Public Health Research Planning, Approval and Conduct

Reviewed Date		**Number**	PP0103
Revised Date	January 24, 2024	**Approved Date**	May 29, 1996

Introduction

The Simcoe Muskoka District Health Unit (SMDHU) 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, a data collection initiative may require an agency-level review or review by an external research ethics board 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

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, in accordance with policy PP0104 (Data Collection and Use Policy), 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 and/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 Protection Act, R.S.O. 2004

Policy Definitions and Interpretation

Please see Appendix A.

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 knowledge translation.
- Standards for quality, feasibility, and usefulness of research.

Executive Committee is responsible for establishing a review process to ensure legal and ethical appropriateness of the data collection initiatives deemed, in accordance with policy PP0104, to pose greater than minimal risk of harm for participants, respondents, and/or any others that may be affected by the initiative; or where the Department Vice President deems there to be a significant investment of human or financial resources.

The Vice President Program Foundations and Finance (PFF) Department is responsible for overseeing the research review process.

The Department Vice President is responsible for ensuring that research conducted within their department is planned and conducted in accordance with agency policy and standards.

The PHASE Program 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 Program Manager leading any data collection initiative involving health care providers must notify the Office of the Medical Officer of Health (OMOH) prior to starting the data collection initiative. The OMOH must be informed of the purpose, target audience, and timelines of the data collection initiative.

The Program Manager leading the data collection initiative is responsible for reviewing and approving all data collection initiatives prior to Department Vice President review/approval, if required. No data collection activities, as defined in this policy, shall be initiated prior to manager assessment and approval as included in the Data Collection Plan (DCP) templates.

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. If expertise is outside the scope of

the PHASE program, PHASE Program Manager, Department Vice President, Vice President PFF, and/or the Privacy Officer, external consultation may be required.

When a proposed data collection initiative requires the engagement of Indigenous peoples, communities, or lands, racialized groups, and/or other equity-seeking populations, communities, or lands, in consultation with the Program Manager of PHASE and the Vice President Program Foundations and Finance, the procedures outlined below may be adapted to support the data collection initiative in accordance with The First Nations Principles of Ownership, Control, Access, and Possession (OCAP®) or other community-based ethics codes, as outlined in Chapter 9 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2).

Procedures

A. Data Collection Initiative Assessment

1. Data collection initiatives that previously received approval from a TCPS 2 compliant Research Ethics Board (REB) where full documentation of the proposal and the review is available qualify for an Administrative Review to ensure legal and ethical appropriateness, feasibility, and quality and usefulness of the data collected. If there has been any change to the data collection initiative previously approved from a TCPS 2 compliant REB, the data collection initiative will follow the internal procedures as outlined in Section B of agency policy PP0104.
    a. The Program Manager sends a copy of all materials reviewed and REB approval to their Department Vice President for review.
2. For all other data collection initiatives, the Program Manager will complete the Public Health Ontario (PHO) Risk Screening Tool (RST) and appropriate DCP or external PHO REB application as per PP0104.
3. The Program Manager will review and approve the DCP and PHO RST using the Program Manager Assessment form included in the DCP (where applicable), prior to initiation of data collection activities to ensure the legal and ethical appropriateness and feasibility of the data collection initiatives and to promote the quality and usefulness of data collected.
4. A review and approval of the PHO RST, DCP, and/or associated documents by the Department Vice President is required for initiatives where:
    a. the overall score from the PHO RST is 2 or 3, and can include;
        - information collected that could be perceived as harmful, sensitive, or offensive;
        - personal information is collected or accessed (i.e., use of data within client records);
        - persons in vulnerable circumstances are the subject of data collection or engaged as participants in the initiative; and/or
        - there is a potential conflict of interest (HR 0102);
    b. the overall score from the PHO RST is a 0 or 1, and one of the following applies;

- there is engagement with First Nations, Inuit, or Métis peoples, communities, or lands; and/or
- there is a significant investment of SMDHU human or financial resources;

c. initiatives have received prior approval from a TCPS 2 compliant REB.

The Department Vice President documents their assessment using the Vice President Assessment for Data Collection Initiatives form (PP0103 F1).

5. The Department Vice President will determine the level of research review required based on the following:

   a. An external REB review is required for all data collection initiatives that score a level 3 on the PHO RST, and there is no prior approval from another external TCPS 2 compliant REB.

   b. An SMDHU Research Review Committee review is required for data collection initiatives that score a level 2 on the PHO RST, or if in the Department Vice President's assessment, the initiative poses **greater** than minimal risk of harm for participants, respondents, and/or any others that may be affected by the initiative.

   c. An Administrative Review is required for all data collection initiatives that previously received approval from a TCPS 2 compliant REB and full documentation of the proposal and the review is available.

