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Research Ethics Board's Operational Policy Framework

**ETHICS REVIEW OF RESEARCH
INVOLVING HUMAN SUBJECTS**

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1. ABOUT THIS POLICY FRAMEWORK

This Operational Policy Framework of the Research Ethics Board (REB) was approved by the Deputy Minister (DM) of Health and the Chief Public Health Officer (CPHO) of the Public Health Agency of Canada (PHAC) in 2010. However, since research ethics is a continually evolving subject matter, this Policy Framework may be modified from time to time. It is the responsibility of all researchers and other readers to ensure that they are using the most recent version. The Policy Framework should be read in conjunction with the REB's Administrative Procedures Manual which provides important information on the procedures adopted by the REB for reviewing research applications.

2. AUTHORITIES

In April 2006, Health Canada and PHAC entered into a Memorandum of Understanding that gave Health Canada's REB the mandate to conduct ethics reviews of PHAC research projects involving human subjects.

In the Fall of 2009, an agreement was reached between officials from Health Canada and PHAC for the establishment of a joint REB. On April 1, 2010, the REB will become fully operational as a joint REB for both institutions. The REB Secretariat will be responsible for managing and communicating with the REB members on all research protocols received for ethics review from both institutions.

2.1 Empowering Authority

The REB derives its legitimacy from authority delegated by the DM and CPHO. For the sake of transparency, the following information shall be kept public at all times: the REB's terms of reference, membership, policy framework and administrative procedures.

2.2 Appointment of Members

The DM and CPHO will jointly appoint all REB members and alternate members to the REB, including the Chair.

2.3 Decisional Authority

The DM and CPHO may delegate their decisional authority functions to a senior official within Health Canada and PHAC respectively, each of whom will be referred to as the "Decisional Authority in Research Ethics" (hereinafter Decisional Authority).

3. MANDATE AND SCOPE

3.1 Mandate of the REB

The REB shall serve as an independent Board to help ensure that all proposed or ongoing research involving human subjects carried out by, funded by, or otherwise under the auspices of Health Canada or PHAC, meets the highest ethical standards, and that safeguards are implemented to provide the greatest protection to human subjects. It will make recommendations as to whether research projects should be approved, rejected, modified, or terminated. The REB shall review applications in accordance with the considerations set forth in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*¹ (TCPS) as the minimum standard.

3.1.1 Definition of Research

For the purposes of this REB, research shall be defined as an activity designed to test a hypothesis, permit conclusions to be drawn and develop or contribute to generalizable knowledge, using scientific methods and standardized protocols. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. In the present context “research” includes both medical and behavioural studies pertaining to human health.

3.1.2 Definition of Human Subjects

The involvement of human subjects is required where progress in medical care and disease prevention depends upon an understanding of physiological and pathological processes or epidemiological findings. The collection, analysis and interpretation of information obtained from research involving human subjects contribute significantly to the improvement of human health. Research involving humans as “research subjects” includes research with

- Living individuals;
- Human remains, cadavers, embryos or fetuses;
- Human biological materials such as tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, hair, nail clippings, faeces, urine, saliva and other body fluids; and
- Information from or about humans, such as information obtained through surveys, and from records of nonliving humans that are not in the public domain.

3.2 Scope of the REB

The REB shall review all research involving human subjects as defined above in circumstances where the research is:

¹ Medical Research Council, Natural Sciences and Engineering Research Council, Social Sciences and Humanities Research Council of Canada (1998) *Tri-Council Policy Statement Ethical Conduct for Research Involving Humans*.

- Carried out by Health Canada or PHAC employees in the course of their employment;
- Carried out on Health Canada or PHAC premises, or involves technical or consultation support including the use of equipment, laboratories or other facilities belonging to HC or PHAC;
- Undertaken in a collaboration or partnership between Health Canada or PHAC and external researchers;
- Funded internally or externally through Health Canada or PHAC grants and contributions; or
- Carried out under contract with Health Canada or PHAC.

