Toronto Public Health

POLICY

Research Ethics Review Policy

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Directorate: Healthy Public Policy

GENERAL INFORMATION

Content Summary

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Subject	Research Ethics Review
Superseded Documents	Policy for Evaluation and Other Research Endeavours (2000)

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Dept/Role	Name	Signatures	Date
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CONTENT

1. **PURPOSE**

The purpose of the Toronto Public Health (TPH) Research Ethics Review Policy is to (a) outline requirements for projects that require TPH research ethics review and (b) describe the TPH research ethics review process.

2. **APPLIES TO**

All and only those projects that meet the criteria for TPH research ethics review (4.43).

3. **EXCEPTIONS OR EXCLUSIONS**

Projects that do not meet the criteria for TPH research ethics review (4.43).

4. **DEFINITIONS**

Further information regarding the operationalization of the policy related to these definitions is in the Procedure for Submission of Proposals for Research Ethics Review.

4.1 **Amendment (or Modification)** [1]

An amendment is a written description of change(s) to or formal clarification of a component of an approved project. Amendments may be minor (i.e., pose no more than minimal risk to subjects) or major (i.e., either increases participant risk or lowers participant benefits).

4.2 **Anonymous (Information/Human Biological Material)** [1]

The information/human biological material never had identifiers associated with it (e.g., anonymous surveys) and the process of data linkage or recording or dissemination of results will not generate identifiable information.

4.3 **Appeal** [1]

An appeal is a process that allows a Principal Investigator(s) to request a review of a Research Ethics Board (REB) decision when, after reconsideration, the REB has rejected a research proposal.

Appeals may only be initiated when a Principal Investigator(s) receives a letter from the REB indicating that, after reconsideration, the research proposal is rejected. The possible grounds for appeal include:

- The occurrence of REB procedural irregularities
- Elements of the REB decision were not supported by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) 2014

4.4 **Approval**

Approval means the research proposal has been assessed by the Research Ethics Board (REB), in accordance with this policy, and found to be ethically acceptable, with a favourable balance between protection of participants and/or their data and

the benefits of the research. When the REB approves a research proposal, a letter is sent to the Principal Investigator(s), outlining any conditions of the approval. The Principal Investigator(s) must comply, at all times, with any REB conditions.

No project can start without TPH REB approval. Some projects will also require a completed Research Agreement(s).

4.5 Auditing

The main purpose of auditing is to detect and correct problems. Administrative auditing is conducted to assess adherence to the research ethics review policy and procedures. Auditing of research projects may occur if there are indicators that research projects are not being conducted as approved.

4.6 Completion

A research project is deemed to be complete when: (a) all data collection and analysis is finished; (b) there is no further need for contact with human participants or use of their data; and (c) the Principal Investigator(s) has submitted an End of Research Reporting form to the REB through erreview@toronto.ca . The Principal Investigator(s) must also submit the final report on the project.

The Principal Investigator(s) must ensure that results of his/her research project are not publicly released or disseminated before the End of Research Reporting form and final report is submitted.

4.7 Conflict of Interest (COI) [1, 2]

A conflict of interest generally arises in research when activities or situations place an individual, group of individuals or institution in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. A conflict of interest may arise from interpersonal relationships, financial partnerships, other economic interests, academic interests or any other interests that may compromise integrity or respect for the core principles of this Policy.

A conflict of interest may jeopardize the integrity of the research and the protection offered to participants.

1. Research Team Member Conflict of Interest

Research Team members, when submitting a research proposal to the Research Ethics Board, shall disclose real, potential or perceived conflicts of interest. Conflicts of interest may arise from an individual's involvement in dual and multiple roles including those within or outside TPH and the City.

2. REB Member Conflict of Interest

When reviewing research proposals, Research Ethics Board (REB) Members shall disclose real, potential or perceived conflicts of interest to the REB. The Personal Health Information Protection Act requires that the REB and Members of the REB be without conflict of interest in order to be eligible to review research proposals involving personal health information. When necessary, the REB may decide that some of its Members must withdraw from REB deliberations and decisions.

3. Institutional Conflict of Interest
Institutional policies and procedures shall support the independence of the Research Ethics Board (REB) in its research ethics decision making so that the REB may be free of inappropriate influence.

4.8 **Dual Review**
A dual review occurs when a research proposal has or will receive one or more Research Ethics Board (REB) review(s) from an institution(s) other than TPH.

The research proposal will proceed through the TPH research ethics review process unless there is an official agreement in place between TPH and one or more institutions in which they accept, with an agreed level of oversight, the Research Ethics review of each other's REBs.

4.9 **Epidemiological Investigation [3]**
An epidemiological investigation is a focused examination into the cause(s) of, and risks for, a health condition experienced by a defined population for the specific purpose of intervention, where possible.

4.10 **Feasibility**
A research application is feasible if it can be completed using available TPH resources, to the degree requested, relative to program priorities and other research priorities. Feasibility takes into consideration:

- Ability to provide requested data
- Accessibility of existing records and documents
- Direct and indirect impacts on service delivery or TPH resources
- Timing and duration relative to service delivery
- Demands on potential project participants
- Risk to clients or services
- Relationships between TPH and its clients
- Space

4.11 **Health Information Custodian (HIC) [4]**
Health Information Custodians are individuals or organizations that have custody or control of personal health information (4.19) and are listed in the Personal Health Information Protection Act. The Medical Officer of Health is a HIC according to section 3(1), paragraph 6 of the Act.

4.12 **Information Management Assessment (Privacy)**
Research proposals submitted to TPH must comply with the Personal Health Information Protection Act (PHIPA), the Municipal Freedom of Information and Protection of Privacy Act (MFIPPA) and all relevant regulations. The TPH Privacy and Information Management Liaison Officer is responsible for assessing research

proposals to ensure compliance with these statutes and other information management related issues.

4.13 **Investigator(s)**

An Investigator is a member of the Research Team who is responsible and accountable for the scientific and/or ethical conduct of at least one component of the research project.

4.14 **Minimal Risk** [1]

Research is considered to be minimal risk if the probability and magnitude of possible harms associated with the research are no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research.

4.15 **Monitoring** [1]

Monitoring refers to the continuing review of research projects following approval to determine if they are implemented as approved.

4.16 **Municipal Freedom of Information and Protection of Privacy Act (MFIPPA) and MFIPPA Regulation 823** [5, 6]

The Municipal Freedom of Information and Protection of Privacy Act (MFIPPA) governs access to general information and individuals' personal information (MFIPPA 2(1)). It also defines requirements for the protection of personal privacy by municipal institutions. All TPH staff are required to comply with MFIPPA.

When collecting, using, disclosing or otherwise handling this information, all TPH management and staff, consultants, contracted agencies, volunteers, researchers, students and any other individuals who perform work for TPH must follow approved procedures and take measures to ensure that personal information is protected at all times.

