

**INSTITUTE OF NEUROSCIENCES,
MENTAL HEALTH AND ADDICTION**
INMHA-CIHR Workshop on Neuroethics

November 8th and 9th, 2002

**Delta Chelsea Hotel
Toronto, Ontario**



*Towards establishing priorities for funding and
setting a research agenda for ethics in Canada*

DRAFT WORKSHOP REPORT

The mission of INMHA is to foster excellence in innovative, ethically responsible research in Canada in the areas of neurosciences, mental health and addiction. The mandate of the Institute also includes the senses, notably vision, hearing and pain. The Institute is committed to the support of excellence, scientific integrity and ethics in research that meets the highest international standards.

In a major step towards achieving its mission the Institute invited 39 experts from across North America to participate in a groundbreaking Workshop on Neuroethics held at the Delta Chelsea Hotel in Toronto, Ontario on November 8th and 9th. Ethicists, scientists and philosophers were joined by a selected number of senior representatives of government, industry and Canadian NGO's as well as several members from the Institute's Advisory Board.

The two-day agenda was structured to be informative and educational while at the same time allowing for meaningful dialogue and a lively exchange of views. The format featured Plenary Lectures followed by smaller Round Table discussions and plenary sessions in each of the three major themes.

This report serves as a synopsis of the key findings, themes and issues identified throughout the course of this historic two-day initiative. The Institute will use detailed notes from the Round Table discussions and the ensuing plenary sessions as it charts its next steps in these strategically important areas.

According to the evaluations, the following Plenary Lectures were successful in setting the stage for enthusiastic and at times heated debate on the issues and the next steps for INMHA in ethics.

Dr. Laura Roberts, M.D. – University of New Mexico Health Sciences Centre – Institute for Ethics
"Evidence-Based Ethics – Imperatives in Mental Health"

Dr. Jurgen Rehm, Ph.D. – Centre for Addiction and Mental Health and the Addiction Research Institute
"Ethical Aspects in Addiction Research and Interventions"

Dr. Jonathan Moreno, Ph.D. – University of Virginia – Centre for Biomedical Ethics
"Ethics in Neuroscience"

PURPOSE OF THE WORKSHOP

The purpose of the Workshop was to identify key areas of research in ethics in neurosciences, mental health and addiction, and to provide advice and direction to the Institute in the development and structure of future funding initiatives in ethics. This report reflects the progress made by Workshop participants in addressing these two fundamental goals. Part 1 of this Report focuses on the ethical issues and challenges identified by participants as having the highest priority for funding and development. It was not intended that the lists comprehensively describe all ethical challenges within each of the areas. Rather, they are a compilation of those issues and problems, identified by this expert panel, as priority areas of research. Part 2 of this Report describes participants' recommendations as to themes and principles to guide the development, formulation, and refinement of the Institute's future funding programs in ethics.

FRAMEWORK FOR DISCUSSION AND DELIBERATIONS

Four questions served to guide participants and stimulate discussion over the course of the two-day Workshop during Round Table and Plenary sessions.

1. In the next 5 to 10 years, what are the most important ethical issues requiring research?
2. What important ethical issues are emerging because of scientific advances and/or social developments?
3. What empirical questions need to be answered and what evidence or data is needed to help address these important ethical issues?
4. What are the most important ethical challenges, amenable to future research, arising from interactions and co-morbidities?

Moreover, the Scientific Director of INMHA, Remi Quirion, PhD, challenged all participants in his opening remarks by asking them to focus not only on the more traditional issues but also to think of emerging challenges in 'NeuroEthics'. A particular emphasis was placed on issues related to enhancing brain functions, legal uses on neuroscience-derived information, and brain reading or brain fingerprinting. INMHA wishes to support innovative research on ethics on these issues, many of which are of more immediate concern than gene therapy of complex CNS disorders.

PART 1 – IDENTIFICATION OF PRIORITY AREAS OF RESEARCH

Issues Relevant To Research Ethics Broadly:

In the course of discussions, participants identified a number of issues relevant to research in ethics generally. While the focus of research supported by the Institute is within the specialized areas of neurosciences, mental health and addiction, discussion of less specific ethics priorities provided a helpful context for the more targeted discussions that followed.