   The Department Vice President requests the appropriate review, as indicated above, from the Vice President Program Foundations and Finance or designate.

B. Research Review

Initiating a Research Review

1. The Department Vice President sends a request for research review to the Vice President Program Foundations and Finance or designate. The request includes the following information:
   - Completed DCP (PP0104 F2) or external REB application with all required documents
   - Completed PHO RST
   - Completed Vice President Assessment form (PP0103 F1)
   - Documentation of approval and a copy of all materials reviewed by a TCPS 2 compliant review board, if applicable
   - Rationale for requesting a review and for the level of review recommended.
2. The Vice President Program Foundations and Finance or designate reviews the package of materials for completeness and confirms the level of review required: administrative review, internal research review committee, or external REB review.
3. PFF is responsible for tracking and keeping records of all research review submissions.
4. **Administrative Review Process** (estimated two weeks turn around)

a. The Vice President Program Foundations and Finance or designate appoints a reviewer from a roster maintained by the PHASE program 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 Administrative Reviewer Terms of Reference. The reviewer may request additional information or documentation to complete the review which may extend timelines.

c. The reviewer documents their review using the Administrative Review Form, (PP0103 F6), appends all materials reviewed, and forwards a signed electronic copy to the PFF Administrative Coordinator for records.

d. If in their assessment, the reviewer determines the initiative does have appropriate approval, the reviewer documents the duration for which approval is given from the external TCPS 2 compliant REB. For research approval purposes, the research project is complete when all tasks in the approved external TCPS 2 compliant REB application are complete and there will be no further contact with research participants.

e. If in their assessment, the reviewer determines the initiative does not have appropriate approval or is missing critical documentation, the reviewer identifies critical missing document(s) from the external TCPS 2 compliant REB. If the project Program Manager or designate cannot provide the critical missing document(s) for approval, the project Program Manager or designate must follow the agency's Internal Procedures as outlined in agency policy PP0104.

f. The reviewer communicates to the Department Vice President and project Program Manager or designate by briefly summarizing the review and providing a copy of the Administrative Review form (PP0103 F6). The reviewer will provide a clear indication of whether the initiative has appropriate prior approval which may be accompanied by questions that need not delay the initiative, or the initiative does not have appropriate prior approval which must be accompanied by identification of critical missing document(s) from the external TCPS 2 compliant REB.

g. All initiatives that are submitted for an administrative review are exempt from completing SMDHU's amendment and status forms, as these forms will be replaced with the external TCPS 2 compliant REB forms and processes.

h. The project Program Manager or designate is to provide any amendment applications, amendment certificates, and status reports they submit/receive from the external TCPS 2 compliant REB to the administrative reviewer and copies the Administrative Coordinator Program Foundations and Finance for records.

5. **Internal Research Review Committee** (approximately four weeks turn around)

a. The Vice President Program Foundations and Finance or designate appoints a review committee chair and two additional reviewers from a roster maintained by the PHASE program 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 Research Review Committee Terms of Reference. The committee may request

additional information or documentation to complete its review which may extend timelines. This request is conveyed via the research review committee chair to the proposal's author and copied to the Department Vice President.

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 electronic copy to the Administrative Coordinator PFF for records. 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 Research Review Decision form (PP0103 F3). Usually, 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 6.13 and article 6.14. For research approval purposes, the research project is complete when all tasks in the approved DCP are complete and there will be no further contact with research participants.

e. The research review committee chair communicates to the Department Vice President and the project Program Manager or designate by briefly summarizing the decision and including copies of the Research Review Decision form (PP0103 F3) and Status Report form (PP0103 F4). 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 required critical revisions to the submitted proposal. There is no conditional approval.