All persons to whom personal information is disclosed for a research purpose must enter into a Research Agreement (MFIPPA 10(1)). The Principal Investigator must agree to comply with any restrictions or conditions regarding the use, disclosure, security or disposal of personal information (MFIPPA s. 14(1e) & MFIPPA Regulation 823 s10 and Form 1) as outlined in the Research Agreement.

4.17 **Not Anonymous Information** [1]

1. Directly Identifying Information
   The information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).

2. Indirectly Identifying Information
   The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).

3. Coded Information
   Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary).

4. Anonymized Information
   The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.

Information which is not anonymous has the potential to identify one or more individuals.

4.18 **Organizational Assessment**

Prior to being reviewed by the TPH Research Ethics Board (REB) research applications receive organizational assessments for relevance, feasibility, scientific merit and information management (privacy) issues. A research application that does not receive all of these organizational approvals will not be reviewed by the REB. During the organizational assessment the need for and content of a Research Agreement(s) will be identified.

4.19 **Personal Health Information (PHI)** [7]

TPH guidance regarding personal health information (PHI) comes from the TPH Personal Health Information Protection Act (PHIPA) Compliance Policy. According to the policy, personal health information is identifying information about an individual in any form (oral or recorded) and includes but is not limited to:

- Individual's health and health care history, physical health, mental health and family medical history
- Donations or derivative(s) of any body part or bodily substance
- Payments and/or eligibility for health care
- Individual's OHIP number
- Identification of the individual's substitute decision maker
- Identification of the individual's health care provider(s)

PHI is considered extremely sensitive information. When collecting, using, disclosing or otherwise handling this information, all TPH management and staff, consultants, contracted agencies, volunteers, researchers, students and any other individuals who perform work on behalf of the Medical Officer of Health (who is a Health Information Custodian (4.11) under PHIPA) who handle PHI, must follow approved procedures and take measures to ensure that PHI is protected at all times.

All researchers to whom PHI is disclosed must enter into a Research Agreement. The researcher must agree to comply with any restrictions or conditions regarding

the use, disclosure, security or disposal of personal health information (use: PHIPA 37(1j) and disclosure: PHIPA 44(5)) as outlined in the Research Agreement. The MOH decision not to disclose PHI cannot be appealed.

4.20 **Personal Health Information Protection Act, 2004 (PHIPA)[4]**

The Personal Health Information Protection Act (PHIPA) is the Ontario provincial legislation which governs the collection, use and disclosure of personal health information (PHI) by Health Information Custodians.

The purposes of this Act are to:

1. Establish rules for the collection, use and disclosure of PHI about individuals that protect the confidentiality of that information and the privacy of individuals with respect to that information, while facilitating the effective provision of health care
2. Provide individuals with a right of access to PHI about themselves, subject to limited and specific exceptions set out in the Act
3. Provide individuals with a right to require the correction or amendment of PHI about themselves, subject to limited and specific exceptions set out in the Act
4. Provide for independent review and resolution of complaints with respect to PHI
5. Provide effective remedies for contraventions of the Act

4.21 **Personal Health Information Protection Act Regulation, O. Regulation 329/04 [2]**

The Personal Health Information Protection Act (PHIPA) Regulation is a regulation under PHIPA and, in part, prescribes requirements for: Research Ethics Board Membership (section 15), research plans (section 16) and disclosure by researchers (section 17).

4.22 **Policy Analysis [8]**

Policy analysis is the process of assessing situations, defining problems, clarifying values and goals, and developing and recommending options and frameworks for implementing and/or evaluating outcomes.

4.23 **Policy Evaluation [9]**

Policy evaluation is a systematic process for assessing the design, implementation and outcomes of public policies.

4.24 **Pre-Screening Assessment**

Pre-screening is a brief assessment, conducted by the Research Coordinator, prior to the submission of a research application. Pre-screening determines if a project meets all three of the TPH research ethics review criteria and requires TPH research ethics review. If necessary, the Research Coordinator will consult with the REB Chair and/or the Principal Investigator.

4.25 **Principal Investigator(s) (PI)**

The Principal Investigator(s) is the leader of the Research Team. The PI has primary responsibility and accountability for the scientific and ethical conduct of the research project, including ensuring that the actions of all members of the Research Team are consistent with the approved research application. The PI(s) also has

primary responsibility and accountability for legal and administrative aspects of the project.

4.26 **Program Evaluation** [10]

Program evaluation is the systematic gathering, analysis, and reporting of data about a program to assist in decision-making. It includes quantitative, qualitative, and/or mixed-method approaches.

4.27 **Primary and Secondary Reviewers** [11]

The Research Ethics Board (REB) utilizes the Primary and Secondary Reviewer model for full REB reviews (4.28 (2)). Primary and Secondary Reviewers are REB Members who conduct in-depth reviews of assigned research proposals. The Reviewers are selected based on availability, absence of conflict of interest, knowledge and skills.

Both reviewers create written reviews for the REB meeting. The Primary Reviewer leads the discussion at the REB meeting. The Secondary Reviewer assesses the research proposal with particular attention to informed consent.

4.28 **Proportionate Assessment Approach to Research Ethics Review** [1]

A proportionate assessment approach to research ethics review involves the consideration of foreseeable risks, the potential benefits and the ethical implications of the proposed research. Proposed research should have a favourable balance of risks and benefits for participants or their data. The level of scrutiny of the research proposal is determined by the level of risk presented by the proposed research. The Research Coordinator will assess research proposals using criteria approved by the REB to determine whether or not a research proposal will be subjected to a delegated review or a full Research Ethics Board (REB) review. If necessary, the Research Coordinator will consult with the REB Chair and/or the Principal Investigator.

1. Delegated Review [1]
   A Delegated Review occurs when a research proposal is considered to be minimal risk. Generally, two reviewers are selected from the REB Membership to perform the delegated review based on availability, absence of conflict of interest, knowledge and skills. The reviewers' assessment of the research proposal and decision regarding approval of the research proposal is documented and formally reported to the full REB.

2. Full REB Review [1]
   A Full REB Review occurs when a research proposal is considered to be more than minimal risk. It takes place at a REB meeting where quorum is maintained. The discussion is led by two REB Members selected to be Primary and Secondary Reviewers (4.27), based on availability, absence of conflict of interest, knowledge and skills. The remaining REB Members contribute to the review. A quorum of REB Members decides whether or not to approve the research proposal.

4.29 **Quality Improvement (QI)** [12]

Quality improvement initiatives are conducted on an ongoing basis and used exclusively for program/service assessment, management and improvement. They

include, but are not limited to: identifying measures, standards, and benchmarks related to outcomes; identifying processes used to achieve goals/outcomes; documenting processes; changing processes; and monitoring results.

4.30 **Quorum** [2]

Quorum requires the presence of more than 50% of the Research Ethics Board Members, five of whom have the qualifications required by the Personal Health Information Protection Act, Ontario Regulation 329/04 as described in 4.35. All agenda items requiring a decision at REB meetings must have quorum.

