Public Health Research Planning, Approval, and Conduct

Reviewed Date		**Number**	*PP0103*
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Introduction

The Simcoe Muskoka District Health Unit is committed to continuing excellence in public health programming. Data collection initiatives contribute to the knowledge base on which we build our programs and services. These initiatives are guided by information privacy legislation, research standards and best practice.

As a public health agency we are accountable for ensuring the legal and ethical appropriateness of data collection initiatives and the quality and usefulness of the data collected. Under certain circumstances an agency-level review of a data collection initiative is required prior to implementation due to:

- the magnitude of possible physical, economic/financial, social, or psychological harms, or harms to people's rights for the individuals or groups participating, providing data or being studied; and/or
- the anticipated financial and/or human resource commitment.

The standards and process for review of these initiatives has been informed by information privacy legislation, research standards and policy statements regarding ethical conduct for research involving humans.

Purpose

The purpose of this policy is to provide the Board of Health, health unit staff, students, volunteers, partners and collaborators with defined parameters and a framework for the planning, review, approval and conduct of data collection initiatives that are deemed to:

- pose greater than minimal risk of harm for participants, respondents, and/or any others that may be affected by data collected or the initiative as a whole; and/or
- involve a significant financial or human resource commitment.

This review is required to ensure the legal and ethical appropriateness of data collection initiatives and the quality and usefulness of the data collected.

Legislative Authority

Municipal Freedom of information and Protection of Privacy Act R.S.O. 1990
Personal Health Information Privacy Act, R.S.O. 2004

Policy Definitions and Interpretation

This policy applies to:

- the planning, review, approval and conduct of data collection initiatives that are deemed by the Service Director to pose greater than minimal risk of harm for participants, respondents, and/or any others that may be affected by data collected or the initiative as a whole;
- the planning, review, approval and conduct of data collection initiatives that are deemed to require a significant financial and/or human resource commitment; and
- requests to access any health unit data or records for research purposes.

Data Collection Initiatives: The systematic gathering of information on persons or places that is not mandated by law or required for the routine provision of service directly to that place or person. (Activities such as evaluations and satisfaction surveys **would** fall under this policy. Activities such as the collection of data for the purpose of creating a health record for a client to whom services are being delivered or for outbreak management **would not** fall into this definition.)

Data Steward: The individual(s) responsible for defining the parameters for collection, use, disclosure, disposal and access to a specific set of data.

Express Consent: See policy IM0103 Information Privacy – Consent.

Health Information Council: The Health Information Council is a working group of the Population Health Assessment, Surveillance and Evaluation (PHASE) team. The purpose of the Health Information Council is to provide a venue for cross-program information sharing and discussion, team building, brainstorming and the proactive planning, collaboration and coordination of current/future projects regarding health information. A main objective of the council is to develop standards, and to draft and recommend policies and procedures that may be required to improve the collection, use and dissemination of health information in the agency.

Health Information Custodian: "health information custodian (HIC)" means a person or organization …who has custody or control of personal health information as a result of or in connection with performing the person's or organization's powers or duties or the work as a medical officer of health of a board of health within the meaning of the Health Protection and Promotion Act , 1990

Implied Consent: A "health information custodian…that receives personal health information about an individual from the individual, the individual's substitute decision-maker or another health information custodian for the purpose of providing health care or assisting in the provision of health care to the individual, is entitled to assume that it has the individual's implied consent to collect, use or disclose the information for the purposes of providing health care or assisting in providing health care to the individual, unless the custodian that receives the information is aware that the individual has expressly withheld or withdrawn the consent." (source Personal Health Information Protection Act R.S.O. 2004 S.20(2) . Implied consent is **NOT** a term that applies to the collection of information for purposes other than the provision of health care.

