RESEARCH ETHICS BOARDS UNDER HEALTH PRIVACY LEGISLATION

In addition to requirements set forth under provincial privacy statutes (see also the Secondary Uses of Health Data for Research Purposes Chart on AccessPrivacy), researchers must also be aware of the requirements of the research ethics board ("REB") approving their research and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* ("**Tri-Council Policy**") when conducting research. A High-level summary of the Tri-Council Policy is provided below.

TRI-COUNCIL POLICY STATEMENT • *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* – TCPS 2 (2022) ("Tri-Council Policy") *Please note that this is a high-level overview of the Tri-Council Policy. Please refer to the Tri-Council Policy Statement for more detail.*	
Definition of *research*	**Tri-Council Policy** **Chapter 2 – Application:** For the purposes of this Policy, "research" is defined as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. The term "disciplined inquiry" refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community.
Composition of REB	**Tri-Council Policy** **Article 6.4:** The REB shall consist of at least five members, including both men and women, of whom at least: a. two members have expertise in relevant research disciplines, fields and methodologies covered by the REB; b. one member is knowledgeable in ethics; c. one member is knowledgeable in the relevant law. That member should not be the institution's legal counsel or risk manager. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research; and d. one community member has no affiliation with the institution. It is advisable that each member be appointed to formally fulfill the requirements of only one of the above categories. To ensure the independence of REB decision making, institutional senior administrators shall not serve on the REB.
Approach to research ethics review	**Tri-Council Policy** **Article 2.7:** As part of research ethics review, the REB shall review the ethical implications of the methods and design of the research. **Application:** The primary test to be used by REBs in evaluating a research project should be ethical acceptability and, where appropriate, relevant disciplinary scholarly standards.

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	Article 6.12: In keeping with a proportionate approach to research ethics review, the selection of the level of REB review shall be determined by the level of foreseeable risks to participants: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review).
Research requiring ethics review by an REB	**Tri-Council Policy** **Article 2.1:** The following requires ethics review and approval by an REB before the research commences. Research involving: a. living human participants; b. human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials, and stem cells. This applies to materials derived from living and deceased individuals. **Article 2.4:** REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information. *For more information on research that requires ethics review, please see Chapter 2 of the Tri-Council Policy.*
Requirements for researchers	**Tri-Council Policy** **Article 6.11:** Researchers shall submit their research proposals, including proposals for pilot studies, for REB review and approval of their ethical acceptability prior to the start of recruitment of participants, data collection, access to data or collection of human biological materials. REB review is not required for the initial exploratory phase, which is intended to establish research partnerships or to inform the design of a research proposal, and may involve contact with individuals or communities. *For more information on research proposal requirements, please see Chapter 6 and Chapter 10 of the Tri-Council Policy.*
Decisions of REBs – Approval, Reconsideration, & Appeals	**Tri-Council Policy** **Article 6.13:** REBs shall function impartially, provide a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions. REBs should make their decisions on the ethical acceptability of research in an efficient and timely manner, and shall communicate all approvals and refusals to researchers in writing, in print or by electronic means, in accordance with their procedures.

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	Article 6.18: Researchers have the right to request, and REBs have an obligation to provide, prompt reconsideration of decisions affecting a research project. **Article 6.19:** Institutions shall have an established mechanism and a procedure in place for promptly handling appeals from researchers when, after reconsideration, the REB has refused ethics approval of the research.

ONTARIO • *Personal Health Information Protection Act*, 2004, SO 2004, c 3, Sch A ("Ontario PHIPA") • *General*, O Reg 329/04 ("Ontario Regulation")	
Definition and composition of *research ethics boards* ("REBs")	**Ontario PHIPA** **S. 2: "research ethics board"** means a board of persons that is established for the purpose of approving research plans under section 44 and that meets the prescribed requirements; ("commission d'éthique de la recherche") **S. 2: "prescribed"** means prescribed by the regulations made under this Act; ("prescrit") **Ontario Regulation** **S. 15.1:** The board must have at least five members, including, i. at least one member with no affiliation with the person or persons that established the research ethics board, ii. at least one member knowledgeable in research ethics, either as a result of formal training in research ethics, or practical or academic experience in research ethics, iii. at least two members with expertise in the methods or in the areas of the research being considered, and iv. at least one member knowledgeable in considering privacy issues.
Definition of *research* and *researcher*	**Ontario PHIPA** **S. 2: "research"** means a systematic investigation designed to develop or establish principles, facts or generalizable knowledge, or any combination of them, and includes the development, testing and evaluation of research; ("recherche") **S. 2: "researcher"** means a person who conducts research; ("chercheur")
Permitted use by a custodian without consent	**Ontario PHIPA** **S. 37(1):** A health information custodian may use personal health information about an individual,… (j) for research conducted by the custodian, subject to subsection (3), unless another clause of this subsection applies;… **S. 37(3):** Under clause (1) (j), a health information custodian may use personal health information about an individual only if the custodian prepares a research plan and has a research ethics board approve it and for that purpose subsections 44 (2) to (4) and clauses 44 (6) (a) to (f) apply to the use as if it were a disclosure.