4.31 **Relevance**

A research application is assessed as relevant if it is appropriate or significant to the work or mandate of TPH. Relevance takes into consideration the:

- Degree to which the proposed research addresses TPH strategic directions
- Ways in which the results of the proposed research will be useful for planning and/or providing programs and services
- Ways in which the findings of the proposed research will further the understanding of emerging public health issues/new policy developments
- Degree to which the proposed research supports the Ontario Public Health Standards goals and requirements

4.32 **Research** [4]

Research is a systematic investigation designed to develop or establish principles, facts or generalizable knowledge, or any combination of them, and includes the development, testing and evaluation of research. Research may involve the collection of new data using quantitative, qualitative or mixed methods. Research also may involve the analysis or synthesis of existing data or research findings.

For purposes of this policy TPH has operationalized the term research to further outline distinctions between projects that <u>are</u>, <u>are not</u>, or <u>may be</u> considered to be research. A screening tool has been developed to help the Research Coordinator, in consultation with the Research Ethics Board (REB) Chair and/or Principal Investigator(s) as necessary, determine if a project is research according to this policy.

A project is research if it meets <u>any</u> of the following criteria:

- REB review is required as part of the funding arrangements or legislation requirements
- The <u>primary</u> purpose is to contribute to the body of knowledge regarding health and/or health systems that is generally accessible through academic (peer reviewed) literature
- The project is <u>primarily</u> designed to answer a specific research question or to test/generate an explicit hypothesis using qualitative or quantitative methodologies
- The project involves randomization or other systematic sampling techniques to divide participants into different comparison groups
- The project has already been reviewed by another REB

A project is likely to be research if it meets <u>any</u> of the following criteria:

- The project is designed to support generalizations that go beyond the particular sample included in the project
- The project imposes additional burdens or collection of additional data on participants beyond what would be expected during standard program/service delivery or role expectation

A project is not research if it does not meet any of the above criteria and if it meets either of the following criteria.

- A routine reporting or investigative practice outlined within an existing approved policy and procedure
- Activities to manage outbreaks by identifying and understanding risks associated with an incident to inform timely public health action

For the purpose of this policy, quality improvement (4.29); routine surveillance (4.40), session feedback (4.42); staff performance reviews, and student course evaluations are not research.

Some initiatives (e.g., program evaluation (4.26); epidemiological investigation (4.9); and projects related to policy analysis (4.22) and policy evaluation (4.23)) may be research.

4.33 **Research Agreement(s)**

TPH has three types of Research Agreements.

1. PHIPA Research Agreement [4]
   The Personal Health Information Protection Act (PHIPA) requires a Health Information Custodian (HIC) to enter into a Research Agreement with the Principal Investigator prior to disclosing personal health information (PHI) to the Principal Investigator. The purpose of the PHIPA Research Agreement is to require the Principal Investigator to comply with conditions and restrictions, if any, that the HIC imposes relating to the use, security, disclosure, return, or disposal of the PHI disclosed by the HIC to the Researcher.

2. MFIPPA Agreement [5]
   The Municipal Freedom of Information and Protection of Privacy Act (MFIPPA) requires that a Principal Investigator must enter into a MFIPPA Agreement if personal information is disclosed to the Principal Investigator(s).

3. Data Sharing Agreement
   A Data Sharing Agreement may be required for some projects.

It should be noted that when a project involves personal health information PHIPA supersedes MFIPPA.

The Privacy and Information Management Liaison Officer, in consultation with Directors, Legal, the Principal Investigator(s) and the Research Coordinator, will provide guidance on the need for and content of the Research Agreement(s). The Research Coordinator will facilitate the completion of the Research Agreement(s), as required.

A TPH REB approved project that is identified as requiring a Research Agreement(s) cannot start until the Research Coordinator has received evidence that the Research Agreement(s) has been signed. The Medical Officer of Health will sign the Agreement on behalf of the City.

4.34 **Research Ethics Board (REB)** [1, 2, 4]

The TPH Research Ethics Board is established to review the ethical acceptability of research involving humans or their data within its jurisdiction, including assessing research proposals, which contain components of the research plan as outlined in 4.37.

4.35 **Research Ethics Board Members**

The TPH Research Ethics Board (REB) will have a minimum of at least 12 Members, five of whom will: (a) have the qualifications required by the Personal Health Information Protection Act (PHIPA) Ontario Regulation 329/04 (4.21), and (b) contribute to the REB quorum (4.30).

The PHIPA Regulation requires that:

1. At least 1 REB Member has no affiliation with person or persons that established the REB (not TPH staff)
2. At least 1 Member is knowledgeable in research ethics
3. At least 2 Members have expertise in the methods or areas of research being considered
4. At least 1 Member is knowledgeable in considering privacy issues

Seven Members will represent the major TPH program or policy areas and have appropriate skills necessary to review research proposals. Some of these seven Members may also have the qualifications required by the PHIPA Regulation. TPH senior management are not eligible to serve on the REB.

All REB Members must adhere to the REB Terms of Reference and relevant components of the TPH Research Ethics Review Policy and related procedure (s).

4.36 **REB Reciprocal Review** [1]

REB reciprocal review occurs when two or more institutions accept, with an agreed level of oversight, the research ethics reviews of each other's REBs.

A REB reciprocal agreement sets out the terms under which a REB will accept a review from another REB or conduct a review of a research proposal on behalf of another REB.

4.37 **Research Plan** [3, 4]

The Personal Health Information Protection Act (PHIPA), Sections 44(1) and 44 (2), and Ontario Regulation 329/04 Section 16 state that a Health Information Custodian (HIC) may disclose personal health information (PHI) to a Principal Investigator(s) if they provide the HIC with:

- An application in writing
- A written research plan that includes:
    - the affiliation of each person involved in the research

- the nature and objectives of the research and the anticipated public or scientific benefit of the research
- a description of the proposed research and the duration of the research
- a description of the PHI required and the potential sources
- a description of how the PHI will be used in the research and if linked to other information a description of the other information as well as how the linkage will be done
- an explanation as to why the research cannot reasonably be accomplished without the PHI and if it is to be linked to other information an explanation as to why this linkage is required
- an explanation as to why consent to the disclosure of the PHI is not being sought from the individuals to whom the information relates
- a description of the reasonably foreseeable harms and benefits that may arise from the use of the PHI and how the Principal Investigator(s) intend to address those harms
- a description of all persons who will have access to the information, why their access is necessary, their roles in relation to the research, and their related qualifications
- the safeguards that the Principal Investigator(s) will impose to protect the confidentiality and security of the PHI, including an estimate of how long information will be retained in an identifiable form and why
- information as to how and when the PHI will be disposed of or returned to the health information custodian
- the funding source of the research
- whether the Principal Investigator(s) has applied for the approval of another research ethics board and, if so, the response to or status of the application
- whether the Principal Investigator(s)'s interest in the disclosure of the PHI or the performance of the research would likely result in an actual or perceived conflict of interest with other duties of the Principal Investigator(s)

The research plan requirements are included in the TPH Research Ethics Review Application form (4.38).