6. **External Research Ethics Board Review** (timeline dependent on external TCPS 2 compliant REB)

    a. The Vice President Program Foundations and Finance or designate will notify the SMDHU Ethics Designate of all requests to use an external TCPS 2 compliant REB. The Vice President Program Foundations and Finance or designate will provide the SMDHU Ethics Designate with the complete package of materials.

    b. The PHO Research Ethics Board will be contacted by SMDHU's Ethics Designate regarding the need for a review. In the event that the PHO REB does not have the capacity to review the data collection initiative, the SMDHU Ethics Designate will identify an appropriate alternate external TCPS 2 compliant REB.

    c. Within **one week** of receiving the package, the Ethics Designate reviews the completed PHO REB application forms or delegated external TCPS 2 compliant REB forms for quality and completeness. The Ethics Designate may provide suggestions to the project Program Manager or designate to ensure completeness of the application.

    d. Once this review is complete, the project Program Manager or designate submits the completed application to the PHO REB or delegated external TCPS 2 compliant REB.

    e. All initiatives that are submitted to PHO's REB or the delegated external TCPS 2 compliant REB are exempt from completing SMDHU's amendment and status forms, as these forms will be replaced with the external TCPS 2 compliant REB forms and processes.

f. The PHO REB or delegated external TCPS 2 compliant REB will communicate their decision to the project Program Manager or designate. The Program Manager or designate will inform the Vice President Program Foundations and Finance or designate of the PHO REB or delegated external TCPS 2 compliant REB decision.

g. Copies of all forms received from the PHO REB or delegated external TCPS 2 compliant REB (e.g., project approval, amendment, project renewal, project completion forms) must be provided to the Administrative Coordinator Program Foundations and Finance for records.

7. Research Review Appeals

If the Department Vice President requesting the review does not agree with the decision of the SMDHU internal research review committee or administrative reviewer, they may appeal the decision.

a. For internal research reviews, the Department Vice President's request to appeal the decision of the research review committee or administrative reviewer is placed on an Executive Committee meeting agenda.

b. The Department Vice President provides documentation of the proposal and the outcome of the review along with rationale for an appeal.

c. Executive Committee may overturn the decision of the internal research review committee or administrative reviewer. The rationale for this decision will be clearly documented in the minutes of Executive Committee along with an email to the internal research review committee chair or administrative reviewer documenting the rationale. These must be provided to the Administrative Coordinator Program Foundations and Finance for records with the research review documentation.

d. For external TCPS 2 compliant REBs, the Department Vice President is to connect with the SMDHU Ethics Designate as appeal processes may differ.

8. Amendments to Projects Approved by Internal Research Review Committees

If a major change in the approved research project is anticipated, the project Program Manager or designate must submit a Research Project Amendment form (PP0103 F5) to the research review committee chair prior to the implementation of any changes.

All data collection initiatives that become routine practice/operational, will be required to submit a Research Project Amendment Form (PP0103 F5) if a major change in the originally approved data collection plan or previously approved amendment(s) is anticipated.

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 or vice versa.
- The addition of research questions not previously approved in the DCP.

- A significant change in timelines, for example, a decision is made to put the project on hold which could push the project timelines beyond the approval date included in the research review committee decision form.
- A change to the risk to human participants and/or to others impacted by the project.

The Research Project Amendment form (PP0103 F5) must identify and describe all changes along with rationale for each amendment. Given that changes may impact the project's overall risk level, the project Program Manager or designate must also complete a new PHO RST.

The process for review of the Research Project Amendment Form (PP0103 F5) will be based on the impact the amendments have on the approved research project.

- If impact does not change or decreases the risk, the Amendment form is reviewed by the research review committee chair;
- If impact changes the risk of the project to a level 3, the data collection initiative with proposed changes will follow the external REB review process.

The research review committee chair will document the decision on the Amendment form and communicates to the Department Vice President, Administrative Coordinator Program Foundations and Finance, and project Program Manager or designate by briefly summarizing and providing rationale for the decision along with electronic copies of the Research Project Amendment Form (PP0103 F5).

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 Program Manager or designate contact the research review committee chair to determine whether an amendment form should be completed.

9. Status Reports

For data collection initiatives that required an internal research review, a status report, using a Research Project Status Report Form (PP0103 F4), is to be completed, in its entirety, by the project Program Manager or designate and submitted to the Administrative Coordinator Program Foundations and Finance for distribution to the original research review committee chair or designate within 30 days from the project's expected completion date as specified in the approved DCP. If a status report has not been submitted within 30 days it is the responsibility of the research review committee chair, or designate, to request completion of a status report by the project Program Manager or designate.

The research review committee chair that granted approval, or designate, 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 project Program Manager or designate of those requirements

prior to extending the approval period. The project Program Manager or designate would then be required to submit an Amendment form outlining the necessary changes.

