Data Collection and Use Policy

Reviewed Date		**Number**	*PP0104*
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Introduction

Data are collected in the course of daily activities to support the delivery of programs and services. Data may also be collected and used for the purposes of disease surveillance, needs assessment, program monitoring, program evaluation and policy analysis. These data collection initiatives contribute to the knowledge base on which we build our programs and services and ensure that we use the most effective and efficient methods to achieve our goals. They are guided by information privacy legislation, research standards and best practice.

Purpose

The purpose of this policy is to guide health unit staff, students, contractors, and volunteers in data collection and use and to establish clear review and approval processes for these activities. These parameters have been put in place to ensure the legal and ethical appropriateness and feasibility of the data collection initiatives and to promote the quality and usefulness of 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

This policy applies to the planning and approval of data collection initiatives as well as the use and management of the data. The policy and procedures apply to all data collection initiatives implemented by, through, or on behalf of the health unit, including internal, external and partnership initiatives.

Please see Appendix A for definitions.

Policy

A written data collection plan (DCP) will be developed for all data collection initiatives, as defined in this policy, that includes as a minimum:

- purpose and objectives
- data uses and users
- methods for data collection and analysis

- a listing of the indicators
- identification of intent to collect personal information or personal health information and strategies to protect privacy and access
- workplan including timelines and resources required to collect, analyze, and disseminate the data.

All original data collected through the data collection initiative that contains personal information, personal health information, or sensitive information that has not been anonymized will only be accessible to the PHASE staff member(s) assigned to support the data collection initiative. This is to ensure the protection of privacy, and as identified in the informed consent.

The Department Vice President and/or Program Manager will ensure that all data collection initiatives are assessed for risk using Public Health Ontario's Risk Screening Tool, except those that have received approval from an external Tri Council Policy Statement 2 (TCPS 2) compliant review board, as per policy PP0103.

Program Managers will review and approve all DCPs using the Program Manager Assessment form included in the DCP templates, 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. Program Managers will apply the current Public Health Ontario (PHO) Risk Screening Tool (RST) to all DCPs.

A review and approval of the PHO RST, DCP, and associated documents by the Department Vice President is required for initiatives as outlined in agency PP0103 (Public Health Research Planning, Approval and Conduct).

The Department Vice President will request the appropriate research review in accordance with agency policy PP0103 if the RST scores a 2 or 3.

The PHASE Program is responsible for establishing and reinforcing the standards for data collection, use, analysis and, with support where applicable from the Health Equity, Health Promotion and Communication Program (HEHPC), knowledge translation and providing training and orientation to best practice theories and concepts.

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.

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, Program Manager, Department Vice President, Vice President Program Foundations and Finance (PFF) 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 Vice President PFF , 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 TCPS 2.

Procedures

A. Determining the Nature of the Health Unit's Relationship to the Initiative

1. Staff member or external partner proposes a data collection initiative to a Program Manager.
2. The Program Manager makes a preliminary assessment of the value and feasibility of the proposed initiative, in consultation with partners. For initiatives initially deemed by the Program Manager to be of value and feasible, the Program Manager clarifies the nature of the health unit's relationship to the initiative using one of the following categories:

   Internal: initiative proposed, planned, and implemented by the health unit alone, working with no external organizations or groups. Follow the procedures in Section B 'Internal Procedures.'

   External: initiative proposed, planned, and implemented by an external party, with no health unit funding, leadership, staffing, or responsibility other than providing access to information/data or opportunities for data collection. Follow the procedures in Section D 'External Requests for Access to Agency Datasets or Records for Research Purposes' or Section E 'External Requests for Access to Health Unit Staff for Research Purposes.'

   Partnership: initiative proposed, planned, and/or implemented by the health unit in collaboration with at least one other external partner. Any of the following aspects of health unit involvement may apply:

   - The initiative will be conducted by a coalition of agencies/organizations of which the health unit is a member;
   - Health unit staff are designing and implementing the data collection/research;
   - An external partner is designing and implementing the data collection/research;
   - The initiative is supported by health unit funds or in-kind resources.
   - The initiative is funded from grant or external funds administered through the health unit.