Research is defined as a systematic investigation designed to develop establish principles, facts or generalizable knowledge (PHIPA 2004). A research initiative consists of a written plan/protocol that includes the following elements:

- A specific research question which gives rise to a clear statement of the aim of the research or a testable hypothesis.
- Identification of a sample from a well-defined target population.
- A plan for the systematic collection, management and analysis of data.

- A plan for the use and dissemination of findings.

Most data collection initiatives undertaken by the agency would fall under this broad definition of research.

Risk of Harm Assessing potential harm is a pro-active process to identify, and then assess the magnitude of, possible physical, economic/financial, social, or psychological harms, or harms to people's rights. Potential harms are assessed for individuals or groups participating, providing data, or being studied in research initiatives; and also for others affected by data collection, data uses, or other aspects of the research initiative. Potential harms to individuals or groups affected by programmatic decisions directly affected by the research initiative (such as cessation of services) may also be considered.

For each potential harm identified for a relevant group, the level of risk should be assessed. Risk should for all participants, respondents, and any others that may be affected by data collected or the initiative as a whole. Minimal risk means that the probability and magnitude of possible harms is no greater than those in everyday life.

Vulnerable Persons: persons whose situation or characteristics may make them unable to provide free and informed consent to participate in research. This group includes children, institutionalized persons, those who have cognitive impairments, and those in a position of inferiority.

Policy

The Board of Health supports and encourages research that contributes to the knowledge base on which public health programs and services are built to ensure the use of the most effective and efficient strategies to achieve our goals.

The Board of Health is responsible for establishing policies and standards for research conducted by, through, on behalf of, and in partnership with the health unit to ensure that research is undertaken in accordance with:

- The vision, mission, values and strategic directions of the agency.
- Applicable information privacy legislation and related agency policy.
- Ethical standards as defined by the research community, professional bodies and agency policy.
- Existing agreements and standards for data collection, analysis, interpretation and dissemination.
- Standards for quality, feasibility, and usefulness of research.

The Medical Officer of Health will ensure that the Board of Health is informed of health unit research initiatives and outcomes through regular reports to the Board of Health.

Executive Committee will establish a review process to ensure legal and ethical appropriateness of the data collection initiatives deemed by the Service Director to pose greater than minimal risk of harm for participants, respondents, and/or any others that may be affected by data collected or the initiative as a whole; or where the Director deems there to be a significant investment of human or financial resources.

The Health Information Council is responsible for establishing and reinforcing the standards for research through policy recommendation, orientation and training and for supporting the Research Review Process by participating in the Research Review Process and training and orienting reviewers.

The Director Program Foundations and Finance is responsible for overseeing the Research Review Process.

The Service Director is responsible for ensuring that research conducted within their service is planned and conducted in accordance with agency policy and standards. The Service Director will request a research review if in his or her assessment the initiative poses greater than minimal risk of harm for participants, respondents, and/or any others that may be affected by data collected or the initiative as a whole; and/or the initiative is deemed to require a significant commitment of financial and/or human resources.

The Research Review Process does not constitute review by a research ethics board as outlined in the PHIPA R.S.O. 2004. Where this form of review is deemed necessary by the Service Director or as a result of the Research Review Process, options will be explored and identified.

When a proposed research initiative requires the disclosure of personal information or personal health information (as in the case where an external party requests access to a health unit data set) action will be taken in accordance with relevant legislation and the privacy policies and practices established by the agency.

Procedures

A. Data Collection Initiative Assessment

1. The Manager forwards a data collection plan to the Service Director for review and approval if one or more of the following apply:
    - the collection of information includes any collection of information that could be perceived as harmful, sensitive, or offensive;
    - personal information is collected or accessed (i.e. use of data within client records);
    - youth under 18 years of age or other vulnerable persons are the subject of data collection or engaged as participants in the initiative;
    - schools or other institutions are engaged as sites for data collection or their clients as participants; and/or
    - there is a significant investment of human or financial resources.

2. The Service Director(s) reviews and documents his/her assessment of the data collection plan against a standard set of criteria.