Permitted disclosure by a custodian to a researcher without consent	**Ontario PHIPA** **S. 29**: A health information custodian shall not collect, use or disclose personal health information about an individual unless, (a) it has the individual's consent under this Act and the collection, use or disclosure, as the case may be, to the best of the custodian's knowledge, is necessary for a lawful purpose; or (b) the collection, use or disclosure, as the case may be, is permitted or required by this Act. **S. 44(1)**: A health information custodian **may disclose** personal health information about an individual to a researcher if the researcher, (a) submits to the custodian, (i) an application in writing, (ii) a research plan that meets the requirements of subsection (2), and (iii) a copy of the decision of a research ethics board that approves the research plan; and (b) enters into the agreement required by subsection (5).
Requirements for research plans	**Ontario PHIPA** **S. 44(2)**: A research plan must be in writing and must set out, (a) the affiliation of each person involved in the research; (b) the nature and objectives of the research and the public or scientific benefit of the research that the researcher anticipates; and (c) all other prescribed matters related to the research. **Ontario Regulation** **S. 16:** The following are prescribed as additional requirements that must be set out in research plans for the purposes of clause 44(2)(c) of the Act: 1. A description of the research proposed to be conducted and the duration of the research. 2. A description of the personal health information required and the potential sources. 3. 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. 4. 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. 5. 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.

	6. 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. 7. 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. 8. 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. 9. Information as to how and when the personal health information will be disposed of or returned to the health information custodian. 10. The funding source of the research. 11. Whether the researcher has applied for the approval of another research ethics board and, if so the response to or status of the application. 12. 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.
Role of REBs in approving research plans	**Ontario Regulation** **S. 15.2:** The board may only act with respect to a proposal to approve a research plan where there is no conflict of interest existing or likely to be perceived between its duty under subsection 44(3) of the Act and any participating board member's personal interest in the disclosure of the personal health information or the performance of the research. **S. 44(3)**: When deciding whether to approve a research plan that a researcher submits to it, a research ethics board **shall consider** the matters that it considers relevant, including, (a) whether the objectives of the research can reasonably be accomplished without using the personal health information that is to be disclosed; (b) whether, at the time the research is conducted, adequate safeguards will be in place to protect the privacy of the individuals whose personal health information is being disclosed and to preserve the confidentiality of the information; (c) the public interest in conducting the research and the public interest in protecting the privacy of the individuals whose personal health information is being disclosed; and (d) whether obtaining the consent of the individuals whose personal health information is being disclosed would be impractical.
Decisions of REBs	**Ontario PHIPA** **S. 44(4):** After reviewing a research plan that a researcher has submitted to it, the research ethics board shall provide to the researcher a decision **in writing**, with reasons, setting out whether the board approves the plan, and whether the approval is subject to any conditions, which must be specified in the decision.

Agreement required by s. 44(1)(b) respecting disclosure	**Ontario PHIPA** **S. 44(5)**: Before a health information custodian discloses personal health information to a researcher under subsection (1), 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.
Compliance requirements for researchers	**Ontario PHIPA** **S. 44(6)**: A researcher who receives personal health information about an individual from a health information custodian under subsection (1) **shall**, (a) comply with the conditions, if any, specified by the research ethics board in respect of the research plan; (b) use the information only for the purposes set out in the research plan as approved by the research ethics board; (c) not publish the information in a form that could reasonably enable a person to ascertain the identity of the individual; (d) despite subsection 49(1), not disclose the information except as required by law and subject to the exceptions and additional requirements, if any, that are prescribed; (e) 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; (f) notify the custodian immediately in writing if the researcher becomes aware of any breach of this subsection or the agreement described in subsection (5); and (g) comply with the agreement described in subsection (5). **Ontario Regulation** **S. 17:** Despite clause 44(6)(d) of the Act, a researcher **may disclose** the information to an entity prescribed under subsection 45(1) of the Act, to a person prescribed for the purposes of clause 39(1)(c) of the Act for use in a registry compiled or maintained by that person, or to another researcher if, (a) the disclosure is part of a research plan approved under section 44 of the Act; or (b) the disclosure is necessary for the purpose of verifying or validating the information or the research. **Ontario PHIPA** **S. 39(1):** Subject to the requirements and restrictions, if any, that are prescribed, a health information custodian **may disclose** personal health information about an individual, … (c) to a prescribed person who compiles or maintains a registry of personal health information for purposes of facilitating or improving the provision of health care or that relates to the storage or donation of body parts or bodily substances;

	S. 45(1): A health information custodian **may disclose** to a prescribed entity personal health information for the purpose of analysis or compiling statistical information with respect to the management of, evaluation or monitoring of, the allocation of resources to or planning for all or part of the health system, including the delivery of services, if the entity meets the requirements under subsection (3). **S. 45(3):** A health information custodian **may disclose** personal health information to a prescribed entity under subsection (1) if, (a) the entity has in place practices and procedures to protect the privacy of the individuals whose personal health information it receives and to maintain the confidentiality of the information; and (b) the Commissioner has approved the practices and procedures, if the custodian makes the disclosure on or after the first anniversary of the day this section comes into force.