   Follow the procedures in Section C 'Partnership Procedures.'

B. Internal Procedures

1. Prior to beginning the internal DCP process, initiatives that previously received approval from a TCPS 2 compliant REB and has no changes to the data collection initiative since approval, will be subject to an administrative review in accordance with the process outlined in agency policy PP0103.

2. For all other data collection initiatives, Project Program Manager or designate determines the appropriate DCP requiring completion by first completing the PHO RST. The completed RST must be downloaded from the PHO RST online tool.

   Project Program Managers or designates are encouraged to access PHASE supports for the appropriate selection and development of their DCPs. PHASE supports can be accessed via the annual Operational Planning Request or PHASE Ad hoc Request Help Desk.

   For instances where any procedure of PP0104 may come into question for data collection initiatives the applicable Department Vice President must consult with the Vice President Programs Foundations and Finance on the requirements for a data collection plan. If in consultation, an agreement cannot be reached about a data collection plan, the Medical Officer of Health/CEO will be consulted for final decision.

   - If the score from the PHO RST is a 0 or 1, the minimum DCP (PP0104 F1) is to be completed. Data collection may begin once the Project Program Manager reviews and approves the plan using the Program Manager Assessment form integrated within the minimum DCP. Regardless of the PHO RST score, all DCPs where First Nations, Inuit, or Métis peoples, communities, or lands are engaged, and/or there is a significant investment of human or financial resources must be sent to the Department Vice President for review and approval. If the data collection initiative will involve adults directly connected to school settings (parents, teachers, administrators, etc.), Department Vice President approval is required.
   - If the score from the PHO RST is a 2, a full DCP (PP0104 F2) must be completed. Once the Project Program Manager reviews and approves the plan using the Program Manager Assessment form integrated within the full DCP, the Project Program Manager sends the completed full DCP, PHO RST and supporting documents to the Department Vice President for review and approval.
   - If the score from the PHO RST is a 3, an external REB application form must be completed by the Project Program Manager or designate. The Project Program Manager or designate will connect with the SMDHU Ethics Designate to receive the appropriate PHO REB forms, application deadlines, and any assistance, as needed. Once the Project Program Manager reviews and approves the application, the Project Program Manager sends the completed application, PHO RST, and supporting materials to the Department Vice President for review and approval.

3. As outlined in agency policy PP0103, the Department Vice President reviews and documents their assessment of the full DCP using the Vice President Assessment for Data Collection Initiatives form (PP0103 F1).
4. Once the DCP is reviewed and approved in accordance with PP0103, the Project Program Manager is responsible for ensuring the data collection initiative is implemented in accordance with the approved plan.
5. If there are any major changes (e.g., changes in methods, tools, timelines, or risk to participants or others) to the DCP after receiving approval, the Project Program Manager or designate must follow the amendment process outlined in PP0103.

6. The DCP is maintained on file within the department, forming part of the record of the initiative, and shared or referenced as required to guide collection, use, information management and knowledge translation. The Administrative Coordinator Program Foundations and Finance will maintain final documentation for all initiatives requiring external research ethics board reviews, internal research committee reviews or administrative reviews.

C. Partnership Procedures

1. While participating in a multi-site or partnership initiative, the Simcoe Muskoka District Health Unit will determine review requirements based on the nature of the partnership:
    a. If SMDHU is the lead on the initiative, then the Project Program Manager or designate will follow the internal procedures outlined in Section B, while also determining the following:
        - REB approval requirements for each collaborating partner.
    b. If SMDHU is not the lead, then an ethics review to one external TCPS 2 compliant REB on behalf of all partners may be delegated to streamline the ethics review process where:
        - The REB has the appropriate expertise to review the initiative;
        - Delegating the review is appropriate for the given data collection initiative; and
        - One or more partnering organizations agree to delegate ethics review to the REB.

