, there must be a strong presumption that the personal consent of the person is invalid. Further, there are special problems with protection of privacy in respect to mentally incompetent persons, particularly in psychiatric research, in which the mentally incompetent are probably more likely to be involved than other members of the community.

Such factors indicate that the need for fully informed personal consent is greater and certainly not less, with respect to non-therapeutic medical interventions on mentally incompetent patients, than with ''normal'' patients. Even looking to the only available alternative, ''proxy'' consent, in relation to children unable to consent for themselves I have argued[614] that the scope of proxy consent should be strictly limited to therapeutically beneficial interventions or at most to minimal risk ones, and there would be no justifiable or logical reason for having a different rule apply in the case of mental incompetents. As Frenkel[615] says, a guardian who could consent to non-therapeutic experimentation would have a right over the incompetent's body not far from slavery. And perhaps the acceptance of slavery in 1667 explains why, at that time, the use of a mental incompetent as an experimental subject for the transfusion of sheep's blood[616] was apparently acceptable and why it should not be today.

E. CONSENT AND PRISONERS AS PATIENTS OR SUBJECTS OF MEDICAL RESEARCH

In different factual circumstances, and in a different form, medical treatment of prisoners and their involvement as subjects of medical research raises many of the questions already discussed, for instance, the issues related to institutionalization and its effect on voluntariness of consent. Some types of medical procedures which have been looked at in a more general context, may need "special treatment" in relation to prisoners. For example, even if psychosurgery is acceptable therapeutic experimentation on consenting members of the non-institutionalized population, are the dangers of abuse, or the difficulty of obtaining "informed" consent, too great in the prison setting to allow it to be performed on prisoners? Further, even if consent is possible, is it appropriate or acceptable to allow a method which irreversibly "neutraliz[es] the violent prisoner or political dissident"[617], as a means of dealing with the perceived problems such persons pose to society? For the purposes of the present discussion, I will assume that the prisoner has factual, mental capacity and is adult. If this is not the case the prisoner must not only be safeguarded as such, but safeguarded under the protections applicable to any other relevant "special" category, such as mental incompetency or minority.

The most acute problems involving a prisoner's capacity to give "informed" consent arise in the medical research context and it is from this base that the difficulties will be examined. Other situations, including therapy, involve the same considerations with respect to consent, but the rules applicable in the latter may be less stringently applied or a wider range of justifications may be present. However, as with all disadvantaged persons, one should start with the presumption that the strictest and most protective rule applies and any derogation from this must be clearly justified. For this reason an examination of consent in relation to conducting medical research on prisoners is particularly worthwhile.

First a problem arises with respect to legal capacity, as a prisoner was traditionally regarded as losing all his rights with imprisonment.[618] But this has been increasingly modified and one hopes that there will be full acceptance of the idea that a prisoner retains enjoyment of all civil rights. However he may partially or totally lose the right to exercise some of these rights during his imprisonment, either personally only, or also by way of an agent or mandatory.[619] A prisoner should only lose the exercise of those rights

essentially connected with the fact of imprisonment, such as loss of the right to freedom of movement, or loss of those rights affected by the necessity to examine the prisoner for contagious disease. Any *additional interference* with the prisoner's physical or mental integrity must be with his fully ''informed'' consent. The attitude to be adopted, I suggest, is that as the prisoner's rights as a human person are necessarily curtailed to some extent, he is entitled to more protection. This added protection should not, as it often is, be confused with leniency, ''soft-treatment'' or pampering of prisoners. Such protection must include, although it should not be limited to, the right of a prisoner to appeal to a court of law to vindicate his right to inviolability.[620] However, it seems that courts have been reluctant to interfere in the internal affairs of a prison,[621] and where this is the case, then a necessary but not sufficient condition precedent to conducting medical research is absent and experimentation on prisoners cannot be justified. How far such a condition should apply in relation to therapy is a more difficult question. It is not relevant when the prisoner gives ''informed'' consent to such an intervention, but it probably is where he refuses therapy.

As to other necessary conditions precedent to conducting medical research on prisoners, there is at least one commentator who believes that one is never, under any conditions, justified in using these persons as research subjects. Bronstein[622] argues that the distinguishing and prohibitive element in the use of prisoners as subjects, is the involvement of the state and the necessary rights it has over the prisoners' bodies simply by virtue of the fact of imprisonment. He makes the thought-provoking statement that ''[i]t is not so much the actual, occasional abuse of captive human subjects, but the potential for abuse which concerns [him]''.[623] Thus it is not necessary to show abuses to invalidate experimentation in prisons, because the ''potential for abuse'' is sufficient to do this. It is important to consider these matters because it makes one realize that a discussion of ''informed'' consent in relation to the use of prisoners as research subjects is not enough, as there may be a duty to not even request the prisoner's consent to participation in the experiment.[624] Kilbrandon[625] states this in a very effective way when he says that to put a man in prison is to deprive him of a large number of consents, therefore it is distasteful to confer on him a consent which is not for his own benefit.

An argument contrary to the above views advocating prohibition of medical experiments on prisoners, or only allowing it under much more restrictive conditions than apply to the unconfined population,

is that prisoners should not be deprived of any more rights that accrue to other members of society, than absolutely necessary. One such right is that of personal inviolability of both mind and body, any exceptions normally depending on consent. And thus the corollary, the right to consent and the right not to consent. For reasons quite apart from medical experimentation, for instance to give a legal right of action against brutality in prisons it may be important to retain for prisoners these rights to inviolability, and to consent, and not to consent. Therefore, in the context of medical treatment or research, the right to consent should not be abrogated for fear that the rights associated with it, that of inviolability and the right not to consent, will also be affected. Rather its exercise must be safeguarded. This is expressed by Ramsey in the following words: ''I am one who happens to believe that prisoners have not been and should not be drummed out of the human race. They ought, therefore, not to be excluded in principle from the community of risk-filled human consent to good purposes, even if the needed practical protections for them are so formidable as to prohibit the general use of prisoners in medical research.''[626]

It may be that if research participation is seen as a privilege, it should not be allowed because distribution of this privilege can become a coercive tool in the hands of wardens and prison authorities, thus affecting the voluntariness of prisoner's consent. This is related to another reason for not allowing research on prisoners. It is that the attitude of prison staff towards prisoners often leaves much to be desired and may amount to coercion to consent, or even ignores, in all but theory, the necessity for free and informed consent. For instance, with respect to prisoner experimentation, a warden at Montana State Prison stated: ''we want our prison to be a living laboratory for the people of Montana . . . There should be no conflict in offering *our* physical and human resources [prisoners] to other disciplines . . . ''[627]

Further, some arguments put forward in support of prison experimentation rely on the *control factor* inherent in imprisonment, as an advantage justifying research on prisoners taking place. But these arguments themselves provide further arguments *against* using prisoners, because they raise serious doubts about the validity of the consent given. Examples of such reasoning are that it is beneficial for experimental purposes to be able to totally control the subjects,[628] and the experimentation and the rewards it offers may themselves augment the effective power of the prison authorities over prisoners. Newman[629] found a reason given to justify the use of prisoner

subjects was the doubtful altruism that wardens, as public officials, were interested in promoting science and, perhaps more realistically if still not acceptable, in promoting a research program which helps the training and education of prisoners. Both these words, training and education, may be used in their genuine sense, but may also be euphemisms for establishing and justifying a more effective system of control of prisoners, without corresponding educative benefit to them. Thus the very advantages of using prisoners—their availability, the convenience they offer as subjects, the ease with which they can be controlled—are precisely the factors throwing doubt on the validity of their consent and weighing against their participation in medical research.

There is a further problem in relation to obtaining ''informed'' consent from prisoners and this relates to the informing of the doctor by the patient or research subject. It is usually taken for granted that this occurs in ''normal'' situations, or if not, and the doctor has not been negligent in failing to enquire, the patient or subject runs the risks associated with his non-disclosure. A presumption that a prisoner has disclosed all relevant facts, which disclosure affects the assessment of risk and the information the doctor should give to the patient or subject, may not be justified in the prison setting. From the community's point of view it has been suggested that prisoners should not be used as experimental subjects because they may not be medically normal and that therefore the results of research may be obscured or distorted.[630] This distortion may occur as a result of latent disease or deliberate concealment of known conditions. Such concealment is more likely with prisoners than members of the unconfined population because, it is said, prisoners are an anti-social group,[631] because there are pressures on them to participate as subjects, and because of other collateral reasons. Such a reason would be for instance holding that medical records of prisoners are the property of the state, in which case a prisoner may be fearful of disclosing some medically significant facts.[632] One way of verifying results from trials on prisoners would be to use a ''free group'' control. This may also have ethical and legal advantages in that it would show that the risk level was acceptable to members of the general population, which would be one factor in assessing whether the prisoner's consent may have been coerced, and would represent a move towards more equitable distribution of the burdens of research.

There is one very special class of prisoner and of experimentation which must be mentioned, and this is the prisoner condemned to death. The question is whether the execution should be allowed by

way of experimentation.[633] Some authors[634] suggest this is acceptable with full and clear consent,[635] others, with whom I agree, reject it.[636] This is at least one instance in which consent should be irrelevant with respect to ''medical'' interventions on prisoners, the intervention in this manner itself being prohibited.

There is another relevant question in relation to obtaining ''informed'' consent of prisoners and this is to what extent does medical experimentation occur in prisons? If the requirements in relation to ''informed'' consent to therapeutic or non-therapeutic research are more stringent than with therapy, the identification of research becomes very important. This is a very difficut question to answer for two reasons. First it is possible that some activities which would be classed as experimentation by one researcher may not be by another; and secondly, it is difficult to survey prisons.

The first reason is particularly affected by how one views crime and prisoners in general. For example, Visscher sees behaviour modification experiments on prisoners as ''therapy for sick people''.[637] Such a classification will profoundly alter the characterization of any activity as either therapy, research, or therapeutic research, which in turn may determine the ethical and legal validity of the procedure, including the consent required.

With regard to the second problem, it is clear that in the United States of America for example there is a great deal of medical experimentation on prisoners, but the real scope of this is unknown.[638] In the United States, the National Commission conducted a survey on the extent of research involving prisoners. The report shows in general terms[639] that in the majority of states, research on prisoners is allowed and that drug companies are heavily involved. Evidence was given to that National Commission that, ''in none of the countries surveyed [which included Canada, France, United Kingdom and Australia] was it found that prisoners are used as volunteer subjects for medical projects, and we know of no countries other than the United States where this is done''.[640] This is consistent with Dickens' statement, that the federal and provincial governments of Canada do not approve research on prisoners,[641] and with the British Medical Journal report that it is generally accepted that there should be no research trials carried out on prisoners in the United Kingdom.[642] However, one would need careful evaluation of the medical and other procedures allowed in prisons to determine that there was no research taking place, even though this may not be as overt as drug trials carried out by pharmaceutical companies.[643]

It is possible to eliminate the remaining theoretical possibility that medical research is taking place in prisons, and hence the problems of ''informed'' consent associated with this, by banning such research in prisons. With regard to codes or legislation, I have already noted that the Nuremberg Code and[644] initially, the Declaration of Helsinki[645], prohibited research on prisoners, but the latter has now been changed.[646] Several American States have banned[647] or regulated[648] the use of prisoner subjects and, in March 1976, the Director of the United States Federal Bureau of Prisons announced that all biomedical research in federal prisons would be discontinued.[649] As far as I have been able to ascertain, the only other relevant jurisdiction which has legislation in this field, is France. There the *Code de procédure pénale*, forbids all medical or scientific experiments on prisoners.[650]

Now, assuming that after analysis of all factors, one favours allowing some medical research on prisoners with, among other safeguards, their ''informed'' consent, what are the problems inherent in this? I have assumed the prisoner has factual and legal capacity, thus difficulties associated with lack of these are eliminated and the problems which must be dealt with are ones relating to informing and consenting.

Leaving aside deliberate deception, which is not normally acceptable with any research subject,[651] informing a prisoner adequately may be a problem even with the best intentions. Ayd[652] found that prisoners volunteered before an explanation of the research was given, suggesting that their motivation may have been irrational and thus, he suggests, ethically unacceptable. But the same phenomenon has been observed in non-prisoner organ donors,[653] and it is therefore debatable whether this factor alone should exclude prisoners. Martin *et al*[654] investigated the degree to which prison volunteers were informed, and found it was low and no greater than with non-volunteers. They noted further that assessment of risk was not a factor in volunteering. Whether consent should be recognized as legally valid when in a given instance an adequate informing process has taken place, regardless of its real effectiveness in influencing the subject's decision-making, is a value judgment which depends on many of the same factors involved in deciding whether subjective, as opposed to objective, comprehension of information should be required. [655]

Assuming that one has fulfilled the legal requirements for informing the prisoner, the next step is consenting and the major

problem here is voluntariness or defects of consent: coercion, duress, and undue influence, arising from even the most advantageous circumstances in which a prisoner may find himself. Often, in practice, such defects arise from the fact that incredibly sub-standard living conditions augment this unavoidable element of coercion inherent in imprisonment. The coercive factors which have been identified in prison life are multiple and can be broken down into two major sub-groups: the effects of institutionalization, and those of deprivation. The former sub-group has been mentioned in relation to institutionalized mental incompetents and is a psychological phenomenon that persons may exhibit who have been confined for a period of time. This phenomenon includes an inability to make decisions and a dependency on those in authority.[656] It would need to be seriously taken into account in assessing the true degree of voluntariness that a decision to be an experimental subject represents, and hence in assessing the legal validity of such consent.

The more extrinsic coercive factor is deprivation, which, apart from the necessary deprivation of liberty, includes: inadequate medical care[657] and loss of freedom of choice of a physician;[658] grossly sub-standard living conditions, including the lack of basic articles or amenities for personal hygiene; a lack of money, especially if it is possible to provide better conditions for oneself as a prisoner with this; no, or little, opportunity to fulfill the need to work *per se*, quite apart from monetary reward for work; boredom, so that the experimental situation offers interest, an exciting change, and the transfer to the hospital ward is seen as a vacation; and finally a lack of company of the opposite sex.[659]

Deprivation may also give rise to secondary coercive effects in two ways. First, the ability to volunteer as a subject, and thus avoid some deprivation, may be seen as a privilege in which case it may be used to coerce certain behaviour. Although this does not represent coercion to consent to research, such a factor increases the general coercion present in the prison situation. Secondly, deprivation is linked to coercion directly affecting consent if there is, or a prisoner thinks there is, any possibility of his volunteering to be a subject being taken into account in either a parole or release decision. It is especially important with regard to prisoners to keep in mind their particular deprivations and hence the possible coercive effects of non-monetary forms of payment, from early parole or reduction of sentence which are probably the most coercive, to better or some medical care, and then to minor ''luxuries'' as rewards, bribery, or pressure, all of which are unacceptable.

This multiple deprivation, which Morris[660] calls a ''poverty of alternatives'', probably explains why prisoners and low income groups are more willing to volunteer as medical research subjects[661] and therefore why the validity of their consent should be more suspect. Meyer[662] demonstrates this dramatically when he shows that prisoners act as subjects for one-tenth the pay of non-prisoners and further that prisoners are twice as willing to participate in any experiment as would be an unconfined person, *even in the absence* of cash payment to the prisoner. This, he says, may be analyzed in terms of opportunity costs. Because the prisoner is so deprived relative to other members of society, he sees himself as having less to lose and more to gain by participation, whereas the same ratio does not apply to a free person.

The reasons given by prisoners for participation in medical experimentation are altruism, money and respect,[663] not necessarily in that order. Probably altruism and respect are acceptable coercions, money or other payment may not be. There is a conflict between doing equity and avoiding coercion in paying prisoners. As a matter of justice they should be paid the same amount as free members of the community would be, but this would be coercive in a prison setting where alternative opportunities to make money are very few and pay badly. Clearly the payment should not be so large as to amount to undue influence, that is it must not obscure appreciation of the risk or weaken the will to self-preservation,[664] but it is very difficult to draw a line between permissible and impermissible payment in this respect. Todd[665] believes that payment may be coercive and exploitive not only in causing prisoners to enter a protocol, but in their continuing as research subjects, as it may cause them not to report adverse reactions because this would risk their dismissal from the project, with the consequence that such prisoners are exposed to excessive risk and the results distorted.

The problems, in summary, with respect to the voluntariness of prisoners' consent, arise from deficiencies of living conditions and health care, arbitrary exercise of authority and restriction of communication[666] and lack of opportunity to earn money or even to work. These deficiencies and the doubts they raise regarding consent can only be overcome by mandating that there shall be no medical experimentation on prisoners unless, *inter alia*, it is open to public scrutiny, grievance procedures are provided in the prison, the standard of living is raised to a basic minimum,[667] an opportunity to work and earn money is provided and there are effective procedures ensuring that parole boards cannot take account of a prisoner's

participation in research and that prisoners know this.[668] Once this state of affairs is achieved some of the coercive effect of monetary payment is eliminated, but it must still not be so high as to constitute undue inducement, or so low that it means taking economic advantage of prisoners.[669] One scheme is to pay additional money into a prisoners' fund used to augment the wages of all prisoners or for distribution to prisoners on release.

Such an approach recognizes that it is not possible to directly determine that a decision is the result of a free power of choice, rather this must be shown by the absence of unacceptable influences and interferences,[670] which is the method of protection of prisoners adopted by both the "National Commission" and the D.H.E.W. in the United States.

Finally the requirements relating to therapeutic treatment of prisoners should be no different with respect to "informed" consent than with any other person, with the possible exception of when a disease state itself threatens other inmates. Here again it is necessary to clearly determine whether therapy is truly involved, or, especially in regard to psychological treatment, whether it is being used as a disguise for activities which should be classified as punishment.[671]

CHAPTER IV

Criminal Law Aspects of Consent to Medical Interventions

Before one can consider the effect of consent on the criminal law liability of doctors, or interpret and compare legislation or cases dealing with this in various jurisdictions, it is necessary to "set the legal scene" in each jurisdiction.

First, here in Canada, criminal law is a matter of federal jurisdiction governed by a *Criminal Code*, and hence for this purpose Quebec and Common Law Canada are one.[672] In the United States of America and in Australia criminal law is primarily a state matter, although the respective federal governments also have jurisdiction in criminal matters pertaining to the exercise of their constitutional powers,[673] which in Australia has been relied on to enact a *Federal Crimes Act*.[674] Some Australian states have a codified criminal law system and others rely on a common law basis, as modified by piece-meal legislation.[675] In the United States of America there is a *Model Penal Code* of the American Law Institute, the proposed official draft of which was published in 1962,[676] but at present, the substantive criminal law in that country is mostly in statutes, not infrequently in administrative regulations, sometimes in constitutions and sometimes found in the common law of crimes.[677]

England and France are unitary jurisdictions. English criminal law remains the uncodified common law,[678] but this is affected in various areas by specific statutory enactments.[679] In France the law is

codified in the *Code Pénal,* but the most significant distinction between this and any of the other jurisdictions, lies in the fact that an injured patient has an option whether to sue civilly or to intervene in a criminal action taken against the defendant, by becoming co-prosecutor with the "ministère public".[680] Further, the jurisprudence has established that the degree of fault which needs to be proved for liability in either regime is the same[681] and that the claimant can recover personal damages before a penal tribunal.[682]

The first point to be considered in discussing the effect of consent in criminal law, as applied in the medical context, is the legality or otherwise of any medical operation or procedure at Common Law or Civil Law. Various justifications for legality have been advanced and even legislated. In my view Sections 45 and 198 of the Canadian *Criminal Code*[683] have the combined effect of making surgical and medical treatment *prima facie* legally valid[684] in this jurisdiction, provided: the doctor has reasonable skill and knowledge, uses reasonable care, that it is reasonable to perform the operation, and it is for the benefit of the patient.[685] If this is the effect of these sections then it reverses the traditional Common Law presumption that such interventions are illegal and only justified on showing the following: consent; therapeutic benefit; that the operation is performed by a person with appropriate medical skills; and that there is lawful justification, an open-ended public policy requirement which is a means of prohibiting certain procedures.[686] Although the legal result flowing from either of these approaches is likely to be the same in many situations, this is not necessarily the case. Particularly in the area of human medical experimentation different attitudes may be engendered according to whether medical interventions are regarded as *prima facie* legally valid or invalid.

Now even assuming that all the necessary conditions are fulfilled in a therapy or therapeutic experimentation situation, the requirement of benefit needed under either of the above approaches is clearly lacking in non-therapeutic medical interventions, including research. However, from the fact that non-therapeutic experimentation takes place without criminal prosecutions being instituted,[687] and from *dicta* in some of the American incompetent organ donor cases,[688] and because court approval is not sought in the case of competent adult organ donors, an important likelihood emerges. In my view in the Common Law jurisdictions being examined, the law is being modified to accept, and the courts are using, consent and benefit as *alternative* justifications legalizing the medical intervention and not cumulative ones as traditionally required.

The same problem of justification of a medical intervention arises under French penal law and some authors argue that the lack of intention to harm and the positive aim to cure supplies this.[689] Levasseur makes the point that "[l]e médecin . . . échappe à toute poursuite sous la qualification de violences volontaires du moment qu'il a agi dans l'exercice *normal* de son activité professionnelle".[690] This raises the question, what is "abnormal" medical practice? It would seem that under French law non-therapeutic interventions would certainly be classified in the latter category, in which case the French penal law looks more to "l'act matériel d'intervention ou de traitement", rather than the motive of the doctor in acting, in order to characterize the intention accompanying the act as voluntary or not, for the purpose of imposing criminal liability.[691] Thus in France, the criminal liability of the doctor and the factors taken into account in seeing whether he was justified in acting as he did could vary simply according to the type of intervention he carried out, but certainly does not depend *prima facie* on the consent of the patient.

In fact Levasseur considers and rejects consent of the patient as a justification for a medical intervention as, he says, the better view is that the impunity of the doctor is based on an implicit authorization of the law—"l'ordre de la loi et le commandement de l'autorité légitime."[692] This means there is a general prohibition against violation of another's integrity, but the doctor's permission to do otherwise is an exceptional derogation from this. There are two inter-related factors underlying any such authorization of law, the significance of which it is necessary to consider more specifically within the context of criminal liability arising within the medical relationship. These factors are the nature and degree of the harm suffered, and the effect of consent in criminal law with respect to medical interventions.

First one should acknowledge that consent is certainly not a sole justification, and may be not even a justification for a medical act which could constitute a crime, although its presence may affect criminality. Then some crimes are only constituted by a certain degree of harm, for example, infliction of grievous bodily harm,[693] and others only where there is no operative consent, for example, assault.[694] All qualifications of rights or obligations protective of personal, physical or mental integrity are related to either the nature and degree of harm, or to the effective scope of consent and I suggest, are based on public policy considerations.[695] The criminal law is enacted primarily in the public interest, and comes into play when an act of one person against another threatens the community

itself in some way.[696] That is, the criminal law is a means of protecting society from acts of individuals which are harmful to it,[697] or acts contrary to the current morés.[698] Thus one can draw flexible and changeable limits which will mark off in any particular situation what is, or is not, criminal conduct. Clearly in many situations the answer is so obvious that it is not necessary to resort to such an analysis, but it is precisely in circumstances such as medical interventions including treatment and research, that this is useful.

Thus whether a certain degree of harm is acceptable and outside criminal liability, will depend on its nature and degree and the reasons for and circumstances under which it is inflicted. For example, in combat sport or medical treatment a certain degree of wounding may be acceptable, where it would not be otherwise, as this degree of harm inflicted for such a purpose in those circumstances is tolerable. Hence one has a ratio for determining acceptability, which I suggest means that below a certain insignificant degree of harm, the nature and purpose of the intervention can have very wide limits. However as the degree of harm increases, then the definition of what constitutes either a valid purpose, or an acceptable type or nature of harm, decreases in content so that in the instance of a life-threatening harm, for example, one arguably needs a therapeutic purpose if the attack is not to attract criminal liability.

Now it is necessary to consider how consent affects criminal liability. One often reads that consent is not a defence to a crime[699] and, in particular, that one cannot consent to death[700] or injury amounting to maim or mutilation[701] being inflicted upon oneself. I suggest that this is because the act is first classified as criminal, or non-criminal, according to the degree and nature of harm and the purposes and circumstances involved. If the act is assessed as criminal on this scale, then consent is irrelevant at least for criminal law purposes because, as Rubenstein says, ''the prohibition is not directed against self-inflicted[702] injury; it is designed to prevent public desecration of one of the law's basic rules of behaviour. Beyond the concern for the physical well-being of the person, there lies the need to preserve the legal rule which prohibits one man from injuring another''.[703]

If, on the other hand, without considering a consent factor, the act is classified as non-criminal initially, it may be that when one takes into account a lack of consent this will change the classification. It may so alter the nature and purpose of the act, that the ratio of degree and nature of harm present, *in the circumstances,* becomes

unacceptable and is designated criminal. Thus consent may affect the criminality of an act when the situation is such that the act would be non-criminal with consent, but criminal without it. Although one could give specific examples of such cases it is not possible to state a general rule any more definitely than this, as such a rule is not overt or express in the law. Rather it can be seen in operation, and I suggest is left in a flexible state, as it is based on public policy considerations which are open-ended and changing in content.

Now applying this rationale to the medical situation, it is possible to see that while some or all medical interventions may or may not give rise to potential criminal liability, there is a range from an intervention almost certain to do so, namely non-therapeutic experimentation causing some harm and done without consent, to an intervention certain not to, namely therapy causing minimal harm and carried out with consent. Similarly, such a range can be seen in the context of euthanasia, if the purpose of the medical act is treatment, necessary for instance to relieve pain and given with the consent of the patient, criminal liability is much less likely to be imposed than where ''active euthanasia'' is practiced.

While canvassing the subject of consent in the criminal law, one must also consider the effect, for criminal law purposes, of a child's or mental incompetent's consent, and of ''proxy'' consent. Firstly, consent within the criminal law is not ''informed'' consent. When consent is relevant, it is sufficient for the person to understand the nature of the act, and he does not necessarily have to understand its consequences.[704] Consequently, it is possible that a child is capable of giving effective consent at a younger age for purposes of criminal law, than for civil law purposes,[705] as in the latter situation effective consent depends on understanding at least some consequences. However, as the operative legal effect and scope of consent is limited in criminal law, in the sense of its being determinative in ''criminalizing'' or ''decriminalizing'' an act, this wider scope for recognizing a minor's consent will probably have little practical effect within the criminal law on the legality of medical interventions involving minors.

In relation to third party consent, I submit that all persons have the right to protection by the criminal law and that for reasons of policy the principle must be that no one else may waive this right. In other words, ''proxy'' consent should never be effective for criminal law purposes. Rather the approach taken should be that if the act was justified this should be established on the basis of implied consent, or

of a defence of necessity, which are generally recognized defences in criminal law. Although implied consent may be criticized as artifical and depends on substituting for the incompetent's judgment, just as "proxy" consent does theoretically, the rules governing the former are arguably different and, I submit, place a preferred emphasis on the rights of the incompetent rather than the power of the proxy consentor. How widely one defines the content of such defences, for instance whether the necessity must be the personal necessity of the incompetent, or may relate to the necessity of others, is once more a policy decision. But, again, it must be kept in mind that the criminal law's essential function is to be protective and that all persons have the right to its equal protection.

If the parents or a guardian have purported to consent to a criminal act on a child or incompetent, they may be guilty of criminal conspiracy, counselling, procuring or inciting a crime, or aiding and abetting a crime or a criminal.[706] One would need also to examine their possible criminal liability under any child abuse legislation applicable in the particular jurisdiction.[707] This could be applicable either by consent to, or perpetration of, or failing to report to the competent authorities, an act harming a child.[708]

Conclusion

Consent is a complex, general doctrine, functioning within both private and criminal law, and is fundamentally a legal mechanism for protecting autonomy and inviolability of the person within the limits to which these rights are recognized by the law.

The medical relationship is only one of a wide range of situations in which consent is relevant, but it crystallizes many of the most difficult problems faced in relation to consent. Firstly, what are the actual parameters of the limits set by the law in the relation to allowing one person to inflict physical or mental harm on another? How does one ensure that true consent is present, even with a "normal" competent adult, when, in the medical relationship, there is a situation which of necessity involves a power differential in relation to knowledge, emotional involvement and needs? And if this discrepancy is "artificially" aggravated by the condition in which the patient is placed, for instance a prison or institution, or even if he is particularly socially disadvantaged, what is the effect on consent? Finally, what happens when consent by the person concerned is impossible, and what does it mean if another gives "proxy" consent?

All of these questions require close and detailed analysis of the purposes sought in requiring consent, the legal and factual ways in which consent functions to serve these purposes, whether it is effective or not in achieving the desired aims and if not, or if consent is not possible, how the necessary aims may be achieved through other mechanisms. In all instances, rights, duties, powers, privileges, interests and immunities involved for of the patient, doctor and community are involved. Through private criminal law regulation particularly by defining the operation, scope and limits of consent, one seeks to balance these claims in acceptable harmony.