ALBERTA • *Health Information Act*, RSA 2000, c H-5 ("Alberta HIA"). • *Designation Regulation*, Alta Reg 69/2001 ("Alberta Designation Reg").	
Designated *research ethics boards* ("REBs")	**Alberta HIA** **S. 1(1)(v.1): "research ethics board"** means a body designated by the regulations as a research ethics board; **S. 108(2):** The Minister may make regulations… (a) designating bodies as research ethics boards for the purposes of sections 48 to 56; **Alberta Designation Reg** **S. 2:** The following committees and boards are **designated as research ethics boards** for the purposes of Part 5, Division 3 of the Act: (c.1) Health Research Ethics Board of Alberta; (d) University of Alberta - Health Research Ethics Board; (e) University of Calgary - Conjoint Health Research Ethics Board;
Definition of *research* and *data matching*	**Alberta HIA** **S. 1(1)(v): "research"** means academic, applied or scientific research that necessitates the use of individually identifying health information; **S. 1(1)(g): "data matching"** means the creation of individually identifying health information by combining individually identifying or non identifying health information or other information from 2 or more electronic databases, without the consent of the individuals who are the subjects of the information;
Permitted use by a custodian	**Alberta HIA** **S. 27(1):** A custodian **may use** individually identifying health information in its custody or under its control for the following purposes: … (d) conducting research or performing data matching or other services to facilitate another person's research (i) if the custodian or researcher has submitted a proposed research protocol to a research ethics board in accordance with section 49, (ii) if the research ethics board is satisfied as to the matters referred to in section 50(1)(b), (iii) if the custodian or researcher has complied with or undertaken to comply with the conditions, if any, suggested by the research ethics board, and

	(iv) where the research ethics board recommends that consents should be obtained from the individuals who are the subjects of the health information to be used in the research, if those consents have been obtained; **S. 51**: If the research ethics board is not satisfied as to any of the matters referred to in section 50(1)(b), the researcher may not apply to a custodian or health information repository under section 52.
Disclosure of health information for research and permissions to perform data matching	**Alberta HIA** **S. 52:** If the **research ethics board is satisfied** as to the matters referred to in section 50(1)(b), the **researcher may** forward to one or more custodians or health information repositories (a) the researcher's research protocol referred to in section 49, (b) the response of the research ethics board to the researcher's research protocol, and (c) a written application for one or more of the following: (i) disclosure of the health information to be used in the research; (ii) performance of data matching; (iii) performance of any other service to facilitate the research. **S. 53(1):** A custodian who has received the documents referred to in section 52 **may, but is not required to, disclose** the health information or perform data matching or other services to facilitate the research. **S. 53(2):** If the custodian decides to disclose the health information or perform data matching or other services to facilitate the research, (a) the custodian (i) must impose on the researcher the conditions suggested by the research ethics board, and (ii) may impose other conditions on the researcher, and (b) if the research ethics board recommended that consents referred to in section 50(1)(a) be obtained, the researcher must obtain the consents before the disclosure of the health information or performance of data matching or other services. **S. 53(3):** A health information repository that has received the documents referred to in section 52 may disclose the health information or perform data matching or other services to facilitate the research only in accordance with the regulations. **S. 54(2):** When an agreement referred to in subsection (1) has been entered into, the custodian may disclose to the researcher the health information requested under section 52 or perform data matching or other services to facilitate the research

	(a) with the consent of the individuals who are the subjects of the information, where the research ethics board recommends that consents should be obtained, or (b) without the consent of the individuals who are the subjects of the information, where the research ethics board does not recommend that consents be obtained. **S. 55:** If the researcher wishes to contact the individuals who are the subjects of the information disclosed under section 54(2) to obtain additional health information, the custodian or an affiliate of the custodian must first obtain consents from those individuals to their being contacted for that purpose. **S. 54(3**): The custodian may set the costs of (a) preparing information for disclosure, or performing data matching or other services (b) making copies of health information, and (c) obtaining the consents referred to in section 55, which must not exceed the actual cost of providing that service.
Requirements for research protocols	**Alberta HIA** **S. 49:** A person who intends to conduct research using health information in the custody or under the control of a custodian or health information repository must submit a proposed research protocol to a research ethics board for review by that board containing (a) the information specified by the regulations, and (b) any other information required by the research ethics board. **S. 108(2):** The Minister may make regulations… (a.1) specifying the information that is to be included in a proposed research protocol under section 49.
Role of REBs in approving research protocols	**Alberta HIA** **S. 50(1):** The research ethics board must (a) consider whether the researcher should be required to obtain consents for the disclosure of the health information to be used in the research from the individuals who are the subjects of the information, and (b) assess whether, in the opinion of the research ethics board, (i) the proposed research is of sufficient importance that the public interest in the proposed research outweighs to a substantial degree the public interest in protecting the privacy of the individuals who are the subjects of the health information to be used in the research, (ii) the researcher is qualified to carry out the research, (iii) adequate safeguards will be in place at the time the research will be carried out to protect the privacy of the individuals who are the subjects of the health information to be used in the research and the confidentiality of that information, and