Further, such research is subject to REB review whether :

- The funding is internal or external;
- The research is conducted inside or outside Canada;
- The subjects are compensated or not;
- The research is conducted by staff or by students;
- The research is conducted in person, remotely (e.g. by mail, electronic mail, fax or telephone) or uses previously collected data/samples and requires no direct contact with subjects;
- The research is to be published or not;
- The research is observational, experimental, correlational or descriptive;
- The research has been reviewed by another REB;
- The research is a pilot study or a fully developed project;
- The research aims to develop basic or applied knowledge; or
- The research is primarily for teaching or training purposes.

3.3 Situations Where REB Review May be Required

3.3.1 General

Some boundaries between research and non-research activities may be difficult to define. As a general rule, whenever there is uncertainty as to whether a proposed activity requires REB review (as in the situations outlined below or otherwise), the following offices should be consulted:

- For Health Canada: the REB Secretariat;
- For PHAC: the Public Health Law and Ethics Program.

3.3.2 Surveillance

Surveillance is often defined as the systematic ongoing collection, analysis and interpretation of health data that is essential to the planning, implementation, and evaluation of public health practice and closely integrated with the timely dissemination of the data to those who need to know. The final link in the surveillance chain is the

application of the data to disease prevention and control. A surveillance system includes a functional capacity for data collection, analysis and dissemination linked to public health programs. Not all surveillance activities may require an ethics review by the HC and PHAC REB. However, since this determination can only be made on a case-by-case basis, the advice of the REB should be sought.

3.3.3 *Supplemental Services*

Health Canada and PHAC officers often receive requests to provide analytical services for research projects led by external research teams. For example a Health Canada or PHAC scientist may be asked to analyze anonymous or anonymized human biological material samples without engaging in their collection. Normally, requests for such supplemental services will require a REB review. However, the component of the project to be undertaken by Health Canada or PHAC may not require an ethics review/approval by the REB in instances where the following three conditions are met:

- The officer's activities in the project consist solely of performing an analytical service;
- Health Canada and/or PHAC is not involved in the collection of the data or biological material; and
- Health Canada and/or PHAC do not plan to be acknowledged or be a partner/co-author in the publications resulting from the project.

In all instances, however, the REB Secretariat or the Public Health Law and Ethics Program should be consulted in all instances.

3.3.4 *Quality Assurance*

Quality assurance is a system that aims to:

- Evaluate and review the quality of a program, service, or a product within a particular institution;
- Identify problems or deficiencies in design or delivery;
- Design activities and procedures to overcome these deficiencies; and
- Monitor the effectiveness of corrective measures.

If the project has any element of research (for example, if it uses a novel approach) an ethics review shall be required by the REB. However, quality assurance that is conducted in a routine or usual manner does not require REB review so long as the following three conditions are met:

- It is intended solely for internal use within an individual institution;
- It only measures the integrity of the functions delivered by the organization or performance of staff internal to the institution while carrying out their duties and responsibilities; and
- It is not intended to contribute to generalizable scientific knowledge about treatments and procedures by being published.

3.3.5 *Analysis of Publicly Available Data*

REB review is generally not required for research involving public policy issues even though these might well involve human subjects.

4. MEMBERSHIP

4.1 Full Membership

The REB will consist of at least nine members. These include the Chair and a Deputy Chair to be named by the Chair.

The REB membership shall include:

- At least three members with broad expertise in the methods of Health Canada or PHAC research: one from outside Health Canada and PHAC, one from Health Canada, and one from PHAC;
- At least two members who are knowledgeable in ethics;
- At least one member who has broad expertise in public health;
- At least one member who is knowledgeable in the relevant law; and
- At least two members who have no affiliation with Health Canada or PHAC, one recruited from the community served by Health Canada and PHAC, and another recruited from the Aboriginal community.

These membership requirements are designed to ensure that the REB has the expertise, independence and multidisciplinary background essential for competent research ethics review. The REB should also reflect gender and official language dualities as well as Canada's geographical and ethnic diversity.

Although the REB community representatives may have some knowledge of human subject research as members of the public, their role is to bring a different perspective from that of individuals who work in the field of human research.