    The SMDHU Ethics Designate should be consulted to determine if the above criteria are applicable to the initiative.

    If the above criteria are met, SMDHU must appoint the external TCPS 2 compliant REB as the board of record for the initiative.
2. Once approved, the SMDHU Project Program Manager or designate receives a copy of all forms required by the external TCPS 2 compliant REB (e.g., project approval, amendment, project renewal, project completion forms) from the lead partner, and sends them to the Administrative Coordinator Program Foundations and Finance for records.
3. If the above criteria are not met, the data collection initiative must either (1) receive approval from a TCPS 2 compliant REB or (2) follow the internal procedures outlines in Section B, in order for the health unit to fully participate in a partnership initiative.
4. Initiatives that previously received approval from a TCPS 2 compliant REB will be subject to an administrative review to ensure legal and ethical appropriateness, feasibility, and quality and usefulness of the data collected. A copy of all materials reviewed by the REB (including application or approval letters) shall be forwarded to SMDHU project lead to facilitate the administrative review process. The administrative review process will be in accordance with the process outlined in agency policy PP0103.
5. Initiatives that have not previously received approval from an external TCPS 2 compliant REB must follow the internal procedures outlined in Section B.

D. External Requests for Access to Agency Datasets or Records for Research Purposes

1. External requests for access to/use of agency data sets or records for research purposes will be reviewed at a program/department level in consultation with the PHASE Program Manager for value and feasibility.
    a. Requestor completes form PP0104 (F3) External Data Request Form
    b. Submits completed form to the Vice President Program Foundations and Finance or designate.
2. The Vice President Program Foundations and Finance or designate logs receipt of the request, identifies the appropriate Program Manager(s) or Department Vice President(s) and forwards for review and endorsement or refusal.
3. The appropriate Program Manager(s) or Department Vice President(s) communicates their decision to the requesting party and copies the Vice President Program Foundations and Finance or designate.
4. The appropriate Program Manager(s) or Department Vice President(s) forwards the endorsed request to the data steward for processing. Timelines will be negotiated with the data steward and are dependent upon the scope of the data request.
5. Documentation or response to the data request is maintained within the systems used by the program/department responsible for the data set or records.
6. If a request for access/use of agency data sets or records containing personal information or personal health information for research purposes is received, a written research plan is also required and will be handled in accordance with the requirements of privacy legislation, as outlined in agency policy IM0101 Personal Health Information Privacy Policy.
    a. The researcher submits to the program 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 REB 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 REB that approves the research plan.

b. The Program Manager reviews the request, including the research plan, with the Department Vice President, and if necessary the Medical Officer of Health and the Privacy Officer, to determine appropriateness, value, and feasibility of responding to the request.

c. 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 REB in respect of the research plan;
- Use the information only for the purposes set out in the research plan as approved by REB;
- 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 in accordance with agency policy IM0108;
- The method for sharing, return and disposal of the information in accordance with SMDHU policy, and
- Comply with the agreement.

d. The Administrative Coordinator Program Foundations and Finance maintains the official documentation in response to data requests on file. For information on receiving, processing, and documenting requests, please refer to IM0101 Personal Health Information Privacy Policy.

E. External Requests for Access to Health Unit Staff for Research Purposes

Approval for Participation

1. External requests for access to staff (front-line staff, management) for research purposes will be reviewed at a program, department or agency level for value, feasibility, and approval.
    a. External requests that require approval from the Program Manager are those that meet the following criteria:
        - All data collection initiatives, regardless of method (online survey, focus groups, key informant interviews, debriefs, hotwashes, etc.) where participants are representing the views of a particular program.
    b. External requests that require approval from the Department Vice President or Executive Committee (for initiatives that span multiple programs or departments) are those that meet the following criteria:
        - All data collection initiatives, regardless of method (online survey, focus groups, key informant interviews, debriefs, hotwashes, etc.) where participants are representing the views of SMDHU, or a particular department, and/or
        - Data collection initiatives that require a research ethics review (as per policy PP0103 and/or PP0104).
    c. External requests that do not require approval from a Program Manager, the Department Vice President or Executive Committee are those that meet the following criteria:
        - Data collection initiatives from professional organizations (e.g., CIPHI, APHEO, ASPHIO, ONA, OPHNL, OPHA, alPHa, ODPH, RNAO, RPNAO, government) that ask questions specific to a public health role, or organizational practices.
        - Informal data collection initiatives, such as webinar polls, or list serve questions regarding health unit practice.