	(iv) obtaining the consents referred to in clause (a) is unreasonable, impractical or not feasible. **S. 50(2):** In making an assessment under subsection (1)(b), the research ethics board must consider the degree to which the proposed research may contribute to (a) identification, prevention or treatment of illness or disease, (b) scientific understanding relating to health, (c) promotion and protection of the health of individuals and communities, (d) improved delivery of health services, or (e) improvements in health system management.
Decision of REBs	**Alberta HIA** **S. 50(3):** The research ethics board must prepare a response setting out (a) its recommendation under subsection (1)(a), (b) its assessment of the matters set out in subsection (1)(b), and (c) any conditions that the research ethics board considers should be imposed on the researcher. **S. 50(4):** The research ethics board must send a copy of the response required in subsection (3) to the Commissioner. **S. 50.1:** If the response of the research ethics board sent to the Commissioner under section 50(4) indicates that the research ethics board is satisfied as to the matters referred to in section 50(1)(b), the Commissioner may publish the response in any manner the Commissioner considers appropriate.
Agreements between custodian and researcher	**Alberta HIA** **S. 54(1):** If the custodian decides to disclose health information to a researcher or perform data matching or other services to facilitate the research, the researcher must enter into an agreement with the custodian in which the researcher agrees (a) to comply with (i) this Act and the regulations made under this Act, (ii) any conditions imposed by the custodian relating to the use, protection, disclosure, return or disposal of the health information, and (iii) any requirement imposed by the custodian to provide safeguards against the identification, direct or indirect, of an individual who is the subject of the health information, (b) to use the health information only for the purpose of conducting the research in accordance with the research protocol, (c) not to publish the health information in a form that could reasonably enable the identity of an individual who is the subject of the information to be readily ascertained,

	(d) not to make any attempt to contact an individual who is the subject of the health information to obtain additional health information unless the individual has provided the custodian with the consent referred to in section 55, (e) to allow the custodian to access or inspect the researcher's premises to confirm that the researcher is complying with the enactments, conditions and requirements referred to in clause (a), and (f) to pay the costs referred to in subsection (3).
Compliance requirements for researchers	**Alberta HIA** **S. 54(3.1):** A researcher that enters into an agreement under this section must (a) comply with the terms and conditions of the agreement and the conditions set out in the research ethics board's response to the research protocol, and (b) collect, use and disclose health information only in accordance with the agreement and the research protocol. **S. 54(4):** If a researcher contravenes or fails to comply with the terms and conditions of an agreement under this section, or the conditions set out in the research ethics board's response to the research protocol, (a) the agreement is cancelled, and (b) the researcher is no longer authorized to use the health information for any purpose and must destroy the health information or return it to the custodian. **S. 56(1):** If a researcher refuses to allow a custodian or health information repository to access or inspect its premises in accordance with the agreement referred to in section 54, the custodian or health information repository may apply to the Court of King's Bench for an order under subsection (2). **S. 107(3):** No researcher shall knowingly breach the terms and conditions of an agreement entered into with a custodian pursuant to section 54. **S. 107(6):** A person who contravenes this section is guilty of an offence and is liable (a) in the case of an individual, to a fine of not more than $200 000, and (b) in the case of any other person, to a fine of not more than $1 000 000.

BRITISH COLUMBIA • *E-Health (Personal Health Information Access and Protection of Privacy) Act*, S.B.C. 2008, c. 38 ("E-Health Act") • *BC Research Ethics Guidance: Public Health Surveillance*, British Columbia Academic Health Science Network, February 23, 2021. ("BC Research Ethics Guidance")	
Definition of *research ethics board* ("REBs")	**BC Research Ethics Guidance** **S. 4:** Research Ethics Board" or "REB" is a body of researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines, etc.) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices.
Definition of *health research purpose*	**E-Health Act** **S. 1: "health research purpose"** means the purpose described in section 4 (h) [collection and use of personal health information]; **S. 4(h):** to conduct or facilitate research into health issues.
Role of the data stewardship committee	**E-Health Act** **S. 11 (1):** The role of the data stewardship committee is to consider requests for the disclosure, for a health research purpose, of protected information. (2) In addition to the data stewardship committee's role under subsection (1), the data stewardship committee may make recommendations to the minister for the purposes of section 8 (3).
Composition and appointment of data stewardship committee	**E-Health Act** **S. 12(1):** The minister must appoint a data stewardship committee consisting of not more than 12 persons. **S. 12(2):** The committee appointed under subsection (1) must include at least (a) one person from within the ministry of the minister, (b) one person chosen as representative of either regional health boards or the Provincial Health Services Authority, (c) one person nominated by the board for the college responsible for carrying out the objects of the Health Professions Act in respect of the health profession of medicine, (d) one person nominated by the board for the college responsible for carrying out the objects of the Health Professions Act in respect of the health profession of pharmacy,