Finally, with the above generalizations in mind, as well as the necessity for fluidity and the possibility of continuing change which they import, I would like to summarize the major particular recommendations which have been made in this paper:

A. At a conceptual level:

1. That both criminal and civil law controls and remedies be retained in the area of consent to medical care.
2. That the rights to autonomy and inviolability be distinguished from each other and recognized.
3. That for the purposes of legal analysis and precedent, a distinction be made between the traditional doctrine of consent and the new doctrine of ''informed'' consent. The latter being wider will encompass the former, though the opposite proposition is not true.
4. That a distinction be made between the patient's consent to the medical contract and his consent to medical care.

B. At a practical level:

1. That the general rule should be that the patient's ''informed'' consent to all medical procedures must be obtained. This means that information about the nature of the proposed procedure and its attendant risks which a reasonable man in the patient's position would want to know, or which the doctor knows the particular patient would want to know, must be explained to the patient. In general the less necessary the procedure and the greater the risks, the more stringent is the content of the duty of disclosure. The doctor may reply on the patient's consent as being valid if there is apparent, subjective understanding of this information by the patient.
2. That the above general rule may be cut down in its operation by application of the doctrine of ''therapeutic privilege''. This means that in a particular case telling the patient some, or all, of the information required to be given under the general rule, would, *in itself*, harm him physically or mentally. It is not sufficient for operation of the privilege that the required disclosure would affect the patient's decision-making. Further, the privilege being an exception is to be construed narrowly, and being a justification the burden of proof of its applicability is on the person relying on it, namely the doctor.
3. That information be disclosed and consent obtained in as non-coercive a manner, language and situation as is possible. Except in very rare circumstances, deception is unacceptable. Further, there must be a constant concern to protect and be sensitive to the rights of privacy of the patient.
4. That both the necessity to inform the patient and to obtain his consent be seen as continuing requirements.

5. That it should be emphasized that the purpose of the doctrine of ''informed'' consent is protection of the patient.
6. That in life threatening situations when the patient refuses treatment, it is a policy decision as to whether the requirement for consent should be dispensed with by the law. In emergency situations where it is impossible to obtain consent a defence of necessity should apply.
7. That consent be regarded as a necessary, but not sufficient, justification for a medical intervention.
8. That consent to any significant medical intervention be obtained before a third party witness and be evidenced in writing.
9. That the coercion naturally present in the doctor-patient relationship, and especially the doctor-dying-patient relationship, be recognized.
10. That with respect to consent to medical interventions on children:
    (a) the ''mature-minor'' rule should be clearly established;
    (b) the term ''proxy consent'' should be abandoned and replaced by either parental authorization or permission;
    (c) the parent may consent to therapy on the child not yet within the scope of the ''mature-minor'' rule. The child should have a right of objection or veto, but this may, be overridden by the parent with justification;
    (d) except in extremely rare circumstances a parent may not consent to non-therapeutic, or more than minimal risk personally non-beneficial interventions on the child;
    (e) special protection must be given to institutionalized children with respect to consent to medical interventions on them.
11. That with respect to consent to medical interventions on foetuses:
    (a) where therapy is involved the same rules apply as for non-discerning children;
    (b) where the intervention is non-therapeutic for the foetus but directed at therapy for the mother the mother's consent is adequate;
    (c) in all other cases any rules on consent should recognize the mother's, and possibly a medical research physician's, conflict of interest.
12. That with respect to consent to medical interventions on mental incompetents:
    (a) their consent should be sought to the extent that they are capable of giving it;

(b) in cases where the mental incompetent is factually incapable of consenting the same rules should apply as suggested for non-discerning children, including institutionalized children.

13. That with respect to medical interventions on prisoners:
    (a) the prisoners' ''informed'' consent to all medical treatment must be sought. The only exception to treating a prisoner without consent is where he has a disease state threatening the health or well-being of other prisoners;
    (b) a very high degree of care must be taken to counteract the coercive effects on consent, of the institutionalization and deprivation suffered by prisoners.

Endnotes

1. *British North American Act* 1867, 30-31 Victoria, c. 3.
2. J.S. Mill, "Utilitarianism, On Liberty, and Considerations on Representative Government", London; J.M. Dent & Sons Ltd., 1972, in "On Liberty", at pp. 71-72.
3. P. Devlin, "The Enforcement of Morals", London, Oxford University Press, 1965. Extracts reprinted in J. Katz ed., "Experimentation with Human Beings", New York; Russell Sage Foundation, 1972 (hereafter referred to as "Katz ed.") at pp. 541-4.
4. For example, E.D. Pellegrino "Editorial: Protection of Patient's Rights and the Doctor-Patient Relationship", Prev. Med. 4(4)398 (1975), at p. 399.
5. See L. Loevinger, "Jurimetrics: Science in Law" in W.A. Thomas, ed., "Scientists in the Legal System. Tolerated Meddlers or Essential Contributors?", Michigan; Ann Arbor Science Publishers Inc., 1974, (hereafter referred to as "Thomas ed.") p. 7.
6. P.A. Freund, "Legal Frameworks for Human Experimentation", in P. Freund ed., "Experimentation with Human Subjects" New York, George Brazilier, 1970, (hereafter referred to as "Freund ed."), p. 105, at p. 106.
7. *Ibid.* The qualification being that the law must balance the individual's right of free choice and self assertion, with solicitude for his or her integrity.
8. A.M. Capron, "Informed Consent in Catastrophic Disease Research and Treatment", (1974-75) 123 University of Pennsylvania Law Revue 340, at p. 428.
9. C. Fried, "Medical Experimentation: Personal Integrity and Social Policy", Amsterdam and Oxford; North Holland Publishing Co., 1974, at p. 97.
10. See, for example, R.C. Fox, "Some Social and Cultural Factors in American Society Conducive to Medical Research on Human Subjects", reprinted in I. Ladimer and R.W. Newman, eds., "Clinical Investigation in Medicine: Legal ethical and Moral Aspects", Boston; Law-Medicine Research Institute, Boston Univ., 1963 (hereafter referred to as "Ladimer and Newman eds.") p. 81, at p. 107.
11. A. Decocq, "Essai d'une théorie générale des droits sur la personne", Paris; Librairie Générale de Droit et de Jurisprudence, R. Pichon et R. Durand, Auzias, 1960, at No. 12.

12. L. Kornprobst, ''Responsabilités du médecin devant la loi et la jurisprudence française'', Paris; Flammarion, 1957, at p. 254.

13. E. Nizsalovszky, ''A Legal Approach to Extraordinary Medical Actions'', Budapest; Akadémiaikiado, 1974, at p. 45 *et seq*.

14. This is to ask whether or not rights in general are in themselves autonomous, that is self-determining, which is really to make the distinction between the ''natural law school'' who regard rights as existing independently of human volition, and ''the positivists'' who do not. Thus autonomy may be looked at as an autonomous right affecting the autonomy of persons.

15. 211 N.Y. 127 at p. 129; 105 N.E. 92 at p. 93 (1914).

16. W.L. Prosser, ''Handbook of the Law of Torts'', 4 ed., Minnesota; West Publishing Co., 1971, at p. 101.

17. P.D.G. Skegg, ''A Justification for Medical Procedures Performed without Consent'', (1974) 90 Law Quarterly Review 512, at p. 514.

18. For example, see B. Starkman, ''Preliminary Study on Control of Life'', unpublished paper presented to the Law Reform Commission of Canada, 1974, who lists cases involving blood transfusions given to non-consenting adults, in the United States.

    I. Kennedy, ''The Legal Effect of Requests by the Terminally Ill and Aged Not to Receive Further Treatment from Doctors'', [1976] Criminal Law Review 217, who says that the right to self-determination in medical treatment situations, when this means refusing medical care, ''is confined within narrow . . . ill-defined bounds'' (at p. 218).

19. R.G. Spece, ''Notes: 'Conditioning and Other Technologies Used to Treat?' 'Rehabilitate?' 'Demolish?' Prisoners and Mental Patients'', (1972) 45 Southern California Law Review 616, at p. 675.

20. This is an interestingly stated view in that it means that one has a primary right *against* treatment together with the power to waive this and, presumably, another *separate* right *to* treatment. This distinction raises the consideration of whether these rights may be based on, or governed by, different value principles.

21. J.G. Fleming, ''The Law of Torts'', 4th ed., Australia; The Law Book Co. Ltd., 1971.

22. *Ibid*., at p. 80. This statement may be supported by reference to *Marshall v. Curry* [1933] 3 DLR 260 where Chief Justice Chisholm states that in ''a great emergency which could not be anticipated . . . it is the surgeon's duty to act in order to save the life or preserve the health of the patient''. In arriving at this conclusion the Judge found two Civil Law cases from Quebec, *Parnell v. Springle* (1899) 5 Rev. de Jur. 74, and *Caron v. Gagnon* (1930) 68 Que. S.C. 155, persuasive (at pp. 272-275). He stated that the ''jurisprudence established in the Province of Quebec [in this respect] . . . can well be adopted in other jurisdictions'' (at p. 275). This is interesting from the point of view of whether the Common Law and Civil Law have different attitudes to the relative values of autonomy and inviolability (see *infra*, pp. 8-10, with respect to the latter) as it assumes, at least in the circumstances of this case, where there is an unanticipated medical emergency and the patient is unable to consent, that they do not.

23. J.G. Fleming, "Law of Torts" 5th ed. Australia; Law Book Co., 1977, at p. 81, states that " . . . the balance between preservation of life and self-determination is found in authorizing [a] medical procedure only when it would be unreasonable, not just inconvenient to postpone until consent could be sought. Justification for this is found not in fictitiously imputing to the patient a consent he has obviously not given, but in the humanitarian duty of the medical profession."

24. See *infra*, pp. 8-9.

25. One may dispose of the legal problems raised in relation to autonomy in such a situation, that is it may still be honoured legally in form, if not in substance, by the devices of either implied consent, or a doctrine of necessity. See P.D.G. Skegg, *supra*, note 117.

    Note also that in *Marshall v. Curry*, cited *supra*, note 22, the Court expressly rejected "resorting to a fiction . . . [of implied] consent".

26. J.G. Fleming, *op. cit.*, note 21, at p. 81, footnote 1.

27. J.G. Fleming, *op. cit.*, note 23, at p. 81

    It is interesting to note these changes between the two editions of this text, as they reflect the uncertain situation of the law. Although both statements are carefully "hedged" they start from opposite propositions of what a Court *may* hold.

28. See I. Kennedy, *supra*, note 18, for an interesting discussion and actual case presentation of the factual and theoretical issues involved in deciding which of these two principles is to be given precedence.

    See also S.H. Imbus and B.E. Zawacki, "Autonomy for Burned Patients When Survival is Unprecedented", NEJM 297(6) 308 (1977).

    For comment on this latter article see E.J. Cassell, "Editorial: Autonomy and Ethics in Action", NEJM 297(6) 333 (1977). Note also that this conflict is at its sharpest in the euthanasia debate.

29. L. Kornprobst, *op. cit.*, note 12, at p. 254

30. See *infra*, p. 11, *et seq*.

31. See *supra*, p. 3, and note 2.

32. See *supra*, p. 6, and note 29.

33. This attitude may reflect the Common Law's tradition of strict distinction, when imposing liability or duty, between omission and commission, or nonfeasance and misfeasance. In the former cases, respectively, the Common Law only exceptionally intervenes.

34. See *infra*, p. 43, *et seq*.

35. This legislation was enacted on 23rd Dec. 1976. For a report on it see, "The French Solution: Removing Cadaver Organs Without Family's Permission", The Hastings Center Report 7(3) 2 (1977).

36. For example see P.J. Doll, "Les problèmes juridiques posés par les prélèvements et les greffes d'organes en l'état actuel de la législation française", J.C.P. 1.D. 2168. R. Savatier, "Les problèmes juridiques des transplantations d'organes humains", J.C.P. 1969.1.2247.

This justification, I suggest, did not widen the right to consent, it merely allowed a defence, or estoppel (fin de non reçevoir), to operate for the purpose of determining legal liability.

37. See *infra*, p. 43, *et seq.*, for a discussion of the limits to the right of consent.

38. See C.R. Burns & H.T. Engelhardt, "Introduction to a Symposium", Texas Reports on Biology and Medicine 32(1) p. ix, (1974), who express the same idea.

39. P.L. Bereano, "Courts as Institutions for Assessing Technology", in "Thomas ed." *op. cit.*, note 5, p. 73, at p. 77.

40. *Supra*, pp. 5-6 and pp. 8-9.

41. P. Laget, "Expérimentation et médecine", in "Le médecin face aux risques et à la responsabilité", textes recueillis par M. Eck, Paris; Fayard, 1968 (hereafter referred to as "Eck ed.") p. 301, at p. 311.

42. H. Jonas, "Philosophical Reflections on Experimenting with Human Subjects", in "Freund ed.", *op. cit.*, note 6, p. 1, at p. 3.

43. A. Mayrand, "L'inviolabilité de la personne humaine", Montréal; Wilson and Lafleur Ltée., 1975, at No. 3.

44. A. Decocq, *op. cit.*, note 11, at No. 12.

45. *Ibid.*

See also Nos. 516 and 517.

46. A. Mayrand, *op. cit.*, note 43, at No. 40.

47. R. & J. Savatier, J.M. Auby & H. Péquignot, "Traité de Droit Médical", Paris; Librairies Techniques, 1956, at No. 247.

48. R. Nerson, "L'influence de la biologie et de la médecine moderne sur le droit civil", (1970) 68 Revue Trimestrielle de Droit Civil, 661.

49. *Ibid.*, p. 672.

50. *Ibid.*

51. *Ibid.*, p. 676.

52. *Ibid.*, p. 675.

52a. Note that unless otherwise stated, or unless the contrary is clear from the context, the term " 'informed' consent" is used in a generic sense as covering all necessary aspects of consent, that is those of competency and voluntariness as well as that of adequate information.

53. For a discussion of fiduciary duty in the medical relationship see: *Radcliffe v. Price* (1902) 18 T.L.R. 466; *Re C.H.G.* [1970] Ch. 574; [1970] 2 All ER 740; *Kenny v. Lockwood*, cited *supra*, note 62; *Hunter v. Brown* 4 Wash. App. 899; 484 P. 2d 1162 (1971); *Dow v. Kaiser Foundation* 12 Cal. App. 3d. 488; 90 Cal. Rpt. 747 (1970); *Natanson v. Kline* 354 P. 2d 670; 350 P. 2d 1093 (Sup. Ct. Kans. 1960); especially Schroeder, J., at p. 1101.

54. See: *R. v. Clarence* (1888) 220 B.D. 23; J.G. Fleming, *op. cit.*, note 23, at pp. 78-79; A. Roddey Holder, "Medical Malpractice Law", New York; John Wiley & Sons, 1975, at pp. 227-8.

See also *infra*, p. 37.

55. This is one example of how the fiduciary duties of a doctor can be super-imposed on other duties, to establish a more satisfactory range and intensity of duties of physicians, with the fiduciary relationship serving as a basis and justification for imposing such obligations. Thus it shows the importance of the Law strongly recognizing and adopting such a fiduciary relationship in situations of doctor-patient interaction.

56. See, for example, G. Boyer Chammard and P. Monzein, "La responsabilité médicale", Paris; Presses Universitaires de France, 1974, at pp. 138-147 and at p. 236, where these authors cite two *Cour de Cassation* cases (one of these being Cass. 27 janvier 1970, B. Civ. 1970.1, No. 37, 30) which state that in the aesthetic surgery situation there is a very stringent duty on the doctor to inform the patient of all risks; A.R. Holder, *op. cit.*, note 54, at pp. 227-8.

57. See *infra*, p. 28 *et seq*.

58. See A.M. Capron, *supra*, note 8, at pp. 367-9.

59. For example, see J. Katz, "The Education of the Physician Investigator", in "Freund, ed." *op. cit.*, note 6, p. 293, at p. 306.

60. Also note that the Ontario High Court has recently twice specifically expressed this as the purpose of requiring "informed" consent, in *Kelly v. Hazlett* (1977) 75 D.L.R. 3d. 536 at p. 556; and; *Reibl v. Hughes* (1977) 78 D.L.R. 3d. 35, at p. 41.

61. See *supra*, pp. 5-6.

62. For discussion of the doctrine of "therapeutic privilege" see; E.D. Pellegrino, *supra*, note 4, at p. 339; B. Dickens, "Information for Consent in Human Experimentation", (1974) 24 University of Toronto Law Journal, 381 at p. 395; G. Boyer Chammard and P. Monzein, *op. cit.*, note 56, at pp. 134, 138-147, 150 and 236; X. Ryckmans and R. Meert-van de Put, "Les Droits et les Obligations des médecins", 2 éd., Tomes I & II, Brusselles; Maison Ferdinand Larcier, S.A. 1971, at T. 1, Nos. 570-3; L. Kornprobst and S. Delphin, "Le Contrat de soins médicaux", Paris; Sirey, 1960, at No. 208; C. Fried, *op. cit.*, note 9, at p. 21; H.W. Smith, "Therapeutic Privilege to Withhold Specific Diagnosis from Patient Sick with Serious or Fatal Illness", (1946) 19 Tennessee Law Review 349. Reprinted in part in "Katz ed.", *op. cit.*, note 3, at p. 677; N. Rice, "Informed Consent: The Illusion of Patient Choice", (1974) 23 Emory Law Journal 503 at p. 506; J. Fletcher, "Human Experimentation: Ethics in the Consent Situation", (1967) 32 Law and Contemporary Problems 620, at p. 640, who advocates some "mediate" rule for withholding information — perhaps telling a relative of the patient or a "physician friend". The adoption of such an approach by a court, is discussed by A. Meisel, "The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability by Way of Informed Consent", (1977) 56 Nebraska Law Rev. 1:51, at p. 101, f.n. 147. For an excellent discussion of "therapeutic privilege" in American law, including problems of who bears the burden of proving or disproving the operation of the privilege, and the standard applicable to judge whether information may be withheld, see

pp. 99-107 of this article; A.M. Capron, "Experimentation and Human Genetics: Problems of 'Consent'" in A. Milunsky and G.J. Annas eds., "Genetics and the Law", New York; Plenum Press, 1976 (hereafter referred to as "Milunsky and Annas eds.") p. 319, at p. 322; H.L. Blumgart, "The Medical Framework for Viewing the Problem of Human Experimentation", in Freund ed., *op. cit.*, note 6, p. 39, at p. 48; R. Boucher *et al*, "La responsabilité hospitalière", (1974) 14 Cahiers de Droit 2:219, at p. 473; P.S. Cassidy, "Cooper & Roberts: A 'Reasonable Patient' Test for Informed Consent", (1973) 34 University of Pittsburgh Law Rev. 500, at pp. 505-6, reviews the United States cases which discussed therapeutic privilege.

"Notes: Restructuring Informed Consent, Legal Therapy for the Doctor-Patient Relationship", (1970) Yale Law Journal, 1532, at pp. 1566-7, where a suggestion for restructuring therapeutic privilege is made; *Male v. Hopmans* (1965) 54 D.L.R. 2d 592; affd. 64 D.L.R. 2d. 105; *Johnston v. Wellesley Hospital* (1970) 17 D.L.R. 3d. 139; *Kenny v. Lockwood* [1932] 1 D.L.R. 507; *Salgo v. Leland Stanford Junior University Board Trustees* 317 P. 2d. 170 (Cal. 1957); *Cobbs v. Grant* 502 P. 2d. 1; 104 Cal. Rptr. 505 (1972); *Canterbury v. Spence* 464 F. 2d. 772 (C.A. Dist. of Col. 1972); *Wilkinson v. Vesey* 295 A. 2d. 676 (1972).

63. Note that the non-application of therapeutic privilege to the non-therapeutic situation is stated by a court in; *Halushka v. University of Saskatchewan* (1965) 53 D.L.R. 2d. 436; and in; *Hyman v. Jewish Chronic Diseases Hospital* 206 N.E. 2d 338 (1965).

See also N. Hershey & R.D. Miller, "Human Experimentation and the Law", Germantown, Maryland; Aspens Systems Corporation, 1976, at p. 35; W.J. Curran, "Governmental Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies", in "Freund ed.", *op. cit.*, note 6, p. 402, at p. 426 *et seq.*, who discusses the United States F.D.A. Regulations governing the experimental use of drugs and the consent required in such situations (see *infra*, note 80) which show "therapeutic privilege" applies, if at all, only in the therapeutic situation.

For further discussion of these regulations in this respect see; M.J. Bloom, "Non-therapeutic Medical Research involving Human Subjects", (1973) 24 Syracuse L. Review 1067, at p. 1080-81; M.F. Ratnoff, "Who Shall Decide When Doctors Disagree? A Review of the Legal Development of Informed Consent and the Implications of Proposed Law Review of Human Experimentation", (1975) 25 Case Western Reserve Law Review 472, at p. 504 *et seq.*; W.J. Curran & E.D. Shapiro, "Law Medicine and Forensic Science", 2 ed., Boston, Little Brown & Co., 1970, at p. 595 *et seq.*; G.J. Annas, L.H. Glantz and B.F. Katz, "Informed Consent to Human Experimentation: The Subject's Dilemma", Cambridge, Massachusetts; Ballinger Publishing Co., 1977, at p. 7.

64. 95 Eng. Rep. 860; 2 Wils, K.B. 362 (1767).

65. The Nuremberg Code was developed by the prosecution in the Nazi War Crimes Case *United States v. Karl Brandt et al.*, Trials of War Criminals Before Nuremberg Military Tribunals Under Control Council Law No. 10 (Oct. 1946 — April 1949) The Medical Case, Washington's United States Government Printing Office, 1947. It is reprinted in W.J. Curran and E.D. Shapiro, *op. cit.*, note 62, at p. 888.

66. Medical Research Council Annual Report for 1962-3. Cmnd. 2382, Her Majesty's Stationery Office, London, 1964. Also reprinted in fall B.H.J. 1964.2.178.

67. Royal College of Physicians (England), Report of the "Committee on the Ethics of Clinical Research Investigations in Institutions", July 1973.

68. "AMA Ethical Guidelines for Clinical Investigation", Adopted by House of Delegates, American Medical Association, Nov. 30, 1966, Chicago; American Medical Association.

69. "Declarations of Helsinki. Recommendations guiding medical doctors in biomedical research involving human subjects". Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1969. As Revised by the 29th World Medical Assembly, Tokyo, Japan, 1975. Published by the World Medical Association, 01210 Ferney-Voltaire, France.

69a. Medical Research Council, "Ethical Considerations in Research Involving Human Subjects", Report No. 6, Ottawa; Supply and Services, 1978, (hereafter referred to as "Ethics in Human Experimentation") at p. 21.

70. 21 C.F.R. § 312.1.

71. Fed. Reg. March 13, 1975; 40 F.R. 50 11854-5 45 C.F.R. § 46.3(c).

72. *Décret du 14 janvier 1974*. Extracts published in La Nouvelle Presse Médicale 3(5) 265 (1974), at p. 266. Published in full in "La responsabilité civile des médecins", V^e^. Colloque de Droit Européen organisé par la collaboration des Universités "Jean Moulin" et "Claude Bernard", Lyon 3-5 juin, 1975.

This duty is limited by Article 34 *Code de Déontologie médicale* (France) Décret No. 55-1591 du 28 novembre 1955, portant *Code de Déontologie médicale* et remplaçant le règlement d'administration publique no. 47-1169 en date du 25 juin 1947, which states "Un pronostic grave peut légitimement être dissimulé au malade. Un pronostic fatal ne peut lui être révélé qu'avec la plus grande circonspection, mais il doit l'être généralement à sa famille, à moins que le malade ait préalablement interdit cette révélation ou désigné les tiers auxquels elle doit être faite".

Cf. Code of Medical Ethics of the Professional Corporation of Physicians of Quebec, second edition (2nd Reprint), June, 1976. Ratified by Decree no. 3391, Oct. 6, 1971, which establishes a general duty not to conceal a serious or fatal diagnosis from a patient requesting its disclosure except with justifiable reasons. This duty is retained in the Draft Regulation *Professional Code* 1973 c. 43 Gazette Officielle du Québec, 31 août 1977, 109^e^ année, No. 34, 4243-4255 at 4247, 2.03.30.

73. *Cf.* Plato's doctor in the "Laws" who obtains "informed" consent — referred to A. Buisson, "Human Experimentation through the Ages", in D.P. Flood, ed., "Medical Experimentation on Man", A Cahier Laenac, Trans. M. Gerrard Carroll, Chicago; Henry Regnery Co., 1955, (hereafter referred to as "Flood ed."), at p. 14.

74. G. Edgar, "Commentaire du Code de morale pour les hôpitaux", Montréal; Wilson & Lafleur, 1957, at p. 34.

This same approach was recently advocated by the American Surgical Association, "American Surgical Association Statement on Professional Liability, September, 1976", NEJM 295(23) 1293 (1976), who want to modify the requirements of "informed" consent in the United States, so that it is only necessary for the doctor to explain at the patient's request.

75. R. Boucher et al., *supra*, note 62, at p. 474.

76. [1974] C.S. 105. Cited *ibid.*, f.ns. 181 & 185.

77. G. Boyer Chammard & P. Monzein, *op. cit.*, note 56, at p. 133.

78. This view may be supported by reference to: C. Blomquist, "A New Era in European Medical Ethics", The Hastings Center Report 6(2) 7 (1976); P. Lombard, P. Macaigne and B. Ondin, "Le médecin devant ses juges", Paris; editions Robert Laffont, 1973, at p. 122 & p. 167 who say American jurisprudence is even now more exacting than the French, on the duty to inform the patient; R.C. Fox, *supra*, note 10, at p. 99, who suggests that more information is given to patients by United States doctors than European ones, because the public in the United States are made more aware of medicine through their mass media.

Although I have spoken generally of the duty to inform the patient in the Common Law, the above authors refer specifically to American Common Law and certainly this shows the longest and strongest development of this trend, although it is present in other Common Law jurisdictions. There are two aspects of this trend, the development of a duty to inform and the development of its required content. It is particularly in the latter aspect that most Common Law jurisdictions trail the American ones. For example, see the statement of W.F. Bowker "Experimentation on Humans and Gifts of Tissue: Articles 20-23 of the Civil Code", (1973) 19 McGill Law Journal 2:161, who, after analyzing the case-law concludes that in Canada physicians "have a wide scope in exercising their judgment" in informing their patients (at p. 169). Note that the author expressly states that this discretion does not extend to non-therapeutic experimentation, citing *Halushka v. University of Saskatchewan*, cited *supra*, note 63, as authority, and would be of doubtful validity except in extreme circumstances in therapeutic experimentation.

79. See *Pedesky v. Blaiberg* 59 Cal. Rpt. 294 (Cal. 1967), for a statement by a Common Law court that a doctor has a duty to ensure the patient understands the information given.

In a Civil Law jurisdiction R. Boucher *et al*, *supra*, note 62, at p. 474, referring to Quebec, say the obligation to inform the patient is one of result "en ce sens que les renseignements donnés devraient avoir pour effet de permettre au patient de donner un consentement libre et éclairé . . . [L]e médecin . . . se devra de donner tous les renseignements nécessaires, toutes les explications suffisantes pour que le patient puisse *comprendre* la portée de l'acte auquel il consent". (Emphasis added). L. Walters, "Some Ethical Issues in Research Involving Human Subjects", Perspectives in Biology and Medicine 20(2) 193 (1977), at p. 205, says that in the research context the choice of a "reasonable patient" standard — that is use of objective criteria to determine both the scope of disclosure and the patient's understanding — or a "subject's need" standard — employing subjective criteria for these purposes — "will significantly affect the stringency of the disclosure requirement".

80. See Medical Research Council, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 21, which requires that "[a] subject has given a proper consent . . . on the basis of well understood . . . information . . . "; J.C. Garham, "Some observations on informed consent in non-therapeutic research" J. Med. Ethics 1(3) 138 (1975); A.M. Capron, "Informed Consent in Catastrophic Disease Research and Treatment", (1974-75) 123 University of Pennsylvania Law Review 340, at p. 413; R. Boucher *et al*, *supra*, note 62; W.G. Todd, "Non-Therapeutic Prison Research: An analysis of Potential Legal Remedies", 1975 Albany Law Review, 799, at p. 810, f.n. 91, citing *Knecht v. Gillman*, 488 F. 2d. 1136 (8th Circ. 1973), as authority for requiring subjective comprehension for "informed" consent; X. Ryckmans and R. Meert-van de Put, *op. cit.*, note 62, at No. 571; N. Hershey and R.D. Miller, *op, cit.*, note 63, at p. 64, in relation to consent to medical research, suggest that an ethical review board should require one of two alternative conditions to be fulfilled before approving research: that the subject understands *or* the subject rejected an offer of information; *Cf.* D.H.E.W. Regulations, Fed. Reg. 23 Aug. 1974, at 30649, which expressly state that to require assurance that the subject comprehends the disclosure "goes beyond requirements for informed consent as they have generally been articulated by the courts". This statement, in turn, must be compared with the definition of "informed consent" in these Regulations (45 CFR § 46.3) which is defined as meaning "knowing consent". Presumably, therefore, the Secretary of D.H.E.W. in the former comment is referring to the Regulations not requiring *assurances* of comprehension, rather than their not requiring *comprehension* by the subject to exist in fact.