4.38 **Research Proposal [2]**

A research proposal must be submitted to the TPH Research Ethics Board (REB) for review and approval. The research proposal consists of:

- TPH Research Ethics Review Application (which includes research plan elements (4.37))
- All appendices
- Assessment of Relevance and Feasibility form
- Assessment of Scientific Merit form
- TPH Privacy and Information Management Assessment form

Additional information may be deemed necessary by the REB for specific projects.

4.39 **Research Team Members**

A Research Team is a group of people who collectively have the skills and knowledge necessary to conduct a research project from conception to dissemination. The team usually includes a Principal Investigator(s) and one or more Investigator(s).

4.40 **Routine Surveillance** [10]

Routine surveillance is the [mandatory] systematic and ongoing collection, collation, and analysis of health-related information that is communicated in a timely manner to all who need to know, so that action can be taken. Dissemination of surveillance analyses may take the form of reports, advisories, healthy public policy recommendations, alerts, or warnings.

4.41 **Scientific Merit**

As part of the organizational assessment, TPH assesses the design and methods of the research to determine if they are capable of answering the research question. TPH will generally avoid duplicating previous assessments of scientific merit.

4.42 **Session Feedback**

End of session forms that collect information on topics such as: meeting objectives, presenter(s) knowledge, and educational strategies or approaches used.

4.43 **TPH Research Ethics Review Criteria**

All projects that meet the following TPH research ethics review criteria must undergo a TPH research ethics review:

1. The project meets the definition of research (4.32) as set out in the TPH Research Ethics Review Policy; and
2. The project involves human participants (including but not limited to, biological samples) or data related to human participants; and
3. The project involves or relates to TPH in at <u>least one</u> of the following ways regardless of who initiates the project (internal, external, collaborative, student):
    a. The project involves TPH staff or clients as project participants
    b. The project uses TPH provided information about individuals/their biological materials which is not anonymous.
    c. The project involves TPH staff, students, or others as delegated, including contract service providers, as Principal Investigator(s) or Investigator(s), as part of their TPH role, accessing participants and/or data related to individuals/their biological materials outside of TPH (if the data/biological materials are not anonymous).

4.44 **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)** [1]

A joint policy that expresses the three Canadian research-supporting Agencies' (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Science and Humanities Research Council of Canada) continuing commitment to promote the ethical conduct of research involving human participants. It has been informed, in part, by leading international ethics norms, all of which may help in some measure to guide Canadian researchers, in Canada and abroad, in the conduct of research involving humans.

4.45 **Unanticipated Issues or Events** [1]

An unanticipated issue or event is an issue or event that may increase the level of risk to research participants or which has other ethical implications which may affect their welfare and which was not anticipated by the researcher in the proposal submitted for research ethics review.

5. BACKGROUND

Toronto Public Health (TPH) is committed to supporting research that is: relevant to its mandate and activities; feasible, scientifically sound, and ethical; and compliant with legislated information management standards. TPH has a responsibility to safeguard the rights, safety and well being of human participants and their data in research involving TPH.

To accomplish this, the TPH Research Ethics Board (REB) will conduct research ethics reviews of all research proposals that meet the TPH research ethics review criteria. The five steps of the TPH research ethics review process, as set out in Appendix 1, outline, in general, how research progresses from an idea to an approved research project and beyond.

The Personal Health Information Protection Act, 2004 (PHIPA) and PHIPA Regulation 329/04 is the statute that governs both the disclosure of personal health information for research purposes and the qualifications of REB Members. This statute also requires that research involving personal health information has a written research plan that is reviewed and approved by a REB, and that the Principal Investigator(s) enters into a Research Agreement with the MOH if personal health information is disclosed to the Principal Investigator(s).

The Municipal Freedom of Information and Protection of Privacy Act (MFIPPA) and MFIPPA Regulation 823 govern the disclosure of personal information for research purposes and the need for a Research Agreement.

In Canada, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) 2014 identifies best practices for ethics review of research proposals involving human subjects and their data. The TCPS2 2014 will be used to inform the processes used by the TPH REB.

6. POLICY

The policy statements should be read in conjunction with the Definitions in Section 4. Defined terms have been italicized.

6.1 The Medical Officer of Health and Senior Management Team will establish the TPH *Research Ethics Board* (REB) which will comply with the *Personal Health Information Protection Act* (PHIPA), *PHIPA Regulation 329/04*, the *Municipal Freedom of Information and Protection of Privacy Act* (MFIPPA) and *MFIPPA Regulation 823*. The TPH REB will have the responsibility and authority to conduct TPH research ethics reviews and it will comply with relevant components of this policy document. It will also be guided by the *Tri-Council Policy Statement: Ethical*

Conduct for Research Involving Humans 2014. Appendix 2 provides a flowchart of the TPH research ethics review process.

6.2 All projects that meet the following *TPH research ethics review criteria* must undergo a TPH research ethics review:

1. The project meets the definition of research (4.32) as set out in the TPH Research Ethics Review Policy; and
2. The project involves human participants (including but not limited to, biological samples) or data related to human participants; and
3. The project involves or relates to TPH in <u>at least one</u> of the following ways regardless of who initiates the project (internal, external, collaborative, student):
   a. The project involves TPH staff or clients as project participants
   b. The project uses TPH provided information about individuals/their biological materials which is not anonymous.
   c. The project involves TPH staff, students, or others as delegated, including contract service providers, as *Principal Investigator(s) or Investigator(s),* as part of their TPH role, accessing participants and/or data related to individuals/their biological materials outside of TPH (if the data/biological materials are *not anonymous).*

A *pre-screening assessment* may be used to determine if the project meets these criteria.

6.3 Prior to TPH *REB* review, research applications must undergo a TPH *organizational assessment* and receive approvals for relevance, feasibility, scientific merit, and information management (privacy) issues. Projects that do not pass these organizational assessments will not receive research ethics review.

6.4 The appropriate TPH Director/designate assesses applications to ensure that they are *relevant* to the mandate/activities of TPH, are *feasible* to perform, and have *scientific merit.* TPH will not duplicate previous assessments of *scientific merit* unless there is a good reason to do so. Investigators must provide evidence of previous assessment of *scientific merit.* The TPH Privacy and Information Management Liaison Officer assesses projects for *information management* (privacy) issues.

6.5 In some cases, where *personal health information*, personal information or aggregate information is disclosed to or provided to a *Principal Investigator(s)*, a *Research Agreement(s)* will be required. The Privacy and Information Management Liaison Officer, in consultation with Directors, Legal, the Principal Investigator(s) and the Research Coordinator, will provide guidance on the need for and content of the *Research Agreement(s).*

6.6 *Research proposals* will be assessed by the Research Coordinator, to determine the most appropriate type of research ethics review. A *proportionate assessment approach* to research ethics review including the concept of *minimal risk* will be used to determine if the research proposal will receive a *full* or *delegated review* by the REB.