	(e) one person nominated by the board for the college responsible for carrying out the objects of the Health Professions Act in respect of the health profession of nursing, (f) one person engaged in health research generally, (f.1) one person engaged in pharmaceutical research, and (g) up to 3 persons chosen as representative of the general public. **S. 12(2.1):** The chief data steward is a non-voting member of the committee appointed under subsection (1). **S. 12(3):** The minister may designate a chair and one or more vice chairs of the data stewardship committee from among the persons appointed to that committee. **S. 12(4):** Members of the data stewardship committee may be paid (a) remuneration set by the minister, and (b) reasonable and necessary travel and out of pocket expenses incurred in carrying out the work of the data stewardship committee.
Disclosure of health information for a health research purpose	**E-Health Act** **S. 14(1):** A person may request protected information for a health research purpose only by submitting to the data stewardship committee (a) a request in the form and in the manner required by the data stewardship committee, and (b) information required by the data stewardship committee for the purposes of evaluating the request. **S. 14(2):** The data stewardship committee may approve the request if both of the following apply: (a) in the case of a request to disclose personal health information, all of the requirements set out in subsection (2.1) are met; (b) in the case of a request to disclose protected information outside Canada, there is express consent, in writing, to the disclosure from each person who is the subject of the protected information. **S. 14(2.1):** The requirements for the purposes of subsection (2) (a) are as follows: (a) the request is for a health research purpose that cannot reasonably be accomplished unless personal health information is disclosed;

	(b) if the protected information is contained in a health information bank, the disclosure is authorized under the terms of the applicable designation order; (c) the disclosure is on condition that it not be used for the purpose of contacting a person to participate in the health research, unless the commissioner approves (i) the health research purpose, (ii) the use of disclosed personal health information for the purpose of contacting a person to participate in the health research, and (iii) the manner in which contact is to be made, including the information to be made available to persons contacted; (d) any data linkage is not harmful to the individuals who are the subjects of the personal health information, and the benefits to be derived from the record linkage are clearly in the public interest; (e) the data stewardship committee has imposed conditions relating to (i) security and confidentiality, (ii) the removal or destruction of individual identifiers at the earliest reasonable time, and (iii) the prohibition of any subsequent use or disclosure of personal health information without the express authorization of the data stewardship committee. **S. 14(3):** If the data stewardship committee approves the request, the administrator may, subject to any conditions set by the data stewardship committee on approving the request, disclose the information to the person who made the request. **S. 14(4):** An administrator must not disclose information under subsection (3) except under an information-sharing agreement (a) with the person who made the request, and (b) made, whether or not personal health information is disclosed, in accordance with section 19 (2) and (3) [information-sharing agreements required for disclosure].
Information sharing agreements required for disclosure	**E-Health Act** **S. 19(1):** Personal health information contained in a health information bank may be disclosed only if (a) disclosure is authorized by the terms of the designation order that relates to the health information bank, (b) the administrator of the health information bank enters into an information-sharing agreement under this section, and (c) if personal health information is to be disclosed on a bulk or regular basis, it is disclosed only to one or more of the following persons: (i) an agency or ministry of the government of British Columbia, of another province or of Canada, including a Crown corporation;

	(ii) a health care body; (iii) an Indigenous governing entity, an educational body or a social services body, as those terms are defined in the Freedom of Information and Protection of Privacy Act; (iv) a public body in another jurisdiction of Canada that is equivalent to one described in subparagraphs (ii) and (iii); (v) a health service provider; (vi) a body responsible for the regulation of health professionals; (vii) an association of health professionals; (viii) a prescribed body that is public in nature. **S. 19(2):** An information-sharing agreement must identify all of the following: (a) the persons, by name, title, position or class, who may collect, use or disclose information under the agreement; (b) the circumstances in which information may be disclosed under the agreement; (c) the limits, if any, on (i) the disclosure of information by the administrator under the agreement, and (ii) the use or disclosure of the information obtained under the agreement by persons identified under paragraph (a); (d) the conditions, if any, on the disclosure of information under the agreement, including conditions respecting (i) security and confidentiality, (ii) the removal or destruction of individual identifiers at the earliest reasonable time, (iii) the prohibition of any subsequent use or disclosure of personal health information without express authorization, and (iv) the monitoring of compliance with the agreement; (e) the term of the agreement and the circumstances in which the agreement may be renewed, suspended or terminated. **S. 19(3):** An information-sharing agreement must include a requirement that (a) protected information disclosed under the agreement will not be used or disclosed for the purpose of market research, and (b) if disclosure is for a health research purpose, the person to whom information is disclosed must comply with (i) the data stewardship committee's policies and procedures established under section 13 (2) [data stewardship committee], and (ii) any conditions imposed under section 14 (2.1) (e) [disclosure for health research purposes].