The Nuremberg Code, *supra*, note 65, at parag. 1, requires that the person "should have *sufficient knowledge* and *comprehension* . . . to make an *understanding* and enlightened decision". (Emphasis added.)

Cf. The Declaration of Helsinki, *supra*, note 69, at I Basic Principles, parag. 9, which is silent beyond requiring that "each potential subject be *adequately* informed . . . " and his "informed consent" obtained.

The United States F.D.A. Regulations, at 21 C.F.R. § 310.102(h), require that the patient be given information "as to enable him to make a decision on his willingness to receive [an] investigational drug . . . [which] means that before the acceptance of an affirmative decision by such person the investigator should . . . tak[e] into consideration such person's . . . ability to *understand* . . . " the information of which disclosure is required.

The National Health and Medical Research Council, "N.H.M.R.C. (Aust.) Statement on Human Experimentation", Reprinted in The Medical Journal of Australia, 1966 (2) 325, requires *comprehension* of the nature of an experiment by the subject or his guardian; J.R. Waltz and T.W. Scheuneman, "Informed Consent to Therapy", (1969) 64 Northwestern Univ. Law Rev. 628. Reprinted in part in "Katz ed.", *op. cit.*, note 3, p. 579 *et seq.* and p. 605 *et seq.*, at p. 580, say the duty is to inform so that a reasonable man (doctor) would think the patient understood, but this is not an absolute duty to ensure the patient understood.

81. Cited *supra*, note 60.

82. Cited *supra*, note 60.

83. *Kelly v. Hazlett*, cited *supra*, note 60, at pp. 563-4.

84. Reibl v. Hughes, cited *supra*, note 60, at p. 41. (Emphasis added).

85. *Ibid.*, p. 44. (Emphasis added).

86. J.C. Garham, *supra*, note 80, carried out an experiment on obtaining informed consent and concluded that despite all efforts to achieve this end, it was only accomplished in five out of forty-one cases in which it was attempted.

See also James Reed "Knowledge, Power, Man & Justice: Ethical Problems in Biomedical Research", Can. J. Genet. Cytol. 17:297 (1975), at p. 300, who states that with the increasing complexity of modern medical technology, it will become more difficult for even the educated layman to understand the impact of what he is told.

87. A. Meisel, *supra*, note 62, at p. 117, makes the observation that if the function of "informed" consent is to safeguard the individual's right to self-determination, even his right to make "foolish" decisions, then the proper emphasis is exclusively on the information disclosed by the physician. If however the function is to *assure* rational decision-making, then one must also focus concern on the patient's comprehension of what is disclosed. I submit that at least in non-therapeutic situations, "informed" consent should serve both functions.

88. A.M. Capron, *supra*, note 8, at p. 414.

89. See for example *Natanson v. Kline*, cited *supra*, note 53, at p. 465.

90. G. Boyer Chammard & P. Monzein, *op. cit.*, note 56, at p. 150; L. Kornprobst & S. Delphin, *op. cit.*, note 62, at No. 208.

Royal College Physicians (England), "Code Ethics", *supra*, note 67, at p. 2, requires that physicians do not seek consent to "beneficial research" where it is inappropriate or inhumane to do so.

Cobbs v. Grant, cited *supra*, note 62, at 502, P. 2d., 12; 104 Cal. Rptr., 516, where the privilege was suggested as operating where "the disclosure would have so seriously upset the patient that the patient would not have been able to dispassionately weigh the risks of refusing to undergo the recommended treatment".

Note that this statement must be distinguished from a case in which the information does not appear likely to "so seriously upset the patient", but may have the effect of causing him to refuse treatment. This is the patient's privilege and in such cases the justification of "therapeutic privilege" does not operate.

91. See, for example, B. Dickens *supra*, note 62, at p. 400. This author does, however, seem to suggest that "public interest" may justify withholding a narrow category of information in some circumstances. To the extent that this is true I respectfully disagree with it, unless what is meant is that the risks envisaged need not be disclosed because they are irrelevant or immaterial, as even if one considers it valid to conscript experimental subjects, I believe they still have a right to know the full extent of that for which they are being conscripted. To do otherwise is not only to use people, but to do so deceptively. It is less contradictory of their rights to use them openly, even if this is contrary to their wills.

92. See A.R. Holder, *op. cit.*, note 54, at p. 226, who cites a list of cases supporting the view that when new or experimental treatment is involved, there is at least a duty-to-warn that all effects are not known. That is, to this extent at a minimum, a "therapeutic privilege" does not apply to even therapeutic research and possibly not to some "new" therapy.

93. See J.R. Mason, "*Kaimowitz v. Department of Mental Health*: A Right to be Free from Experimental Psychosurgery", (1974) 54 Boston University Law Review 301, at p. 317; J.R. Waltz, "The Liability of Physicians and Associated Personnel for Malpractice in Genetic Screening", in "Milunsky and Annas, eds.", *op. cit.*, note 62, at p. 148; C. Fried, *op. cit.*, note 9, at p. 20.

Davies v. Wyeth Laboratory Inc. 399 F. 2d.(9th Circ. 1968), where a one in a million chance of contracting polio from a vaccine used to immunize the patient was held to be a material fact which should have been disclosed.

See *Canterbury v. Spence*, cited *supra*, note 62, at pp. 786-7.

Wilkinson v. Vesey, cited *supra*, note 62, at p. 689, for a definition of a material risk, which is when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to undergo the proposed therapy.

94. B. Dickens, *supra*, note 62, at p. 395; G. Edsall, "A Positive Approach to the Problem of Human Experimentation", in "Freund ed.", *op. cit.*, note 6, p. 276, at p. 281. Refers to the unreported proceedings against the two doctors involved in the "cancer-cell case" (the injection of live cancer cells into geriatric patients for experimental purposes, which gave rise to *Hyman v. Jewish Chronic Diseases Hospital*, cited *supra*, note 63) before the New York Board of Regents, the pertinent medical licensing authority, which suspended the licences of the two physicians with a stay of implementation, on the ground *inter alia* that the physicians had no right to withhold any of the facts that the volunteer might have regarded as *revelant*.

"Notes: Yale L.J.", *supra*, note 62, at pp. 1559-60.

95. G. Edsall, *ibid.*, says the individual patient or research subject must "be given full opportunity to exercise *his own judgment*" which implies a subjective standard if such opportunity is to be as "full" as possible; A. Meisel, *supra*, note 62, at p. 109 and f.n. 165, states that many commentators "have assumed the subjective test applied". He is speaking here of a subjective or objective test of causation of injury by the non-disclosure. In other words, whether the test is, would this particular patient (a subjective test), or would a reasonable patient (an objective test), on the balance of probabilities, have changed his decision if the required disclosure had been made. As a matter of logical consistency, the same test as that used to determine causation must be applied at the time of disclosure to determine what must be disclosed, although it is being used one step in advance at the stage of disclosure. Thus on this line of argument, a subjective test, from the patient's point of view, would be used to determine the content of the required disclosure if a subjective test of causation is used.

96. *Halushka v. University of Saskatchewan*, cited *supra*, note 63.

Canterbury v. Spence, cited *supra*, note 62, at pp. 790-1.

Cobbs v. Grant, cited *supra*, note 62, at 502 P. 2d. p. 11; 104 Cal. Rptr. p. 515; J.R. Mason, *supra*, note 92, at p. 317.

"Notes: Yale L.J.", *supra*, note 62, at pp. 1559-60; J.R. Waltz and T.W. Scheuneman, *supra*, note 80, at p. 640; "Katz ed.", at p. 580.

97. Cited *supra*, note 62.

See also *Wilkinson v. Vesey*, cited *supra*, note 62.

Cf. Karp v. Cooley and Liotta, 349 F. Supp. 827 (S.D. Tex. 1972), 493 2d. 408 (Fed. Ct. of Apps. 1974), where the standard of disclosure was set by the court on the basis of what a reasonable doctor would disclose. It may be that a Harvard Law Review case note, "Physician's Duty to Warn. *Di Fillipo v. Preston* (Del. 1961)" (1962) 75 Harv. L.R., 1445, was seminal in this change to a "lay standard" by the courts in the United States. This "note" argued that the duty to warn should be based on the patient's needs and not on medical practice; J.A. Robertson, "Compensating Injured Research Subjects II The Law", The Hastings Center Report 6(6) 29 (1976) at p. 31, says about one quarter of the states in the United States follow *Canterbury v. Spence* (*ibid.*).

98. Cited *supra*, note 60.

99. *Ibid.*, p. 558.

100. *Ibid.*, p. 565.

101. *Ibid.*

102. *Ibid.*

103. It is not clear if a subjective or objective test applies in relation to disclosure of risks relevant to a cause of action in assult and battery, but it is probably objective, that is risks which a reasonable patient would consider to be "basic to the nature and character of the operation", (*Kelly v. Hazlett ibid.*, p. 558) must be disclosed. Although such a test, based on the reasonable patient, was expressly rejected in relation to the negligence standard (*ibid.*, p. 565) this, or the more onerous subjective test, must apply in relation to the standard of disclosure relevant in assault and battery, as the Court held that medical evidence was not necessary in this respect. (at p. 565).

It is not stated by the Court, but it may be that the distinction in content of information between the two classes of duty to obtain consent, is based on a distinction between the "old" law, and the "new" law. In the former the determination of what constitutes a sufficient consent to negate the torts of assault and battery, is less onerous than the degree of consent needed for a doctor to escape liability under the latter, modern negligence law, for failure to inform the patient adequately.

For a case apparently to the contrary, in that it indicates that provided the patient submits to the treatment and does not seek information about risks, there is sufficient consent to protect the physician from legal liability, although risks were not disclosed, see *McLean v. Weir, Goff and Royal Inland Hospital* [1977] 5 W.W.R. 609.

104. In fact, in the case itself, the Judge has difficulty in classifying the risk and speaks of the "substantial" "nature and character of the operation", (p. 558)

on the one hand, in contrast to "collateral", (p. 558), "special", (p. 564), "usual", (p. 564), and "material" (p. 559) risks on the other. In *Reibl v. Hughes* (cited *supra*, note 60) Mr. J. Haines expressly adds (at p. 42) to the test expounded in *Kelly v. Hazlett* (at pp. 558-9) for classifying risks, that "it is not only the probability of a particular risk but the severity of its realized consequences which controls its characterization as an 'integral feature of the nature and character of the operation'". (*Kelly v. Hazlett*, *ibid.*).

Thus, according to these cases, what must be disclosed to avoid liability in assault and battery differs from that which needs to be disclosed to fulfill a duty of care in negligence. The latter relates to informing the patient of "*specific* risks within the surgeon's [doctor's] knowledge *peculiar* to the contemplated treatment. The scope of this professional duty of care is defined by the evaluation of a variety of interrelated factors which bear uniquely on each case, factors such as the presence of an emergency requiring immediate treatment; the patient's emotional and intellectual make-up, and his ability to appreciate and cope with the relevant facts; the gravity of the known risks, both in terms of their likelihood and the severity of this realization". (*Reibl v. Hughes*, p. 42, emphasis added).

105. *Kelly v. Hazlett*, *ibid.*, p. 556.

106. *Ibid.*

107. L. Kornprobst, "Les orientations prises, depuis trente ans, par la jurisprudence en matière de responsabilités médicales (II)", La Nouvelle Presse médicale 2(28) 1874 (1973), at p. 1875.

For the situation in Quebec see R. Boucher et al., *supra*, note 62, at p. 472 *et seq.*, where the content of the duty to inform appears to be similar to that in Common Law, but possibly with wider exceptions applicable. Although it is not expressly stated by the authors, it may be implied that the facts which must be included in a disclosure are judged from a patient's viewpoint: "le médecin . . . se devra de donner tous les renseignements nécessaires, toutes les explications suffisantes pour que *le patient* puisse *comprendre la portée* de l'acte auquel il consent" (at p. 474. Emphasis added). I suggest that this means "la portée de l'acte" from the standpoint of the patient and not from that of the doctor, in which case the patient must be told the facts which he considers relevant in assessing consequences, or at least which a "bon père (patient) de famille" would consider relevant, and not only those a doctor would consider relevant.

108. *Cour de Cass.* (civ) 21 Fév 1961 J.C.P. 1961.12129.

109. J. Vidal and J.-P. Carlotti, "Le consentement du malade à l'acte médical", in "Premier congrès international de morale médicale. Rapports" Ordre National des médecins, Paris, 1955, at p. 79.

110. H. et L. Mazeaud et A. Tunc, "Traité Théorique et Pratique de la Responsabilité Civile Délictuelle et Contractuelle", 6e éd. Paris; Éditions Montchrestien, 1965, Tomes I & II, at Tome I, No. 511.

111. For a summary of, and references to, this jurisprudence, see: L. Kornprobst, *op. cit.*, note 12, at pp. 356-7.

112. Note the words "simple", and "intelligible", and, also, perhaps in the same sense of aiding understanding by the patient, "approximative", which are

used by the *Cour de Cassation*, cited *supra*, note 108, when speaking of the requirements of informing for the purpose of obtaining consent.

The requirement of subjective and understanding probably also applies in Quebec law. See, for example, the quote from R. Boucher *et al.*, *supra*, note 107.

113. 26 App. Div. 2d. 693; 272. N.Y.S. 2d. 557 (Sup. Ct. 1966); reversed in part 19 N.Y. 2d. 407; 227 N.E. 2d. 296 (1967).

114. J.R. Waltz and T.W. Scheuneman, *supra*, note 80, at pp. 630-5; in "Katz ed.", *op. cit.*, note 3, p. 605.

115. 42 U.S.L.W. 2063 (Circ. Ct. Wayne County Michigan 1973). Also published in fall in W.H. Gaylin, J.S. Meisler and R.C. Neville eds., "Operating on the Mind (The Psychosurgery Conflict)" New York; Basic Books Inc. 1975 (hereafter referred to as "Gaylin, *et al* eds.") at Appendix, p. 185 *et seq.*

116. Fed. Reg. 13th March 1975, 40 F.R. 50, 11854; 45 C.F.R. § 46.3(c).

117. 21 C.F.R. § 310.102(h), § 312.1.

117a. These DHEW and F.D.A. provisions specifying the scope of the required disclosure of information should be compared with those recently recommended by the Medical Research Council of Canada, ("Ethics in Human Experimentation", *supra*, note 69(a), at pp. 21, 22) which state that the information "should explain the following:

— the procedures that involve the subject, including the use of drugs or radioisotopes.
— foreseeable risks, side effects and discomforts.
— the nature of the experiment, including randomization procedures and the uncertainties of the experiment.
— possible benefits, both to the subject himself and to others, stressing that these benefits are by no means assured.
— the right to withdraw from the experiment at any time without penalty.
— precautions that will be taken to ensure the anonymity of the subject."

118. There has been some discussion whether or not there is a duty to disclose alternative *experimental* treatments which are available. See: C. Fried, *op. cit.*, note 9, Introduction, at p. 29; *Fortner v. Koch*, 272 Mich. 273; 261 N.W. 762 (1935).

One may also consider no treatment as an alternative form of treatment of which the patient must be advised. In this respect it is interesting that R. Boucher *et al* (*supra* note 62, at p. 485) state that there is an obligation to advise a patient of the consequences of refusing treatment. The authors do not suggest it, but this duty could be extended to disclosing the risks and benefits of "no treatment", when this is the result of the doctor's decision rather than the patient's as in refusal of treatment.

119. 21 C.F.R. § 310.102(h).

120. *Ibid.*

121. For example see: W.R. Barclay, "Statement of the American Medical Association. Re: Human Experimentation" before the Subcommittee on Health, Committee on Labour and Public Welfare, United States Senate,

March 8, 1973 (copy supplied to the author by the American Medical Association), at p. 2; N. Hershey and R.D. Miller, *op cit.*, note 63, at p. 33, who interpret the D.H.E.W. definition as only *requiring* the purposes of the procedures to be followed to be disclosed, but who recommend that information on the "general purpose" of the study also be given to the subject on a voluntary basis.

The situation discussed by L.A. Ebersold, "The University of Cincinatti Whole Body Radiation Study for Whose Benefit?", (1973-74) 15 Atomic Energy Law Journal 155, where persons were subjected to experiments with whole body radiation, possibly for defence purposes, without this purpose being disclosed, is instructive when considering whether a disclosure of general purpose should be mandated and suggests that it should be.

B. Dickens, *supra*, note 62, at p. 395, says the question is whether the subject must approve the entire purpose and scheme of the research, or it is sufficient that he consents to what is involved in his own participation. Dickens makes a distinction between giving the subject misinformation, which is unacceptable, and confining information to that pertinent to the subject's participation, which he says may be allowed.

122. If medical research is not limited to medical purposes this will affect the ethical justification for conducting the research, which depends on the validity of the purpose sought in comparison with risks taken; also it may be relevant to know the general purpose in designing adequate protections for subjects, or even in alerting subjects to protect themselves. See the discussion by the "U.S. National Commission" of research involving human subjects carried out by the "Intelligence Community", for example the United States Central Intelligence Agency (C.I.A.) [National Commission for the Protection of Human Subjects, "Summary of Minutes of Meeting July 8-9, 1977", certified by K.J. Ryan 13th Aug. 1977 at p. 2, ditto Aug 12-13, 1977, at p. 1], in which it is stated that special protections, such as "second review" and appointment of a "resident expert" who is identified to subjects as a contact in case of injury, should be instituted for all such research, as the identity of the sponsor or the purpose of the research may not be disclosed for security reasons.

123. Report of a WHO Scientific Group, Wld. Hlth. Org., Technical Report Series, 1968, No. 403, at p. 19.

Such disclosure would be limited to remuneration received above the researcher's normal salary, which would be payable whether or not he conducted the experiment.

124. Which is not to say he would be given the treatment at a future time, as other factors, extrinsic to the doctor's willingness to give the treatment, may indicate that this is undesirable.

125. N. Hershey and R.D. Miller, *op. cit.* note 63, at pp. 62-3.

126. J.A. Robertson, *supra*, note 97 at p. 30.

If there is no express term in the contract of experimentation then whether there is a legal right to compensation will depend on whether a term to this effect can be implied, either from the circumstances or by custom or usage.

127. Also with respect to the language used one must be careful that there is not subtle intentional, or unintentional, deception. For example B. Gray, "Human Subjects in Medical Experimentation", New York; John Wiley & Sons, 1975, at pp. 221-2, found that the consent form used in the experimental study he was investigating, did not use the word research and that the medical and para-medical staff employed euphemisms such as "new drug", rather than experimental drug, when speaking to patient/subjects. (at p. 217).

128. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 39.

129. D.C. Martin, J.D. Arnold, T.F. Zimmerman, R.H. Richart, "Human Subjects in Clinical Research — A Report of Three Studies", N.E.J.M. 279 (26) 1426 (1968), at p. 1427.

130. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 33 and p. 63, recommend that the information should be given in the form of an invitation to participate to avoid coercion.

131. L.C. Epstein and L. Lasagna, "Obtaining Informed Consent: Form or Substance", Arch. Int. Med. 123(6) 682 (1969), found the degree of comprehension of information by research subjects was inversely proportional to the length of the consent form used, all of which contained the basic, essential information necessary to "informed" consent; F.J. Ingelfinger, "Informed (but uneducated) Consent", N.E.J.M. 287(9) 465 (1972), at p. 466.

132. B. Gray, *op. cit.*, note 127, at p. 220.

133. *Ibid.*, at p. 220.

134. *Ibid.*, p. 138

135. B. Barber, J. Lally, J.L. Makarashka and D. Sullivan, "Research on Human Subjects (Problems of Social Control in Medical Experimentation)", New York; Russel Sage Foundation, 1973, at p. 113.

    Also see H.O. Tiefel, "The Cost of Fetal Research: Ethical Considerations", NEJM 294(2) 85 (1976) at p. 86, who concludes that it is necessary for the experimenter to identify with the subject to see him as human and therefore to treat him as such. One of the purposes of obtaining consent is to cause this identification by the researcher to occur, as well as to allow the subject to identify with or reject, at his option, the research endeavour. Thus if the researcher does not himself obtain the consent, part of the protective mechanism of the consent process is lost, although one must look to the *net balance* of protectiveness provided by the consent process and discount for possible coercion involved in the experimenter obtaining consent. The point I wish to make here is that consent can serve as a double identification process: of the subject with the experiment and of the researcher with the subject.

136. It is not internally inconsistent to formulate a non-delegable duty, which may be carried out vicariously, as in such cases it is the liability arising from breach which is non-delegable, not the actual performance, although this may also be made non-delegable in some cases by operation of law or contractual agreement.

In terms of this analysis the non-delegable duties proposed here are the one to obtain "informed" consent, which is non-delegable only as to liability, and the one to ensure that "informed" consent is obtained, which is non-delegable with respect to both liability and performance.

137. R. Slovenko, "Commentary: On Psychosurgery", The Hastings Center Report, 5(5) 19 (1975), at p. 21.

138. See R. Boucher *et al*, *supra*, note 62, at p. 475, citing *Pincovsky v. Tessier* (1930) 36 R.L. 327; B. Dickens, *supra*, note 62, at p. 402. This author also adds that as well as a continuing duty to disclose new factors which become apparent in relation to risk, because the subject consents to a procedure for a particular *purpose*, if the purpose changes he must be informed of this to maintain the validity of his consent (at pp. 403-4).

C. Fried, *op. cit.*, note 9, at pp. 24, 34-35; N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 150.

138a. See, for example, Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 25.

139. See *Johnston v. Wellesley Hospital*, cited *supra*, note 62, for a discussion of the Common Law approach to causation in non-disclosure of information cases.

140. D. Giesen, "La Résponsabilité par Rapport aux Nouveaux Traitements et aux Expérimentations", in "La Responsabilité civile des médecins", *op. cit.*, note 72, p. 63, at p. 69 (footnotes omitted).

141. This is the same line of argument as used by the French jurisprudence with respect to its "loss of a chance of cure" doctrine. This may be described as a duty of a doctor not to lose for a patient, a chance, that he otherwise has, of cure or survival. See P. Lombard *et al op. cit.*, note 78, at p. 14 *et seq*.

The necessary causal link between a doctor's non-disclosure and a patient's injury, in order to establish liability of the former, has been described in some American cases on the basis that the jury (the trier of fact) must determine what a prudent person in the patient's position would have decided if adequately informed, and there is then only causality if the decision would have been different from what it in fact was.

Cobbs v. Grant, cited *supra*, note 62; *Canterbury v. Spence*, cited *supra*, note 62; *Fogel v. Genesee Hospital*, 344 N.Y.S. 2d. 552 (1973); *Cooper v. Roberts*, 286 A. 2d. 647 (1971).

That is, an objective assessment is made of whether the patient would have refused to participate if the full disclosure had been made. In other words the non-disclosure must have caused the decision to participate, where proper disclosure would have reversed this decision from an objective standpoint. This *decision to participate* is then seen as the damage and not the risk which eventuated, which rather quantifies the damage.

This same approach to causation in "non-disclosure cases" is taken by the English Courts. See, for example, *Bolam v. Friern Hospital Management Committee* [1957] 1 W.L.R. 582; [1957] 2 All E.R. 118.

The "loss of a chance" approach looks at the situation from the other side, that is the damage is the loss of a *chance not to participate*, which is present whichever way the patient would have decided with full information. This in fact, imposes strict or risk liability for the non-disclosure, which I suggest is desirable at least when there are no therapeutic reasons for carrying out the procedure, or it is experimental, and possibly even in the purely therapeutic situation, as the doctor may always rely on the justification of "therapeutic privilege" if this is appropriate.

142. P. Lombard *et al, op. cit.*, note 78, at p. 165.

Note that although I have suggested that a "loss of a chance" approach should be taken with respect to non-disclosure by physicians, French doctrinal writers have not yet done this. Rather the evolution of this doctrine has been in the area of "la faute médicale", in the more traditional sense of malpractice relating to performance of a medical procedure, such as giving sub-standard treatment, which is then characterized as causing a loss of a chance to receive proper treatment.

143. *Cf.* L. Kornprobst and S. Delphin, *op. cit.*, note 62, at No. 231, who state that the absence of consent transfers the risk of the treatment to the doctor, but the fault of non-disclosure is only actionable if the treatment fails, that is if there is damage. This would make the overall result in a case involving such circumstances the same in the United States and France, the difference being that the claim arises at different times. In the United States there would probably only be nominal damages awarded in assault and battery, for failing to obtain consent, where the treatment was successful. In such a case no claim arises under French Law. But in either case, if the treatment fails, damages appear to be recoverable, providing the appropriate tests of causation are met — see discussion, *supra*, note 141.

G. Boyer Chammard and P. Monzein, *op. cit.*, note 56, at p. 139, state that a doctor is not liable if he acts without consent, if this turns out to be for the good of the patient; R. Boucher *et al*, *supra*, note 62, at p. 478, discuss the situation in Quebec. They say for the doctor to act without consent is fault, but this fault must be the cause of the damage for liability to ensue and it seems submitting a person to a risk he did not agree to take does not itself constitute damage. There is some authority in Quebec, *Beausoleil v. Communauté des Soeurs de la Charité de la Providence* [1965] B.R. 37 per Casey J. and Owen J., that even if there is no fault on the doctor's part, (sic) if he overrules the patient's wishes he carries the risk of having to compensate the patient if bad results occur. This case can be limited however, on its facts, as only applying where a doctor acts *against* a patient's express wishes, rather than without his consent. In a not very clear statement, the majority of the Court in this case, Lefebvre J., Lamontagne J. and Brossard J., seem to hold that because a doctor is only under an obligation of "means" he does not take liability for all resulting risks when he acts without the patient's consent. I suggest that the relevant obligation of means to be applied here relates to the duty to inform, and although the same standard of obligation may also apply to the treatment given this is not pertinent at this stage, and that if there is not the required *diligence in informing*, the damage arising from this fault may be quantified by assessing medical complications caused by the intervention, even those which arise without fault of the doctor.

144. P. Lombard *et al*, *op. cit.*, note 78, at pp. 167-8.

It may be that this approach of the Common Law can be explained by postulating that it applies a similar doctrine to "loss of a chance" at the level of informing. That is the patient must have all chances of choice at this stage, which is consistent with an over-riding autonomy of self-determination principle. In comparison the Civil Law allows for more choice of treatment by the doctor, rather than the patient (which is certainly historically correct), but is more inclined to find liability at a later stage when it determines that the patient lost, not a chance of choice as in Common Law, but a chance of cure, which is more consonant with fully upholding an inviolability principle aimed at protecting the health and well-being of the individual rather than his autonomy. (See *supra*, pp. 4-7.)

145. R. Miller and H.S. Willner, "The Two-Part Consent Form", NEJM 290(17) 964 (1974), at p. 965.

Also see Fed. Reg. 14 Jan. 1977, 3089, where it is reported that the Clinical Research Center for Vaccine Development (United States) requires volunteer subjects to pass an exam assessing their comprehension of information regarding the research, prior to their being experimentally innoculated.

146. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 41.

147. B. Gray, *op. cit.*, note 127, at p. 200.

148. Fed. Reg. 23rd Aug. 1974, 39 F.R. 165 30653; 45 C.F.R. § 46.305. Deleted by Fed. Reg. Aug. 9, 1975, 33527, on the recommendation of the United States National Commission, *supra*, note 37, Chapter I.

149. See Statement by the Committee on Ethics of the American Heart Association, "Ethical Considerations of the Left Ventricular Assist Device", JAMA 235(8) 823 (1976).

Also see Declaration of Helsinki, *supra*, note 69, at I Basic Principles, parag. 10, which suggests that an independent physician may obtain consent.

150. On this latter point see J. Viret, "L'expérimentation clinique. Quelques réflexions sur l'aspect juridique du problème," Revue Médicale de la Suisse Romande 89(9) 911 (1969), at p. 915, who says the information must be simplified and put in commonly used and understood language and therefore a doctor should only use "une caricature de la vérité".

151. For example in *Lotspeich v. Chance Vought Aircraft Corporation* 369 S.W. 2d 705 (Tex. 1963), a pre-employment physical examination, including a chest X-ray, indicated tuberculosis which the plaintiff did not become aware of until three years later. The court held that because there was no physican-patient relationship there was no duty to disclose the diagnosis to the plaintiff, there being only a duty in this respect to her employer, who had commissioned the examination.

See also, *Candler v. Crane Christmas and Co.* [1951] 2 K.B. 164, per Denning L.J., at p. 183.

152. M. Hemphill, "Pre-testing for Huntington's Disease. An Overview", The Hastings Center Report 3(3) 12 (1973); F.R. Freemon, "Pre-testing for Huntington's Disease, Another View", The Hastings Center Report 3(4) 13 (1973).