4.2 Alternate Membership

Article 1.3 of the *TCPS* provides that institutions should also consider the nomination of substitute REB members so that Boards are not paralysed by illness among its members or other unforeseen events. The use of alternate members should not, however, alter the membership structure as outlined in this section and in the *TCPS*.

Alternate membership of the REB shall consist of:

- Three members with broad expertise in the methods of research conducted by Health Canada/PHAC: one from outside Health Canada/PHAC, one from Health Canada, and one from PHAC;
- One member who is knowledgeable in ethics;
- One member who has broad expertise in public health;

- One member who is knowledgeable in the relevant law; and
- Two members who have no affiliation with Health Canada/PHAC, one recruited from the community served by Health Canada/PHAC, and another recruited from the Aboriginal community.

Alternate members shall be invited to REB meetings on a rotational basis. They may participate in the discussion of the research application but may not participate in the final decision of the Board. When a REB member is unable to attend a meeting and an alternate member attends in that member's place, the alternate member may participate fully in the decision-making of the Board.

4.3 Appointment

REB members, alternate members and the REB Chair are appointed by the DM and the CPHO for a three-year term. Their terms of membership may be renewed to ensure the continued availability of qualified members on the REB.

The REB Secretariat shall provide to the REB members and alternate members an orientation guide to Health Canada and PHAC, a description of the responsibilities of the REB, and ongoing training.

5. ROLES AND RESPONSIBILITIES

5.1 Decisional Authority

The Decisional Authority of Health Canada or PHAC shall be responsible for the implementation of Health Canada or PHAC's research ethics policy, respectively, and shall have the following responsibilities in particular:

- Directing, in writing, that researchers must submit their proposals to the REB if they have not done so;
- Conveying, in writing, the REB recommendations and his or her decisions to the Principal Investigator (PI);
- Directing, in writing, that the research be suspended if it has not received an ethics review or if there is reason to believe it is proceeding contrary to the recommendations of the REB;
- Promptly advising the DM or CPHO, as the case may be, of serious adverse events, and the suspension or termination of an approved research project, as recommended by the REB, providing a statement of the reasons for the action taken; and
- Reporting annually to the DM/CPHO on the REB's activities and recommendations.

5.2 REB Chair

The REB Chair shall be responsible for the overall management of the REB and its ethics review process. The duties of the Chair shall include:

- Chairing the meetings;
- Determining if proposals are suitable for expedited review;
- Reaching a decision on whether to recommend that the Decisional Authority allow the proposed research to proceed on ethical grounds;
- Conveying, in writing, the REB ethics recommendations to the Decisional Authority;
- Speaking on behalf of the REB;
- Developing guidelines and procedures for implementing the requirements of this policy consistent with the needs of the relevant research disciplines served by the REB;
- Monitoring the REB's recommendations for consistency and ensuring that these recommendations are recorded properly;
- Promptly reporting any adverse events and recommended suspension or termination of a research project to the Decisional Authority and other institutional officials as deemed appropriate by the REB, and providing a statement of the reasons for the action taken;
- Providing an Annual Report on REB activities to the Decisional Authority; and
- Performing all of the duties of a REB member as outlined in the subsection below.

5.3 REB Members/Alternate Members

REB members, including alternate members, shall work to ensure that all research involving human subjects carried out by, funded by, or otherwise under the auspices of Health Canada or PHAC meets the highest ethical standards and that safeguards are implemented to provide the greatest protection to human subjects, by:

- Undertaking timely ethics reviews of proposed research projects;
- Conducting the continuing ethics review of ongoing research projects, amendments and any adverse events reported by the PIs until the project is completed or terminated;
- Providing their professional recommendations to the Decisional Authority as to whether the research projects should be approved, rejected, modified, or terminated;
- Requesting that additional information be provided by the researchers in order to conclude the ethics review of the research projects;
- Reviewing and monitoring additional information requested by the REB to ensure compliance with the *TCPS* as well as the REB's Policy and Procedures Manual;
- Assisting in the development of guidelines and procedures for implementing the requirements of the REB's policies consistent with the needs of the relevant research disciplines served by the REB;
- Assisting in the monitoring of the REB's ethics recommendations; and
- Assisting the REB Secretariat in preparing the Annual Report to be submitted to

the Decisional Authority.