Participation Process

1. Staff who receive a request to participate in a data collection initiative that requires approval are to inform their Program Manager or, if the Program Manager receives the request, their Department Vice President.
2. The Program Manager or Department Vice President will consider the following:
    - Adds value to SMDHU and population health,
    - Relates to the Ontario Public Health Standards,
    - Resourcing for staff and time required to complete the survey,
    - Participation in a meeting/interview/debrief session or involvement in a research initiative,
    - Any areas of concerns regarding capacity to participate.
3. Once the Program Manager determines participation is appropriate as outlined above, the Department Vice President will be informed of the request for approval purposes.
4. Once the Department Vice President determines participation is appropriate as outlined above and the initiative spans multiple programs or departments, Executive Committee will be informed of the request for approval purposes.
5. Once participation is approved, a lead will be assigned to coordinate responses and to send final feedback to the requestor.
6. The assigned lead will request a copy of the data collection tool (in Word format), if not included in the original email. This will aid in determining the appropriate internal respondents, ease response completion, and for record keeping purposes. If applicable, the assigned lead will request protocols and REB documents (including approvals, if applicable).
7. The assigned lead, with input from appropriate management will determine who (e.g., internal staff/management) should be asked to participate in the data collection initiative, particularly if the topic of interest crosses multiple programs or departments.
8. The assigned lead then connects with potential participants, requests feedback, and collates responses using the data collection tool.
9. For requests that span multiple departments or programs, the assigned lead advises Executive Committee via email, with the Program Manager of PHASE copied, of the request including the following:
    - The purpose of the data collection initiative,
    - Staff leading data collection or participating in focus groups/key informant interviews/research
    - Timelines and deadline dates for data collection/participation.
10. The assigned lead will save all associated documents (e.g., invitation email, data collection tool questions and responses/summary of responses, final reports, research protocols, REB approvals, and other relevant documentation) in a central location:

- \\Jenner\Sharedata\Health Unit\Research and Evaluation\External Evaluations (for those with non-sensitive responses)
- M:\Management\Research and Evaluation\External Evaluations (where responses are only to be seen by management)

11. The assigned lead will email the appropriate individuals (Program Manager, Department Vice President, Executive Committee) and copy the Program Manager of PHASE once SMDHU participation has concluded.

Related Policies

HR0102 Conflict of Interest
IM0101 Personal Health Information Privacy Policy
IM0108 Information Privacy and Security Incident Management Policy
PP0103 Public Health Research Planning, Approval and Conduct
IM0110 Records Management

Related Forms

PP0104 (F1) - Minimum Requirements for a Data Collection Plan
PP0104 (F2) - Full Data Collection Plan
PP0104 (F3) - External Data Request Form
PP0103 (F1) - Vice President Assessment

Public Health Ontario Risk Screening Tool (PHO RST)
Public Health Ontario Ethics Review Board Application Form
Research Review Process Flow Chart

Final Approval Signature: _____

Review/Revision History:

September 2010 Policy re-numbered, previous number A1.021

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Appendix A Glossary

Board of record: Research Ethics Board (REB) that has been given authority for 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: Are 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 the Simcoe Muskoka District Health Unit 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

Indicator: A clue, sign or marker that measures the objectives of the data collection initiative and answers the research questions. Indicators are realistic and measurable criteria of the data collection initiative outcome.

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 purposes 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 is to provide 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 and 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. (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 Boards, also known as Ethics Review Boards, henceforth 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 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 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).Appendix A Glossary

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.