These authors were specifically speaking of the dilemma of pre-testing for Huntington's chorea, an incurable inherited disease, which may be detected at a relatively young age and which is characterized by the gradual onset of insanity and loss of physical coordination, with death in middle age.

Also see; Article 34 *Code de Déontologie* (France) cited *supra*, note 72, with which the approach I have suggested concurs.

Article 14 *Code of Medical Ethics of the Professional Corporation of Physicians of Quebec*, cited *supra*, note 72.

O. Enjolas, "Morale traditionnelle et progrès en génétique", La Nouvelle Presse médicale 2(13) 865 (1973).

153. See, for example, B.L. Kaiser "Patients' Rights of Access to their Own Medical Records: The Need for New Law", (1975) 24 Buffalo Law Rev. 2:317.

Note that under *The Public Hospitals Act* (Ontario), R.S.O. 1970 c. 378, section 11, "the medical record compiled in a hospital for a patient or an out-patient is the *property of the hospital* . . . " (emphasis added).

154. *Code de la Santé publique* (France), Article R5120.

155. U.S.C. § 552.

156. *Washington Research Project Inc. v. D.H.E.W.* 504 F. 2d 238, *cert. denied* 421 U.S. 963 (1975).

157. Also see Report and Recommendations of the United States National Commission on "Disclosure of Information under the Freedom of Information Act", D.H.E.W. Publication No. (05) 77-0003, at pp. 7-12, 22-4.

157a. Cited supra, note 155.

158. S.Q. 1971 c. 48, as amended by S.Q. 1973 c. 38; S.Q. 1974 c. 42; Statutes of 1975, Bill 36 and Bill 86, Statutes of 1977, Bill 10.

159. *Ibid.*, section 7.

160. J.M. Gustafson, "Ain't Nobody Gonna Cut on My Head!", The Hastings Center Report 5(1) 49 (1975), at pp. 49-50.

161. H.K. Beecher, "Consent in Clinical Experimentation — Myth and Reality", J.A.M.A. 195(1) 124 (1966).

162. E.B. Brody, "The Right to Know. On the Freedom of Medical Information", Journal of Nervous and Mental Diseases 161(2) 73 (1975), at p. 76.

163. *Cf.*, A.M. Capron, *supra*, note 62, at p. 321, who says the aim of the law in requiring consent is to protect the "well-being" of the person. The term "well-being" may be intended to be synonymous with self-protection, or could include a right to self-determination even where this was "non-self-protectively" exercised.

164. H. Jonas, *supra*, note 42, at p. 19.

165. P.A. Crépeau, "Le Consentement du Mineur en Matière de Soins et Traitements Médicaux ou Chirurgicaux selon le Droit Civil Canadien", (1974) 52 Rev. du Barr. du Can. 247, at p. 256; *Cf.*, H.K. Beecher, *supra*,

note 161, who sees the major value of consent as being in the fact that the patient then knows what he is involved in, for instance, an experiment, "and knowing can reject the opportunity if he chooses to do so" (at p. 124). This is an approach that arises from a starting point that consent is a "myth" and therefore the positive willing foreseen by Crépeau and Jonas is an impossibility and the benefit of consent is not in allowing one to participate voluntarily, but in allowing one to *refuse* to do so. The net result of this approach is that one therefore has "consent" when one has the façade of consent and there has been no refusal of consent after a proper effort to obtain it.

166. See W.H.V. Rogers, "Winfield and Jolowicz on Tort", 10th ed., London; Sweet and Maxwell, 1975, (hereafter referred as to "Winfield and Jolowicz") at p. 614.

167. *Ibid.*

168. See *Christopherson v. Bare* (1848) 11 Q.B. 473, at p. 477 where it was decided that lack of consent should be raised under the general issue, not being a matter for "justification" to be pleaded by way of "confession and avoidance". Referred to by J.C. Fleming, *op. cit.*, note 23, at p. 77, f.n. 24.

168a. That the defendant's admitting the act is not a "confession and avoidance" mechanism, as the act itself does not constitute wrong-doing to which the defendant can confess when consent is present.

169. Thus the defendant is limited, in a defence based on consent, by the plaintiff's ability to consent to the act in question — it may be that this is restricted by public policy or public order and good morals.

170. J. Paquin, "Morale et Médecine", Montréal; Immaculée Conception, 1955, at p. 354.

171. G.J. Annas and L.H. Glantz, "Psychosurgery: The Laws Response", (1974) 54 Boston University Law Review, at p. 254.

172. An exception perhaps to the necessity of transfer of power from the patient to the doctor, or where the doctor may be regarded as having the power to "interfere" with the patient vested in him, is the emergency situation, especially where, as in some jursidictions, the doctor may intervene against the patient's will.

173. T.A. Shannon, "The Problem of Interests and Loyalties: Ethical Dilemmas in Obtaining Informed Consent", Bioethics Digest 1:1 (1976).

174. *Ibid.*, pp. 4-5.

175. *Ibid.*, p. 5.

176. *Ibid.*

177. *Ibid.*, p. 7.

178. *Ibid.*, p. 2.

179. See, for example J. Katz, *supra*, note 59, at p. 306.

180. C.H. Baron, M. Botsford and C.F. Cole, "Live Organ and Tissue Transplants from Minor Donors in Massachusetts", (1975) 55 Boston Univ. Law Rev. 2:159, at p. 168.

181. A.M. Capron, *supra*, note 80, at p. 349.

182. See W.E. May, "Proxy Consent to Human Experimentation", Linacre Quarterly 43(2) 73 (1976).

183. Note that "against their will" is not necessarily the same as "without consent". One may act without consent, but not against a person's will, as the act would have accorded with the person's will *if* he could have expressed it. Or one may even act without consent, because the person lacks legal capacity to consent, but not against his expressed will, because he has factual capacity and used this to make his wishes known. In the former case the legality of the act hinges on excéptions to, or implications of, consent, not will; in the latter case, perhaps, a "lacunae" should mean that one must be presumed to be acting against a person's will. That is when a person is factually capable of choosing the failure to give an opportunity of choice causes a presumption to arise that one acted against that person's will, from the mere fact of not consulting his will. It is a separate and secondary question whether or not this is justified in some circumstances.

184. I. Berlin, "Four Essays on Liberty", London; Oxford University Press, 1969, at p. 138.

185. P. Freund, *supra*, note 6, at p. xvi and p. 114.

See also H.K. Beecher, *supra*, note 161, who speaks of the "*myth*" of informed consent a word with a strong connotation of symbolism.

186. P. Freund, *ibid.*, at p. xvii.

187. Cited *supra*, note 115.

188. Discussed by V.C. Heldman, "Behavior Modification and Other Legal Imbroglios of Human Experimentation", (1974) 52 Journal of Urban Law 155, at p. 164 *et seq*.

189. G. Calabresi, "Reflections on Medical Experimentation in Humans", in Freund ed., *op. cit.*, note 6, p. 178, at p. 195.

190. See G. Calabresi, "The Cost of Accidents — A Legal and Economic Analysis", New Haven; Yale University Press, 1970.

191. J.F. Childress, "Compensating Injured Research Subjects: I. The Moral Argument", The Hastings Center Report 6(6) 21 (1976).

192. See also H. Jonas, *supra*, note 42, at pp. 14-15 and p. 17, who speaks of consent being the "non-negotiable minimum requirement" for tapping reserves of self-sacrifice.

193. A.M. Capron, "Legal Considerations Affecting Clinical Pharmacologic Studies in Children", Clinical Research 21(2) 141 (1973), at p. 146.

It is interesting that Capron uses the word "suffer" in describing the purpose of "informed" consent, as "to assure that one *suffers* only those risks he has chosen". (Emphasis added.) This again connotes an element of sacrificiality even though this is positively, rather than negatively, expressed, that is with more emphasis on the right of choice present than the sacrifice involved.

194. For example, see R. McCormick, "Experimentation in Children: Sharing in Sociality", The Hastings Center Report 6(6) 41 (1976) at p. 46.

195. For example, A.M. Capron, *supra*, note 8, at p. 349; F. Rosner, "Modern Medicine, Religion and Law", New York State J. Med. 75(5) 758 (1975), at p. 759.

196. W.E. May, *supra*, note 182, at p. 79-80.

See also I. Berlin, *op. cit.*, note 184, at p. 156, who describes the process of personal identification in this way: "[M]y individual self is not something which I can detach from my relationship with others, or from those attributes of myself which consist in their attitude towards me".

197. J. Fletcher, *supra*, note 62, at p. 644.

198. *Ibid.*, p. 633.

199. See H.O. Tiefel, *supra*, note 135; B. Barber *et al*, *op. cit.*, note 135, at p. 113.

200. H. Jonas, *supra*, note r2, p. 19.

201. P. Ramsay, "The Ethics of a Cottage Industry in an Age of Community and Research Medicine", NEJM 284(13) 700 (1971) at p. 705.

202. P. Ramsay, "The Patient as a Person — Explorations in Medical Ethics", New Haven; Yale University Press, 1970, at p. 5.

203. T. Parsons, "Research with Human Subjects and the 'Professional Complex'", in "Freund ed.", *op. cit.*, note 6, p. 116, at pp. 132-5.

204. B. Gray, *op. cit.*, note 127, at p. 239.

205. See S. Siegel, "A bias for life", The Hastings Center Report 5(3) 23 (1975), at p. 25.

206. G. Edsall, *supra*, note 94, at p. 282.

207. R. Slovenko, *supra*, note 349, at p. 21.

208. A. Meisel, *supra*, note 325, at pp. 107-113, 123-132.

209. See *Kaimowitz v. Department of Mental Health for the State of Michigan,* cited *supra*, note 115, at pp. 194-200, 204 where the Court refused to permit psychosurgery on a mental incompetent on the ground, *inter alia*, that the subject's consent was necessary, but impossible to obtain.

210. For example, see *California Penal Code* (Supp. 1975) § 2670.5(b) "No person . . . who lacks the capacity for informed consent shall be administered or subjected to psychosurgery . . . ".

211. See B. Dickens, *supra*, note 62, at p. 387.

212. Committee on Ethics of the American Heart Association "Ethical Implications of Investigations in Seriously and Critically Ill Patients" Circulation 50(6) 1063 (1974), at p. 1068. In fairness, taking into account the tone of the later statement by the Committee on Ethics of the American Heart Association, *supra*, note 461a, the criticism levelled in my comment probably needs to be modified.

213. W. Wolfensberger, "Ethical Issues in Research with Human Subjects", 155 Science 47 (1967), at pp. 50-51. Also reprinted in "Katz ed.", *op. cit.*, note 3, p. 923, at p. 924.

214. See *infra*, p. 37 *et seq.*

215. See G.J. Annas, L.H. Glantz, B.F. Katz, *op. cit.*, note 171, at p. 49, who quote a social scientist as saying that unrealistic standards for medical research, for example, only breed cynicism.

216. Fed. Reg. 13th March 1975; 40 F.R. 50, 11854; 45 C.F.R. § 46.3(c). Note this definition takes many elements from the Nuremberg Code and the Declaration of Helsinki and, therefore, is of general interest.

217. Fed. Reg. 23rd Aug. 1974, 39 F.R. 165, 30655; 45 C.F.R. § 46.501(b).

218. Fed. Reg. 13th March 1975; 40 F.R. 50, 11854; 45 C.F.R. § 46.2(b) (3). (Emphasis added.)

219. *Ibid.*, 40 F.R. 50, 11856; 45 C.F.R. § 46.9. (Emphasis added.)

220. "A Submission to the Medical Research Council [Canada]: The University of Toronto's Experience with the Review of Research Involving Human Subjects", by T.C. Clark, Director, Feb. 3, 1977, at p. 2. (Made available by kind permission of the authors and the Medical Research Council.)

221. *Ibid.*, pp. 2-3.

222. See *supra*, p. 23.

223. *Cf.* T. Parsons *supra*, note 203, at p. 135, who, speaking of medical experimentation, describes this as taking place in a voluntary association complex and says the most important protection of the individual is his *right to resign* from this complex, which implies not only a positive act being necessary, but, perhaps, some duties attached to the resignation procedure.

Also *cf.* R. Boucher *et al*, *supra*, note 62, at p. 485, who say that in Quebec the patient at all times retains *"son droit de refuser"* as to hold otherwise would be contrary to Article 19 *Civil Code of the Province of Quebec* which statutorily enacts inviolability. Article 20 of this Code expressly legislates a *right of revocation* with respect to organ transplant donors and subjects of experimentation.

224. A.M. Capron, *supra*, note 8, at p. 364.

225. The exception to a contractual relationship being present may be where a doctor was justified in administering treatment against a patient's expressed will, when one could not reasonably imply a contract.

See P.D.H. Skegg, *supra*, note 17; J. Penneau, "Faute et Erreur en matière de responsabilité médicale", Paris; Librairie Générale de droit et de Jurisprudence, R. Pichon et R. Durand-Anzias, 1973, at p. 15, says that in French law it is only when there is no consent present that an action lies in delict, as an action based on a defect in the consent obtained is within the contractual regime of liability.

226. See L. Kornprobst and S. Delphin, *op. cit.*, note 62, at Nos. 16, 113 and 114.

227. See A.G. Guest ed., "Anson's Law of Contract", 24th ed., Oxford; Clarendon Press, 1975, (hereafter referred to as "Anson"), at pp. 5-6.

In comparison, in the Civil Law "consensus ad idem" is judged more subjectively. See J.-L. Baudouin, "Les Obligations", Montréal; Les Presses

de l'Université de Montréal, 1970 at Nos. 71-79. If consent to the contract attracts an objective standard, as in Common Law, this may explain the necessity to evolve the doctrine of "informed" consent to treatment, with its more subjective standard, and also shows one possible reason why the doctrine of "informed" consent developed earlier and more strongly in Common Law.

228. V.C. Heldman, *supra*, note 188, at p. 169, suggests that the use by American Courts of constitutional bases for allowing or preventing medical interventions, shows a move away from narrow contract theories of rights in these situations, to a human rights basis; *Cf.* A Mayrand, *op. cit.*, note 43, at No. 41, who assumes that the same rules, at least as far as capacity is concerned, apply to consent relevant to entering a contract, as to consent needed for the purposes of the rule against inviolability: "Celui qui est incapable de contracter ne pouvant consentir valablement à ce que l'on porte atteinte à sa personne . . . ", which seems to be retaining rights in the medical situation entirely within a contractual framework.

    It must be admitted that establishing a more general foundation for these rights, does not solve the problem of which basic human right of the patient is to predominate, when there is a conflict between one or more of them. I have suggested that any resolution of such a conflict involves a value judgment and that the values of the patient must predominate, with the possible exception that these rights cannot be abused, that is used to achieve a purpose for which they were not intended, such as relying on inviolability of the body to prevent life-saving treatment.

229. W. Prosser, *op. cit.*, note 16, at p. 103.

230. See "Anson", *op. cit.*, note 227, at pp. 8-18, for a brief history of the development of contract in Common Law.

231. J.F. Toole, "Informed Consent", Circulation 48(1) 1 (1973).

232. Here I am only considering whether it is *possible* to obtain "informed" consent. It is another matter to consider the *feasibility* of securing person-to-person "informed" consent in large scale genetic screening programs for example. (See J. Fletcher, R. Roblin and T. Powledge, "Informed Consent in Genetic Screening Programs", Birth Defects 10(6) 137 (1974), at p. 138. The distinction is between possibilities and feasibilities.

233. H.K. Beecher, *supra*, note 161.

234. H.K. Beecher, "Some Fallacies and Errors in the Application of the Principle of Consent in Human Experimentation", Clinical Pharmacology and Therapeutics 3(2) 141 (1962). Reprinted in "Ladimer & Newman eds.", *op. cit.*, note 10, p. 133, at p. 137.

235. L. Portes, "A la recherche d'une éthique médicale", Paris; Masson, 1954, "Du Consentement du Malade à l'Acte Médical", at p. 83-84.

236. *Ibid.*

    Note: It is interesting historically to conjecture whether Beecher knew of Portes' description of consent as "une notion mythique" published twelve years before Beecher's most quoted quote: the "myth" of informed consent.

237. E.D. Pellegrino, "Humanism in Human Experimentation: Some notes on the investigator's fiduciary role", Tex. Rep. Bil. and Med. 32(1) 311 (1974), at p. 316.

238. F.J. Ingelfinger, *supra*, note 131.

239. F.J. Ingelfinger, *ibid.*, thus interprets the requirement of "informed" as being fulfilled with some, or perhaps even total, lack of comprehension of the information given. See *supra*, pp. 15-16, for a discussion of comprehension. Legal capacity only requires the potential to comprehend, not actual comprehension, and thus one could have a legally capable, totally non-comprehending patient or subject.

240. M.J. Vidal and J.P. Carlotti, *supra*, note 109, at p. 83.

241. Thus referring to the "dual consent" concept discussed earlier (*supra* p. 36), Vidal and Carlotti require only free and clear consent to the medical contract and not necessarily to the treatment given under it.

242. For examples of such an attitude see: Committee on Ethics of the American Heart Association, *supra*, note 212; J.F. Toole, *supra,* note 231.

243. See *supra*, pp. 3-10.

244. R. McCormick, "Proxy Consent in the Experimentation Situation", Perspectives in Biology and Medicine 18(1) 2 (1974), at p. 3.

245. See C. Freid, *op. cit.*, note 9, at p. 21.; *Cf.* P.D.G. Skegg, *supra*, note 17, at pp. 513-4, who argues that such implications of consent are artificial and that justification of emergency interventions should rather be based on a "doctrine of necessity".

Also see J.G. Fleming, who, in the earlier edition of his text, *op. cit.*, note 21, at p. 78, regarded the justification of the emergency intervention as being based not on implied consent, but on "the preservation of life", which was changed in the later edition, *op. cit.*, note 23, p. 81, to "the humanitarian duty of the medical profession".

Cf. X. Ryckmans and R. Meert-van de Put, *op. cit.*, note 62, at No. 569, who say consent is not necessary when the treatment involves no danger. This is to make a distinction between consent to treatment and consent to risks, and to assume that consent is only necessary in relation to the latter.

Also see P.J. Doll, *supra*, note 36, at No. 41, who argues that in the emergency situation one has present a notion of "tentative autorisée", which is sufficient justification for the intervention, although, apparently, it does not amount to an implying of the "free and clear" consent which is normally required.

246. See: L. René, "Risque et responsabilité en chirurgie", in "Le médecin face aux risques et à la responsabilité", textes recueillis par M. Eck, Paris; 1968 (hereafter referred to as "Eck, ed."), at pp. 242-3, who says consent is not required, if it is not feasible or humane to obtain it; X. Ryckmans and R. Meert-van de Put, *ibid.*, at Nos. 570 and 572 who allow "therapeutic privilege" and urgency of the situation as a justification for acting without consent; R. Boucher *et al*, *supra*, note 62, at pp. 477, 479 *et seq.*, who analyze the *Beausoleil Case* (cited *supra*, note 143) and show that in Quebec

it is not clear if one can legally override a patient's wishes. They conclude (at p. 485) that a doctor probably cannot force a competent adult patient to receive care he refuses; *Cf.* A. Mayrand, *op. cit.*, note 43, No. 38, who argues this is justified to save life, but admits the situation is not clear in Quebec; L. Kornprobst, "Peut-on admettre un refus de transfusion sanguine par convictions religieuses?", La Nouvelle Presse Médicale 3(19) 1262 (1974), who says there is no damage in saving the patient against his will and hence such an act would not be legally actionable; R. Piédelièvre et E. Fournier, "Médecine légale", Paris; Ballière, 1963; Tomes I and II, at Tome I, p. 103, say the strict juridical review is that a patient can refuse treatment.

247. D.A. Frenkel, "Consent of Incompetents (i.e. Minors and the Mentally Ill) to Medical Treatment", Unpublished paper presented at the Third World Congress on Medical Law, Ghent, Belgium, Aug. 19-23, 1973, p. 3, cites two United States cases *Erikson v. Dilgard* 252 N.Y.S. 2d. 705, and *In re Brook's Estate* 32 Ill. 2d. 361; 205 N.E. 2d. 435 (1965), which upheld the patient's right to refuse life-saving treatment, and which show, as a corollary, that consent is always necessary where the patient can give it. However, he says these cases are contrary to the general rule that a patient may not refuse life-saving treatment.

J.R. Mason, *supra*, note 93, at p. 327, f.n. 146, argues that as Judges can order non-consensual emergency treatment this shows that consent is not always necessary.

Application of President Directors of Georgetown College 331 F. 2d. 1000 (D.C. Cir.), certiorari denied 377 U.S. 978 (1964), where the Court ordered a transfusion to be carried out on a competent adult woman despite her express denial of consent.

Cf., *In re Brook's estate*, one of the cases relied on by Frenkel above, where the court held a circuit court's order to administer a blood transfusion against the will of the competent adult patient was unconstitutional as against freedom of religious belief.

See also *Schloendorff v. Society of New York Hospital*, cited *supra*, note 15.

248. For examples of statements that consent is necessary in *all medical research* see: Declaration of Helsinki, *supra*, note 69, at I. Basic Principles, parag. 9; D.J. Whalan, "The Ethics and Morality of Clinical Trials in Man", Medical Journal of Australia 1(16) 491 (1975), at p. 493; I. Ladimer, "Ethical and Legal Aspects of Research on Human Beings", in "Ladimer and Newman eds.", *op. cit.*, note 10, p. 179, at p. 503. This is an extract from the unabridged article I. Ladimer, "Ethical and Legal Aspects of Medical Research on Human Beings", (1954) 3 Journal of Public Law 467; G. Calabresi, *supra*, note 189, at p. 195; Canada Council, Report of the Consultative Group on Ethics, "With Respect to Research Involving the Use of Human Subjects", May 1976; *Cf.* A. Decocq, *op. cit.*, note 4, at No. 334, who tentatively proposes that it may be a fault on the patient's part to refuse therapeutically needed experimental treatment, if it is known to be harmless. This may mean consent is not needed in such a situation, which, if it exists at all, would be very rare according to this jurist.

249. The most universally accepted statement of this requirement is the Declaration of Helsinki *ibid.*

Also see Medical Research Council Report (United Kingdom), *supra*, note 66, which states that consent is essential in non-therapeutic research; Royal College of Physicians Committee (United Kingdom), *supra*, note 67, at p. 2; J.F. Childress, *supra*, note 191, at p. 25.

250. C. Blomquist, "Ethical Guidelines for Biomedical Research", Annals Clinical Research 7(6) 291 (1975), at p. 293.

251. Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 25. But note the provision in this Code goes beyond the use of information already obtained about a person, to allowing use of the remainder of "partly used . . . samples obtained for diagnostic or treatment purposes, tissues obtained during surgical treatment, or information stored in registers or data banks . . . for research purposes".

Statement by the Medical Research Council (United Kingdom), "Responsibility in the Use of Medical Information for Research" B.M.J. 1973.(1).213. The use of such information is subject to complying with certain safeguards, but these do not include a right of refusal of the patient to have his records used.

J.A. Baldwin, J. Left and J.K. Wing, "Confidentiality of Psychiatric Data in Medical Information Systems", British J. Psychiatry 128:477 (1976), at p. 423.

252. M.B. Visscher, "Ethical Constraints and Imperatives in Medical Research", Illinois; Charles C. Thomas, 1975, at p. 25.

253. Under the D.H.E.W. Regulations, 45 C.F.R. § 46.3, such epidemiological or retrospective research would be regarded as research on human persons requiring "informed" consent.

See also N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 17, who state that research "need not be [an] interactive [process]; observation of humans through a one-way glass, by tape recording their conversations, or by examining their records may be classified as research . . . ".

254. For example B. Dickens, *supra*, note 62, at p. 397.

255. M.D. Eilenberg, R. Williams and L.J. Witts, "New Horizons in Medical Ethics: Research Investigation in Adults", B.M.J. 2(860) 220 (1973), at p. 223, who state that an ethical review committee at Northwick Park Hospital, Middlesex has a list of "minor procedures", where the doctor does not need to ask consent, as this would be "more upsetting . . . than otherwise" to the patient.

256. Fed. Reg. 13th March 1975, 40 F.R. 50, 11856; 45 C.F.R. § 46.10(c). This is a possible, but probably unjust interpretation of this section, when it is read in the full context of the Regulations.

257. One can distinguish the therapeutic exceptions where consent may not be required at this level, as in those cases the person is not being used for any purpose extrinsic to himself and as one is one's own purpose, therefore pursuing this intrinsic purpose is not a *use* of the person, whether with or without his consent.

258. C. Fried, *op. cit.*, note 9, at p. 23.

258a. For instance, by being a carrier of, but not a sufferer from, some serious infectious disease.

259. See W. Modell, "Let Each New Patient be a Complete Experience", in "Ladimer & Newman eds.", *op. cit.*, note 10, p. 73 at p. 77; F.J. Ingelfinger, "Those 'Ingredients Most Used by Doctors'", NEJM 295(11) 616 (1976); P.L. Bereano, *supra*, note 39, at p. 88, who says that when technology assessment is involved in a court adjusting the interests between parties to litigation, the court must take into account how this will affect the diffuse and numerous interests of *non-parties*; D.S. Greenberg, "Drug Advertising on T.V.: A New Inquiry", NEJM 294(17) 963 (1976).

Also see and compare: S.C. Schoenbaum, B.J. McNeil and J. Kavet, "The Swine-Influenza Decision", N.E.J.M. 295(14) 759 (1976), for an analysis of the "swine-flu" vaccination program which shows "non-subjects", that is non-participants in the vaccination program, may benefit directly from a certain level of participation of subjects, as this will reduce the risk of an epidemic in which "non-subjects" would be more likely to be infected.

260. A.B. Hill, "Medical Ethics and Controlled Trials", B.M.J. 1963.1.1043, at p. 1046.

261. *Supra*, p. 28 *et seq*.

262. X. Ryckmans and R. Meert-van de Put, *op. cit.*, note 62, at No. 595.

263. J.R. Waltz and T.W. Scheuneman, *supra*, note 80, in "Katz ed.", at p. 604.

264. A. Decocq, *op. cit.*, note 4, at No. 369.

265. J.K. Wing, "The Ethics of Clinical Trials", Journal of Medical Ethics 1975:1:174.

266. J. Hamburger, "Protection of Donor Rights in Renal Transplantation", in V. Fatturosso ed., "Biomedical Science and the Dilemma of Human Experimentation", Paris, Council for International Organizations of Medical Sciences, 1967, p. 44. Reprinted in "Katz ed.", *op. cit.*, note 3, p. 621.

267. E. Cahn, "Drug Experiments and the Public Conscience", in Paul Talalay ed., "Drugs in our Society" Baltimore; The John Hopkins Press, 1964, p. 255. Reprinted in part in "Katz ed.", *ibid.*, p. 721.

268. A.M. Capron, *supra*, note 8, at p. 373.

269. Certainly a person cannot consent to likely death or certain serious harm, but what is reasonable is to some degree a value judgment. For instance one can query if the risk taken in the *Halushka Case* (cited *supra*, note 63), that is of general anaesthetic and cardiac catheterization, had been fully disclosed and consent obtained, whether this would have been objectively reasonable or not.

270. T.A. Shannon, *supra*, note 173, at p. 2.

271. See for example: *Marshall v. Curry* [1933] 3 D.L.R. 266; 60 Can. C.C. 136 (N.S. S.C.); *Mulloy v. Hop Sang* [1935] 1 W.W.R. 714 (Sask. C.A.); *Murray v. McMurchy* [1949] 2 D.L.R. 442; I N.W.R. 989 (B.C.); *Cour Cass.* 15 mars 1966 J.C.P. 64.4.67; *Trib. Civ. Seine* 25 janv. 1949, Gaz. Pal. 1949.1.217; H.M. Street, "The Law and Torts", 6th ed. London; Butterworths, 1976, at p. 75, f.n. 4, says there is a striking absence of English

cases litigated on the basis of consent in the medical relationship, and one of the very few is *Beatty v. Illingwoth* (1896) British Medical Journal 21st Nov. 1896, p. 1525; *Mohr v. Williams* 104 N.W. 12 (Minn. 1905); *Kennedy v. Parrot* 90 S.E. 2d. 754 (N.C. 1956); *Dufresne v. X* [1961] C.S. 119 (Qué.); H.P. Green & A.M. Capron, "Issues of Law and Public Policy in Genetic Screening", Birth Defects: Original Article Series, 10(6) 57 (1974), at p. 65; J.G. Fleming, *op. cit.*, note 23, Chapter I, at p. 81.