The members shall be made aware of and are expected to comply with the Treasury Board of Canada's *Values and Ethics Code for the Public Service*, the TCPS, and the REB's own conflict of interest considerations, as outlined in subsection 5.6 below.

5.4 REB Secretariat

The REB Secretariat shall manage all the administrative affairs of the REB and shall be responsible for:

- Managing all applications received from Health Canada and PHAC;
- Developing the REB's policy framework and administrative procedures for REB and senior management approval;
- Communicating with the PIs on the required revisions to be made to the proposed research project as recommended by the REB;
- Dealing with all communications regarding individual applications submitted to the REB;
- Managing the REB's ongoing administration during and after REB meetings;
- Developing and delivering departmental training programs on the REB; and
- Maintaining the REB website.

5.5 Confidentiality

All REB members are required to protect any confidential or privileged information submitted to the REB for the members' review at monthly REB meetings, or divulged during the day-to-day operations of the REB. Members must not discuss or divulge this information with persons not sitting on the REB until it has been officially released for public distribution.

Documents leaving the REB meetings must be securely stored at all times and any confidential information provided must be returned or securely destroyed. If any such information is knowingly sent to anyone outside of the REB, the REB Secretariat, the offices of the Decisional Authorities, the Office of Public Health Practice, the Office of the DM, or the office of the CPHO, it will be considered a breach of confidentiality and the member's term with the REB will be automatically terminated.

5.6 Conflict of Interest of REB Members

The expression "conflict of interest" refers to situations in which financial, professional, ideological, or other personal considerations may compromise a member's professional judgment in reviewing research projects. Such conflict could affect the member's impartiality or independence.

To help maintain the independence and integrity of the ethics review, it is of the highest importance that members of the REB avoid actual, apparent, perceived or potential

conflicts of interest, and comply with the conflict of interest considerations outlined in section 4.1 of the TCPS.

For example, a conflict of interest for REB members may exist under any of the following circumstances:

- When a member's assets, situation or outside activities give rise to the perception that he/she could derive an unfair advantage through working with the REB;
- When a member has a close personal or institutional relationship with the applicant that may create pressure to act against his/her REB-related responsibilities;
- When a member has a personal interest in the research under review or could be exposed to a personal or professional loss or gain as a direct or indirect result of a recommendation made by the REB;
- When a member has a clearly identified position on a specific issue or has had personal or professional differences with the applicant such that their participation in deliberations on the issue could give rise to the perception of bias in the REB recommendations; and
- When a member's own research projects are under review by the REB or when a member has been in direct academic conflict or collaboration with the researcher whose proposal is under review.

A REB member should immediately disclose to the REB Chair and the REB Secretariat any actual, perceived, apparent or potential conflict of interest in regard to a research project. Further, REB members must update their conflict of interest disclosure statements annually, and also as required by a change in circumstances.

5.7 Policy on Indemnification

Pursuant to the Treasury Board's *Volunteers Policy*, Health Canada/PHAC accept the possibility of the Crown being vicariously liable for the actions of REB members under certain circumstances. However, they also expect members to behave honestly and without malice, exercise due caution, take care of any Crown property entrusted to them, and refrain from any act that could be a cause for disciplinary action if the member were an employee.

Accordingly, it is Health Canada and PHAC policy to:

- Indemnify REB members against personal civil liability incurred by any act or omission within the scope of the member's REB-related activities;
- Make no claim against members based upon such personal liability;
- Provide legal assistance to REB members in the following circumstances, to the extent that they are within the scope of the member's REB-related activities:
 - a. When they are required to appear before or be interviewed in connection with a judicial, investigative, or other inquest or inquiry;
 - b. When they are sued or charged with an offence; or

- c. When they are faced with other circumstances that are sufficiently serious to require legal assistance.