3. If in the Service Director's assessment, the initiative poses **greater** than minimal risk of harm for participants, respondents, and/or any others that may be affected by data collected or the initiative as a whole and/or requires a significant investment of human or financial resources, the Service Director(s) requests an agency-level review.

4. The Service Director(s) assesses the level of review required.

a) An Expedited Review can be considered when the research proposal has received approval from an external ethics committee or review board and full documentation of the proposal and the review is available.
b) A Research Review by a Research Review Committee will be considered appropriate in all other circumstances.

B. Research Review
Initiating a Research Review

1. The Service Director sends a Request for a Research Review to the Director Program Foundations and Finance and copies Executive Committee. The request includes the following information:
   - A complete data collection plan (PP0103 F1) with all required appendices
   - Completed director assessment
   - Rationale for requesting a review and for the level of review recommended

2. The Director Program Foundations and Finance reviews the package of materials for completeness and confirms the level of review required (expedited review or research review panel)

3. The Director Program Foundations and Finance works with the Administrative Assistant Program Foundations and Finance to document the complete proposal submission date and track review turnaround and completion in relation to target timelines.

4. Expedited Research Review Process (estimated two weeks turn around)
   a) The Director Program Foundations and Finance appoints a reviewer from a roster maintained by the Health Information Council and provides the reviewer with the complete package of materials.
   b) Within **one week** of receiving the package, the appointed reviewer undertakes the review in accordance with the agency defined standards. The reviewer may request additional information or documentation to complete the review.
   c) The Reviewer documents his or her decision using the Research Review Decision Form, (PP0103 F3) appends all materials reviewed and forwards a signed hard copy to the Administrative Assistant Program Foundations and Finance for filing.
   d) If approved, the Reviewer documents the duration for which approval is given and requirements for providing status report(s) on the decision form. Normally approval is granted for one year. It may be longer if the proposed length of the research project exceeds one year, or for a shorter period where the level of risk is of concern. For more information refer to TCPS 2, article 6.14. For research approval purposes, the research project is complete when all data has been collected and analyzed and there will be no further contact with research participants.
   e) The Reviewer provides an email or letter briefly summarizing the decision along with copies of the decision form, status report template (PP0103 F5), and related material to the Service Director(s) and applicant. The Reviewer will provide a clear decision of either approval, which may be accompanied by questions that need not delay the initiative, or non-approval which must be accompanied by identification of critical questions that must be answered and/or critical revisions to the submitted proposal required. There is no conditional approval.

f) The Service Director(s) requesting the review notifies Executive Committee of the outcome of the review process and this information is documented in the Executive Committee minutes.

5. Research Review Committee (approximately four weeks turn around)
   a) The Director Program Foundations and Finance appoints a review committee chair and two additional reviewers from a roster maintained by the Health Information Council and provides the committee with the complete package of materials.
   b) Within one week of receiving the package, The Research Review Committee Chair convenes the committee and undertakes the review in accordance with the agency defined standards. The committee may request additional information or documentation to complete its review. This request is conveyed via the Review Committee Chair to the proposal's author and copied to the Service Director(s).
   c) The Research Review Committee Chair documents the decision of the Committee using the Research Review Decision Form (PP0103 F3), appends all materials reviewed and forwards a signed hard copy to the Administrative Coordinator Program Foundations and Finance for filing. Individual committee member reviewer forms or other documentation is not retained with the committee level decision documentation.
   d) If approved the Research Review Committee Chair documents the duration for which approval is given and requirements for providing status report(s) on the decision form. Normally approval is granted for one year. It may be longer if the proposed length of the research project exceeds one year, or for a shorter period where the level of risk is of concern. For more information refer to TCPS 2, article 6.14. For research approval purposes, the research project is complete when all data has been collected and analyzed and there will be no further contact with research participants.
   e) The Research Committee Chair provides an email or letter briefly summarizing the decision along with copies of the decision form, status report template (PP0103 F5), and related material to the Service Director(s) and applicant. The committee will provide a clear decision of either approval, which may be accompanied by questions that need not delay the initiative, or non-approval which must be accompanied by identification of critical questions that must be answered and/or critical revisions to the submitted proposal required. There is no conditional approval.
   f) The Service Director requesting the review informs Executive Committee of the outcome of the review process and this information is documented in the Executive Committee minutes.
6. Research Review Appeals