MANITOBA • *The Personal Health Information Act*, C.C.S.M. c. P33.5, ("Manitoba PHIA") • *Personal Health Information Regulation*, Man. Reg. 245/97 ("Manitoba Regulation") • *The Research Manitoba Act*, C.C.S.M. c. R118 ("Research Act")	
Mandate of Research	**Research Act** **S. 3(1):** The mandate of Research Manitoba is to promote and support, and coordinate the funding of, research in the health, natural and social sciences, engineering and the humanities in Manitoba.
Definition of *trustee*	**Manitoba PHIA** **S. 1(1):** "trustee" means a health professional, health care facility, public body, or health services agency that collects or maintains personal health information. (« dépositaire »)
Disclosure for health research	**Manitoba PHIA** **S. 24(1):** A trustee may disclose personal health information to a person conducting health research if the research has been approved under this section**.**
Disclosure to health research organization	**Manitoba PHIA** **S. 24.1(1):** A trustee may disclose personal health information to a health research organization for a purpose mentioned in subsection (2) only if the organization is prescribed in the regulations and meets the requirements of this section.
Approval for health research projects	**Manitoba PHIA** **S. 24(2):** An approval may be given by the committee established under section 59. **S. 59(1):** The minister must establish a committee in accordance with the regulations for the purpose of approving health research projects under section 24.
Conditions for research approval	**Manitoba PHIA** **S. 24(3):** An approval may be given under this section only if the committee has determined that (a) the research is of sufficient importance to outweigh the intrusion into privacy that would result from the disclosure of personal health information; (b) the research purpose cannot reasonably be accomplished unless the personal health information is provided in a form that identifies or may identify individuals; (c) it is unreasonable or impractical for the person proposing the research to obtain consent from the individuals the personal health information is about; (d) the research proposal contains (i) reasonable safeguards to protect the confidentiality and security of the personal health information, and

	(ii) procedures to destroy or remove, at the earliest opportunity consistent with the purposes of the research, any information that, either by itself or when combined with other information available to the holder, allows individuals to be readily identified; and (e) any other requirements specified in the regulations are complied with.
Agreement required for research approval	**Manitoba PHIA** **S. 24(4):** An approval under this section is conditional on the person proposing the research project entering into an agreement with the trustee, in accordance with the regulations, in which the person agrees (a) not to publish the personal health information requested in a form that could reasonably be expected to identify the individuals concerned; (b) to use the personal health information requested solely for the purposes of the approved research project; and (c) to ensure that the research project complies with the safeguards and procedures described in clause (3)(d). **S. 24.1(4):** Before disclosing personal health information to a prescribed health research organization, the trustee must enter into an agreement with the organization that includes any requirements specified in the regulations.
Manitoba health research privacy committee approval	**Manitoba PHIA** **S. 8.2(1):** A research applicant seeking approval for a health research project under section 24 of the Act must provide the health research privacy committee with the following information: (a) the purpose of the health research; (b) the name of the principal researcher or researchers responsible for the project, including any collaborating researchers if the project is multi-centre in scope; (c) the duration of the project, the date of commencement and the projected date it will conclude; (d) a detailed description of the personal health information required for the research; (e) a description of any possible linkage or merging of the personal health information with other information and the rationale for that linkage or merger; (f) whether the research project will require direct contact with individuals; (g) a description of the methods to be employed to maintain security of the personal health information, including disposal of the information; (h) the names of persons who will receive the project results, including any proposed submissions for publication; (i) identification of the sources and duration of funding for the research project; (j) [repealed] M.R. 146/2001; (k) any additional information the committee considers necessary.
Compliance requirements for health research organizations	**Manitoba PHIA** **S. 24.1(3):** A prescribed health research organization must

	(a) use personal health information disclosed to it under this section for the purpose for which it was disclosed and no other; (b) have in place policies and procedures that protect the privacy of the individuals whose information is disclosed to it and that ensure the security and integrity of the information; and (c) as soon as reasonably possible having regard to the use of the information, remove any information that, either by itself or when combined with other information available to the organization, allows the identity of the individuals to be readily ascertained.