6. MEETING REQUIREMENTS

As stated in Article 1.7 of the *TCPS*, face-to-face meetings are essential for adequate discussion of research proposals and for the collective education of REB members. The HC-PHAC meetings will be held on a monthly basis except during the summer and the calendar of these meetings shall be posted on the REB website so that researchers can plan their research projects accordingly.

The REB may also hold general meetings, retreats and educational workshops in which members can:

- Participate in educational opportunities that may benefit the overall operation of the REB;
- Discuss any general issues arising out of the REB's activities; and
- Review REB policies and recommend revisions.

Regular attendance by REB members at meetings is important. Members who are frequently absent (i.e. five or more consecutive absences) may be asked to resign by the REB Chair. Special consideration for scheduled absences, i.e. maternal or paternal leave, can be given by the REB.

Researchers may be asked to attend REB meetings to participate in discussions when their research proposals are under review by the REB, but must not be present when the REB makes its final recommendation.

At the REB Chair's discretion, independent consultants with specific expertise in a certain area may be invited to the REB meeting or to provide written comments, subject to the applicable confidentiality agreements.

Recommendations regarding projects requiring full review are made only if a quorum of at least five members exists and if these members possess the range of background and expertise required by the *TCPS*. Alternate members shall be asked to attend meetings in order to ensure that the required range of expertise and background is available. The Chair, or in his/her absence the Deputy Chair, shall have the final authority to decide whether the quorum has been met.

7. TYPES OF REB REVIEW

7.1 Full review

Research proposals involving human subjects will normally receive a full review by the REB. In particular circumstances, the REB may review applications on an expedited or time sensitive basis, as outlined below.

7.2 Expedited Review

Decisions regarding expedited review are at the discretion of the REB Chair or Deputy Chair, for those categories of research that are confidently expected to involve minimal risk to research subjects. Examples of such categories might include:

- Retrospective studies such as chart reviews, reviews of patient records by hospital personnel, etc;
- Studies involving no direct subject contact or reporting only aggregate data;
- Studies dealing only with leftover tissue (however, studies involving fetal waste tissue or genetic material will always require full REB review);
- Studies involving non-invasive product testing or quality assurance activities;
- Annual renewals of approved projects in which there has been little or no change in ongoing research;
- Research protocols that have been previously reviewed and approved by an external REB that is guided by the ethical principles found in the *TCPS*; or
- Any minor protocol amendment, e.g. administrative changes such as deleting the name of a co-investigator or a change in sponsorship/study budget (however, any amendments likely to affect the rights, safety and/or well-being of the research subjects will always require full REB review).

7.3 Time Sensitive Review

The REB is guided by Article 2.8 of the *TCPS* when reviewing research in emergency situations. Where REB review is urgently required due to circumstances beyond the researchers' control, the REB Chair or Deputy Chair may also allow an application to be reviewed on a time-sensitive basis via teleconference in one of the following cases:

- Epidemiological studies where incidences of the study target are limited, such as research conducted in the context of an outbreak of a new disease;
- Studies of time limited events; or
- Research whereby a delay caused by waiting for the next REB meeting would place individuals at risk.

8. ELEMENTS OF THE REB ETHICS REVIEW

The primary task of the REB lies in the review of research proposals and their supporting documents, with special attention given to the informed consent process, documentation, the suitability and feasibility of the proposed research and protection of privacy and confidentiality. The REB will take into account prior scientific reviews, if any, and the requirements of applicable laws and regulations. The following considerations should be taken into account.

8.1 Scientific Design and Conduct of the Study

- The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research subjects.
- Justification of predictable risks and inconveniences weighed against the anticipated benefits for the research subjects and the concerned communities.
- Criteria for withdrawing research subjects.
- Criteria for suspending or terminating the research.
- Adequacy of provisions made for monitoring the conduct of the research.
- Adequacy of the site, including the support staff, available facilities and emergency procedures.
- The manner in which the results of the research will be reported and published.
- Whether the results of the research can be validated.