⇒ Ethical Standards of Research

- The influence of industry on investigators and research institutions -- describing and managing conflicts of interest
- Ethics and justice in international research
- The appropriate involvement of patients in research
- Conceiving research as a community based enterprise

- Exploring how social attitudes shape the research agenda
 - The influence of advocacy groups on society's research agenda
 - Care of non-human research subjects -- animals. What are appropriate standards for care, monitoring, risks, etc?
- ⇒ Research Ethics Boards: Governance and Process of Review
- Monitoring on-going research and standards for requiring on-going consent
 - Ethical and scientific training of REB members
 - Description and process for REB decision-making
 - Standards for scientific review
 - Conceptual and practical issues in the way that risk is assessed, perceived, and communicated
- ⇒ Allocation of scarce resources
- The role of community input – who should decide? Who should participate?
 - Establishing ethical norms of priority setting
 - Use of economic models to determine resource allocation
 - Balance of focus on treatment vs. rehabilitation (with rehabilitation traditionally de-emphasized)
- ⇒ Privacy: Balancing the protections of privacy with beneficial uses of clinical/research information
- Individual rights vs. the good of the community
 - Electronic databases and tissue banks
 - Third party access to information
- ⇒ Decision-Making Capacity: Conceptualization and Assessment
- The cultural or community context in concepts of autonomy and decision-making capacity
 - The Relationship of determination of capacity to level of risk?
 - The appropriate role for a substitute decision-maker in research
 - The appropriate use of models or tools to assess capacity.
 - Decision-making when capacity is lost.
- ⇒ Aboriginal Health Care
- Access to health care
 - Understanding the social structure of aboriginal communities and traditional conceptions of illness and cure
 - Mental Health care and addictions in an increasingly urban population
 - Consent issues involving collective populations
- ⇒ Education and Training
- What are the best strategies for training researchers and clinicians in ethics related to topics covered by INMHA? What are their perceived needs?
- ⇒ Issues relating to the media
- Exploring the ways that ethical, particularly genetic and drug enhancing, issues are reported
 - Scientists' interactions with the media

Issues Relating Primarily To Mental Health

Dr. Laura Roberts of the University of New Mexico led off the discussion with a plenary lecture reflecting her extensive work in mental health ethics and research ethics. One significant focus of her presentation was to describe and encourage mental health research using empirical methodologies, as an adjunct to, and as grounding for, conceptual and philosophical work. A lively discussion followed, with participants both endorsing a prominent role for empirical research in ethics but also underscoring the importance of theoretical research that both describes and challenges existing social structures and norms.

Following is a list of priority areas within mental health ethics:

- ⇒ Stigmatization, discrimination and disenfranchisement of persons with mental disorders
 - Housing, education and income support.
 - Access to services and delivery of mental health services
 - Acknowledgment that these are "real illnesses"
 - The impact of stigma on obligations of confidentiality

- ⇒ Decision-making capacity: Can persons with mental illness:
 - Understand and assess risks appropriately?
 - Understand the difference between research and ordinary clinical care?
 - Understand the implications of various kinds of study design?

- ⇒ Suicide
 - The ethics of intervention vs. a right to suicide
 - Confidentiality and protecting information about suicidal acts and feelings

- ⇒ Cultural, social, gender, age, religious and other contextual elements attending mental health care and research

- ⇒ Social and individual implications of using biochemical vs. psychosocial treatment modalities

- ⇒ Medicalizing social or behavioural problems

- ⇒ Standards for informed consent to psychotherapy

- ⇒ Forensic psychiatry
 - Understanding mental health issues facing the aboriginal population in the criminal justice system, and ensuring access to appropriate treatment
 - Access to treatment for young offenders within the criminal justice system

Issues Relating Primarily To Addictions

Dr. Jurgen Rehm offered a broad ranging discussion of ethical issues in the area of addictions. In doing so, he challenged Workshop participants to think about the distinction between ethical issues and purely scientific ones. There was agreement that this distinction is important but can be difficult to draw in a conceptually rigorous way.

The discussions that followed identified the following key areas of research and addiction ethics:

⇒ The nature of addictive illness

- How is addiction treated differently than other disorders? Should it be? Is there a "double standard?"
- What is the ethical significance of the influence of social factors in addictive behaviours?

⇒ Coercion and Consent

- Understanding and describing the sources of coercion in drug treatment and research
- Understanding the ethical implications of the varieties of coercion
- Is coercive treatment of addictions justified?

⇒ Challenging treatment paradigms in addiction

- The medicalization of addiction -- are all addictions treated the same?
- Are differing social attitudes between different addictions appropriate? How do differing social or cultural conceptions of addiction affect appropriate treatment strategies for treating addiction?
- What is the role of the severity of addiction in treatment and in our social understanding of the phenomenon
- Addiction as a biopsychosocial condition
- Harm reduction vs. abstinence approaches; e.g. maintenance treatment or needle exchange vs. abstinence

⇒ Challenging research paradigms in addiction

- What is the effect of disproportionately lesser funding for addiction research? What are the individual, social, and group effects of underfunding?
- Do social views of addiction and addiction research affect the acceptability of certain study designs?
- Do some ethical norms penalize research on addictions?