PRINCE EDWARD ISLAND • *Health Information Act*, R.S.P.E.I. 1988, c. H-1.41 ("Prince Edward Island HIA"). • *Health Information Regulations*, P.E.I. Reg EC359/17 ("Prince Edward Island Regulation")	
Definition of *research* and *researcher*	**Prince Edward Island HIA** **S. 1(y):** "research" means a systematic investigation designed to develop or establish principles, facts or general knowledge, or any combination of them, and includes the development, testing and evaluation of research; **S. 1(bb):** "researcher" means a person whose research plan has been submitted to a research ethics board pursuant to section 30;
Definition of *research ethics board* ("REBs")	**Prince Edward Island HIA** **S. 1(aa):** research ethics board" means a research ethics board designated in the regulations;
Definition of *research data repository*	**Prince Edward Island HIA** **S. 1(z):** "research data repository" means an organization that has entered into an agreement with the province for the purpose of (i) conducting and facilitating research to describe and explain health care patterns and profiles of health and illness, (ii) assisting in the evaluation of monitoring of health care service planning or the delivery of a government service, or (iii) facilitating research between or among areas such as health care, justice, education and social services;
Permitted collection of personal health information by a custodian without consent	**Prince Edward Island HIA** **S. 17(1):** A custodian may collect personal health information relating to an individual if (a) the custodian has the individual's consent under this Act and the collection, to the best of the custodian's knowledge, is necessary for a lawful purpose; or (b) the collection is otherwise permitted or required by this Act. **S. 17(2):** A custodian may collect personal health information relating to an individual without the individual's consent if (a) the individual is incapable of providing or communicating consent; (b) the decision of a substitute decision-maker respecting consent cannot be obtained in a timely manner; and (c) the collection of the personal health information is necessary for the provision of health care to the individual.
Authorized uses of personal health information	**Prince Edward Island HIA** **S. 22(5):** A custodian may use personal health information in its custody or under its control for one or more of the following purposes:

	(a) for the purpose for which the personal health information was collected or created and for all the functions reasonably necessary for carrying out that purpose, unless the individual expressly instructs otherwise; (b) another use to which the individual who is the subject of the personal health information consents; (c) for a purpose for which the use of the personal health information is authorized by this Act, an enactment or an Act of the Parliament of Canada; (d) to prevent or reduce a risk of significant harm to the health or safety of the public or a group of people; (e) if the custodian is a public body, for planning or delivering programs or services that the custodian provides or that the custodian funds in whole or in part, allocating resources to any of those programs or services, evaluating or monitoring any of them or detecting, monitoring or preventing fraud or any unauthorized receipt of services or benefits related to any of them; (f) for the purpose of risk management or error management or for the purpose of activities to improve or maintain the quality of health care or to improve or maintain the quality of any related programs or services of the custodian; (g) for educating agents of the custodian to provide health care; (h) for the purpose of disposing of the personal health information or de-identifying the personal health information; (i) for the purpose of seeking the individual's consent, or the consent of the individual's substitute decision-maker, if the personal health information used by the custodian for this purpose is limited to the name and contact information of the individual and the name and contact information of the substitute decision-maker, if applicable; (j) for the purpose of a proceeding or contemplated proceeding in which the custodian or the agent or former agent of the custodian is, or is expected to be, a party or witness, if the personal health information relates to or is a matter in issue in the proceeding or contemplated proceeding; (k) if the custodian is a Minister of the Crown, for the purpose of recovering health care costs; (l) for the purpose of obtaining payment for or processing, monitoring, verifying or reimbursing claims for payment for the provision of health care or related goods and services; (m) for a research project approved by a research ethics board under section 30; (n) for the purpose of conducting research or performing other services to facilitate another person's research (i) if the custodian or researcher has submitted a research plan to a research ethics board in accordance with section 30, (ii) if the research ethics board has approved the research plan, (iii) if the custodian or researcher has complied with or undertaken to comply with any conditions imposed by the research ethics board, and (iv) where the research ethics board recommends that consents should be obtained from the individuals whose personal health information is to be used, if those consents have been obtained; (o) for the purpose of performing data-matching;

	(p) subject to any requirements and restrictions prescribed by regulation, for the purposes of complying with an enactment or a treaty, agreement or arrangement made under an enactment or an Act of the Parliament of Canada; (q) for the purpose of the custodian's (i) planning and resource allocation, (ii) health system management, (iii) public health surveillance, (iv) health policy development, or (v) delivery or administration of health care; (r) to produce de-identified information.
Permitted disclosure of personal health information to specified persons	**Prince Edward Island HIA** **S. 23(7):** Unless the disclosure is contrary to an express request of the individual, a custodian may disclose personal health information without the consent of the individual to whom the information relates (a) to a custodian, where the disclosure is necessary for the provision of health care to the individual; (b) to a person, where the disclosure is necessary for the provision of health care to the individual; or (c) to a person other than a custodian, for the purpose of contacting a relative, spouse, friend or potential substitute decision-maker of the individual, where the individual is injured, incapacitated or ill and unable to give consent personally.
Permitted disclosure of personal health information for specified purposes	**Prince Edward Island HIA** **S. 23(13):** A custodian may disclose personal health information relating to an individual without the consent of the individual if the disclosure is (a) for the purpose of determining or verifying the eligibility of the individual to receive health care or related goods, services or benefits provided under an enactment or an Act of the Parliament of Canada and funded in whole or part by the Government or the Government of Canada; (b) for the purpose of determining or providing payment to the custodian for the provision of health care or for processing, monitoring, verifying or reimbursing claims for payment for the provision of health care; (c) to a department of the government of another jurisdiction or to an agency of that government to the extent necessary to obtain payment for health care provided to the individual to whom the personal health information relates; (d) for the purpose of delivering, evaluating or monitoring a program of the custodian that relates to the provision of health care or the payment for health care; (e) for the purpose of review and planning necessary for the provision of health care to the individual to whom the personal health information relates by another custodian; (f) to an information manager in accordance with this Act; (g) to a person who requires the personal health information to carry out an audit for, or to provide legal services, error management services, risk management services, peer reviews or quality improvement services to, the custodian; (h) to a research data repository in accordance with the terms of an agreement between the research data repository and the custodian;