272. See: F.H. Beale, "Consent in the Criminal Law", (1895) 8 Harvard Law Review 317. There has been controversy in Common Law jurisdictions whether or not consent to an act which is criminal, bars a civil action to recover the damage inflicted. The opposing views are that allowing the civil action has a deterrent effect and, on the other hand, that one should not be compensated when one has willingly participated in a criminal act; J.G. Fleming, *ibid.*, pp. 80-81, who discusses *Matthew v. Ollerton* (1693) Comb. 218, which held that the plaintiff's consent to an act which was "unlawful" did not bar the plaintiff's civil right of action. Fleming suggests that as prior to 1694 trespass involved a fine payable to the Crown, this may have influenced the Court in this "dictum"; W. Prosser, *op. cit.*, note 16, at p. 107; G. Boyer Chammard et P. Monzein, *op. cit.*, note 56, at p. 70.

    See *infra*, p. 105 *et seq.*, for a discussion of what conduct constitutes a criminal act in the medical context.

273. A. Decocq, *op. cit.*, note 4, at Nos. 377-8.

274. See, "Notes: 'The Sale of Human Body Parts'", (1974) 72 Michigan Law Rev. 1182, at p. 1238.

275. E. Nizsalovszky, *op. cit.*, note 13, at p. 65.

276. J.J. Lynch, "Human Experimentation in Medicine: Moral Aspects", in "Ladimer & Newman eds.", *op. cit.*, note 10, at p. 289.

277. This argument is fully presented by Pope Pius XII in "The Moral Limits of Medical Research and Treatment", 44 Acta Apostolica Sedis 779 (1952) Rome, where he likens the rights one has over one's body to a "usufruct" — a right of use but not of destruction, or one may say not of "waste", in the Common Law Real Property sense of this term.

278. E. Cahn, "The Lawyer as Scientist & Scoundrel: Reflections on Francis Bacon's Quadricentennial", (1961) 36 New York University Law Rev. 1, at p. 12.

278a. Note that the Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 22, does not require written consent, but recommends it.

279. P. Lombard *et al*, *op. cit.*, note 78, at p. 116.

280. Fed. Reg. 13th March 1975, 40 F.R. 50, 11854; 45 C.F.R. § 46.10.

281. *Loi sur Les Services de Santé et Les Services Sociaux* L.Q. 1971, c. 48, Art. 3.2.1.11.

    See also O. Reg. 100/74, 49 pursuant to *The Public Hospitals Act* (Ontario) R.S.O. 1970, c.378, section 39.

282. P.A. Crépeau, *supra*, note 165, at p. 258.

283. See, for example, Article 21 *Civil Code of the Province of Quebec*.

Pro Forma Act: *Human Tissue Gift Act* (1965) (Proceedings of Conference of Commissioners on Uniformity of Legislation in Canada (1965) 104) on which all the Common Law Provinces in Canada have based their "organ donation" Acts.

Pro Forma Act: *American Anatomical Gift Act* 1968 (8 Uniform Law Annotated, Master Edition (1972) 22) on which the states of the United States have based their Acts.

Human Tissue Act (1961) 9 & 10 Eliz. 11 c.54 (England).

Tissue Grafting & Processing Act (1955-1966) N.S.W. (Australia).

See also The Law Reform Commission (Australia), Working Paper No. 5, 28 Jan. 1977 "Human Tissue Transplants". And by the same body "Human Tissue Transplants" Report No. 7, Canberra; Australian Government Publishing Service, 1977, especially Draft Legislation "*Transplantation and Anatomy Ordinance 1977*", Part III, Donations of Tissue after Death.

For a report on recent French legislation on transplants, see London "Times" 21st Dec. 1976 and *supra*, note 35.

284. Article 20 *Civil Code of the Province of Quebec* at least allows, even if it does not require, written revocation of consent. See P.A. Crépeau, *supra*, note 165, at p. 258, who says that writing is only a matter of form and not of substantive validity of the revocation. The provision states that "[the] consent must be in writing; it may be revoked in the same way". I suggest that the proper interpretation of this is that the verb "may" is to be contrasted with "must", which indicates that the latter part of the provision is not obligatory; and that the reason for including this provision on revocation, is to rebut any implication that as the "consent must be in writing", so must its revocation. That is revocation is not limited to a written form, rather the provision in this respect is purely facultative.

Also see A. Mayrand, *op. cit.*, note 43, at No. 62, who adds that although a written consent under Article 20 may be instantaneously withdrawn orally, "[l]e droit de révocation peut être exercé fautivement et donner lieu à un recours en dommages-intérêts".

285. 45 C.F.R. § 46.103(c) (United States D.H.E.W. Regulations).

286. B. Gray, *op. cit.*, note 127, at p. 204.

287. E. Cahn, *supra*, note 278, at p. 11.

288. For example at Common Law "duress" has a very limited meaning of violence, or threats of violence, to the person of the contracting party, or to his parent, wife, or child. See M.P. Furmston "Cheshire & Fifoot's 'Law of Contract'", 9th ed. London; Butterworths, 1976, (hereafter referred to as "Cheshire and Fifoot") at p. 286.

"Undue influence" is described as an equitable principle wider than duress, which consists of any pressure which prevents a party from exercising an independent judgment. *Ibid.*, pp. 285-94.

Article 991 *Civil Code of the Province of Quebec* provides that: "Error, fraud, violence or fear, and lesion are causes of nullity in contracts . . . ".

Also see Article 1109 *Code Napoléon* (France).

With respect to the standard against which coercion, duress or undue influence should be judged for the purpose of determining the validity of "informed" consent to medical interventions, I suggest that even if this is normally objective, that is the threat must be such as to overcome the will of a reasonable man, one must additionally look to the state of mind induced in the patient, taking full account of his particular susceptibilities to the extent that these increase coercion, to ascertain whether there was coercion to consent to a particular medical intervention.

289. See *supra*, pp. 36-37.

290. "Cheshire & Fifoot", *op. cit.*, note 288, at p. 291.

291. A. Mayrand, *op. cit.*, note 43, at No. 34.

292. G. Boyer Chammard & P. Monzein, *op. cit.*, note 56, at p. 141. See pp. 141-150 for a full discussion of the relevant jurisprudence.

293. *Cour de Cass.* 29 mai 1951, referred to *ibid.*, at p. 141.

294. Note that this reasoning recognizes the distinction between the two consents (see *supra*, pp. 36-37), that is between consent to the contract and the contractual obligation to obtain consent and the Court is speaking of the burden of proof in relation to the latter.

295. For a summary of the Common Law position with respect to defects of consent, discussed in relation to consent to human medical experimentation, see B. Dickens, *supra*, note 62, at p. 395 *et seq.*

Also see A.R. Holder, *op. cit.*, note 54, at p. 276, who says duress vitiates consent and therefore assault and battery actions will lie in such circumstances; and further that duress is a tort in itself and, that if this is committed by any person associated with, or funded by, a federal agency of the United States Government, then one also has, in that jurisdiction, a violation of constitutional rights; W. Prosser, *op. cit.*, note 16, at p. 106, who likewise states that duress invalidates the consent relevant to barring certain tort actions.

296. See *supra*, pp. 29-30 and *infra*, pp. 107-109.

297. B. Gray, *op. cit.*, note 127, at p. 205.

298. See also H.M. Spiro, "Constraint and Consent — On Being a Patient and a Subject", N.E.J.M. 293(22) 1134 (1975), who supports this finding. He says the physician-patient relationship is so strong that consent cannot be considered an act of free will, as the patient tries to please the physician; *Cf.* L.B. Berman, "Ethics of Studies in Anephric Patients", N.E.J.M. 286(15) 842 (1972), who fails to see coercion in the physician-patient relationship, because "informed consent is between people well known to each other and bears no resemblance to the caricature of a remote scientist intimidating a frightened patient".

299. See *infra*, p. 67 *et seq.*

300. F.J. Ingelfinger, *supra*, note 131.

301. See F.J. Ayd, "Motivations and rewards for volunteering to be an experimental subject", Clinical Pharmacology and Therapeutics 13(5)(2) 771 (1972), at p. 777, who gives an example of cancer patients participating in research for such reasons.

302. S.W. Bloom, "The Doctor and His Patient: A Sociological Interpretation", New York; Russell Sage Foundation, 1963, at p. 218 and at p. 231, f.n. 7, referring to W. Caudill, "The Psychiatric Hospital as a Small Society", Cambridge Mass; Harvard Univ. Press, 1958.

303. E. Goffman, "Asylums, essays on the social situation of mental patients and other inmates", Chicago; Aldine, 1961. This and other references to Goffman's writings are given by S.W. Bloom *ibid.*, at f.ns. 10, 11 and 12.

In the area of medical experimentation one should consider as analogous relationships to that between doctor and patient, those between students and teachers, between military personnel, and between laboratory, or hospital, workers and research staff, etc. That is, wherever there is a relationship in which one person is in some position of authority over another, which authority may be transmitted in a request to act as a volunteer subject for experimentation.

304. S.W. Bloom, *ibid.*

305. See R.N. Smith, "Safeguards for Healthy Volunteers in Drug Studies", The Lancet 1975.II.449, who gives details of these practices.

306. This "case" is reported by S.L. Chorover, "Psychosurgery: A Neuropsychological Perspective", (1974) 54 Boston Univ. Law Rev. 231, at p. 241.

307. See C. Fried, *op. cit.*, note 9, at p. 36. Also the "*Willowbrook experiments*", (see "Katz ed.", *op. cit.*, note 3, at pp. 1007-10; G. Edsall, *supra*, note 24, at pp. 283-5; G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at pp. 179-83; and *New York State Association for Retarded Children, Inc. v. Carey* 393 F. Supp. 715 (1975), for a description of these experiments and the Willowbrook institution) could be considered in this light. There agreement of the parents to allow their mentally defective child to participate in a "hepatitis study" was a condition for obtaining a "hard-to-get" place in the institution for the child.

308. M.H. Pappworth, "Human Guinea Pigs Experimentation on Man", London; Routledge and Kegan Paul, 1967, at p. 216.

309. Note that "payment" is not necessarily restricted to money, but can include such compensation as academic credit, better grades, special privileges etc. Where not otherwise impliedly or expressly indicated the comments on payment should be read as applicable in this extended sense.

Also note that payment may be regarded as inducement rather than coercion. It is submitted, however, that undue inducement amounts to, or has the same effect as, coercion, in that both affect the voluntariness of consent. What is undue depends on the circumstances of each case.

310. 28 Eng. Rep. 838, at p. 839 (Ch. 1762).

311. See, for example, S. Shipko, "Human Experimentation: From the Other Side", NEJM 289(17) 924 (1973).

See also Fed. Reg. 14th Jan. 1977, 3076-3091, at Part IV. Reports to the Commission. Chapter 8. Philosophical Perspectives 3086, for a summary of a submission to the United States National Commission by Dr. Wartofsky, in relation to the coercive effects on prisoners of payment for participation in research.

312. C. Fried, *op. cit.*, note 9, Introduction, at p. 166.

313. R. Nerson, *supra*, note 48, at pp. 676-7; R. Savatier, *supra*, note 36; P. Lombard *et al*, *op. cit.*, note 78, at p. 242; J. Caroff, "Problèmes moraux et responsabilité du médecin lors des essais thérapeutiques", Thérapie 1971 xxvi, 1107, at p. 1113; P.-J. Doll, *supra*, note 36.

In fact, under traditional Civil Law doctrine not only contracts of sale, but all contracts of which the human person was the object, were forbidden. This policy underlies Article 1780, *Code Napoléon* and Article 1667 *Civil Code of the Province of Quebec* which only permits a person to hire out his service "for a limited term, or for a determinate undertaking". (Article 1667 *Civil Code of the Province of Quebec*.)

314. P.-J. Doll, "L'aspect moral, religieux et juridique des transplantations d'organes", Gaz. Pal. 1974.2. doctr. 820, 28 Sept. 1974, at p. 821; R. Nerson, *ibid*.

315. It is possible to argue that in Common Law Canada there is case-law support for a view of the law that allows "compensation" or even payment for participation as a subject of medical research, in that the Court in the *Halushka Case* (cited *supra*, note 63) impliedly, by not commenting that the payment made to the volunteer subject in the experiment involved was illegal, supported the validity of it. Certainly payment of experimental volunteers is so public and widespread in both the United States and Canada that it could almost be regarded as formulation of law by "common custom".

Also see Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 24, which allows compensatory remuneration and even "reward" remuneration, provided it is not excessive so as to serve "as an unethical inducement to participate in a research project".

Inter vivos sale of organs or tissue is not prohibited in the United States, or England, nor is "post-mortem" sale in England except that there are legal problems involved due to the fact that, at Common Law, the rule is that there can be no property in a dead body.

See D.W. Louisell, "Transplantation: Existing Legal Constraints" in G.E.W. Wolstenholme and M. O'Connor eds., CIBA Foundation Symposium, "Ethics in Medical Progress: with special reference to transplantation", London; J.A. Churchill Ltd. 1966, (hereafter referred to as "Wolstenholme and O'Connor eds.") p. 78, at p. 87; A.T.H. Smith, "Stealing the Body and its Parts", [1976] Crim. L. Rev. 622.

In the United States the *Uniform Anatomical Gift Act* (cited *supra*, note 283) has an unclear effect with respect to "post-mortem" sale of body parts, (see Notes, The Sale of Human Body Parts", (1974) 72 Michigan Law Rev. 1182,

at p. 1248) and there is some State legislation, in Delaware for example, prohibiting payment.

In Common Law Canada *inter vivos* sale of all tissues and organs except blood is prohibited: see for example *Ontario Human Tissue Gift Act* S.O. 1971 c.83, s.10.

The current legal situation in Australia is the same as in England, but the legislation just proposed by The Law Reform Commission of Australia (cited supra, note 283, at Part VII — Prohibition of Trading in Tissue, section 40) would not only make all sales of tissue void, but imposes a fine of up to $A500 for being involved in such an act. An express exception to this provision allows for "reimbursement of expenses" incurred by the donor.

Note that in the United Kingdom no payment for "foetal material" is allowed beyond meeting the costs incurred ("The Use of Foetuses and Foetal Material for Research", Report of the Advisory Group, London; Her Majesty's Stationery Office, 1972, at p. 9); and in the United States the National Commission, in its report on foetal research, recommended that no monetary or other inducement to terminate pregnancy for the purposes of research be allowed. This was enacted as subordinate legislation in Fed. Reg. 8th Aug. 1975, 33529; 45 C.F.R. § 46.206. Depending on whom one considers to be the experimental subject here, the mother and/or the child, this could be interpreted as a prohibition of payment of an experimental subject in order to eliminate any possibility of coercion.

With respect to payment for participation in medical research it is also, relevant legally to consider whether such participation constituted a sale or a service. See *Perlmutter v. Beth David Hospital* 123 N.E. 2d. 792 (1954).

316. See, for example, B. Dickens in "A Submission to the Medical Research Council: The University of Toronto's Experience with the Review of Research Involving Human Subjects", *supra*, note 220, at p. 41.

317. A. Mayrand, *op. cit.*, note 43, No. 60.

318. *Ibid.*, No. 61.

F. Heleine, "Le dogme de l'intangibilité du corps humain et ses atteintes normalisées dans le droit des obligations du Québec contemporain", (1976) 36 Rev. du Barr. du Qué. (1)2, at pp. 55-63, also expresses doubt as to whether Article 20 forbids payment for experimentation.

319. P.A. Crépeau, *supra*, note 165, at p. 257.

320. See the discussion of "special subjects", especially that relating to prisoners, *infra*, p. 94 *et seq*.

321. E. Cahn, *supra*, note 267.

322. D. Daube, "Transplantation: Acceptability of Procedures and the Required Legal Sanctions", in "Wolstenholme and O'Connor eds.", *op. cit.*, note 315, p. 188, at p. 198.

323. B. Freedman, "A Moral Theory of Informed Consent", The Hastings Center Report 5(4) 32 (1975), at p. 36.

This statement must be read as based on the belief that in any defined community each person has a right to a certain minimum standard of living,

which differs with each community, but that there is also a universal lowest common denominator in this respect, which would give a person a right, for example, against certain conditions of imprisonment.

324. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 65.

325. Fed. Reg. 23 Aug. 1974, 39 F.R. 165, 30655; 45 C.F.R. § 46.404(4).

326. Issued by the Association of the British Pharmaceutical Industry, London, 1970, at p. 2.

327. This same type of "Catch-22" situation is demonstrated with regard to the requirement of written consent which is normally regarded as a safeguard for the patient. See R.W. Smithells, R.W. Beard and a barrister, "New Horizons in Medical Ethics. Research Investigations and the Foetus" B.M.J. 1973.2(864) 464, at p. 465, per R.W. Beard, who comments that written consent may be an unreasonable influence on a patient not to withdraw from an experiment if he later changes his mind.

328. G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 241.

329. See M.H. Pappworth, *op. cit.*, note 308, at p. 82.

Report of the Committee to Investigate on Medical Experiments on Staff Volunteers (United Kingdom), *supra*, note 326, at § 3:2.

330. A ban on psychosurgery could be viewed in this way.

331. See *infra*, pp. 102-103.

332. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 65.

333. Deception is defined for the purpose of human experimentation, by the Canada Council Consultative Group on Ethics (*supra*, note 248, at p. 15) as the intentional misleading of a subject or subjects to believe that the procedures and purposes of a research project are not what they actually are. There is a problem in definition here because of the intentional requirement. Legally one usually sees deception, in a general sense, as encompassing misrepresentation, which may be innocent or negligent, both of which are unintentional, or fraudulent, which requires intention to deceive. It is probably best, in the context of medicine and medical experimentation, to reserve use of the word "deception" to situations where the physician or researcher knew of the misrepresentation or had no belief in the truth of the representation giving rise to the deception, and to deal with unintentional deceptive influences as either innocent or negligent misrepresentation, or within doctrines of coercion or mistake.

334. See, for example, *Bell v. Lever Bros.* [1932] A.C. 161.

It is also worth mentioning that with respect to mistake the remedies are complicated by the fact that the historical division of Common Law and Equity has affected the area, each of these courts having its own rules on the matter. See "Anson", *op. cit.*, note 227, at pp. 315-7.

335. "Anson", *ibid.*, at pp. 287-8.

336. See "Anson", *ibid.*, p. 271. But note that the effect of mistake in Equity may be different from what it is at Common Law. (Anson, *ibid.*, pp. 315-7.)

337. "Anson", *ibid.*, at p. 271 *et seq*.

338. See: Article 992 *Civil Code of the Province of Quebec;* Article 1110 *Code Napoléon*.

339. See: J.-L. Baudouin, *op. cit.*, note 227, at Nos. 99-123.

See also: Office de Révision du Code Civil, Comité du Droit des Obligations, "Rapport sur les obligations", XXX, Montréal, 1975, Articles 29-33 and 52-61 and the doctrine and jurisprudence cited in the commentary attached to these Articles.

340. At Civil Law, if the rule requiring nullity of the medical contract for mistake, was held to be one applied in the public interest, then any interested person, or the Court, *ex proprio motu*, could invoke the declaration of nullity.

See "Rapport sur les obligations", *ibid.*, at Article 54.

Also see Article 1000 *Civil Code of the Province of Quebec* and Article 1117 *Code Napoléon*.

341. See *supra*, pp. 17-21.

342. See, for example, *O'Brien v. Cunard S.S. Co.* (1891) Mass. 272; 28 N.E. 266.

343. See, for example, *Smythe v. Reardon* [1948] Q.S.R. 74; *Papadimotropoulos v. The Queen* (1957) 98 C.L.R. 249; *R. v. Harris* [1944] 2 D.L.R. 61; *R. v. Bolduc and Bird* (1967) 59 W.W.R. 103 (B.C. C.A.).

344. This term is used as defined in note 333, *supra*.

345. E.A. Carr, "Discussion", Clinical Pharmacology and Therapeutics 13(5) 790 (1972), at pp. 791-2.

346. The rate of autopsy in some hospitals is as high as 90 per cent of deaths. See Law Reform Commission (Australia) Working Paper, *supra*, note 283, at p. 74.

347. E.A. Carr, *supra*, note 345.

348. There is here deception of all subjects, but the content of it differs between the terminally and non-terminally ill.

349. See for example: Fed. Reg. 13th March 1975, 40 F.R. 50 11854; 45 C.F.R. § 46.3(c).

350. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 31.

351. L. Lasagna, "Drug Evaluation Problems in Academic and Other Contexts", Annals of the New York Academy of Sciences 169:506 (1970). Reprinted in "Katz ed.", *op. cit.*, note 3, at p. 689; E.D. Pellegrino, *supra*, note 327, at p. 316; R.J. Prineas, "Common Problems in Clinical Trials Medical Journal of Australia 1971.2(8) 425, at p. 430.

352. It is a moot point whether one could have "informed" consent to deception. I suggest the answer is probably not.

353. See: "Notes", Yale Law Journal, *supra*, note 62, at p. 1563, f.n. 91; "Anson", *op. cit.*, mote 227, at pp. 233-242.

As to what conduct amounts to legally operative misrepresentation, normally this requires a positive verbal or non-verbal representation of fact and there is probably no obligation to inform the other party of his mistaken belief when this has not been induced by an act of the party knowing the true circumstances. However, an exception to this general rule is found in confidential or fiduciary relationships, when there is a positive duty to disclose.

Also B. Dickens (*supra*, note 316, at p. 36) says deception includes stating half-truths and that the line between allowable non-information and misinformation is fine. That is one could argue, as in other areas, that even though there may be no initial obligation to disclose, if one commences to do so it must be done fully.

354. See: H. et L. Mazeaud et J. Mazeaud "Leçons de Droit Civil" 5ième éd. Paris; par M. de Juglart; Ed. Montchrestien, 1972, Tomes I and II, at Tome II "L'erreur, nos. 161-186, "Le dol", nos. 187-198 and "Les effets de la responsabilité civile", at No. 602 *et seq*.

Code Napoléon Articles 1382-3 (delict); 1142, 1144 (contract); 1116 (fraud); 1117 (error); 1159, 1150, 1151 (damages for inexecution of an obligation).

Civil Code of the Province of Quebec Articles 1053 (delict); 1065 (contract); 993 (fraud); 1000 (error); 1073, 1074, 1075 (damages for inexecution of an obligation).

"Anson", *ibid*., pp. 226-258.

J.G. Fleming op. cit., note 23, at pp. 164-169, pp. 616-634 who says (at p. 167) that negligent words giving rise to *physical* (as compared with economic) injury, have long been recognized as a source of liability at Common Law and, further, that a failure to warn (see duty to inform of risks *supra*, p. 12 *et seq*.) may be a negligent misrepresentation.

355. For a case where a deceit action was taken against a doctor see *Hedin v. Minneapolis Medical & Surgical Institute* 62 Minn. 146, 64 N.W. 158 (1895).

For a discussion of deceit by medical practitioners see A.R. Holder, *op. cit*., note 54, at p. 345.

Also see The Canada Council, "Report of the Consultative Group on Ethics", *supra*, note 248, at p. 15, which states that deception may amount to the criminal offence of false pretences if it is done for gain at the subject's expense.

356. See The Canada Council, "Report", *ibid*.

Seeing deception as ethically objectionable because it infringes human dignity, relates to the value of autonomy, and possibly to that of inviolability, if waiver of the latter depends on *informed* consent and this is not considered present even if one consents to be deceived. It does seem, however, that one can validly waive the right to inviolability without "informed" consent in the full sense, as one can choose not to be informed in a therapeutic situation, and also the "therapeutic privilege" of the doctor operates outside "informed" consent without transgressing the right of inviolability, although this privilege may alternatively be regarded in the light of justifying the transgression of inviolability that does occur.

357. M. Mead, "Research with Human Beings: A Model Derived from Anthropological Field Practice", in "Freund ed.", *op. cit.*, note 6, p. 152, at pp. 166-8.

358. See also S. Bok, "The Ethics of Giving Placebos", Scientific American 231 (15) 17 (1954), at p. 19, who argues that doctors who deceive for therapeutic reasons become progressively more used to employing deception and therefore extend its use.

359. *Supra*, note 248, at p. 16.

See also Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at pp. 23-24, where it is stated that the use of deception requires, 'inter alia', "scientific justification of the highest order", that the risk of the research must be "negligible", and that the subject must be debriefed.

360. Is a consent to being deceived the same as consent to information being withheld? Even if these represent the same reality, the language of the former would put the subject more on notice of that to which he was consenting.

361. E.D. Pellegrino, *supra*, note 327, at p. 316.

362. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 70.

Note the Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 24, does not require such information to be destroyed, but that the deceived subject's wishes regarding the use of the data be respected and if he declines it must not be used.

363. C. Fried, *op. cit.*, note 9, at p. 102.

364. Office of Science & Technology "Privacy and Behavioural Research", Washington D.C.; U.S. Government Printing Office, 1967. Reprinted in part in "Katz ed.", *op. cit.*, note 3, at p. 729.

365. T. Parsons, *supra*, note 203, at p. 140.

366. See G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 35.

367. O.M. Ruebhausen and O.G. Brim, "Privacy and Behavioural Research", (1965) 65 Columbia Law Rev. 1184, at p. 1197.

368. See *supra*, pp. 20-21.

369. O.M. Reubhausen and O.G. Brim, *supra*, note 367, at p. 1186.

See also M. Ouellette-Lauzon, "Chroniques Régulières. Le droit à l'image", (1974) 34 Rev. du Barreau (Québec) 1.69, who says: "La doctrine a reconn[u] que tout individu a le droit, entre autres, à son honneur, à son image, à sa "sphère d'intimité" (right to privacy)".

370. *Supra*, note 248, at p. 23.

371. This may be described as the conflict of privacy and progress. See the statement of the United States Office of Science & Technology, "Privacy and Behavioural Research", *supra*, note 364.

372. See L. Dérobert, "Droit Médical et Déontologie Médicale", Paris; Flammarion Médecine-Sciences, 1974, at pp. 249-58; G. Boyer Chammard and P. Monzein, *op. cit.*, note 56, at pp. 216-30.

373. I. Berlin, *op. cit.*, note 184, at p. 129.

374. *Pavesich v. New England Life Insurance Co.* 122 G.A. 190, 193-198; 50 S.E. 68, 69-71 (1905), per Cobb J..

375. See P. Lombard *et al*, *op. cit.*, note 78, at pp. 171-216, who trace the history and jurisprudential development of the obligation of medical secrecy in French Law and who say the "ancien droit" did not recognize such an obligation, but that it developed with 19th century individualism and, further, that now, with socialized and collective medicine, it is retracting.

376. "Universal Declaration of Human Rights" Adopted and proclaimed by the General Assembly of the United Nations 10th Dec., 1948, O.R. Third Session Gen. Assl, Doc. A/810, Article 12.

377. "Declaration of Geneva. Medical Vow", Adopted by the General Assembly of the World Medical Association at Geneva, Switzerland, September, 1948. Amended by the 22nd World Medical Assembly, Sydney, Australia, August 1968. Reprinted in "Katz ed.", *op. cit.*, note 3, at p. 312.

378. *Privacy Act* S.B.C. 1968, c. 39, as amended by S.B.C. 1975, c. 37.

379. *Privacy Act* S.M. 1970, c. 74, as amended by S.M. 1971, c. 23.

380. 1977, 25-26 Eliz. II, c. 33, section 2(b) and Part IV.

381. *Ibid.*, section 2(b).

382. *Ibid.*, Part IV.

383. *Ibid.*, section 50.

384. *La Charte des Droits et libertés de la Personne* L.Q. 1975, c. 50, Article 1.

385. *Ibid.*, Article 5.

386. *Ibid.*, Article 49.

387. *Ibid.*

388. Second edition (2nd Reprint), June 1976. Ratified by Decree No. 3391, Oct. 6, 1971.

389. *Ibid.*, at section 52, Article 20.

390. See for example: *Griswold v. Connecticut* 381 U.S. 479 (1965); *Roe v. Wade* 410 U.S. 113 (1973), at p. 154; *Stanley v. Georgia* 394 U.S. 557 (1968); *Eisenstadt v. Baird* 405 U.S. 438 (1972); Cf. *Doe v. Cwths. Attorney* 90 S.Ct. 1439 (1976); H.P. Green and A.M. Capron, *supra*, note 271, at p. 71, say there are two groups of rights associated with the constitutional right to privacy, as developed by the United States Supreme Court. These are: rights relating to marriage and procreation; and rights of control over one's own body. Both categories are relevant to medical treatment and research considerations.

391. "American Medical Association. Ethical Guidelines for Clinical Investigation". Published by the American Medical Association, 535 North Dearborn St., Chicago, Illinois 60610.

392. British Medical Association (B.M.A.), "Medical Ethics" London, 1974, at p. 13.

393. Statement by the Medical Research Council, *supra*, note 251.

394. See, for example: A.R. Holder, *op. cit.*, note 54, at p. 265; H.P. Green and A.M. Capron, *supra*, note 271, at p. 63.

395. See: *Saltman Engineering Co. Ltd. v. Campbell Engineering Co. Ltd.* [1963] 3 All E.R. 413 n.; *Seager v. Copydex Ltd.* [1967] 1 W.L.R. 923; *Seager v. Copydex* (No 2) [1969] 1 W.L.R. 809; *Argyll v. Argyll* [1965] 1 All E.R. 611, where the jurisdiction to award an injunction preventing a breach of confidence was founded on a general "policy of the law" (at p. 625); "Winfield and Jolowicz", *op cit.*, note 166, at pp. 493-4; A.R. Holder, *ibid.*, p. 271.