8.2 Recruitment of Research Subjects

- The characteristics of the population from which the research subjects will be drawn (including gender, age, literacy, culture, economic status and ethnicity).
- The means by which initial contact and recruitment is to be conducted.
- The means by which full information is to be conveyed to potential research subjects or their representative(s) for the purposes of free and informed consent.
- Inclusion and exclusion criteria for research subjects.
- Whether the requirements for free and informed consent are met, including that it must be voluntarily given, and without a risk of real or perceived manipulation, undue influence or coercion.
- Whether prospective subjects are given assurances that they are free not to participate, and have a right to withdraw at any time without prejudice to pre-existing entitlements.

8.3 Care and Protection of Research Subjects

- Suitability of the qualifications and experience of the investigator(s) for the proposed study.
- Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action.
- Medical care to be provided to research subjects during and after the course of the research.
- Adequacy of medical supervision and psycho-social support for the research subjects.
- Steps to be taken if research subjects voluntarily withdraw during the course of the research.
- Criteria for extended access to, the emergency use of, or the compassionate use of study products.
- Arrangements, if appropriate, for informing the research subject's general practitioner (family doctor), including procedures for seeking the subject's consent to do so.

- Description of any plan to make the study product available to the research subjects following the research.
- A description of any financial cost to research subjects.
- Remuneration for research subjects (including money, services or gifts) and reimbursement for expenses.
- The provisions for compensation/treatment in the case of the injury/disability/death of a research subject attributable to participation in the research.
- The insurance and indemnity arrangements.

8.4 Protection of Research Subject's Confidentiality

- The persons who will have access to the personal data of the research subjects, including medical records and biological samples.
- Applicable privacy laws (e.g. the *Privacy Act*).
- The measures taken to ensure the confidentiality and security of personal information concerning research subjects.

8.5 Informed Consent Process

- The process for obtaining informed consent, including the identification of those responsible for obtaining consent.
- The adequacy, completeness, and clarity of written and oral information to be given to the research subjects and, when appropriate, their legally authorized representative(s).
- Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining substitutive consent for the participation of such individuals from their parents, guardians or other legally authorized representative(s), as appropriate.
- How research subjects will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety and well-being), and be given the opportunity to withdraw at any time without prejudice to pre-existing entitlements.
- Provisions made for receiving and responding to queries and complaints from research subjects or their representative(s) during the course of a research project.

8.6 Community Considerations

- The impact and relevance of the research on the local community and on the concerned communities from which the research subjects are drawn.
- Steps taken to consult with the concerned communities during the course of designing the research.
- Influence of the community on the consent of individuals.
- Proposed community consultation during the course of the research.
- The extent to which the research contributes to capacity building, such as the

- enhancement of local healthcare, research, and the ability to respond to public health needs.
- The availability and affordability of any successful study product to the concerned communities following the research.
 - The manner in which the results of the research will be made available to the research subjects and the concerned communities.

9. REB ETHICS RECOMMENDATIONS

The REB operates on the principle of consensus. All REB ethics recommendations require a strong majority and only members who participate in the review shall participate in making the final recommendation. Furthermore, recommendations shall only be made when:

- Sufficient time has been allowed for a review and discussion of an application; and
- The documents required for a review of the application are complete and the relevant elements considered.

All REB ethics recommendations shall be communicated in writing to the PI within 15 days of the meeting at which the recommendation is made. Positive recommendations include a statement of the PI's responsibilities, including:

- Confirming the acceptance of any requirements imposed by the REB;
- Submitting an annual progress report;
- Notifying the REB of protocol amendments (other than amendments involving only logistical or administrative aspects of the study);
- Notifying the REB in the case of amendments to the recruitment material, research subject information, or the informed consent process or form;
- Reporting unforeseen circumstances or the termination of the study; and
- Submitting a final summary report upon completion of the study.

A negative recommendation from the REB shall be supported with reasons.

10. REB RECONSIDERATION AND APPEALS

10.1 Reconsideration of a Negative Ethics Recommendation

In accordance with Article 1.10 of the *TCPS*, researchers have the right to request, and the REB has an obligation to provide, a reconsideration of negative recommendations concerning a research project.

Any PI who seeks a reconsideration of a negative recommendation must provide a clear basis for his or her disagreement and a request for reconsideration by the REB. This is to

be sent by letter or email to the REB Secretariat within 10 days of receiving notification from the REB of the negative recommendation.