10. Documentation

a. The PHASE program 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:

- DCP along with any additional documentation that provides further details regarding the plan
- Completed PHO RST
- Final review (SMDHU Research Review Decision Form PP0103 F3) and correspondence– signed by the chair
- Administrative Review forms (PP0103 F6) – signed by the administrative reviewer
- Research Project Amendment forms (PP0103 F5)
- Research Project Status Report forms (PP0103 F4)
- All forms required by the PHO REB or delegated external TCPS 2 compliant REB (if applicable) (e.g., application, amendment, project renewal, project completion forms)

Terms of Reference – Administrative Reviewer

Terms of Reference – Research Review Committee

Related Policies

HR0102 Conflict of Interest

IM0101 Personal Health Information Privacy Policy
IM0108 Information Privacy and Security Incident Management Policy

IM0110 Records Management

PP0104 Data Collection and Use Policy

Related Forms

PP0103 F1 – Department Vice President Assessment

PP0103 F2 – Research Reviewer Assessment

PP0103 F3 – Research Review Decision

PP0103 F4 – Research Project Status Report

PP0103 F5 – Research Project Amendment

PP0103 F6 - Administrative Review

Research Review Process Flow Chart

Knowledge Translation Tool

Public Health Ontario Risk Screening Tool

Final Approval Signature: _____

Review/Revision History:

Revised: January 24, 2024

2008 March 5 – Revised
September 2010 Policy re-numbered, previous number A1.020
January 22, 2014 – Revised

Appendix A Glossary

Board of record: Research Ethics Board (REB) that has been given authority of ethics review and oversight for a particular research study.

Conflict of Interest: See Policy HR0102 Conflict of Interest.

Data Collection Initiatives: The systematic gathering of evidence-generating information involving persons or places that is not mandated by law (e.g., *Health Protection and Promotion Act R.S.O. 1990*, Ontario Public Health Standards, *Personal Health Information Protection Act R.S.O 2004*). Activities such as evaluations, surveys, or surveillance activities used for program planning and/or decision making and are not mandated by law **would** fall under this policy. Activities such as evaluations using existing program records, surveillance activities mandated by law or the collection of data for the purpose of creating a health record for a client (e.g., individuals, businesses, community groups, organizations, external partners) 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.

Equity Seeking Group: Groups that identify barriers to equal access, opportunities, and resources due to disadvantage and discrimination and actively seek social justice and reparation.

Ethics Designate: A member of the Population Health Assessment, Surveillance and Evaluation (PHASE) Program who acts as a liaison between SMDHU and external Research Ethics Boards and supports staff through the ethics process.

First Nations, Inuit and Métis Lands: Include First Nation communities (Indian reserves as defined by the Federal Government), Métis settlements, and lands governed under a self-government agreement or an Inuit or First Nations land claim agreement or as defined by the most recent version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2).

Health Information Custodian: 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.

Indigenous Peoples: Persons of First Nations (Indian as defined by the Federal Government), Inuit, or Métis descent regardless of where they reside and whether or not their names appear on an official register or as defined by the most recent version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2) as this document guides, in part, ethical research involving First Nations, Inuit, and Metis Peoples.

- If the initiative involves Indigenous Peoples, the initiative must comply with Chapter 9 of the TCPS 2.

Institution: For the purpose of this policy***,*** an institution may include child care centers, supported group living residences, intensive support residences, homes for special care, long-term care homes, psychiatric facilities, correctional institutions, detention facilities, or hospitals, as defined by section 21(1) of the *Health Protection and Promotion Act, 1990*.

Knowledge Translation*:* The practice of communicating research/evaluation findings using processes and strategies that ensure the results can be accessed and understood in a manner that can benefit a range of knowledge users as appropriate.

Personal Health Information: See policy IM0101 Personal Health Information Privacy Policy.

Personal Information: Means recorded information about an identifiable individual, including:

- information relating to the race, national or ethnic origin, colour, religion, age, sex, gender, sexual orientation, or marital or family status of the individual,
- information relating to the education or the medical, psychiatric, psychological, criminal, or employment history of the individual or information relating to financial transactions in which the individual has been involved,
- any identifying number, symbol, or other particular assigned to the individual,
- the address, telephone number, fingerprints, or blood type of the individual,
- the personal opinions or views of the individual except if they relate to another individual,
- correspondence sent to an institution by the individual that is implicitly or explicitly of a private or confidential nature, and replies to that correspondence that would reveal the contents of the original correspondence,
- the views or opinions of another individual about the individual, and
- the individual's name if it appears with other personal information including personal health information relating to the individual or where the disclosure of the name would reveal other personal information including personal health information about the individual.