⇒ Responsibility for addictive behaviours

- What is the appropriate understanding of responsibility, accountability, and autonomy in the context of addictions?
- Is a medical model appropriate for the understanding of addictive disorders?

⇒ Stigma and Discrimination

- Describing and understanding the stigma felt by persons with addictions and the common social view of addicts as morally inferior persons. How are such social values translated into ethical norms?
- Stigma resulting in vulnerability for persons with addictions
- Are addiction treatment programs adequately evaluated and are patients properly matched to treatment program?
- What accounts for the unequal treatment of persons with addictions e.g. access to liver transplantation and Hepatitis C treatment?

⇒ Other Research issues

- Should persons with addictions be compensated for research involving the addictive behaviour in question?

- Should persons with addictions be included in non-treatment research, where there is no reasonable likelihood of benefit?
- Can persons with addictions give voluntary consent to participate in treatment or research while under the authority of a drug court?

⇒ Decision-making Capacity

- How should we understand and assess decision-making capacity for research or treatment in persons with addictions?
- Under what circumstances is surrogate decision-making to treatment or research appropriate in addictions?

⇒ Forensic issues

- Appropriate standards for drug treatment programs in prison
- Consent, capacity, confidentiality and other issues arising under drug court program
- Appropriate to sentencing in response to addiction-related criminal behavior
- Understanding the aboriginal population and addictive behaviors in the criminal justice system.
- Fetal alcohol syndrome and the responsibility of the mother

Issues Relating Primarily To Neuroscience

Dr. Jonathan Moreno, in his plenary lecture on ethics in neuroscience (or neuroethics), offered a philosophical perspective drawing upon historical sources to help make sense of issues relating to the exciting new knowledge and technological advances in neuroscience. He challenged participants to look at traditional sources of wisdom in assessing the relationship between brain structure and function on one hand, and behaviour, personality, and responsibility on the other.

The following issues were identified in the discussions that followed:

⇒ Implications of technology

- Understanding correlations between brain and behaviour
- The effect of technological advance on privacy. Will technology allow the monitoring of behaviours, traits, and predispositions?
- Access to insurance based on neuroscientific information?
- Are there some boundaries beyond which we should not go? If so what are they?
- The use of neurogenetics to make pre-implantation diagnoses and other predictions about personality or other behavioural traits
- Using our understanding of the brain structure and activity to make predictions about personality or behavioural traits

⇒ Understanding illness: mind and brain

- Once we understand how behaviours correlate with particular brain functions, how should we understand such concepts as free will, responsibility, criminality and dignity?
- What are the implications of having knowledge of brain functions, and how should this knowledge be used?
- What is the danger of reductionism in neuroscience? Do we risk ignoring social and environmental factors in understanding the causality of mental functions?
- Are we in danger of privileging the observable or measurable over the subjective?

- Understanding the distinction between neurodegenerative disorder and the associated "mental element"
- How will our expanding knowledge of neuroscience affect our conceptions of the self and personal identity?
- Can we better understand ethics itself through advances in neuroscience?

⇒ Modifying brain function

- How is enhancement different from treatment, and when is either ethically acceptable?
- Does it matter if the benefit of enhancement flows primarily to the individual or to the common good?

Cross-cutting Issues In Neurosciences, Mental Health and Addiction

Participants stressed the importance of interdisciplinary research, including research that touches each of these disciplines. Certainly as the science of neuroscience, mental health and addiction develops, the connections and interrelationships become more pronounced. It is fundamentally important to view ethical questions in broader contexts that challenge traditional modes of thinking and traditional silos and disciplinary boundaries. Participants identified the following priority issues as cross-cutting, or interdisciplinary, in this way:

⇒ Challenging Paradigms

- The nature of disability in the context of neurosciences, mental health, and addiction
- Understanding and describing the nature of vulnerability, and whether and how vulnerability may be measured
- Understanding and describing the role of emotion and reason in ethical decision-making

⇒ Genetics

- Enhancement and modification through genetic intervention.
- Using genetic tests or screening to predict behaviour, including criminal and anti-social behaviours
- Understanding and communicating genetic risk, including employment and insurance risks
- Consent for genetic testing or screening within groups
- Establishing standards for counseling persons being tested and their family members
- Genetic reductionism; genetic essentialism; genetic determinism

⇒ Pharmacological Enhancement of brain functions and behaviours

- Enhancements of mental functions such as mood, cognitive abilities (attention and memory) and personality traits
- Impact that drugs and CNS interventions may have on society's conception of normal
- potential side effects of enhancement, including long term and delayed effects
- The equitable distribution of enhancement
- Impact of enhancement on our conceptions of what is normal