6.7 *Research proposals* that have been previously reviewed by another *REB* (*dual reviews*) will also be given a *pre-screening assessment.* Projects meeting the criteria for *TPH Research Ethics Review* will undergo TPH *organizational assessment* for *relevance*, *feasibility*, *scientific merit*, and *information management* (privacy) issues. A *proportionate assessment approach* to research ethics review will also be used.

6.8 All *research proposals* will be reviewed by Members of the *REB*. *REB Membership* is prescribed in part by the *PHIPA Regulation 329/04*. The REB will meet monthly as required and maintain *quorum* for all agenda items requiring decisions.

6.9 All individuals associated with a *research proposal* (*Research Team Members*, TPH Directors, the Research Coordinator, *Research Ethics Board Members, and* AdHoc Reviewers) must identify and manage real, potential, or perceived *conflicts of interest*, where appropriate, to maintain public confidence and trust, meet professional obligations and ensure accountability of the research ethics review process.

6.10 The TPH *REB* will produce written decisions for all *research proposals* reviewed. The final REB decision will set out whether the research proposal is approved or rejected and, if approved, whether that approval is subject to any conditions. The *Principal Investigator*(s) may *appeal* a TPH REB decision under specific circumstances.

6.11 All research projects require TPH REB *approval* before they can start. Some research projects will also require the Research Coordinator to receive a signed *Research Agreement(s)* before they can start.

6.12 REB *approval* is valid for one year from the date of the approval letter. Research that extends beyond one year requires renewal annually until completion.

6.13 The *Principal Investigator(s)* and the *REB* shall have an ongoing relationship. All approved research proposals are subject to *monitoring* processes. In addition, *auditing* of research proposals may occur if necessary. The Principal Investigator(s) is responsible for notifying the REB of any *amendments or modifications* to the *approved* research proposal, indicating the significance of the deviation.

6.14 The Research Coordinator, in consultation with the REB Chair, as necessary, is responsible for investigating all research related complaints following the procedures in the TPH Complaints Management Policy and Procedure.

6.15 The *Principal Investigator(s)* can withdraw the research application at any point prior to its review. Following review and *REB* approval, the Principal Investigator(s) may request that a project end early by seeking and receiving approval from the REB. The project cannot end early without the approval of the REB.

6.16 The Principal Investigator is required to notify the REB without delay if there is an *unanticipated issue or event* that increases the level of risk to participants or which has other ethical implications that may affect participants' welfare.

6.17 The *REB* may suspend or terminate a research project for reasons including but not limited to: change in risk for either participants or TPH; not being informed of *unanticipated issue(s) or event(s)*; concerns for participant safety; insufficient protection of *personal health information* and/or personal information and/or data; receiving complaint(s) regarding the research; a change in the functioning of the Health Unit (e.g., during an emergency); or for any other reason that the REB deems appropriate.

6.18 The *Principal Investigator(s)* is responsible for *completing* the research project and submitting the End of Research Reporting form and final report to the REB through erreview@toronto.ca .

6.19 Individuals who are either affected by, or subject to, this policy must adhere to the Procedure for Submission of Proposals for Research Ethics Review and use *REB* related resources (forms and materials).

7. ROLES AND RESPONSIBILITIES

TPH Medical Officer of Health (MOH) (Health Information Custodian (HIC))

Specific responsibilities include, but are not limited to, the following:

1. Establishing the TPH REB and ensuring that the REB has sufficient financial and administrative resources to fulfill its duties
2. Approving and appointing the REB Chair
3. Sharing reports related to TPH research ethics review with the Senior Management Team and TPH staff
4. Ensuring that TPH Directors review research proposals for relevance, feasibility and scientific merit
5. Deciding whether or not to disclose personal health information and personal information based on information contained in the research proposal
    - Determining if there will be conditions for personal health information disclosure
6. Signing Research Agreement(s)
7. Delegating duties as necessary

TPH Senior Management Team (SMT)

Specific responsibilities include, but are not limited to, the following:

1. Providing approval for the establishment of a TPH Research Ethics Board (REB) as well as the roles and responsibilities outlined in this policy
2. Approving and appointing the REB Members, the Vice Chair and Alternate Members

TPH Directors

Specific responsibilities include, but are not limited to, the following:

1. Supporting development of scientifically sound and ethical research that is relevant to TPH, feasible to accomplish and compliant with all legislative and regulatory requirements
2. Ensuring that all projects that meet the three TPH research ethics review criteria are submitted for review by the TPH Research Ethics Board (REB)

3. Reviewing, or ensuring the review of, research applications related to his/her program area for relevance, feasibility and scientific merit
    - If the Director has a conflict of interest with the project the application should be reviewed by his or her designate who is not a Principal Investigator or an Investigator, but who has responsibility for the program area most directly impacted by the research application
    - If assessment of scientific merit is required the Director or designate may perform the assessment or refer the research application to an internal or external peer review process
    - If the application involves multiple Directorates, or is an organizationally cross cutting project, the Medical Officer of Health or designate will determine relevance, feasibility and scientific merit
4. Assessing, or ensuring the assessment of, research applications related to his/her program area for Research Agreement(s) needs

TPH Healthy Public Policy Director

In addition to the TPH Directors' responsibilities, the Director of Healthy Public Policy's (or designate's) responsibilities also include, but are not limited to, the following:

1. Coordinating the research ethics review process and supporting the TPH REB
2. Acting as primary contact for TPH organizational issues related to the research ethics review process
3. Producing an annual report of TPH research activities
4. Ensuring the research ethics review process, including the TPH REB, has a sufficient budget

TPH Information Management Services Manager (TPH Privacy and Information Management Liaison Officer)

Specific responsibilities include, but are not limited to, the following:

1. Assessing all TPH research applications for and making decisions regarding information management related issues
2. Providing guidance regarding the need for and content of Research Agreement(s)
3. Liaising with Corporate Information Management Services (CIMS), when appropriate
4. Liaising with the Information and Privacy Commissioner of Ontario, when appropriate
5. Liaising with the Research Coordinator, when appropriate, regarding the TPH Complaints Management Policy and other issues
6. Liaising with Legal, when appropriate

REB

Specific responsibilities include, but are not limited to, the following:

1. Adhering to the Research Ethics Board's Terms of Reference
2. Reviewing all research proposals for ethics and approving or rejecting proposals
3. Conducting full or delegated reviews of research proposals
4. Complying with requirements of PHIPA, PHIPA Regulation 329/04, MFIPPA and MFIPPA Regulation 823
5. Receiving guidance through the TCPS2 2014
6. Meeting monthly, as required

7. Providing written initial (approval and non-approval) and final (approval and rejection) decisions for all submitted proposals, including any conditions of approval
8. Maintaining appropriate transparency with Principal Investigator(s), TPH and other stakeholders
9. Monitoring and auditing approved research projects until completion

REB Member

REB Members are accountable to the REB Chair. Specific responsibilities include, but are not limited to, the following:

1. Adhering to the REB Terms of Reference and relevant components of the TPH Research Ethics Review policy and related procedures
2. Participating in the REB orientation process
3. Respecting the integrity and independence of the research ethics review process
4. Maintaining confidentiality of all research proposals and REB discussions
5. Refraining from discussing the review of proposals with Investigators outside of convened REB meetings
6. Remaining current and knowledgeable about ethics and research related developments, which includes participating in an annual self-evaluation process, identifying learning needs, and attending two annual professional development activities
7. Conducting full or delegated reviews of research proposals, as assigned, including making decisions about the ethical acceptability of the proposals
8. Advising the REB Chair and/or Research Coordinator if a conflict of interest exists and recusing him/herself from discussions of a specific proposal if the conflict of interest cannot be mitigated or if requested by the Chair
9. Advising the REB Chair and/or Research Coordinator if additional expertise is required to review a research proposal or to reassess its level of risk
10. Providing all comments and feedback electronically no later than 10 working days after receiving a proposal
11. Attending monthly REB meetings and being prepared to discuss proposals
12. Supporting the continuous quality improvement (CQI) process
13. Monitoring approved projects until completion

REB Chair

The REB Chair is accountable to the Medical Officer of Health. Specific responsibilities include, but are not limited to, the following:

1. Contributing to the selection of REB Members, as required
2. Contributing to the development of REB procedures and forms and ensuring ongoing quality improvement
3. Contributing to and participating in the REB orientation process
4. Identifying needs/opportunities for and supporting professional development of REB Members
5. Ensuring that the REB is compliant with the REB Terms of Reference and relevant components of the TPH Research Ethics Review policy and related procedures
6. Acting as the spokesperson for the REB and signing all REB notifications
7. Suspending or terminating research projects, as necessary, and providing written notice of suspension or termination with rationale to the Principal Investigator(s)
8. Supporting effective communication among REB Members

9. Developing and maintaining collaborative relationships with and serving as a resource to key stakeholders (e.g., REB Members, the Research Coordinator, Principal Investigators and TPH) and managing disagreements when necessary
10. Chairing monthly REB meetings and guiding discussion of research ethics proposals
11. Managing conflict of interest identification and mitigation
12. Conducting delegated reviews in special circumstances
13. Contributing to the annual REB report and other REB related communications
14. Meeting with the MOH quarterly as necessary
15. Delegating responsibilities, as appropriate, to qualified individual(s)such as the REB Vice Chair and Research Coordinator

REB Vice Chair

The REB Vice Chair is accountable to the REB Chair. In addition to REB Member responsibilities the Vice Chair responsibilities, also include, but are not limited to, the following:

1. Chairing meetings of the REB and acting on behalf of the REB Chair, when the Chair is unable to do so

Ad Hoc Reviewer

Ad Hoc Reviewers are accountable to the REB Chair. Specific responsibilities include, but are not limited to, the following:

1. Respecting the integrity, confidentiality and independence of the research ethics review process
2. Advising the REB Chair and/or Research Coordinator if a conflict of interest exists and recusing him/herself from discussions of a specific proposal if a conflict of interest cannot be mitigated
3. Serving as a Reviewer for a full REB review or delegated review as required
4. Making decisions about the ethical acceptability of research proposals
5. Attending REB meetings, when required, at the request of the Research Coordinator
6. Providing all comments and feedback electronically no later than 10 working days after receiving a proposal

Research Coordinator

Specific responsibilities regarding coordination of research ethics review include, but are not limited to, the following:

1. Liaising with the REB Chair on research ethics related issues and/or issues related to the functioning of the REB
2. Reporting to the Director of Healthy Public Policy or designate on TPH organizational issues related to the research ethics review process
3. Facilitating communication between the REB Chair and the Medical Officer of Health
4. Coordinating REB administrative support
5. Ensuring confidentiality is maintained in the research ethics review process
6. Conducting a pre-screening assessment to determine if a project requires review by the TPH REB
7. Supporting the research application's progress through organizational assessment
8. Coordinating the completion of Research Agreement(s), when required

8.1. Liaising with Legal, when appropriate
8.2. Liaising with TPH Privacy and Information Management Liaison Officer
8.3. Liaising with TPH staff responsible for the data, when appropriate

9. Conducting proportionate assessments and assigning specific REB Members for delegated and full REB review of research proposals based on availability, knowledge and skills, in consultation with the REB Chair and Principal Investigator(s) as necessary
10. Identifying and mitigating, where applicable, any conflict of interest issues related to the review of the research proposal
11. Supporting delegated review of research proposals
    - Distributing the research proposal and identifying the time line for the review
    - Responding to REB Members' questions, obtaining information from Principal Investigator(s), where necessary, and sharing new information with Reviewers
12. Supporting REB full review of research proposals and regular meetings
    - Ensuring meeting packages, including research proposals, are distributed
    - Ensuring Ad Hoc Reviewers are invited
    - Ensuring quorum is maintained for each agenda item that requires a decision
    - Coordinating visitor requests
13. Receiving REB Members' comments, coordinating the REB notification process with the REB Chair and contributing to drafting REB initial decisions, final decisions, and other REB communications:
    - Ensuring that written communication of the REB's decisions are sent promptly to the Principal Investigator(s)
    - Responding to REB decision appeal requests
    - Prompting renewals for previously approved research projects
    - Receiving amendment or modification forms, consulting with the REB Chair, and determining appropriate actions
    - Receiving Unanticipated Issues or Events forms, consulting with the REB Chair, and determining appropriate actions
    - Receiving requests for Early Termination forms, consulting with the REB Chair, and determining appropriate actions
    - Receiving withdrawal requests, consulting with the REB Chair, and determining appropriate actions
    - Receiving End of Project Reporting forms and final reports
14. Ensuring that the signed Research Agreement(s) is received, when required, before giving the Principal Investigator(s) notification that the approved research project can begin
15. Supporting REB meetings during special circumstances (e.g., declared emergencies and diminished health unit functioning)
16. Processing research and organizational related complaints following the TPH Complaints Management policy
17. Establishing and implementing quality assurance and reporting mechanisms including monitoring, auditing and external audits
    - Coordinating production of REB reports

Specific responsibilities, in conjunction with the REB Chair, related to ensuring the coordination of education, training and consultation for TPH research ethics review include, but are not limited to, the following:

1. Developing REB related policies, procedures and educational materials
2. Coordinating recruitment, training and orientation of REB Members
3. Planning and coordinating professional development opportunities for REB Members and relevant TPH staff
4. Providing information about the TPH Research Ethics Review process internally and externally
5. Maintaining the TPH Research Ethics Review intranet and internet websites

Support Assistant

Specific responsibilities include, but are not limited to, the following:

1. Scheduling all REB meetings
2. Taking minutes at all REB meetings
3. Providing administrative support for the REB and Research Coordinator as necessary
4. Creating and maintaining files, records and databases related to the TPH research ethics review process
5. Ensuring the confidentiality of research ethics review files

Principal Investigator(s)

Specific responsibilities include, but are not limited to, the following:

1. Communicating with the Research Coordinator regarding the completion and submission of project summaries, research applications, organizational assessments, and Research Agreement(s), when required
2. Ensuring that corporate, divisional, legal and privacy requirements are met
3. Identifying, documenting and, where possible, mitigating potential conflicts of interest
4. Submitting a research application for research ethics review
5. Complying with all written notifications provided by the REB
6. Obtaining TPH REB ethics approval in writing and ensuring that all necessary Research Agreement(s) are completed and signed prior to starting the research
7. Ensuring that all members of the Research Team carry out sound ethical research consistent with the research proposal approved by the TPH REB
8. Informing the REB of amendments or modifications to the previously approved research proposal and receiving approval when necessary
9. Reporting any unanticipated issues or events involving participants to the REB immediately
10. Ensuring that progress reports, requests for continuing review, and final reports are submitted to the REB in accordance with the REB policy and procedure
11. Complying with REB mandated monitoring and auditing processes
12. Obtaining approval from the REB before withdrawing a project after it has been approved
13. Responding to REB notifications of project suspensions or terminations
14. Adhering to this policy and its related procedure

8. **RELATED POLICY/PROCEDURE DOCUMENTS**
Researchers should be aware of the following policies and procedures that may be relevant to research projects:

Corporate (City of Toronto)

1. Corporate Information Management Services (Corporate Access and Privacy Unit)
   Privacy Guidelines -
   http://wi.toronto.ca/intra/clerks/cco_policies.nsf/4FA7DB72A42C27B1852578A00048B167/$file/Privacy%20Guidelines.pdf
2. Conflict of Interest Policy -
   http://wi.toronto.ca/intra/hr/policies.nsf/9fff29b7237299b385256729004b844b/429ad1b158a6de7c8525693b004bdc49?OpenDocument&Highlight=0,conflict,of,interest

Divisional (Toronto Public Health)

1. Documentation of Client/Customer Services provided by Toronto Public Health staff
   http://insideto.toronto.ca/health/policies/pdf/policy_documentation.pdf
2. Complaints Management Policy
   http://insideto.toronto.ca/health/policies/pdf/complaints_mgmt_policy.pdf
3. Personal Health Information Protection Act (PHIPA) Compliance Policy
   http://insideto.toronto.ca/health/policies/pdf/phipa_compliance.pdf
4. PHIPA Compliance – Disclosure Standard
   http://insideto.toronto.ca/health/policies/pdf/PHIPA_disclosure.pdf
5. Submission of Proposals for Research Ethics Review Procedure
6. Research Ethics Board Terms of Reference

9. **CONTINUOUS IMPROVEMENT/QUALITY ASSURANCE**
This policy will be formally reviewed three years after it comes into full effect. In the interim, minor edits and revisions as well as process improvements identified through continuous improvement/quality assurance can be made.

Annual monitoring for compliance, using the following research ethics review performance indicators will be documented:

- Number of REB meetings
- Attendance at REB meetings
- Number of consultations provided
- Number of project summaries assessed
- Number of research proposals reviewed, including dual reviews
- Number of research proposals approved
- Number of change forms processed
- Number of monitoring forms processed
- Number and type of REB professional development activities
- Number and outcome of complaints related to research approved by the TPH REB

- Production and distribution of an annual report of TPH research activities
- REB review time
- Organizational assessment review time