Breach of confidence may give rise to an action for breach of fiduciary duty, as well as an action within the area of intentional torts as suggested by Holder.

See also W. Prosser, *op. cit.*, note 16, at pp. 812-814, who speaks of a tort of placing a person in a "false light in the public eye", which need not necessarily be defamatory. Where there is some inaccuracy in a disclosure, which is also a breach of confidence, this tort could be considered as well.

396. H.P. Green and A.M. Capron, *supra*, note 271, at p. 63.

397. See J.G. Flemimg, *op. cit.*, note 23, at pp. 122-133; H.P. Green and A.M. Capron, *supra*, note 271, at p. 62; N. Hershey and R.D. Miller, *op cit.*, note 63, at p. 147.

398. *Michigan Stats. Ann.* Section 14-533.

See also *The Professional Standards Review Organization Act* 42 U.S.C. § 1320c-c-19 (Supp. II, 1970) at § 1320c-15a, which legislates a duty of confidence for doctors treating patients pursuant to the provisions of this Act and which carries a penalty for breach of this duty of six months imprisonment, or a $(US)1,000 fine.

399. Article 7 *Code de Déontologie médicale* (France), *supra*, note 72.

400. Article 378 *Code pénal* (France).

401. Most of the categories which I describe here as exceptions J.R. Waltz, *supra*, note 93, at p. 151, lists as defences to an action against a doctor for invasion of privacy.

402. G. Levasseur, "La responsabilité pénale du médecin", in "Eck ed.", *op. cit.*, note 246, p. 133, at p. 146, says there is a conflict in French Law whether a doctor must testify as to medical secrets. Levasseur is of the opinion that the doctor is justified in not doing so.

403. A.R. Cross, "Evidence", 4th ed. London: Butterworths, 1974, at p. 258, makes reference to both the English and American Law on medical privilege; H.P. Green and A.M. Capron, *supra*, note 271, at p. 62, citing *AB v. CD* Sess. Cas. (Dunlop) 2d. Ser. 177 (1851) say English and United States Common Law gave little protection of the medical secret; A.R. Holder, *op. cit.*, note 54, at p. 271; R.J. Levine, "Guidelines for Negotiating Informed Consent with Prospective Subjects of Experimentation", Clinical Research 22:42 (1974), at p. 45, says the State of Connecticut does not recognize medical privilege except if a psychiatrist is involved and even then the privilege is limited.

404. See J.R. Waltz, *supra*, note 93, at p. 150; H.P. Green and A.M. Capron, *ibid.*; *Cf.* L. Dérobert, *op. cit.*, note 372, at p. 260, who says that the professional secret is "d'ordre public".

405. See O.M. Ruebhausen and O.G. Brim, *supra*, note 367, at p. 1209.

For legislation of this privilege in relation to specific medical research situations, for example research on drug or alcohol abuse, see N. Hershey and R.D. Miller, *op. cit.*, note 63, at pp. 113-122.

406. L. Portes, *op. cit.*, note 235, at pp. 161-3.

407. See British Medical Association, "Medical Ethics" *supra*, note 392, at pp. 17-18.

408. See *supra*, p. 13 and note 62, for a discussion of "therapeutic privilege" and *supra*, p. 26 *et seq.*, for comments on the duty to give a patient access to his medical records or disclose results to him.

409. B.L. Kaiser, "Patients' Rights of Access to their Own Medical Records: The Need for New Law", (1975) 24 Buffalo Law Rev. 2:317.

410. See British Medical Association, "Medical Ethics", *supra*, note 392, at p. 13, which states this duty generally in the following terms: "rarely, the public interest may persuade the doctor that his duty to the community may override his duty to maintain his patient's confidence".

Also see American Medical Association, "Opinions and Reports of the Judicial Council", Illinois; 1972, at Section 9, p. 43, which states the doctor may reveal confidence entrusted to him in the course of medical attendance if the welfare of the individual, or the *community*, requires it.

H.A. Davidson, "Legal and Ethical Aspects of Psychiatric Research", Am. J. Psych. 126(2) 237 (1969), at p. 239 describes the latter part of the exception regarding the community, as a loophole in confidentiality.

The Canada Council, Report of the Consultative Group on Ethics, *supra*, note 248, at p. 29, also recognizes that in exceptional circumstances there may be reasons of public safety overriding a duty of confidentiality.

L. Dérobert, *op. cit.*, note 372, at p. 262, says there may be certain derogations from medical secrecy to preserve society.

411. See R. Macklin, "Ethics, Sex Research, and Sex Therapy", The Hastings Center Report 6(2) 5 (1976); G.J. Annas, "Problems of Informed Consent and Confidentiality in Genetic Counseling", in "Milunsky and Annas eds.", *op. cit.*, note 62, p. 111, at p. 119, says there are some legal precedents in the United States that a doctor has a duty to warn others, even if this is a breach of confidentiality.

412. See the discussion on Huntington's Chorea, *supra*, p. 26 and note 152; *Cf.* J.R. Waltz, *supra*, note 93, at p. 150, who says there may be stigmatization of the individual by breach of privacy in genetic screening so that one is in a situation where to disclose will harm the individual, additionally to the harm comprised *per se* in the breach of his right of privacy, and not to disclose, will harm others; Mahoney, "Discussion" (*inter alia* of Waltz' paper, *ibid.*, in "Milunsky and Annas eds.", *supra*, note 62, at p. 192) suggests one way to overcome this difficulty may be to develop a legal notion of the family as a unit of confidentiality for genetic information rather than the individual.

413. Statement by the Medical Research Council (United Kingdom), *supra*, note 251.

414. See for example: *Loi 15 fév 1902* (France), cited by L. Kornprobst, "Du secret professionnel médical", in "Eck ed.", *op. cit.*, note 246, p. 39, at p. 48, and by L. Kornprobst and S. Delphin, *op. cit.*, note 62, at No. 367; *Décret 29 janv. 1960*, as modified by *décrets 20 mai 1964* and *27 nov. 1968* (France).

Articles 259 and 662 *Code de la santé publique* (France).

415. *Washington Research Project Inc. v. D.H.E.W.* 504 F. 2d. 238, *cert. denied* 421 U.S. 963 (1975).

In general, medical files are exempted from the operation of the provisions of the *Freedom of Information Act* 5 U.S.C. § 552, on the basis of personal privacy.

416. *Ibid.*

417. See for example: Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at pp. 26-27; Statement by the Medical Research Council (United Kingdom), *supra*, note 251; Canada Council, Report of the Consultative Group on Ethics, *supra*, note 248, at p. 28.

Query the effect of the D.H.E.W. Regulations in this respect 45 C.F.R. § 46.119(b): "except as otherwise provided by law, information in the records or possession of the institution acquired in connection with [research] . . . which information refers to or can be identified with a particular subject, may not be disclosed except: (1) with the consent of the subject or his legally authorized representative; or (2) as may be necessary for the Secretary to carry out his responsibilities under this part". It is not clear what "refers to" means, whether it just means is referable to a subject in a general sense, or that it "refers to", in the sense of names, the subject. In view of the inclusion of the alternative provision regarding identification, which would otherwise be superfluous, and the use of the word "particular" to qualify "subject", I suggest the latter, more limited interpretation is the correct one, and therefore some epidemiological research could be conducted without consent.

Cf. the interpretation of the D.H.E.W. Regulations by N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 36. They believe a physician must even ask a patient's consent to giving the patient's name to a researcher as a possible subject, that is the patient must consent to being approached, and that the same rules apply to any use of the patient's records.

Cf. O.M. Reubhausen and O.G. Brim, *supra*, note 367, at pp. 1196-7, who argue that consent and anonymity are not alternative, but cumulative, requirements, that is that one needs consent to have access to the information and anonymity in using it.

418. Note that there is legislation relevant to some presentations at scientific meetings in Quebec, see *An Act to Amend the Public Health Protection Act* Bill No. 88 assented to 27th June 1975, Third Session, Thirtieth Legislature, National Assembly of Quebec, section 10, adding Article 37a *Public Health Protection Act* which provides that: "No person may present or allow the presentation, for *other than educational or scientific purposes*, of a show or exhibition in which the feeblemindedness or mental illness of a human being

who personally appears in the show or exhibition is put on display or exploited, or act as organiser of such a show or exhibition''. (Emphasis added)

419. See American Medical Association, ''Opinions and Reports of the Judicial Council'', *supra*, note 410, at section 9, p. 52; L. Kornprobst and S. Delphin, *op. cit.*, note 62, at No. 395.

Also see *Rebeiro v. Shawinigan Chemicals (1969) Ltd.* [1973] C.S. 389 (Quebec), where it was held that a photograph taken of the claimant could not be used by the defendant without the claimant's consent in general terms, if it could embarrass the claimant.

420. I refer here more to publication by writing, as if the publication involves a presentation which requires active participation by the patient, as at a scientific meeting, consent will be expressed or implied, provided the patient has the required capacity to consent.

421. L. Kornprobst, *supra;* note 414, at p. 99, says that in France this exception is based on ''usage'', which still does not inform one whether or not the foundation of the custom is implied consent.

It appears that in the United States the patient's consent to publication or discussion of his case must be obtained, even if anonymity is preserved. See A.R. Holder, *op. cit.*, note 54, at pp. 272-6, and *Bachrach v. Farbenfabriken* 344 N.Y.S. 2d. 286 (N.Y. 1973)

422. See: A Report of a Task Force established jointly by the Department of Communications and the Department of Justice, ''Privacy and Computors'', Ottawa; Information Canada, 1972; Medical Reearch Council of Canada, ''Ethics in Human Experimentation'', *supra*, note 69(a), at pp. 26-27.

423. See J.K. Wing, *supra*, note 265, who refers to a document of the Royal College of Psychiatrists (England), on confidentiality of information collected by information systems

''Editorial'' Med. J. Aust. 1973.2.1022, reporting on the 27th World Medical Association Assembly, Munich, which was held to discuss problems of confidentiality associated with computors in medicine

World Health Organization, ''L'élément santé dans la protection des droits de l'homme'', Chronique O.M.S. 30:391 (1976), at p. 400, reporting on 27th W.M.A. Assembly, as above.

424. See J.A. Baldwin *et al*, *supra*, note 251, at p. 419.

425. *Ibid.*, at p. 421.

426. C. Levine, ''Sharing Secrets: Health Records and Health Hazards'', The Hastings Center Report 7(6) 13 (1977), at p. 15.

427. D.J. Whalan, ''Protection of Privacy has become Pressing'', The Australian Financial Review June 24th 1969, at p. 36. Referred to by H.H. Dickenson, ''Medical Ethics and the Law. The Position of the Medical Administrator'', Med. J. Aust. 1970 1(16) 794.

428. Cited *supra*, note 380.

429. *Ibid.*, section 2(b).

430. *Loi sur les services de santé et les services sociaux*, cited *supra*, note 281, section 7.

431. *Ibid.*

432. P. Lombard *et al*, *op. cit.*, note 78, at p. 192.

433. G. Boyer Chammard and P. Monzein *op. cit.*, note 56, at p. 133.

434. L. Kornprobst and S. Delphin, *op. cit.*, note 62, at No. 372.

435. See *Barber v. Time Inc.* 348 Mo 1199; 159 S.W. 2d 291 (1942).

436. J.A. Baldwin *et al*, *supra*, note 251, at p. 418.

437. See for example: *Professional Standards Review Organisation Act*, cited *supra*, note 398.

See also the formerly proposed and now lapsed Australian legislation, *National Compensation Bill 1974*, which is analyzed section by section by H. Luntz, "Compensation & Rehabilitation", Melbourne; Butterworths, 1975. This would have enacted (at section 103) a statutory duty of confidentiality, of what would be primarily medical information, binding on all "officers", a much broader group than just medical practitioners.

438. See "Report and Recommendations Psychosurgery. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research", D.H.E.W. Publication No. (OS) 77-0001, U.S. Gov't. Printing Office, Washington, D.C., 1977, at pp. 57, 59-60; *Aden v. Younger* 129 Cal. Rptr. 535 (Ct. App. 4th Dist. Div. 1, 1976).

439. See G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 231, who report that a "Task Force" on psychosurgery, appointed by the Massachusetts Commissioner of Mental Health, split on the issue of whether consent of the proposed patient for psychosurgery should be reviewed by interviewing the patient before a multidisciplinary committee. *All physicians* on the "Task Force" vigorously objected to such review; *Aden v. Younger ibid*. And also as discussed in Annas, Glantz and Katz, at pp. 226-8.

440. G.B. Forbes, "Marginal Comments: Ethics and Editors", American Journal of Diseases of Children 127(4) 471 (1974), at p. 472.

441. This would overcome the undesirable situation with respect to confidentiality, exposed by J.P. Tupin, "Ethical Considerations and Behaviour Control", Tex. Rep. Biol. & Med. 32(1) 249 (1974) at p. 255, where a prison psychiatrist had all his confidential records confiscated and a court held that they belonged to the institution. In such circumstances a prisoner will be less likely and willing to disclose information which could be significant to his medical or psychological treatment.

442. See J.A. Baldwin *et al*, *supra*, note 251, at pp. 421-25.

443. See O.M. Ruebhausen and O.G. Brim, *supra*, note 367, at p. 1206, who say in default of such consents the data must be destroyed.

Cf. the suggestion made with regard to deception, *supra*, p. 56, of giving a copy of the information to the patient but otherwise destroying it, if the patient does not subsequently consent to its retention and use. This could also be done where deception is not involved, but the patient has not consented to the use

or retention of information prior to its being collected and subsequently refuses consent.

444. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 36.

445. See for example *Iowa Code Ann.* § 204.504 (Supp 1975); *Cal. Health & Safety Code* (1975) § 11603; *Cal. Welf & Inst Code* § 5328 (Supp 1975); *Pa. Stat. Ann Tit.* 71, 1690.104 (Supp 1975); *Illinois Ann. Stat.* Ch. 51 (1966) § 101, § 104.

446. T. Parsons, *supra*, note 203, at p. 140, suggests this in very convulated and complicated language, such that it is extremely difficult to determine exactly what he means by his statement, which appears to be to this effect.

See also United States National Commission, "Disclosure of Research Information under the Freedom of Information Act", *supra*, note 160, at p. 7-9.

447. See O.G. Ruebhausen and O.M. Brim, *supra*, note 367, at p. 1186; J.W. Symington and T.R. Kramer, "Does Peer Review Work?", American Scientist 65(1) 17 (1977), at p. 19.

448. J.S. Baldwin *et al*, *supra*, note 251, at p. 418.

449. The term "incompetent" is used in a very general sense here and is intended to include any person who needs special protection of the law in relation to consent to a medical contract or medical care, because of factual or legal disability or incapacity.

450. See for example: Article 1124 *Code Napoléon* (France); Articles 290, 985, 986, 1029 *Civil Code of the Province of Quebec; "Anson", op. cit.*, note 227, at pp. 196-225; "Cheshire & Fifoot", *op. cit.*, note 288, at pp. 401-430.

451. See *supra*, pp. 35-37.

452. See *supra*, pp. 30-31.

453. See *supra*, pp. 48-49.

454. See for example *Karp v. Vooley and Liotta*, cited *supra*, note 97, where an artificial heart was transplanted into the patient.

455. This effect may arise from decreased intellectual facilities due to illness, or drugs used for pain relief or treatment, or from the effect the knowledge that they are dying may have on some persons. A.M. Capron, *supra*, note 8, at p. 387, says that dying patients may become "pliant experimental subjects" from a fear of abandonment by the doctor if they refuse consent, which fear is particularly acute in the dying.

456. Public Health Council of the Netherlands Report on Human Experimentation, at § 6h. Summary published in 4 World Medical Journal 299 (1957); or W.J. Curran and E.O. Shapiro, *op. cit.*, note 68, at p. 889; and in "Codification and Principles", "Ladimer and Newman eds.", *op. cit.*, note 10, p. 154.

457. M.D. Eilenberg *et al*, *supra*, note 255.

458. W.J. Carran, *supra*, note 63, at pp. 427-8.

Other authors advocating that the dying should not be used as subjects of medical research include: E. Tesson, "Moral Reflection", in "Flood ed.", *op. cit.*, note 73, at p. 109; M.H. Pappworth, *op. cit.*, note 308, at p. 78; H.K. Beecher, "Experimentation in Man", in "Ladimer and Newman eds.", *op. cit.*, note 10, p. 2, at p. 8.

459. H.K. Beecher, *ibid.*, at p. 17.

460. See, for example, A. Mayrand, *op. cit.*, note 43, at No. 111.

461. The United States: *Uniform Anatomical Gift Act,* cited *supra*, note 283.

Common Law Canada: *Pro forma Human Tissue Gift Act*, cited *supra*, note 283.

Quebec: Articles 21 and 22 *Civil Code of the Province of Quebec*, provide a "contracting-in" and modified "contracting-out" system.

England: *Human Tissue Act*, cited *supra*, note 283, a "contracting-in" system.

462. France: *Caillavet Law*, *supra*, note 35.

Australia: Law Reform Commission (Australia) Report, *supra*, note 283, *Draft Bill* section 25, which provides for both "contracting-in" and "contracting-out", but the basic presumption chosen is the latter.

See also "Report of the Special Committee on Organ Transplantation", BMJ 1970, 1, 750.

463. *The Human Tissue Gift Act*, S.O. 1971, c. 83, section 4(1) (Ontario).

464. See, for example: "Bar Council Report on Organ Transplants", BMJ 1971.3.716; Editorial, "Determination of Death", The Lancet 1970, I, 1092.

None of the "organ transplant legislation" referred to in notes 461-3 above, legislates a definition of death. However, the Law Reform Commission of Australia has proposed a definition in its Draft Legislation, "*Transplantation and Anatomy Ordinance 1977*", Part III, Donations of Tissue after Death, cited *supra*, note 283, at section 42: "A person has died when there has occurred:

(*a*) irreversible cessation of all function of the brain of the person; or
(*b*) irreversible cessation of circulation of the blood in the body of the person."

Some States in the United States have definitions of death. These include Kansas: *Kan. Stat. Ann.* § 77-202 (Supp. 1973); Maryland: *Md. Ann. Code* at 43 § 54 F (Supp. 1973); Connecticut: *Conn. Gen. Stat. Ann.* § 19-139 (Supp. 1973).

Also see "Notes 'Sale of Human Body Parts'", Michigan Law Rev., *supra*, note 274; J.F. Leavell, "Legal Problems in Organ Transplants", (1973) 44 Mississippi Law J. 5.865, at p. 880.

See in particular: H.L. Hirsh, "Brain Death — Medico Legal Status", Southern Med. J. 69(3)286 (1976), which includes a most comprehensive list of references on this topic, available on request from this author.

For discussion of the legislation currently applicable in France, with respect to determining death, which legislation is not really a definition of death, but rather lists a series of tests on the results of which a doctor may conclude death has occurred, see: "Critères de la mort et greffes d'organes", Cahiers Laennec No. 3, Sept. 1970; R. Nerson, *supra*, note 48, at p. 668; J. Malherbe, "Médecine et Droit Moderne", Paris; Masson, 1969, at p. 41 *et seq.*; R. Savatier, "Les Problèmes Juridiques des Transplantations d'organes humains", J.C.P. 1969. 1.2247; J. Savatier, "Et in hora mortis nostra: Le problème des greffes d'organes prélevés sur un cadavre". D.1968.89; P.-J. Doll, *supra*, note 36.

These French laws are *Décrets* 3 Déc 1941, 20 Oct 1947, 27 Jan 1955; *Loi* 7 Juillet 1949; *Circular* No. 67, 24 Avril 1968; *Bull.* 21 Fév. 1968.

See also: "Declaration of Sydney. Statement on Death". Adopted by the 22nd World Medical Assembly, Sydney, Australia, August, 1968.

465. See M. Houts and J. Hunt, 1 Death § 1.03 (1970). Quoted by J.F. Leavell, *ibid.*, at pp. 887-8, f.n. 94.

466. Note that requiring different safeguards for different purposes is not the same as defining death differently for different purposes. The Law Reform Commission of Australia in its "Report", *supra*, note 283, at p. 59, No. 127, expressly rejected defining death for only one purpose, in this case transplantation.

467. For a relevant statement of this general legal principle see Statement by the Medical Research Council (United Kingdom), *supra*, note 66.

See also G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at pp. 68-70, who cite *Lacey v. Laird* 166 Ohio St. 12, 139 N.E. 2d. 25, 30 (1956), to the effect that any rule that a minor cannot consent to medical treatment is not based upon determination of his factual capacity to consent, but upon the right of parents whose liability for support and maintenance of their child may be greatly increased by an unfavourable result from medical procedures. Thus a parent has at least some right to withhold consent and, as a corollary, some right to consent. It is worth stating the right in this way, as it shows it is not an unlimited right to consent, or to withhold consent, and the question then becomes what are the limits?

468. See: Lord Kilbrandon, "Chairman's Closing Remarks", in "Wolstenholme and O'Connor eds.", *op cit.*, note 315, p. 212; D. Louisell, *supra*, note 315, at pp. 84-5; A.R. Holder, *op. cit.*, note 54, at p. 17; L. Kornprobst, *supra*, note 246.

Also see "La Charte du Malade hospitalisé" (France), *Décret 14 janv. 1974*. Extracts published in *La Nouvelle Presse Médicale*, 3(5) 265 (1974) at p. 266. Published in full in "La responsabilité civile des médecins", *op. cit.*, note 140, at p. 127, which provides that where a parent refuses consent "le ministère public" can be approached for the authorization; *Child Welfare Act* R.S.O. 1970 c. 64 section 20 (Ontario) under which the State can authorise treatment necessary for the health or well-being of a child; *Medical (Blood Transfusion) Act* 1960 Victoria (Australia), which allows a Court to override a parent's refusal of an operation on a child.

468a. For 'pro forma' legislation of this type recommended for adoption by all Canadian provinces, see Proceedings of the Fifty-seventh Annual Meeting of

the Uniformity Law Conference of Canada, August 1975, *Medical Consent of Minors Act* Appendix N.

469. *Loi de la protection de la santé publique*, L.Q. 1972, c.42, at Article 36.

470. For example in the State of N.S.W. *Minors (Property & Contracts) Act*. Act No. 60, 1970 N.S.W. section 49.

471. *Public Hospitals Act* R.S.O. 1970 c.378 as amended, Ontario Rev. Reg. 729, Ontario Reg. 100/77 §§ 49, 49a.

472. *Infants Act* R.S.B.C. 1960 c.193 as amended by *Act to Amend the Infants Act* S.B.C. 1973 (1st Sess.) c. 43, section 23.

473. *Family Law Reform Act* 1969 17 & 18 Eliz. II c. 46, section 8.

474. For a comprehensive chart setting out the nature and extent of this legislation, in each of the States of the United States, see H.F. Pilpel, "Minor's Rights to Medical Care", (1972) 36 Albany Law Rev. 462.

475. See, for example, the Regulations made under the *Public Hospitals Act* (Ontario), cited *supra*, note 153.

476. Cited *supra*, note 473, at section 8(3).

477. Article 36, *Public Health Protection Act*, cited *supra*, note 469.

Note that the Quebec statute includes an exception allowing for authorization of treatment by a judge of the Superior Court, when consent of the person exercising paternal authority cannot be obtained, or is refused and this is contrary to the child's best interests.

Also note that in view of the recent change from paternal to parental authority in the Civil Code. (see *An Act to Amend the Civil Code*) Bill 65, assented to 17 November 1977, 31st Legislature 2nd Sess., Assemblée Nationale du Québec, and in particular Article 9 of this Act, paternal authority is to be interpreted in the more general sense of parental authority in all statutes and subordinate legislation.

478. R. Dierkens, "Les droits sur le corps et le cadavre de l'homme", Paris; Masson, 1966, at No. 5, p. 43.

Also see L. Kornprobst, *op. cit.*, note 12, at p. 240, and f.n. 7.; *Cf.* H. Anrys, "La Responsabilité Civile Médicale", Bruxelles, Maison Ferdinand Larcier, 1974, at No. 56, p. 84, who argues parental consent is always necessary.

Note that in French Law, pursuant to Article 1124 *Code Napoléon*, minors have no capacity to contract, which, if one accepts that they can consent to medical treatment as some of the jurists quoted suggest, further supports the notion of the dual consent (see *supra*, pp. 35-37) and that the capacity needed for each consent is not the same.

CF. Article 986 *Civil Code of the Province of Quebec*, where minors are not subject to a general incapacity but are only legally incapable of contracting "in the cases and according to the provisions contained in th[e] code". Thus, arguably, in Quebec a minor could both enter a medical contract and because of the statutory provision (*supra*, note 477), provided he was at least fourteen years old, he could also consent to medical treatment.

Also see P. Chassagne, "Risques médicamenteux et responsabilité médicale", in "Eck ed.", *op. cit.*, note 246, at p. 349; P. Lombard *et al*, *op. cit.*, note 78, at p. 162.

479. P.A. Crépeau, *supra*, note 165, at p. 252.

480. Article 36 *Public Health Protection Act*, cited *supra*, note 469.

481. *Cf.* J.-L. Baudouin, *op. cit.*, note 339, at No. 109, who argues the legislative scheme governing minors under Quebec law is a protection taking "la forme d'une incapacité d'exercice quasi générale".

Cf. Dixon v. U.S. 197 F. Supp. 803 (W.D.S.C. 1961), where the Court said that the disability of a minor is a privilege to be exercised for his benefit the object being to protect him from damaging himself or being imposed on by others.

482. P.-A. Crépeau, *supra*, note 165, at p. 252.

483. In fact the statement by P.-A. Crépeau is more definitive than Article 36, which does not expressly require that the minor be capable of discernment, although the necessity for this is implied in requiring that the minor must "consent".

484. Co. Littleton 172a.

485. (1610) 1 Bulst. 39.

486. This is commonly referred to as the "mature minor rule". See: H.L. Nathan, "Medical Negligence; being the law of negligence in relation to the medical profession and hospitals", with the collaboration of A.R. Barrowclough, London; Butterworths, 1957, at pp. 171-179; *Johnston v. Wellesley Hospital* (Ont. H.C.), cited *supra*, note 62, at pp. 144-5, where the Court states that: "The Common Law does not fix any age below which minors are automatically incapable of consenting to medical procedures. It all depends on whether the minor can understand what is involved in the procedure in question".; G.S. Sharpe, "The Minor Transplant Donor", (1975) 7 Ottawa Law Rev. 85, at p. 86; W.F. Bowker, *supra*, note 78, at p. 172; P.D.G. Skegg, "Consent to Medical Procedures on Minors", (1973) 36 Mod. Law Rev. 370, at p. 375; G.E. Railt, "The Minors Right to Consent to Medical Treatment. A Corollary of the Constitutional Right of Privacy", (1975) 48 S. Calif. Law Rev. 6:1389, argues on quite a different basis that, in the United States, a child has a right to consent to medical treatment arising from its constitutional right to privacy, as established for all citizens in *Roe v. Wade*, cited *supra*, note 390. Presumably a right to privacy increases in scope with increasing maturity and hence at a younger age one may more readily interfere with, or override it.

See also American Law Institute, "Restatement of the Law", Torts 2d, 1965, § 59, which allows a child capable of understanding the serious character of an operation for his benefit to consent to it.

For application of the "mature minor rule" by American Courts see: *Bach v. Long Island Hospital* 49 Misc. 2d 207 (N.Y. Sup. Ct. 1966); *Gulf & S.I.R. Co. v. Sullivan* 119 So. 502 (Sup. Ct. Miss. 1928); *Lacey v. Laird* cited *supra*, note 467.

487. W. Wadlington, "Minors and Health Care: The Age of Consent", (1973) 11 Osgoode Hall Law J. 1.115, at p. 124.

488. However as the situation involved is, by definition, one of necessity, the doctor operating on such a minor would be protected from legal action by either a defence of necessity, or implied consent of the patient, or parent, to the operation. See P.D.G. Skegg, *supra*, note 17, at p. 512, who says that "there is widespread agreement that in English law a doctor will sometimes be justified, for the purpose of the crime and tort of battery, in performing medical procedures without consent. Judges have made extra-judicial statements to this effect, and doctors are constantly acting in the belief that this is so. However there is not a single reported English decision which has so much as discussed the existence or limits of such a justification".

489. At note 486, *supra*.

490. G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 64 *et seq*.

491. W. Blackstone, "Commentaries on the Laws of England", Oxford; 1776-79, 4 vols., at Book I, 463.

See generally "Of Parent and Child", 446 *et seq*., "Of Guardian and Ward", 460 *et seq*.