⇒ Research Ethics Boards: Standards of Review and Assessment

- Appropriate standards for reviewing protocols involving vulnerable subjects, e.g. children, the mentally ill, those with risk of suicide, dementia
- Understanding and assessing the notion of minimal risk

- Appropriate standards for determining decision-making capacity in persons with mental illness and brain disorders
- ⇒ Brain Reading (Fingerprinting)
- The use of MRI, PET scan, EEG to visualize brain regions associated with particular behaviours or traits such as violence, gambling and addiction, memory, sensitivity to stress, lying etc.
 - Impact on insurance, employment, legal processes, counter-terrorism measures and immigration

PART 2 – THEMATIC AND STRUCTURAL CONSIDERATIONS IN SHAPING THE RESEARCH AGENDA

Thematic Considerations in Research

Throughout the course of the three Round Tables and Plenary sessions several major themes emerged that crossed the three streams of neuroscience, mental health and addiction. These themes identify important dimensions of the priority research areas described in this Report.

- ⇒ Cultural dimensions of ethical reasoning: The examination of ethical issues within a contextual framework that assumes dominant cultural values is too narrow and may be insensitive to the distinct cultural and social values held by a significant proportion of the Canadian population. With this in mind, participants stressed the importance of:
- Examining cultural issues as they apply to all areas of research
 - Examining how health issues are treated differently in different social or cultural contexts
 - Exploring how culture affects science?
 - Taking account of different cultural approaches
- ⇒ Spirituality, Religion and Consciousness: Modern brain sciences often ignore these important elements. Within the context of research in neurosciences, mental health and addictions, it will be important to develop a framework and strategy for examining spirituality, religion and consciousness.
- Examining the impact of spiritual beliefs in treatment of mental illness and addictions
 - Exploring neurobiology of religion and spirituality (Neurotheology)
 - Examining altered states of consciousness and their linkage to neurosciences, mental health and addictions
- ⇒ International participation: Research must reflect the increasingly global nature of health care, health care research, and scientific advance. No nation, or research community, can afford to turn its back on the extraordinary amount to be learned from international consultation and collaboration. At the same time, we must be mindful of the obligations that developed nations owe to those at different stages of development. In this regard, participants noted that:
- International research must be encouraged but subject to close scrutiny.
 - There is a need for comparative legal analysis of international laws relating to health care.
 - Policies and research methodologies must be international in scope.
- ⇒ Ensuring an appropriate balance between the rights of individual and those of society/community: While this tension is a key facet of most ethical analysis, it is important to recognize the variety of

socially distinct communities, cultural or otherwise. The individual's relationship with communities depends critically on the nature of the society or community in which she or he lives. Accordingly, there is a:

- Need to balance rights of individual with good of community e.g. First Nations
- Need to understand different conceptions of autonomy: individual vs. society's concept

⇒ Allocation of resources: There will never be adequate resources for all of society's health care needs, so some allocation, or priority setting, will always be necessary. How can this be done fairly?

- What factors are used in determining who gets treatment?
- How do we decide on allocation of resources to particular disease or intervention?

⇒ Interdisciplinary research: Repeatedly, participants stressed the importance of bringing together researchers and scholars from various disciplines. There is no substitute for viewing questions, issues and problems from a broad range of perspectives. The Institute was urged to:

- Include specialists from other fields
- Seek out interdisciplinary research opportunities
- Encourage CIHR research programs to promote an interdisciplinary approach

⇒ Emerging Issues in Neuroethics

- Enhancements of normal functions
- Court-ordered CNS intervention
- Brain reading (fingerprinting)
- Altering brain function under court-ordered rehabilitation (Forensic)

Structural Considerations in Developing Funding Initiatives

The Institute was strongly urged that funding initiatives should have the following features:

⇒ Collaboration

- Link with colleagues nationally and internationally to share expertise, methods, and perspectives

⇒ Integration

- Integrate ethics into existing clinical, community, and research endeavours

⇒ **Impact**

- **Give priority to research where findings could provide an empirical basis for resolving immediate and pressing ethical concerns that currently influence the conduct of research, for example, research on obtaining informed consent from persons with mental illness.**

⇒ Commitment to the future

- Encourage groups that are well-positioned to pursue research and training initiatives
- Build relationships with communities
- Reward forward-thinking and innovative work
- Nurture multidisciplinary and early career scientists

- Provide training in ethics for scientists, clinicians and others
- ⇒ A proper balance between empirical and theoretical research
 - “Empirical ethics can be a vaccine against ideology, but can also be a disguise for ideology”
- ⇒ A fair peer-review process
 - Push for high calibre committees that include community and international member(s)