   If the Service Director requesting the review does not agree with the decision, he or she may appeal the decision of the review committee or the expedited reviewer.

   a) The Service Director(s)'s request to appeal the decision of the Research Review Committee or Reviewer is placed on an executive committee meeting agenda.
   b) The Service Director(s) provide documentation of the proposal and the outcome of the review along with rationale.
   c) Executive Committee may overturn the decision of the Review Committee or Reviewer. The rationale for this decision will be clearly documented in the minutes of Executive Committee along with a letter to the review committee or reviewer documenting the rationale.

7. Amendments

If a major change in the approved research project is anticipated, an amendment must be submitted to the Expedited Reviewer or Review Committee Chair prior to implementing the changes. The process for review of the amendment form (PP0103 F6) is the same as outlined in items 4 and 5 above, with the decision being documented directly on the amendment form. The Research Review Committee Chair or Expedited Reviewer provides an email or letter briefly summarizing the decision along with copies of the amendment form (PP0103 F6) to the Service Director(s) and applicant.

A major change could include, but is not limited to, any one of the following:

- A change in methods, for example, a decision is made to conduct face-to-face interviews rather than use an anonymous online survey.
- A change in tools, for example, a decision is made to use a paper questionnaire instead of an online survey tool (i.e. SurveyMonkey, FluidSurveys) or vice versa.
- A significant change in timelines, for example, a decision is made to put the project on hold for months from the original submission, with the potential to affect the results.

Where there is any question of whether a change being considered for a research project would be considered a major change, it is advised that the project lead contact either the Expedited Reviewer or Review Committee Chair to determine whether an amendment form should be completed.

8. Status Reports

A status report (Form PP0103 F5) is to be completed by the project lead and submitted to the Administrative Coordinator, Program Foundations and Finance for distribution to the original Research Review Committee Chair or Expedited Reviewer or delegate within 30 days from the end date of the original or subsequent approval.

The Expedited Reviewer or the Research Review Committee Chair that granted approval, or delegate, will review the report to ensure the project has used or will continue to use sound research and evaluation practices and complies with the SMDHU policies, and to provide an extension of the approval period if appropriate. Reviewer(s) will follow the research review procedures in place at the time of the original submission and/or subsequent amendments in their assessment of this status report.

If the project has been completed, the status report will be filed to complete the research review documentation process. If the project requires an extension of the approval period, and the review results in changes that are required to comply with this policy, the reviewer will inform the primary contact of those requirements prior to extending the approval period. The primary contact would then be required to submit an amendment form outlining the necessary changes.

9. Documentation
    a. The Health Information Council will maintain an electronic file of all documentation related to each review for reference purposes.
    b. The Administrative Coordinator Program Foundations and Finance will maintain final documentation regarding each review. This will include:
        - Data collection plan or research plan along with any additional documentation that provides further details regarding the plan

- Final review (assessment form PP0103 F2 and decision form PP0103 F3) – signed by the chair or expedited reviewer.
- Amendment requests and decision
- Status reports.

c. Health Information Council will maintain a summary of completed reviews on the agency Intranet.