492. See for example *Porter v. Toledo Terminal Railway Co.* 152 Ohio St. 463, 90 N.E. 2d 142 (1950); *Centrello v. Basky* 164 Ohio St. 41, 128 N.E. 2d 80 (1955); *Heisler v. Moke* [1972] 2 O.R. 466; *Gough v. Thorne* [1966] 3 All E.R. 398; *McHale v. Watson* (1966) 39 A.L.J.R. 459.

493. See G.J. Annas, L.G. Glantz and B.F. Katz, *op. cit.*, note 63, at pp. 68-70 and discussion at note 467, *supra*.

494. See "Notes 'Sale of Human Body Parts'", *supra*, note 274, at p. 1196.

495. G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 70.

496. See for example L. Kornprobst and S. Delphin, *op. cit.*, note 62, at No. 51.

Note that the N.S.W. *Minors (Property & Contracts) Act*, cited *supra*, note 470, at section 49, raises some potential conflicts in this respect, as it provides that a minor of fourteen years of age or more may consent to medical treatment and that a surgeon is legally protected from proceedings for assault, if a parent or guardian of a minor under sixteen years of age gives consent to medical treatment on such a minor. It would seem that the minor aged between fourteen and sixteen years may consent to, but not refuse, treatment.

497. See U.S. National Commission, "Staff Draft. Research Involving Children Recommendations", 1st April, 1977, at Recommendation 5, p. 13. (Supplied to the writer by the Secretary of the United States National Commission).

The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research "Report and Recommendations, Research Involving Children", D.H.E.W. Publication No(OS) 77-0004, U.S. Government Printing Office, Washington, D.C., 1977, at Recommendations 7, pp. 12-13. That the right to veto treatment arises before a right to consent is exactly the reverse of the situation under the N.S.W. *Minors (Property & Contracts) Act*, discussed *ibid*.

498. H.F. Pilpel, *supra*, note 474, at p. 462.

See also W. Wadlington, *supra*, note 487, at p. 124.

499. I suggest that in the case of a mature minor, one is probably no more justified in inflicting medical treatment on him against his will, than one would be in the case of a dissenting adult.

500. The Canada Council Consultative Group on Ethics, *supra*, note 248, at p. 35, would allow non-therapeutic research to be conducted on children with the consent of the parents, subject to the child having the right of veto.

Also see U.S. National Commission, "Staff Draft, Research Involving Children. Recommendations", *supra*, note 497, at Recommendation 5, p. 13, and "Report and Recommendations", *supra*, note 497, at Recommendation 7, pp. 12-13.

501. The Medical Research Council (United Kingdom), *supra*, note 60, at p. 179, suggests that depending on the age, intelligence, situation and character of the subject and the nature of the "investigation", a child not below the age of twelve years may be able to consent to non-therapeutic research.

502. The Nuremberg Code (*supra*, note 65), does not allow for "proxy consent" to non-therapeutic research, as it requires legal capacity of the subject to consent. In comparison the Declaration of Helsinki (*supra*, note 69), provides for this, as does the Report of the Canada Council Consultative Group on Ethics, (*supra*, note 248), and the F.D.A. Regulations in the United States (21 C.F.R. § 310.102(b)). The Regulations indirectly mandate research on children, as they specify that before drugs can be approved for marketing for use in children, they must be proved "safe and effective" for that group (21 C.F.R. § 310.6) which necessitates clinical trials on children. What often happens is that the drugs are marketed for adult use, but in practice are used for children.

B.L. Mirkin *et al*, "Panel on Pediatric Trials", Clin. Pharm. & Therap. 18(5).2.657, deplore this haphazard use and suggest that approval for adult use should be contingent on conducting trials in children, where the drug may be used paediatrically.

A. Mayrand, *op. cit.*, note 43, at No. 47, says that in Quebec the legal limit of parental consent is to treatment required by the state of health of the child.

503. Possibly the best concise summary of all these lines of argument is to be found in the United States National Commission, "Report and Recommendations. Research involving Children", *supra*, note 497.

504. See P. Ramsey: *supra*, note 201; "Shall we 'Reproduce'? Pt. I. The Medical Ethics of In Vitro Fertilization", J.A.M.A. 220(10) 1346 (1972); "Pt. II. Rejoinders and Future Forecast", J.A.M.A. 220(11) 1480 (1972); "The Enforcement of Morals: non-therapeutic research on children", The Hastings Center Report 6(4) 21 (1976).

In agreement with Ramsey is W.E. May, *supra*, note 182.

505. For the initial article by R. McCormick see *supra*, note 244; also see *supra*, note 194; and "Foetal Research, Morality and Public Policy", The Hastings Center Report 5(3) 26 (1975).

506. Feasibility is not determinative of ethics, although *cf.* J. Fletcher's "situational ethics", (see "Ethical Aspects of Genetic Controls. Designed Genetic Changes in Man", N.E.J.M. 285(14) 776 (1971); and *supra*, note 62), under which he advocates that all data, which would include feasibility,

should be weighed for ethical decision purposes in each new situation, rather than determining definite principles of right and wrong applicable to all situations. Even if one does not give feasibility ethical weight it must be taken into account at least in legislating, if not in establishing personal, moral precepts.

507. S. Toulmin, "Exploring the Moderate Consensus", The Hastings Center Report, 5(3) 31 (1975), at p. 34.

508. See R. Savatier, *supra*, note 36; R. Dierkens, *op. cit.*, note 477, at p. 31; P.-J. Doll, "L'aspect moral, religieux et juridique des transplantations d'organes", Gaz. Pal. 1974 2. doctr. 820, 28 Sept. 1974.

509. See P.-J. Doll, *ibid.*, at p. 822, who describes such exceptional circumstances as a donor child acting to save a brother, sister, or twin.

510. P.-J. Doll, *ibid.*, reports that on the 14th March, 1961, "La Chancellerie" took account of the consents of a fourteen year old with full understanding, and of his parents, and of the favourable view of the "Conseil National de l'Ordre des Médecins", and gave permission for a transplant of a kidney to his sister, this being the only hope of saving the life of the latter.

511. *An Act to Amend the Civil Code*, cited *supra*, note 477.

512. See *supra*, pp. 71-75.

513. A. Mayrand, *op. cit.*, note 43, at No. 7.

Note that although such a right has been legislated, and special conditions for its exercise imposed in the case of minors, as far as the author is able to ascertain there has never been an application to a Court in Quebec pursuant to Article 20. As there are many active medical research institutions in the Province either the requirements of Article 20 are being ignored, or all research involving children has ceased.

514. See *infra*, p. 81 *et seq*.

515. *Human Tissue Gift Act*, cited *supra*, note 463.

516. *Human Tissue Act*, S.B.C. 1968 c.19; *Human Tissue Gift Act*, S.B.C. 1972, c. 27.

517. *Human Tissue Act*, R.S.N.S. 1967.

518. *Human Tissue Act*, S. Nfld. c. 132, 1971, No. 66.

519. Note tissue is defined to exclude "tissue replaceable by natural process of repair" (see, for example, Ontario *Human Tissue Gift Act* section 1(c)). Presumably the validity of a minor's consent with respect to procedures such as blood donation or other regenerative tissue, therefore depends on the Common Law.

520. Proc. Conference of Commissioners on Uniformity of Legislation in Canada, (1965) 104.

521. P.D.G. Skegg, *supra*, note 486, at p. 375.

522. See: *Re L* [1968] P. 119 (C.A.); *B (BR) v. B(J)* [1968] P. 466 (C.A.); *S. v. McC (McC & W v. W)* [1972] A.C. 24.

523. See: P.D.G. Skegg, *supra*, note 17, at p. 375 *et seq*; B. Dickens, "The Use of Children in Medical Experimentation", (1975) 43 Medico-Legal Journal 166.

524. G. Dworkin, "Law relating to organ transplantation in England", (1970) 33 Modern Law Review 353, at p. 360.

525. Especially if one considers that "best interests" may include "financial interests" of the child — see *S. v. McC*, cited *supra*, note 522, at p. 42, and P.D.G. Skegg, *supra*, note 486, at p. 379. Skegg suggests that *S. v. McC* should be used as a basis for adopting a rule that a parent can consent where a reasonable parent would consent, that is, where it is not against the child's interest and is in the public interest. Such a test would allow a parent to consent to non-therapeutic experimentation on his child. One queries whether dicta handed down within the narrow confines of the question of whether or not a blood test can be inflicted on a child, *for the purpose* of establishing its legitimacy, should be extended to the full scope of non-therapeutic experimentation, especially when such a blood test is authorized by statute (*Family Law Reform Act*, 1969 17 & 18 Eliz. II c.46, section 20) which presumably establishes its basic legitimacy. The same cannot be said with respect to non-therapeutic experimentation on children.

526. 139 A.L.R. 1366 (1941), especially at p. 1369; 126 F. 2d 121 (1941).

527. It is not clear from the judgment in *Bonner v. Moran* (*ibid.*), whether the parents' consent would have been sufficient without the boy's consent. The case may be interpreted as stating that in the non-therapeutic situation the "mature minor" rule only applies if supplemented by parental consent. It is not informative about the situation where the minor is incapable of consent; A.M. Capron, "Legal Considerations Affecting Clinical Pharmacologic Studies in Children", *supra*, note 193, at p. 143, argues *Bonner v. Moran* should not be interpreted as including the implication that parents can consent to non-beneficial treatment on a child, as, he says, the court in that case and subsequent courts have avoided ruling on the question. This is true in cases where the courts found psychological benefit and therefore consent to a *beneficial* procedure, but *cf. Nathan v. Farinelli* (Unreported) Eq. No. 74-87, Mass. July 3, 1976 (Mass U.S.), which is discussed in the text which follows.

528. 289 A. 2d 386 (Conn. 1972).

529. Cited *supra*, note 527.

530. (Unreported) No. J74-57 (Mass. Aug. 28, 1974).

531. 445 S.W. 2d 145 (Ky 1969).

See also *Howard v. Fulton-Dekalb Hospital Authority* 42 U.S.L.W. 2322 (Ga. Sup. Ct., Fulton City, Nov. 29, 1975) where the Court relying on its *parens patriae* power authorized a kidney donation from a fifteen year old "moderately retarded" girl to her mother, taking into account avoidance of the emotional shock which would be caused to the daughter if her mother died, although there was "no intelligent written consent by" the daughter.

532. Note that the Court authorized the donation under its equitable *parens patriae* or "substituted judgment" power, that is its power to act in the *best interests* of a minor or incompetent, and did not support its decision "via" the parents' consent (*ibid.*, pp. 147-9, especially at p. 149). For a full discussion of the substituted judgment doctrine, which is basically premised on a guess at what

the incompetent would choose if competent, see J.A. Robertson, "Organ Donations by Incompetents and the Substituted Judgment Doctrine", (1976) 76 Columbia Law Rev. 48.

533. 284 So 2d. 185 (La App. 1973). Note that here, although it was not significant in the case, the mental incompetent was also a minor.

Also see *Lausier v. Pescinski* 67 Wis. 2d. 4, 226 N.W. 2d. 180 (1975), where the Court expressly held that neither it, nor the guardian of a thirty-nine year old mental incompetent with a mental age of twelve, could substitute their consent for that of the ward, when the procedure involved, kidney donation, was non-beneficial to the latter.

534. See G. Dworkin, *supra*, note 524, at pp. 356-7.

535. See *Strunk v. Strunk*, cited *supra*, note 531, at p. 146.

Also see notes 523 and 525, *supra*.

536. All are unreported, but are referred to in *Hart v. Brown*, cited *supra*, note 528, at p. 387. The cases are: *Masden v. Harrison*, No. 68651, Eq. Mass. Sup. Jud. Ct. (June 12, 1957); *Hushey v. Harrison*, No. 68666, Eq. Mass. Sup. Jud. Ct. (Aug. 30, 1957); *Foster v. Harrison*, No. 68674, Eq. Mass. Sup. Jud. Ct. (Nov. 20, 1957).

537. See W.J. Curran, "A Problem of Consent: Kidney Transplantation in Minors", in "Ladimer and Newman eds.", *op. cit.*, note 10, p. 237, at p. 242; C.H. Baron *et al*, *supra*, note 180, at p. 161, after analyzing these cases come to the conclusion that the Courts did not treat the consents of the parents, or children, involved, as effective. "Instead [in each instance] it heard evidence and decided for itself whether, under the circumstances the operation should be permitted to go forward". If true, this may be explained on the basis that these cases sought declaratory judgments as to "the lawfulness of the procedure" (see D.W. Meyers, "The Human Body and the Law", Chicago, Aldine-Atherton, 1970, at p. 123) and it is possible that the Courts were not so concerned with the issue of consent *per se*, as with banning any future legal action against the doctors.

538. Cited *supra*, note 528.

539. See the comments by G.S. Sharpe, "The Minor Transplant Donor", (1975) 7 Ottawa Law Rev. 85 at p. 98.

540. Cited *supra*, note 527.

541. See G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 89.

542. *Ibid.*, pp. 85-87.

543. A.M. Capron, *supra*, note 193, at p. 146; and *supra*, note 81, at p. 319.

Essentially Capron suggests replacing parental consent by a model of decision-making, that is a decision-making framework, of "successive limited approximations", which narrows down the issues and points the way to alternative safeguards, which include, but are not limited to, parental consent. The steps are: *to limit* the perceived need for the experiment as much as possible; *to limit* the risk; then *to limit* the participants (a) by use of therapeutic experimentation on sick children where possible; (b) if normal children are used by: (1) eliminating institutionalized children; then 2(i)

allowing selection by the guardian; then (ii) selection on the basis of medical and psychological fitness; and then (iii) random choice among those eligible; finally *to limit* damage by on-going monitoring. (Clinical Res. *ibid.*, at pp. 145-7). As Capron goes on to say (*ibid.*, p. 147) the "most uncomfortable feature" of selecting child subjects on the basis of fitness and random choice is the power given to the state.

544. This language has been adopted by the United States National Commission in their "Staff Draft. Research Involving Children. Recommendations", *supra*, note 497, at p. 3, and in "Report and Recommendations", *supra*, note 497, at Recommendation 3, p. 5.

Also see B. Freedman, "A Moral Theory of Informed Consent", The Hastings Center Report 5(4) 32 (1975), at pp. 37-8, who says "proxy consent" given for children is a different entity from consent in adults.

545. United States National Commission "Staff Draft. Research Involving Children. Recommendations", *ibid.*, at p. 14.

See also J. Viret, *supra*, note 150, at p. 915, who says one cannot speak of "un consentement éclairé" of someone other than the patient.

546. "No risk" or "minimal risk" is a difficult concept to define for practical purposes and the United States National Commission ("Staff Draft", *ibid.*, p. 4) suggest that, within the medical research context, it means the research "does not involve any risks or discomforts to children greater than those normally encountered in their daily lives or in routine medical or psychological evaluations . . . " and further (p. 5), that if there is substantial uncertainty regarding the risks, they cannot be considered minimal.

Although it is implied in this statement, if should be clearly recognized that "minimal risk" encompasses both likelihood of the risk eventuating and the magnitude of the harm if it does, that is I am using the term as meaning minimal risk of minimal harm. This draft Recommendation should be compared with the final version, "Report and Recommendations", *supra*, note 497, which substitutes for the separation of risks into no "risks or discomforts . . . greater than those normally encountered in . . . daily li[f]e" . . . and "risks or discomforts greater than th[e]se . . . ", a division of "not . . . greater than minimal risk . . . ", "more than minimal risk . . . ", and "a minor increase over minimal risk . . . " (at Recommendations 3, 4, & 5 respectively). It would seem that the latter classification is broader with respect to risks in the first category, which has less stringent approval requirements, and is probably of wider overall scope as far as allowing research is concerned, as risks falling within the third class are not dealt with as stringently as those within the second group.

Whether parents can ever consent to non-therapeutic research on their children is in issue in *Neilson v. Regents of University of California et al* (Civ. Case No. 665-049 Sup. Ct. of Calif., County of San Francisco filed Aug. 23rd, 1973, as amended Dec. 20th, 1973) which seeks a declaration prohibiting a proposed non-therapeutic, allergenic research project on children, for whose participation the parents would be paid. The case is still pending.

The Royal College of Physicians (United Kingdom), "Code" *supra*, note 67, at p. 2, allows for "proxy consent" to non-beneficial procedures on children and mental incompetents, where there is negligible risk.

Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at pp. 30-31, would also allow such procedures.

547. See Statement by the Medical Research Council (United Kingdom), *supra*, note 66, at p. 179, "that in the strict view of the [English] law parents and guardians of minors cannot give consent on their behalf to any procedures which are of no particular benefit to them and may carry some risks of harm".

Also see Louisiana statutory provision: *La. Stat. Ann* title 14' § 87.2 (1974), which requires consent of the subject of experimentation, with no provision being made for any exception to this.

Cf. New York, *N.Y. Pub. Health Law* § 2441(5) which allows the legal representative to consent to research on the subject incapable of consenting for himself.

547a. It is necessary, to say "arguably" as there is still the objection that consent not only protects against the infliction of unconsented to risk or harm, but also unconsented to role-playing. See *supra* p. 86.

There are also other objections to such a proposal to allow non-consensual "no risk", or "minimal risk", non-therapeutic experimentation on non-discerning children, one being that consent is needed in such circumstances when adults are involved. However, one may be able to distinguish the adult situation from that involving non-discerning children, by arguing that consent is required basically to protect a right to autonomy, which a non-discerning child does not have, and a right or privacy, which has intrinsic and extrinsic features, with only the extrinsic ones being relevant to a non-discerning person and therefore needing protection. Apart from this the duty is to respect the person and protect him from harm, arguably neither of which aspects are contravened by "no risk" experimentation, and the latter only in an insignificant way by "minimal risk" procedures. I prefer such a line of reasoning to recognizing parents' "proxy" consent as effective because of the ramifications of the latter. (See *supra*, pp. 172-173).

This is really to argue that "proxy consent where it is acceptable, which I suggest are McCormick's "ought", or Toulmin's "could not object" situations (*supra*, pp. 161-162) is a legal fiction. Rather the reality is that the same reasoning would apply as where it is argued that consent is not necessary, as in epidemiological research. For examples of the latter see R. Doll, "Obstacles Within the Practice of Medicine: Public Benefit and Personal Privacy; The Problems of Medical Investigation in the Community", Proc. Roy. Soc. Med. 67(12) Pt. 2, 1281 (1974), at p. 1283; Statement by the Medical Research Council (United Kingdom), "Responsibility in the Use of Medical Information for Research", B.M.J. 1973.1.1213.

548. Note that the determination of "no risk", or "minimal risk", must be by an independent body, preferably an ethical review committee.

549. See U.S. National Commission, "Staff Draft. Research Involving Children. Recommendations", *supra*, note 497, at p. 12. "Report and Recommendations", *supra*, note 497, at Recommendation 2, p. 2.

550. A.H. Schwartz, "Children's Concepts of Research Hospitalization", N.E.J.M. 287(12) 589 (1972).

551. For a view relying on a justification other than discernment, for involving children in non-therapeutic research see W.G. Bartholome, "Parents, Children, and the Moral Benefits of Research", The Hastings Center Report 6(6) 44 (1976), who believes it is possible for children aged five to fourteen years to benefit morally from involvement in research and that the parent not only has a duty to protect the child, but also one to enhance his moral development, and therefore such participation by children should be allowed.

552. See the minority position of P.A. Crépeau, Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 30.

For a contrary view see: W.J. Curran and H.K. Beecher, "Experimentation in Children: A Re-examination of Legal Ethical Principles", J.A.M.A. 210:77 (1969).

Editorial, "The Ethics of research involving children as controls", Archives of Disease in Childhood (United Kingdom) 1973.48.751, at p. 752.

552a. *Cf.* the position of the majority, in the "Code" of the Medical Research Council, (*ibid.*, at pp. 30-31) that subject to the additional special safeguard of "second level proxy consent" by a "subject advocate or ombudsman" medical research on those unable to consent for themselves may be carried out. Note there is no requirement that the research be of a truly exceptional nature.

553. In support of this approach see: *Kaimowitz v. Michigan Department of Mental Health*, cited supra, note 115, at pp. 197-8, where the court held that the consent of a parent or guardian "is legally ineffective in the psychosurgery situation".

Also see R. Neville, "Pots and Black Kettles: A Philospher's Perspective on Psychosurgery", (1974) 54 Boston Univ. Law Rev. 340, at p. 348, who, speaking of psychosurgery, says there must be strict personal consent and "proxy" consent should only be allowed after adversarial court proceedings. This statement can be generalized so that it applies when the situation is one of a more than minimal risk, non-therapeutic, or doubtfully therapeutic, medical intervention, on any person who is himself incapable of consent.

554. See U.S. National Commission, "Staff Draft. Research Involving Children. Recommendations", *supra*, note 497 at p. 6, which requires for allowing such research, that is more than minimal risk non-therapeutic research on children unable to give "informed" consent, that an institutional review board, a national ethical advisory board, and, after appropriate opportunity for public review, the Secretary of Health Education and Welfare, determine that: the risks are acceptable; a grave health problem generally affecting children exists and such research is the only adequate measure to deal with it; and conditions for assent of the children and permission of the parent as set forth in the recommendations will be met.

See, likewise, "Report and Recommendations", *supra*, note 497, at Recommendation 6, p. 10, which applies similar approval requirements to research that is more than "a minor increase over minimal risk".

555. See H. Jonas, *supra*, note 42.

556. See *infra*, p. 89 *et seq.*

557. *3 Pa. Bull.* No. 2667 (1973). Cited by B. Mishkin, "Multidisciplinary Review for the Protection of Human Subjects in Biomedical Research: Present and Prospective H.E.W. Policy", (1974) 54 Boston Univ. Law Rev. 278, at p. 284.

558. For example in the "Willowbrook Experiments", see *supra*, note 307, parents of mentally handicapped children were told that the only chance of their child being admitted to the institution was if the parent consented to experimentation on the child.

559. *Supra*, note 497.

560. *Supra*, note 497.

561. "Staff Draft. Research on Children", *supra*, note 497, Recommendation 8, p. 22, as amended by the "U.S. National Commission" Meeting June 10-11, 1977, Summary of Minutes Recommendation 9, p. 2.

562. See D.H. Russell, "Law, Medicine and Minors", Pt. IV, N.E.J.M. 279(1) 31 (1968). "Child abuse" legislation can be found in all relevant jurisdictions.

563. *Cal. Penal Code* § 273(a) West 1970. Query if non-therapeutic experimentation is "unjustifiable" within the terms of this Statute. It has been argued in *Nielson v. Regents of University of California*, cited *supra*, note 546, that it is.

564. R.J. Levine, "In Comment . . . ", JAMA 232(3) 259 (1975), at p. 261.

565. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 147.

566. *An Act respecting the protection of children subject to ill-treatment* S.Q. 1974, c.59, section 14j.

566a. It is necessary to distinguish spontaneous and induced abortion as the ethical implications in the former are not the same. The spontaneously aborted foetus would be governed by the same considerations as apply to children or dying or dead subjects, as appropriate.

567. Note that this is the same question as that asked in relation to killing condemned prisoners by medical experimentation, see *infra*, p. 98.

568. Fed. Reg. 8th Aug. 1975, 33546.

Also see T.W. Ogletree, "Values, Obligations and Virtues: Approaches to Bio-Medical Ethics", Journal of Religious Ethics 4(1) 105, 1976, at pp. 111-112, who says that "the National Commission gives special emphasis to the risk of violating the dignity of the foetus as a human subject worthy of protection. Yet if respect for the foetus does not protect it from an abortion decision or from being an unconsenting subject of experimentation, this "risk" cannot meaningfully have as its primary referent the fetus itself. It rather appears to be important chiefly for its bearing upon the moral and psychological well-being of the "parents" and researchers involved in the experimentation, or more generally, for its impact on the moral health of the society which accepts and supports the research". That is, the risk assessed is to others, not to the foetus, with respect to whom the concept of risk is eliminated in substance though not in form, by comparing any possibility of harm to the foetus with the actuality of the situation in which it is placed. One

queries why the National Commission retained such a meaningless concept and I suggest that Ogletree's analysis explains this.

569. Fed. Reg. 8th Aug. 1975, 33528; 45 C.F.R. § 46.209(*d*). This provision requires "informed consent" of the mother and father to research on the aborted foetus, with certain exceptions in the latter case.

570. "The Use of Fetuses and Fetal Material for Research. Report of the Advisory Group", London; Her Majesty's Stationery Office, 1972, (hereafter referred to as the "Peel Report") at p. 8.

571. "Peel Report", *supra*, note 570, at pp. 8-9.

572. *Human Tissue Act*, cited *supra*, note 283.

573. *Ibid.*, at p. 12.

574. *Ibid.*, at p. 9, No. 42.

575. *Ibid.*, at p. 12. Recommended Code of Practice, section 4(1).

576. *Ibid.*, p. 7, No. 32, and see *supra*, pp. 70-71.

577. G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 206.

578. The author, on the basis of personal interviews has reason to believe that this represents the current practice in some Canadian hospitals.

579. R. Wasserstrom, "The status of the fetus", The Hastings Center Report 5(3) 18 (1975), at pp. 20-1.

580. H.O. Tiefel, *supra*, note 135, at p. 88.

581. 45 C.F.R. § 46.206 4(b).

582. *Supra*, note 570, at p. 9, No. 44, and p. 12.

583. See "Report on Injuries to Unborn Children", The Law Commission (United Kingdom) No. 60. Cmnd. 5709 London; Her Majesty's Stationery Office, 1974. *Congenital Disabilities (Civil Liability) Act* 1976 Eliz. II c. 28; *Watt v. Rama* [1972] V.R. 353 (Australia); *Duval v. Seguin* (1972) 26 D.L.R. 3d. 418 (Ontario); *Montreal Tramways Company v. Leveillé* [1933] S.C.R. 456 (Quebec); *Cour d'appel d'Amiens* 28 avril 1964, Gaz. Pal. 1964.2.167.; *Cour d'appel de Paris* 10 janv. 1959, Gaz. Pal. 1959.1.223.; *Bonbrest v. Kotz* 65 F. Supp. 138 (D.D.C. 1946).

See also P.A. Lovell and R.H. Griffith-Jones, "'The Sins of the Fathers' — Tort Liability for Pre-Natal Injuries", (1974) 90 Law Quarterly Rev. 513; J.G. Fleming *op. cit.*, note 23, at pp. 159-61, 644-5, & 668-9; W. Prosser, *op. cit.*, note 16, at pp. 335-8, 864, 883; J. Carbonnier, "Droit Civil", 9e éd. Paris; Presses Universitaires de France, 1971, Tomes I and II, at Tome I, pp. 179-84; G. Marty and P. Raynaud, "Droit Civil" 2e éd. Paris; Sirey, 1967, Vols. I and II, at Vol. II, p. 360.

The parent may also have a right of action, see for example: *O'Neill v. Morse* 385 Mich. 130; 188 N.W. 2d. 785 (1971); *Trib. gr. inst. Sein* 20 janv. 1962, J.C.P. 62éd. G. IV 68; *Langlois v. Meunier* [1973] C.S. 301 (Québec).

584. See references, *ibid.*, generally, and Law Commission (United Kingdom) Report, in particular, especially at p. 41.

585. See Editorial, "The Rights of the Mentally Handicapped", The Lancet 1973, 1(818), 1295, where a further distinction is suggested between the mentally ill and the mentally handicapped in that the latter can mature, develop and function as ordinary citizens if given the chance. There is also an argument for including those with temporarily reduced mental capacity, such as patients in extreme pain, within the class of the "temporarily factually, mentally incompetent" and according them the safeguards which this entails, as far as consent to medical interventions is concerned.

Also see G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 151, who divide mental incompetency into two classifications, mental illness and mental retardation, and say that one must distinguish numerous levels within each of these.

586. See *supra*, p. 83 *et seq.* and *infra*, pp. 100-101.

Also see Annas, Glantz and Katz, *ibid.*, at pp. 147-151.

587. R. Neville, *supra*, note 553, at p. 349.

588. *Ibid.*

589. See Fed. Reg. 23rd Aug. 1974, 30656 (Proposed Rules); 45 C.F.R. 46 § 46.504(c) which provides: "Institutionalized mentally disabled individuals may not be included in [research] — unless: — (c) The individual's assent to — participation [in research] has also been secured, when — he or she has sufficient mental capacity to understand what is proposed and to express an opinion as to his or her participation".

590. That institutionalization does not *necessarily* connote legal incompetence nor, of course, factual incompetence has been legislated in California: see *California Penal Code* (Supp. 1975) § 2672(b) (c).

Institutionalization may be voluntary or involuntary, but this does not automatically determine factual or legal competence to give "informed" consent, as the criterion for involuntary admission to a mental hospital may be dangerousness to oneself or others (see for example, *The Mental Health Act* R.S.O. 1970 c.269, section 8(1)(*a*)), which does not, of itself, connote factual incompetency. With respect to legal incompetence, it depends whether in the particular jurisdiction involuntary commitment carries a presumption of this. The Ontario legislation (*ibid.*), for example does not. *Section 32(3)* requires a medical examination after admission on the basis of which a certificate of incompetence *may* be issued.