***Persons in Vulnerable Circumstances*:** May include persons whose situation or characteristics may limit their ability to provide free and informed consent to participate in data collection initiatives or who have historically or may currently be at increased risk of being treated inequitably in or from data collection initiatives. This may include:

- Named ethnic or cultural groups, faith-based groups, persons of a specific sexual orientation or gender, immigrant populations or refugees that may experience study-related harms, or unintended negative health impacts
    - If the initiative involves Indigenous Peoples, the initiative must comply with Chapter 9 of the TCPS 2.
- Linguistic communities (e.g., uncomfortable using English or French, those whose literacy affects communication)
- Persons whose health or equity could be impacted by their age, developmental factors, or physical changes (e.g., infants, children, youth, seniors)
- Populations served by institutions (e.g., patients, residents, students – regardless of age)
- Persons engaging in illegal activity
- Persons associated with or engaged in potentially stigmatizing condition or activity (e.g., drug use, gambling, diagnosed with drug-resistant tuberculosis (XDR-TB))

- Persons that may have a limited ability to understand the purpose, risks, and benefits of an initiative (e.g., conditions impacting cognition)
- People who, because of an acute or chronic condition or current circumstance, may be more vulnerable to study-related harms (e.g., acutely ill, mental illness, new mothers, recently bereaved, unemployed, persons living in marginal housing or without a home, persons living in low income)
- People who, because of their position, may feel pressured to participate (e.g., prisoners, students, employees, people being approached by peers or caregivers)
- Identifiable neighbourhoods or communities (e.g., small geographic regions at the street or neighbourhood level)

Individuals or groups may experience vulnerability to different degrees and at different times, depending on their circumstances or the nature of the data collection initiative.

This list can be adapted if the program feels there may be another group that may, because of their situation or characteristics, be limited in their ability to provide free and informed consent or may be at risk for study-related harms or inequity. For more information, please see the Ministry of Health's most recent Health Equity Impact Assessment Workbook or Tool.

Note the terms listed above may or may not be the terminology used or preferred by the members of the community in question. Communities should be consulted for preferred terminology.

Persons in vulnerable circumstances refers to the use of any of these categories or other persons in vulnerable circumstances as an inclusion criterion in the data collection initiative because the persons are a specific focus of interest. It does not apply to the chance inclusion of individuals with these characteristics where the focus is on the general population.

***Population Health Assessment, Surveillance and Evaluation (PHASE) Program*:** The PHASE Program provides leadership and coordination in addressing the Ontario Public Health Standards' Foundational Standard requirements which include population health assessment, surveillance, research and knowledge translation, and program evaluation.

Research: A systematic investigation designed to develop established 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. (See Knowledge Translation Tool as a tool to guide dissemination or knowledge translation planning).

Initial exploratory work to help a researcher design a study or establish a research partnership does not fall within this definition of research, and therefore does not require REB review. Consultations with a community to obtain the authorization to proceed with a research study or to obtain information that will be used to develop the research proposal are examples of exploratory work (TCPS 2).

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

Research Ethics Board, also known as Ethics Review Board or Research Review Board, hence forth referred to as Research Ethics Board (REB) for the purpose of this policy. Chapter 6 of the Tri-Council Policy Statement (TCPS 2; 2022) sets out the elements of a research ethics board "including the procedures necessary to establish a research ethics board (REB), and operational guidelines for the REBs and research ethics review, both initially and throughout the course of the research project."

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 for all participants, respondents, and any others that may be affected by data collected or the initiative as a whole. REBs and researchers need to understand the influence of the culture, values and beliefs of the population being studied, or the social and economic circumstances of the individuals being recruited for participation. Minimal risk means that the probability and magnitude of possible harms is no greater than those in everyday life.

Surveillance: Surveillance includes "the continuous, systematic collection, analysis, and interpretation of health data, needed for the planning, implementation, and evaluation of public health practice", as defined by the *Population Health Assessment and Surveillance Protocol* of the *Ontario Public Health Standards*.

Unintended Impacts: Unintended positive and negative impacts for those who are included and excluded from the data collection initiative. For example, a diabetes prevention and management program provided online may exclude those with no internet access, unintentionally having a potential inequitable impact on health among those groups (Ministry of Health (MOH), Health Equity Impact Assessment (HEIA) Workbook).

Unintended impacts are an important consideration in the overall welfare for participants and/or others impacted by the initiative. Other considerations for welfare include considering the short and long-term risks and benefits of the initiative on all aspects of health (e.g., physical, mental, spiritual, social, and economic) at the individual level, the group level and/or the broader community. Risks should be minimized or mitigated whenever possible.