C. Requests for Agency Datasets or Records

1. External requests for access to/use of agency data sets or records for research purposes will be reviewed at a program/service level for value and feasibility as outlined in section A steps 2-6 above.
2. Where the data requests do not include access to personal information
    a. complete Form PP0103 F4Data Request Form
    b. submit to Director Program Foundations and Finance.
3. The Director Program Foundations and Finance logs receipt of the request, identifies the responsible Program Manager and Service Director(s) and forwards for review and endorsement or refusal.
4. The responsible Program Manager or Director communicates his/her decision to the requesting party and copies the Director Program Foundations and Finance.
5. The responsible Program Manager or Director forward endorsed request to data steward for processing. Timelines will be negotiated with the data steward and are dependent upon the scope of the data request.
6. Documentation of response to data request is maintained within the systems used by the program/service responsible for the data set.
7. Where data requested includes personal information from agency datasets the external party will be handled in accordance with the requirements of current privacy legislation.
    a) The researcher submits to the program an application in writing a research plan that meets the following requirements:
        - the affiliation of each person involved in the research;
        - the nature and objectives of the research and the public or scientific benefit of the research that the researcher anticipates.
        - a description of the research proposed to be conducted and the duration of the research.
        - a description of the personal health information required and the potential sources.
        - a description of how the personal health information will be used in the research, and if it will be 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 personal health information 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 personal health information 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 personal health information and how the researchers 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 researcher will impose to protect the confidentiality and security of the personal health information, including an estimate of how long information will be retained in an identifiable form and why.
- information as to how and when the personal health information will be disposed of or returned to the health information custodian.
- the funding source of the research.
- whether the researcher has applied for the approval of another research ethics board and, if so the response to or status of the application.
- whether the researcher's interest in the disclosure of the personal health information or the performance of the research would likely result in an actual or perceived conflict of interest with other duties of the researcher.
- a copy of the decision of a research ethics board that approves the research plan.

b) The Program Manager reviews the request with the program Service Director(s) and the Medical Officer of Health to determine appropriateness, value and feasibility of responding to the request. If the request is not supported within the service, the Service Director(s) responds to the researcher with the rationale.

c) If the request is endorsed, the Service Director(s) responds to the researcher outlining the decision and requirements for a contract.

d) Before a health information custodian discloses personal health information to a researcher, the researcher shall enter into an agreement with the custodian in which the researcher agrees to comply with the conditions and restrictions, if any, that the custodian imposes relating to the use, security, disclosure, return or disposal of the information. This agreement will include as a minimum the following conditions:

- comply with the conditions, if any, specified by the research ethics board in respect of the research plan;
- use the information only for the purposes set out in the research plan as approved by the research ethics board;
- not publish the information in a form that could reasonably enable a person to ascertain the identity of the individual;
- not disclose the information except as required by law and subject to the exceptions and additional requirements, if any, that are prescribed;
- not make contact or attempt to make contact with the individual, directly or indirectly, unless the custodian first obtains the individual's consent to being contacted;
- notify the custodian immediately in writing if the researcher becomes aware of any breach; and
- comply with the agreement.

e) The Administrative Coordinator maintains the official documentation in response to data requests on file.

Terms of Reference – Expedited Reviewer
Terms of Reference – Research Review Committee

Forms

PP0103F1 – Data Collection Plan Template
PP0103F2 – Research Reviewer Assessment
PP0103F3 – Research Review Decision
PP0103F4 – Data Request Form
PP0103F5 – Research Project Status Report Template
PP0103F6 – Research Project Amendment Form

Related Policies

Policy IM0101 Personal Information Including Personal Health Information Privacy – Principles
Policy IM0102 Personal Information Including Personal Health Information Privacy – Accountability
Policy IM0103 Personal Information Including Personal Health Information Privacy – Consent
Policy IM0104 Personal Information Including Personal Health Information Privacy – Collection & Use
Policy IM0105 Personal Information Including Personal Health Information Privacy – Disclosure
Policy IM0106 Personal Information Including Personal Health Information Privacy – Access
Policy IM0107 Personal Information Including Personal Health Information Privacy – Correction
Policy IM0108 Personal Information Including Personal Health Information Privacy – Privacy Breach
Policy PP0104 Data Collection and Use Policy

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