591. Legal incompetency can arise in two ways which represent two factual realities, but both of which have the same legal implications. Firstly a person may be described as legally incompetent because he is factually incompetent and the effect of this is legal incompetence. Secondly a person may have been declared legally incompetent by a legal process of commitment or interdiction, in which case he is and remains legally incompetent, totally or partially depending on the effect of the legal process, until the order is lifted, even though he may have intervals of factual competence. In every case the circumstances relating to the factual competency of each individual person must be examined, in conjunction with the applicable laws of the jurisdiction relevant to mental incompetents in order to determine a particular person's legal competency, and thus one can assess the overall competency of that person to consent to a medical intervention or to medical research.

592. See P. Laget, *supra*, note 41, at p. 310; F. Heleine, *supra*, note 318, at p. 43; L. Kornprobst and S. Delphin, *op. cit.*, note 62, at Nos. 55, 60, 65; R. Boucher *et al, supra*, note 62, at p. 488; R. Piédelièvre et E. Fournier, *supra*, note 246, at Tome I, p. 103; X. Ryckmans and R. Meert-van de Put, *op. cit.*, note 62, at No. 595; A. Mayrand, *op. cit.*, note 43, at No. 41; P.-J. Doll, *supra*, note 36, at No. 5; R. Kierkens *op. cit.*, note 477, at No. 195; V.C. Heldman, *supra*, note 188, at pp. 163-170; M.F. Ratnoff, *supra*, note 63, at p. 495 *et seq*; J.A. Robertson, *supra*, note 532; R.G. Spece, *supra*, note 19; A.R. Holder, *op. cit.*, note 54, at p. 243.

"Notes 'Sale of Human Body Parts'", *supra*, note 315, at p. 1197; D.A. Frenkel, *supra*, note 247; *Kaimowitz v. Department of Mental Health for the State of Michigan*, cited *supra*, note 115.

593. See W.F. Cook, "Transplantation — Incompetent Donors: Was the first Step or the Last Taken in Strunk & Strunk? (Ky 445 S.W. 2d. 145)", (1970) 58 Calif. L. Rev. 754, where the author suggests a possible justification for using a criterion of social worth, that is the worth of the proposed incompetent organ donor in comparison with that of the competent recipient, is the result thereby attained of "social good by restoring a more productive citizen to gainful employment" (at p. 769).

Also see R.A. Koory, "Equity — Transplants — Power of Court to Authorize Removal of Kidney from Mental Incompetent for Transplantation into Brother", (1970) 16 Wayne L. Rev. 1460, at p. 1467, f.n. 62, where the point is considered whether an incompetent might provide a useful function supplying others with organs and thus "pay his own way through life".

594. See: Laget, Heleine, Kornprobst, Boucher, Piédelièvre, Ryckmans and Meert-van de Put, Mayrand, Doll, Dierkins, all as cited *supra*, note 592.

595. L. Kornprobst, *op. cit.*, note 12, at p. 243.

596. See Articles 290, 325, 343, 986 *Civil Code of the Province of Quebec*.

597. A. Mayrand, *op. cit.*, note 43, at No. 42; F. Heleine *supra*, note 318, at p. 43.

This interpretation is adopted on the basis that Article 20 expressly provides, under certain conditions, for experimentation on, or organ donation by, either a competent adult, or a discerning minor who may be legally incompetent, although he must be factually competent, and that the need for, and existence of, this express provision rebuts any implication that such interventions may be performed on persons not falling within one or other of these two categories, and any implication that "proxy" consent alone can be effective in any such situation.

598. See J.-L. Baudouin, *op. cit.*, note 339, at No. 192.

599. See Heldman, Ratnoff, Robertson, Spece, Holder, Michigan Law Rev., and Frenkel, all as cited *supra*, note 592.

600. See statutes cited *supra*, notes 463, 516, 517, 518.

601. Working Paper No. 5, *supra*, note 283, at No. 50, p. 28. "Report" *supra*, note 283, at p. 51, No. 113.

602. See *supra*, pp. 78-80.

603. See *supra*, note 532.

604. Cited *supra*, note 115.

605. See G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at pp. 175-178.

606. See, for example, *In re Moore* 221 S.E. 2d. 307 (N.C. 1976); *Cook v. Oregon* 9 Ore. App. 224, 495 P. 2d. 768 (1972); *In re Sallmaier* 378 N.Y.S. 2d. 989 (N.Y. Sup. Ct. Jan 26, 1976).

607. Fed. Reg. 23rd Aug. 1974, 30655; 45 C.F.R. § 46.504a.

Also see R.Q. Marston, "Medical Science The Clinical Trial and Society", The Hastings Center Report 3(2) 1 (1973) who believes the only type of research that should be allowed on the mentally ill is that related to mental disease.

608. *Supra*, note 65.

609. B. Mishkin, *supra*, note 557, at p. 282.

610. *Supra*, note 69, at I Basic Principles parag. II.

Note that the "Draft Code of Ethics on Human Experimentation (1961)" B.M.J. 1962, 2, 1119, which was the "avant-projet" of the Declaration of Helsinki, required the subject to "be in such a mental, physical and legal state as to be able to exercise fully his power of choice" (this is clearly taken from Article 1, Nuremberg Code, *supra*, note 65) and excluded experimentation on children, incompetents or "captive groups". This was altered, apparently largely due to American influence, to allow for "proxy" consent to be given for a "legally incompetent" person ("Declaration of Helsinki. Recommendations guiding medical doctors in biomedical research involving human subjects" Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, at parag. III 3(a)) and for the use of prisoners as subjects (see M.J. Bloom, *supra*, note 63, at p. 1087). This original 1964 Declaration of Helsinki, however, retained a provision (III 3(b)), that "the subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice".

It is interesting that the 1964 Declaration was amended, in Tokyo in 1975, *inter alia* by omitting the provision III 3(b). One can only speculate why this was done, but there was probably an implication from the cumulative effect of the two paragraphs referred to above, that factual competence was required, and perhaps freedom of movement, and "proxy" consent could only be given in a situation where legal, and not factual, incompetence was the sole defect. The 1975 Declaration provides for situations of "consent under duress", "legal incompetence" and "physical or mental capacity making it impossible to obtain informed consent", when "proxy" consent is acceptable. This may represent a major change as far as "special" subjects are concerned between the 1964 and 1975 versions of the Declaration of Helsinki.

Also see W.H.O. Principles for the Clinical Evaluation of Drugs *supra*, note 123, at § 4.1, p. 18, which allows for consent of the legal guardian in cases of "legal incapacity", seemingly to non-therapeutic research as the statement is made that "the subjects . . . may be healthy volunteers . . . whose consent has not been sought because . . . they were not competent to give it" (at p. 7). Because "legal incapacity" is specified, this may raise a presumption that such consent may not be given on behalf of a factually incompetent person, although the Declaration of Helsinki also speaks of "legal incompetence",

which presumably is a synonym for "legal incapacity" and makes clear this includes "physical or mental incapacity" (*ibid.*, 1975 version at I Basic Principles, parag. II).

611. *Supra*, note 67, at p. 2.

612. "The Report of the Committee to Investigate Medical Experiments on Staff Volunteers" *supra*, note 326, at § 3:2.

613. *Supra*, note 68.

Cf. New York State, *N.Y. Pub. Health Law* § 2440-2446 (Supp. 1976) which governs non-therapeutic human research and, at § 2442 under the title "Informed Consent" requires that no such research "may be conducted in this State in the absence of the voluntary informed consent subscribed to in writing by the human subject. . . . If the human subject be . . . legally unable to render consent, such consent shall be subscribed to in writing by such other person as may be legally empowered to act on behalf of the human subject". This provision is far from clear, as the title and first part imply that "informed" consent is essential and that therefore the second part of the provision should be interpreted as only making an exception to personal "informed" consent in the case of legal, but not factual, incapacity.

614. See *supra*, pp. 80-81.

615. D.A. Frenkel, *supra*, note 247, at p. 9.

616. See G.E.W. Wolstenholme, "An Old-Established Procedure: The Development of Blood Transfusion", in "Wolstenholme and O'Connor eds.", *op. cit.*, note 315, p. 24, at p. 26, who gives this historical example of research.

617. See G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 240.

618. See, for example, *Ruffin v. Commonwealth* 62 Va. [21 Gratt] 790 [1871] (Virginia), where the Court stated the prisoner "has, as a consequence of his crime, not only forfeited his liberty, but all his personal rights except those which the law in its humanity accords to him. He is for the time being the slave of the State"; P.-J. Doll, *supra*, note 508, at p. 822, who says that Article 36 du *Code pénal* (France) "dispose que l'individu condamné à une peine afflictive perpétuelle est déchu de tous ses droits civils" and all power, or right, to give consent therefore appears to be excluded.

619. For a discussion of prisoners' rights and legal capacity in general, see: G. Hawkins, "The Prison. Policy and Practice", Chicago and London. The University of Chicago Press, 1976.

And with particular reference to such rights in the medical relationship see: W.G. Todd, *supra*, note 80, at p. 800 *et seq.*; A.R. Holder, *op. cit.*, note 54, at pp. 13-15; L. Vandervort, "Legal Aspects of the Medical Treatment of Penitentiary Inmates", (1977) 3 Queen's Law J. 3:368.

620. B. Starkman, *supra*, note 18, at p. 23, with whom I agree, argues that procedural protections of institutionalized persons are not enough, rather the substantive law must articulate the civil rights of these persons in the context of practices involving the integrity of the individual.

621. See for example: W.G. Todd, *supra*, note 80, at p. 805; G. Hawkins, *supra*, note 619, at p. 136, who says that "until well into the 1960s . . . the prisoner

found that the law, to use Gerhard Mueller's phrase, 'left him at the prison entrance'''.

622. A.B. Sabin, A.J. Bronstein, W.N. Hubbard, ''The Military/The Prisoner'', in ''Experiments and Research with Humans: Values in Conflict'', National Academy of Sciences, Academy Forum, Washington, 1975, (hereafter referred to as ''National Academy of Sciences Forum'') p. 127, per Bronstein, at pp. 130-5.

623. *Ibid.*, at p. 131.

624. See S. Spicker, ''Inquiry and Commentary'', part of the discussion led by A.B. Sabin *et al*, *ibid.*, at p. 145.

625. Lord Kilbrandon, ''Final Discussion'', in ''Wolstenholme and O'Connor eds.'', *op. cit.*, note 315, p. 202, at p. 205.

626. P. Ramsey, *supra*, note 201, at p. 705.

627. W.J. Estelle, ''The Changing Profile and Conditions Surrounding Clinical Research in Prisons'', Clin. Pharm. & Therap. 13(5) 831 (1972) (Emphasis added).

Note the use of the possessive pronoun when describing prisoners and also the way in which they are seen as commodities rather than persons.

628. J.D. Moore, ''The Deer Lodge Research Unit'', Clin. Pharm. & Therap. 13(5) 833 (1972), at p. 834.

629. R.W. Newman, ''The Participation of Prisoners in Clinical Research'', in ''Ladimer and Newman eds.'', *op. cit.*, note 10, at p. 467.

630. J.C. Wohlleb, ''Research on Prisoners'', N.E.J.M. 288(14) 742 (1973); F.G. McMahon, ''The 'Normal' Prisoner in Medical Research'', J. Clin. Pharm. 12(2) 71 (1972); R. Burt, ''Inquiry and Commentary'', in ''National Academy of Sciences Forum'', *supra*, note 622, at p. 144.

631. P.B. Meyer, ''Drug Experiments on Prisoners. Ethical Economic or Exploitative?'', Massachusetts; Lexington Books, 1976, at p. 35.

632. J.P. Tupin, *supra*, note 441, at p. 255; G. Bach — Y — Rita, ''The Prisoner as an Experimental Subject'', J.A.M.A. 229(1) 45 (1974), notes that there is a problem of privacy when any information the prisoner discloses becomes the property of the state, especially when there is no guarantee the information will not be used against the prisoner.

633. W.B. Bean, in ''A Testament of Duty: Some Strictures on Moral Responsibility in Clinical Research'', Arch. Int. Med. 134 (5) 854, refers to condemned criminals being used for medical experiments in ancient Persia and Egypt, and during the Renaissance.

634. For example J. Paquin, *op. cit.*, note 170, at p. 359; R. Dierkens, *op. cit.*, note 477, at Nos. 198, 199.

635. Assuming this is possible, see *infra*, pp. 100-103.

636. A. Decocq, *op. cit.*, note 11, at No. 100, p. 79: G. Bourguignon, ''Les conditions morales de l'expérimentation sur l'homme sain ou malade'', in ''Premier congrès international de morale médicale. Communications'', Paris; Ordre National des Médecins, 1955, p. 67, at p. 68.

Also see: C. Bernard, "An Introduction to the Study of Experimental Medicine", translated by Henry Copley Green, New York; MacMillan Co., 1927, at p. 101; J. Fletcher, *supra*, note 62, at p. 636; M.H. Pappworth, *op. cit.*, note 308, at p. 194; P.B. Meyers, *op. cit.*, note 631, at pp. 65-66, 79-80; P.-J. Doll, *supra*, note 508, at p. 822; and B. Dickens, *supra*, note 316, at p. 22, who argue against allowing the use of prisoners as experimental subjects, which would apply *a fortiori* to the death penalty being carried out in this way.

637. M.B. Visscher, *op. cit.*, note 252, at p. 65.

638. P.B. Meyer, *op. cit.*, note 631, at p. 6.

639. Fed. Reg. 14th Jan 1977, 3082-3.

640. See R. Branson, "Prison Research: National Commission Says 'No, Unless . . .'", The Hastings Center Report 7(1) 15 (1977), citing M.E. Jaffe and C.S. Snoddy, "An International Survey of Clincal Research in Volunteers", Report prepared for the National Commission, Feb 10, 1976, p. 4.

641. B. Dickens, *supra*, note 316, at p. 22.

642. M.D. Eilenberg *et al*, *supra*, note 255.

Also see M.H. Pappworth, *op. cit.*, note 308, at p. 194, who says prisoners are not used as experimental subjects in Britain.

643. For example, see a paper prepared for the Law Reform Commission of Canada by G. Ferguson, "A Survey of the Literature on Psychiatric & Medical Techniques used in Canada for Personality Control", (unpublished) which shows that clearly experimental procedures, of doubtful therapeutic efficacy, are used in some Canadian prisons.

Also see N. Goodwin, "The Legal Aspects of Human Experimentation", Canadian Hospital 47(1) 33 (1970), at p. 35, who, as Director of Medical Services, *Department of Correctional Services*, Government of Ontario, advocated in an article in a medical journal, that *to avoid* litigation a researcher should: (a) conduct the experiment as part of treatment; (b) arrange for it to be prescribed by the personal physician from whom the subject (*Note* the description used is subject, not patient!) sought help; and (c) only if (a) and (b) were impossible was it necessary to obtain consent and explain the dangers involved, but to "promote the natural laws of research by means of human experimentation it is prudent to avoid the necessity for (c)". There is obviously deception of the subject advocated and intended here, but I query the extent to which deception of the wider community is also desired, and the extent to which such practices are used to mask experimental procedures carried out in prisons?

644. Cited *supra*, note 65.

645. Cited *supra*, note 69.

646. *Supra*, note 610.

647. For example Pennsylvania: *3 Pa. Bull* No 2667 (1973); A.J. Bronstein, *supra*, note 622, at p. 134, says Massachusetts and Illinois have also banned the use of prisoners.

Also see United States National Commission "Report", Fed. Reg. 14th Jan. 1977, 3082, Chapter 4, parags. 4 & 5.

648. For example:

Okla. Stat. Ann. Tit. 63 (1973) § 47.1- § 47.5;

Iowa Code Ann. § 246.47 (1969);

Cal. Penal Code § 3049.5 (Supp. 1975).

Also see G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, pp. 128-132.

649. Fed. Reg. 14th Jan 1977, 3082, f.n. 2.

650. L'article D. 380 *Code de procédure pénale* (complet par le décret 12 septembre 1972).

651. Although the contrary was suggested, in essence, by N. Goodwin, *supra*, note 643.

652. F.J. Ayd, *supra*, note 301, at p. 772.

653. C.H. Fellner and J.R. Marshall, "Twelve Kidney Donors", JAMA 206(12) 2703 (1968).

654. D.C. Martin *et al*, *supra*, note 129, at p. 1427.

655. See *supra*, pp. 15-16.

656. See G. Bach-Y-Rita, *supra*, note 632, at p. 45, who describes the phenomenon of institutionalization in terms of a desire to acquiesce to the wishes of the keeper and an emotional transference to a parent-child relationship; B.S. Laves, "Legal Aspects of Experimentation with Institutionalized Mentally Disabled Subjects", J. Clin. Pharm. 16(10) Pt. 2.592 (1976), at p. 597.

657. F.J. Ayd, *supra*, note 301, at p. 776.

658. Loss of freedom of choice of his physician may have a coercive effect apart from that represented by loss of this liberty, itself. If the treating physician is seen by the prisoner as part of the prison institution, because the physician is chosen or employed by the prison, the prisoner may feel compelled to consent to recommended treatment, for fear of receiving a "bad mark", or an unfavourable medical report, which may count against him in such matters as parole decisions.

659. See Report & Recommendations United States National Commission, "Research Involving Prisoners", Fed. Reg. 14th Jan 1977, 3076-3091.

660. R. Curtis Morris, "Guidelines for accepting volunteers: Consent, ethical implications and the function of a peer review", Clin. Pharm. Therap. 13(5) 782 (1972), at p. 785.

661. D.C. Martin *et al*, *supra*, note 129, at p. 1428, Table 1.

662. P.B. Meyer, *op. cit.*, note 631, at p. 58.

663. See: D.C. Martin *et al*, *supra*, note 129, at p. 1427; P.B. Meyer, *ibid.*, pp. 10-15; L. Lasagna, "Special Subjects in Human Experimentation", in

"Freund ed.", *op. cit.*, note 6, p. 262, at pp. 264-5, who says prison volunteers become "the elite of their own society". Is this, in itself, a coercive element, especially when there is peer group pressure on individual members by this elite, to conform to the regime of the experiment? See F.J. Ayd *supra*, note 301, at p. 777.

664. See P. Freund, "Ethical Problems in Human Experimentation", N.E.J.M. 273(13) 687 (1965), at p. 691.

665. W.G. Todd, *supra*, note 80, at p. 811.

666. Fed. Reg. 14th Jan 1977, 3078.

667. *Ibid.*, 3080, Recommendation 3C, Comment (iii).

Note that the requirements recommended by the United States "National Commission" in this respect, are very specific and include seventeen separate headings such as single occupancy cells, private toilets, etc.

668. *Ibid.*, Comment (iv).

669. Fed. Reg. 14 Jan. 1977, 3079.

670. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 65.

671. See for example: *Mackey v. Procunier* 477 F. 2d. 877 (9th Circ. 1973); *Knecht v. Gillman* 488 F. 2d. 1136 (8th Circ. 1973).

672. *Criminal Code* R.S.C. 1970 c-34, as amended by R.S.C. c.11 (1st Supp.); R.S.C. 1970 c.2 (2nd Supp); S.C. 1972 c.13; S.C. 1973-74 c.50.

Note that the Code abrogates all common law offences, section 8(a), but retains any "rule and principle of the common law that renders any circumstance a justification or excuse for an act or a defence to a charge", "except . . . as . . . altered by or inconsistent with this Act or any other Act of the Parliament of Canada", section 7(3).

Also note that under the *British North America Act* 1867 30-31 Victoria c. 3, section 92(15), the provinces have some incidental criminal jurisdiction. This is exercised, for example, in *The Human Tissue Gift Act* of Ontario (cited *supra*, note 283) section 13, which provides that a person knowingly contravening the Act is liable to a fine or imprisonment.

In fact this is the same situation, with respect to division of criminal jurisdiction, as pertains in the two other federal systems, the United States of America, and Australia, except that in these latter two general criminal jurisdiction is vested in the states and only criminal jurisdiction incidental to the specific heads of power of each of the federal governments, is vested in them.

673. United States Constitution Article I § 8.

The Constitution 63 and 64 Victoria, c. 12. *An Act to constitute the Commonwealth of Australia* section 51.

674. *Crimes Act* 1914 — 1973 (Cwth. Australia).

675. Note that even when the criminal law has been codified, the common law still plays a part, for example in interpretation of the elements of an offence.

For a comprehensive account of criminal law in Australia, see: C. Howard, "Australian Criminal Law", Sydney, Australia; The Law Book Co., 1970.

676. See W.R. LaFave and A.W. Scott, "Handbook on Criminal Law" St. Paul, Minn; West Publishing Co., 1972, at p. 3.

677. *Ibid.*, at p. 57.

678. See J.C. Smith and B. Hogan, "Criminal Law", 3rd ed., London; Butterworths, 1973.

679. For example, *Offences against the Person Act* 1861 24 and 25 Vict. c. 100.

680. P. Lombard *et al*, *op. cit.*, note 78, at pp. 126 and 132-3.

681. *Ibid.*

See also: J. Penneau, *op. cit.*, note 225, at No. 265.; G. Boyer Chammard and P. Monzein, *op. cit.*, note 56, at p. 71.

682. G. Boyer Chammard and P. Monzein, *ibid.*, at p. 73.

683. Cited *supra*, note 672.

684. I submit that the wording of section 198, "surgical or medical treatment . . . or any other lawful acts . . .", implies that such treatment is lawful. *Cf.* situation at Common Law, discussed *infra*, p. 106. (It is necessary, here to add a 'caveat'. Probably the more accepted interpretation of section 198 is that it does not affect the 'prima facie' legality or illegality of a medical intervention, rather it constitutes a *defence* to an act which would otherwise carry criminal liability, because the act in question falls within the parameters of an offence legislated in the *Criminal Code*. In my view the interpretation I have suggested is preferable, but this depends on the phrase "any other lawful acts" qualifying "surgical or medical treatment", which historically was probably not intended in drafting the legislation, as the former phrase was meant to cover acts, other than medical ones, which were dangerous but lawful. See H.E. Taschereau, "The Criminal Law Consolidation and Amendments Acts of 1869, 32-33 Vict. for the Dominion of Canada", Vol. I & II, Montreal; Lovell Printing and Publishing Co., 1874, at Vol. I, p. 204.)

685. Note that there is no requirement for consent of the patient, but, I suggest, this may be implied into the requirement of "reasonable care", in sections 45 and 198. There is, however, a historical difficulty with this interpretation, as shown by B. Starkman (*supra*), note 18, at pp. 5-6) who analyzes Stephen's Digest of Criminal Law, 1st and 4th eds. Macmillan & Co., London, 1877, 1887, on which these sections are based, and who concludes that *section 45* was only intended to cover emergency situations where the patient was incapable of consent.

686. See G. Dworkin, *supra*, note 524, at pp. 356-7.

687. For example, B. Starkman, *supra*, note 18, at p. 47, says as far as he was able to ascertain there has never been a criminal charge resulting from medical experimentation laid in Canada.

688. See for example, *Strunk v. Strunk*, cited *supra*, note 53, at pp. 147-8, where the Court requires "benefit of such persons as are incapable of protecting themselves" to authorize an organ donation operation, but makes no mention

of benefit when referring to the "common clinical practice" "of transferring tissue from one human being to another".

689. See P. Lombard *et al*, *op. cit.*, note 78, at p. 128; G. Boyer Chammard et P. Monzein, *op. cit.*, note 56, at p. 175.

690. G. Levasseur, *supra*, note 402, at p. 140. (Emphasis added)

691. *Ibid.*, p. 139.

692. Article 327 *Code pénal* (France).

693. See for example, *Offences against the Person Act* 1861 (United Kingdom), cited *supra*, note 679, section 20.

694. For example *Criminal Code* (Canada) cited *supra*, note 672, section 244.

695. See for example: *Mathew v. Ollerton* 90 Eng. Rep. 438; Comberback 218 (1693), where the court held a licence by a person to beat him was void as being *against the peace*.

696. It is possible that the practice (or rather malpractice) of medicine could pose threats to the community. See, for example, G. Levasseur, *supra*, note 402, at p. 138: "Le bien des citoyens conditionnant le bien de l'État, les pouvoirs publics se doivent d'accorder au bon exercice de la profession médicale: facilités, encouragements, récompenses, garanties de qualité et succès. Il leur appartient d'assurer pas des mesures appropriées . . . la sauvegarde de la santé publique, qui doit être un de leurs soucis majeurs."

More generally see: *Spead v. Tomlinson* 73 N.H. 46, 59A. 376 (1904), which held the state has a right and duty to secure the well-being of all and, to this end, can impose duties which are then owed to the state and not to the individual for whose benefit they are imposed. This approach shows why the consent of the individual is not a defence to a criminal charge as the individual does not have the power to waive the duty owed to the state; J. Penneau, *op. cit.*, note 225, at No. 327, who says juridical liability expresses society's reprobation of the transgression of one of its rules, which are necessary to the *moral equilibrium* of the *group*.

697. See G. Dworkin, *supra*, note 524, at p. 355, who discusses the old Common Law crime of mayhem (maim), which was committed when a person so injured another as to make him less able to fight, or to defend himself, or to annoy an adversary. The act was illegal because it *deprived the king of a fighting man* — that is on the basis of community interest or public policy.

698. See for example *Bravery v. Bravery* [1954] 3 All E.R. 59, where Lord Justice Denning held that a sterilization operation on a man was unlawful even though he consented, there being "no just cause or excuse" for it and that it was "plainly injurious to the public interest". The "mores" that this judgment reflects may have changed in England. Also note that the characterization of unlawfulness is based on injury to the society, and that the procedure is then not justified by consent of the patient, but rather by the procedure being undertaken "for the sake of a man's health". Assuming that there are justifications other than therapy for some medical interventions, (for example benefit to the community) this raises the issue of the lawfulness of non-therapeutic human experimentation in the form of the question: does the good to society ever justify the injury to the public interest perpetrated by using humans as experimental subjects, and if so, when? That is, consent is

necessary to but not determinative of, the lawfulness of such an intervention, as it is the public interest which is being protected by the criminal law in protecting the individual.

699. See for example: F.H. Beale, *supra*, note 272: "Notes 'Sale of Human Body Parts'", *supra*, note 274, at p. 1238.

For an excellent recent discussion of this matter see: A. Rubenstein, "The Victim's Consent in Criminal Law: An Essay on the Extent of the Decriminalizing Element of the Crime Concept", in E.M. Wise and G.O.W. Mueller, eds., "Studies in Comparative Criminal Law", Illinois; Charles C. Thomas, 1975, at pp. 189-210; G. Levasseur, *supra*, note 402, at pp. 140-1, who says a person cannot confer on another the right to attack his physical integrity. That is consent is necessary, except in special circumstances, but it is not a sufficient justification in French Law for an act constituting civil or penal fault — in other words it is not solely determinative of legality.

700. See for example, *Criminal Code* (Canada), cited *supra*, note 672, section 14.

701. W. Blackstone, "Commentaries", *op. cit.*, note 491, at 4:205-8; H. Roxburgh, "Experiments on Human Subjects", (1963) 3 Medicine Science and the Law, 132, at pp. 135-6.

702. The word "self-inflicted" should, I suggest, be read in the sense of meaning the injury was willingly sustained, rather than meaning the act of infliction was carried out by the person themselves.

703. A. Rubenstein, *supra*, note 699, at p. 200.

704. *R v. Clarence* (1888) 22 Q. B.D. 23: *Papadimotropoulous v. R* (1957) 98 C.L.R. 249.

See: B. Dickens, *supra*, note 62, at pp. 395-6, who discusses the effect of mistake on consent, when the latter is relevant for criminal law purposes. Simply stated, mistake will not vitiate the consent, unless it is as to the nature of the act and not just its consequences.

705. B. Starkman, *supra*, note 18, at p. 43.

Note that Article 204 of Stephen's Digest, *supra*, note 685, provides that: "Everyone has a right to consent to the infliction of any bodily injury in the nature of a surgical operation upon himself or upon any child under his care, and *too young to exercise* a *reasonable discretion* in such a matter . . . " Stephen appended a footnote that he "knew of no authority for these propositions, but . . . they require none". The former statement recognizes the capacity of a child capable of discretion to consent for himself and implies that he must do so for criminal law purposes.

It was a defence at common law if a minor of the age of discretion consented to a criminal offence that required the absence of consent to constitute the offence. See Starkman, *ibid*.

706. See for example: *Criminal Code* (Canada) *supra*, note 672, sections 21, 22, 421, 422, 423: C. Howard, *supra*, note 675, at pp. 250-86.

These criminal offences arising from ancillary responsibility would apply generally to any medical situation recognized as involving criminal activity, not just to those where the involvement arose from giving "proxy" consent.

707. For example *Cal. Penal Code* § 273(a) West 1970, which provides it is a misdemeanor to endanger a minor's health or subject him to unjustifiable physical or mental suffering.

708. See, for example, *An Act respecting the protection of children subject to ill-treatment, supra*, note 566.