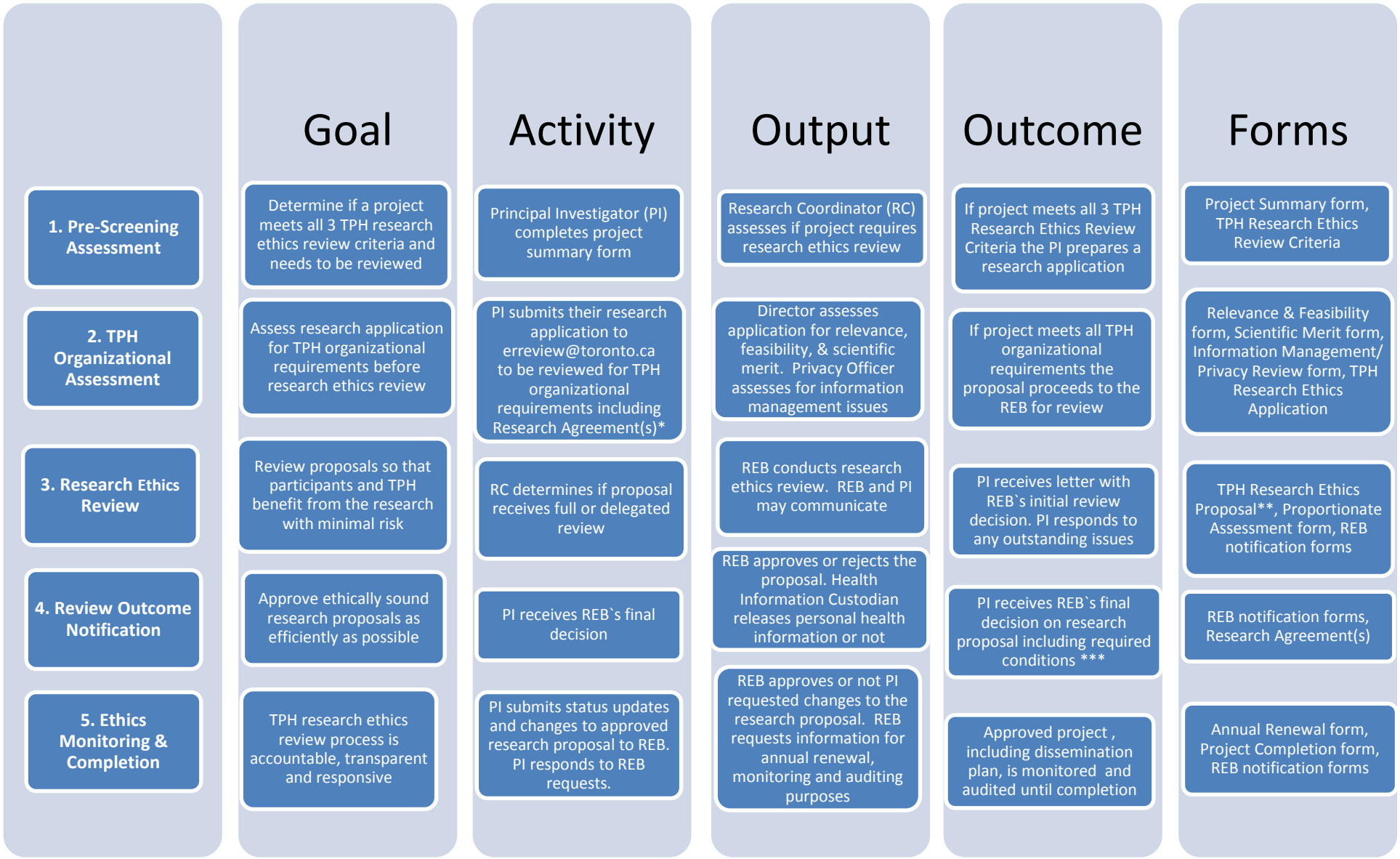
10. **REFERENCES/SOURCES**

1. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada (2014). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Available at http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf
2. Ministry of Health and Long Term Care (2004). Ontario Regulation 329/04, Personal Health Information and Privacy Act. Toronto, ON: Queen's Printer for Ontario. Available at http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_040329_e.htm
3. Toronto Public Health (2011). Personal communication, Communicable Disease Surveillance Unit (CDSU).
4. Ministry of Health and Long Term Care (2004). Personal Health Information Protection Act (PHIPA). Toronto, ON: Queen's Printer for Ontario. Available at http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm
5. Ministry of Health and Long Term Care (1990). Municipal Freedom of Information and Protection of Privacy Act (MFIPPA). Toronto, ON: Queen's Printer for Ontario. Available at http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90m56_e.htm
6. Ministry of Health and Long Term Care (1990). Ontario Regulation 823, Municipal Freedom of Information and Protection of Privacy Act. Toronto, ON: Queen's Printer for Ontario. Available at http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_900823_e.htm
7. Toronto Public Health (2007). Personal Health Information Protection Act (PHIPA) Compliance Policy. Accessed on April 22, 2013: http://insideto.toronto.ca/health/policies/pdf/phipa_compliance.pdf
8. Health Canada (2003). Public Policy and Public Participation: Engaging Citizens and Community in the Development of Public Policy. Produced by Bruce L. Smith for the Population and Public Health Branch, Atlantic Regional Office.
9. Hall, S (2011). What is Policy Evaluation? Accessed on June 29, 2011: http://www.ehow.com/about_5368766_policy-evaluation.html
10. Ministry of Health and Long-Term Care (2008). Ontario Public Health Standards. Toronto, ON: Queen's Printer for Ontario. Available at http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/ophs_2008.pdf
11. Sunnybrook Health Sciences Centre (2011). REB-SOP-II-02.002: Duties of Research Ethics Board Members. Accessed on April 22, 2013: http://sunnybrook.ca/uploads/REB-SOP-II-02_002_Duties_of_REB_Members.pdf
12. Kahan B, Goodstadt M (1999). Continuous Quality Improvement and Health Promotion: Can CQI Lead to Better Outcomes? Health Promotion International, 14(1): 83-91.

11. APPENDICES

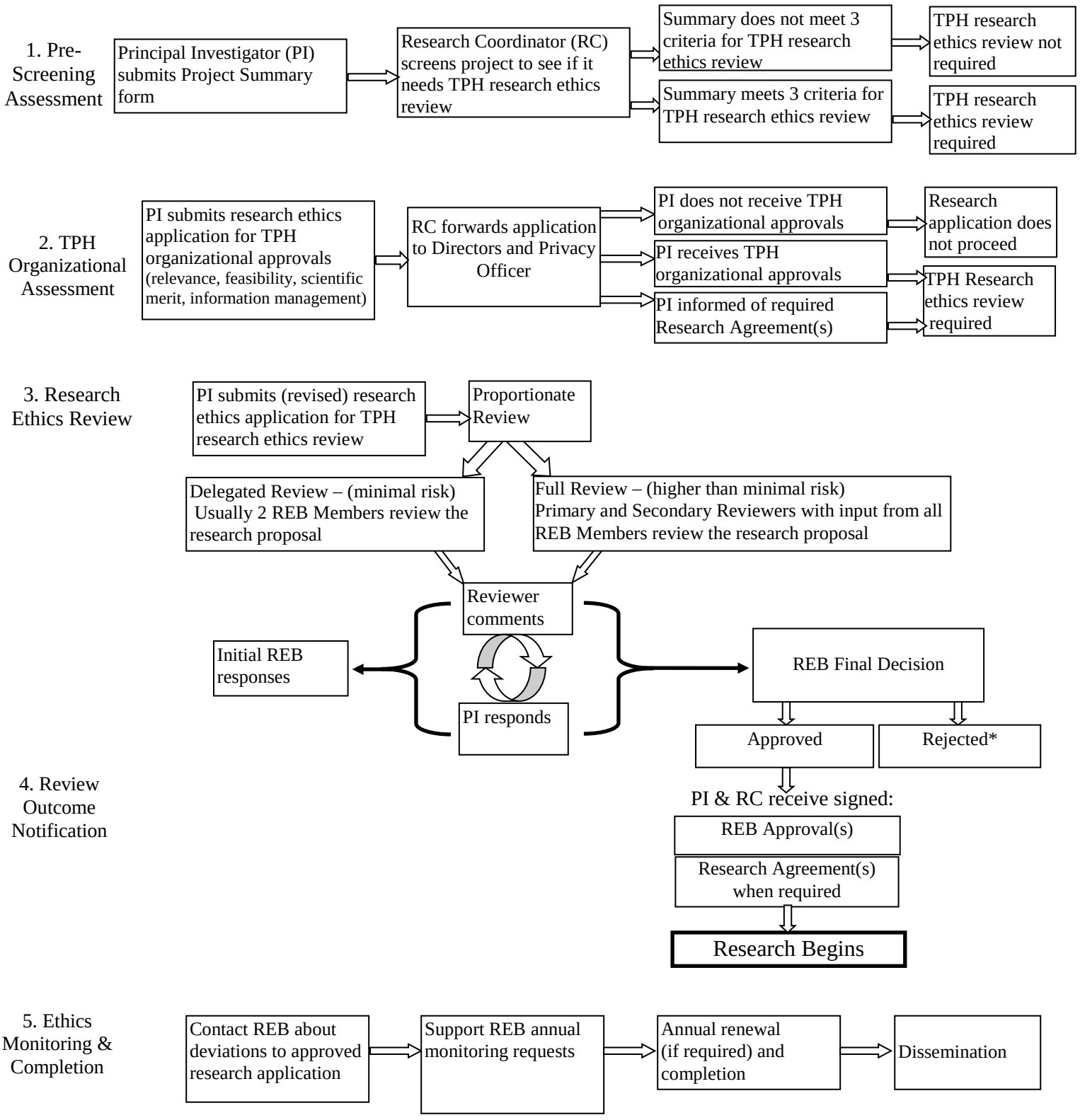
1. Steps in the TPH Research Ethics Review Process
2. TPH Research Ethics Review Process Flowchart

Appendix 1: Steps in the TPH Research Ethics Review Process



* Privacy Officer, in consultation with Directors, Legal, Principal Investigator(s) and Research Coordinator, will identify need for and content of Research Agreement(s)
**The TPH Research Proposal is comprised of four forms: TPH Research Application, Relevance & Feasibility form, Scientific Merit form, and Information Management/Privacy Review form.
** Research Coordinator must receive the signed Research Agreement(s), when required, before the approved project can start

Appendix 2: TPH Research Ethics Review Process Flowchart



* Under limited conditions the Principal Investigator may appeal the REB final decision