A meeting between the REB and the PI shall be scheduled at the earliest possible REB monthly meeting. At that meeting, the PI shall be invited to further discuss the project with the REB with a view to having the REB reach a decision on the issues that are subject to disagreement, and should bring all relevant documentation that will support the case for reconsideration.

The PI will receive notice from the REB within two weeks of the meeting providing the results of the reconsideration.

10.2 Appeal of a Negative Ethics Recommendation Following Reconsideration

Article 1.11 of the *TCPS* provides that, in cases when researchers and the REB cannot reach agreement through discussion and reconsideration, an institution should permit review of a REB recommendation by an appeal board, provided that the REB's membership and procedures meet the requirements of the *TCPS*. No *ad hoc* appeal boards are permitted.

If an understanding was not reached between the REB and the PI during the reconsideration of the REB's earlier recommendation, the PI can initiate an appeal process within Health Canada/PHAC within 30 days from the date of receiving the notice from the REB providing the results of the reconsideration.

Appeals are not allowed on the grounds that the PI disagrees with the REB on the ethics of the research project. An appeal will only be considered on the grounds of a:

- Perception of bias;
- Lack of due process; or
- Real or apparent conflict of interest.

To initiate an appeal process, the PI must send a letter to the Decisional Authority and the REB Secretariat setting out the basis for the appeal and supporting evidence. Upon receipt of the appeal letter, the Decisional Authority will call upon the Appeal Board to meet within two months. The Appeal Board composition shall reflect the expertise profile of the REB, but REB members shall not sit on the Appeal Board.

The Appeal Board can seek assistance from other experts in fields relevant to the appeal. The PI and the REB Chair will be invited to present their evidence to the Appeal Board. The Appeal Board will consider all relevant evidence before advising the Decisional Authority as to whether there was a failure in the REB's ethics review process for the project under appeal. The Decisional Authority will, in turn, advise the Deputy Minister/CPHO.

If the Deputy Minister/CPHO finds that a failure in the ethics review process has

occurred, the project will be referred back to the REB for a further ethics review. If he/she does not find a failure in the REB ethics review process, the recommendation made by the REB will stand. The Deputy Minister/CPHO's decision is final and binding on the PI who requested the appeal.

11. CONTINUING ETHICS REVIEW

The REB will review each study that has been the subject of a positive ethics recommendation and received subsequent approval until termination of the research. Approved studies will be reviewed at least annually, though the REB may require more frequent reviews based on the nature, potential risks and planned milestones of a research project. The following shall require follow-up review:

- Protocol amendments likely to affect the rights, safety or well-being of the research subjects or the conduct of the study;
- Serious and unexpected adverse events related to the study; and
- Any event or new information that may affect the benefit/risk ratio of the study.

Any decision arising from a follow-up review must be issued and communicated by the Decisional Authority to the PI, indicating a modification, suspension, or termination of the REB's original recommendation, or confirming that the original recommendation is still valid.

12. ANNUAL REPORT

The REB Chair shall report on an annual basis to the Decisional Authority. This Annual Report shall be made publicly available on the REB website.

13. DOCUMENTATION AND ARCHIVING

All documentation and communication of the REB shall be dated, filed and archived for a minimum period of 15 years following the completion of a study. These include:

- Written standard operating procedures of the REB and annual reports;
- Curriculum vitae of all REB members;
- A record of all income and expenses of the REB;
- Published guidelines for submission established by the REB;
- Agenda of the REB meetings;
- Minutes of the REB meetings;
- One copy of all materials submitted by an applicant;
- The correspondence by REB members with applicants or concerned parties regarding an application, decision and follow-up;
- A copy of the recommendation and any advice requirements sent to an applicant;
- All written documentation received during a follow-up;
- Notification of the completion, premature suspension, or premature termination of

- a study; and
- The final summary or final report of the study.

The REB Secretariat will maintain these records as specified above and will destroy them in accordance with Library and Archives Canada's *Retention and Disposal Standards*.