	(i) to a potential successor of the custodian for the purpose of allowing the potential successor to assess or evaluate the operations of the custodian, on condition that the potential successor first enters into an agreement with the custodian to keep the personal health information confidential and secure and not to retain the personal health information any longer than is necessary for the purpose of the assessment or evaluation; (j) for the purpose of ensuring the safety of the national blood supply; and (k) to the successor of the custodian if (i) the custodian transfers records to the successor as a result of the custodian's ceasing to be a custodian or ceasing to provide health care, and (ii) the successor is a custodian
Custodian to prepare a privacy impact assessment	**Prince Edward Island HIA** **S. 25(1):** Subject to subsection (2), a custodian shall prepare a privacy impact assessment and submit the assessment to the Commissioner for review and comment in the following situations: (a) for the new collection, use or disclosure of personal health information or any significant change to the collection, use or disclosure of personal health information; (b) for the creation of a personal health information system or personal health information communication technology or a significant modification to a personal health information system or personal health information communication technology; or (c) if a custodian performs data matching with personal health information collected by it or with any personal health information held by another custodian or another person. **S. 25(2):** A custodian or class of custodians may be exempted by the regulations from the requirements of subsection (1). 2
Permitted data matching by custodian and as between custodian and non-custodian	**Prince Edward Island HIA** **S. 26(1):** A custodian may perform data matching using personal health information that is in its custody or under its control. **S. 28(1):** A custodian may perform data matching by combining personal health information that is in its custody or under its control with personal health information that is in the custody or under the control of a person that is not a custodian.
Research plan requirements	**Prince Edward Island HIA** **S. 30(1):** A person who proposes to use personal health information for research purposes shall submit a research plan respecting the proposed research to a research ethics board for approval. **S. 30(2):** A research plan for the purposes of subsection (1) shall be in writing and shall set out (a) the affiliation of each person involved in the research;

	(b) the nature and objectives of the research and the public or scientific benefit of the research that the researcher anticipates; and (c) all other prescribed matters related to the research. **Prince Edward Island Regulation** **S. 5:** In addition to the matters set out in clauses 30(2)(a) and (b) of the Act, a research plan shall include (a) a research protocol, including a description of the specific information or variables required for the research; (b) a plan for the de-identification of data, including a data flow diagram, if applicable; and (c) any information known to the person submitting the research plan relevant to the consideration of the research ethics board under clause 30(3)(a) of the Act.
Approving of research plans, factors in assessment	**Prince Edward Island HIA** **S. 30(3):** A research ethics board to which a research plan is submitted shall (a) consider whether the custodian of the personal health information specified in the research plan should be required to obtain consents for the disclosure of the personal health information to be used in the research from the individuals to whom it relates; (b) consider whether the objectives of the research could reasonably be accomplished without the disclosure or use of personal health information; and (c) assess whether, in the opinion of the research ethics board, (i) the proposed research is of sufficient importance that the public interest in the proposed research outweighs to a substantial degree the public interest in protecting the privacy of the individuals who are the subjects of the personal health information to be used in the research, (ii) the researcher is qualified to carry out the research, (iii) adequate safeguards will be in place at the time the research will be carried out to protect the privacy of the individuals whose personal health information will be used in the research and the confidentiality of the personal health information, and (iv) obtaining the consents referred to in clause (a) is unreasonable, impractical or not feasible. **S. 30(3):** In making an assessment under clause (3)(c), the research ethics board shall consider the degree to which the proposed research may contribute to (a) identification, prevention or treatment of illness or disease; (b) scientific understanding relating to health or illness; (c) promotion and protection of the health of individuals and communities; (d) improved delivery of health services; or

	(e) improvements in health system management
Custodian to impose conditions on researcher	**Prince Edward Island HIA** **S. 32(2):** If a custodian decides to disclose the requested personal health information or perform data matching or other services to facilitate the research, (a) the custodian (i) shall impose on the researcher the conditions suggested by the research ethics board, and (ii) may impose other conditions on the researcher, relating to the use, protection, disclosure, return or disposal of the personal health information or providing safeguards against the identification, direct or indirect, of the individuals who are the subjects of the personal health information, as the custodian considers necessary or advisable; and (b) if the research ethics board recommended that consents referred to in clause 30(3)(a) be obtained, the custodian shall obtain the consents before the disclosure
Compliance requirements for researcher	**Prince Edward Island HIA** **S. 32(3):** If a custodian decides to disclose personal health information to a researcher or perform data matching or other services to facilitate the research, the researcher shall (a) comply with (i) this Act and the regulations made under this Act (ii) any conditions imposed by the custodian relating to the use, protection, disclosure, return or disposal of the health information, and (iii) any requirements imposed by the custodian to provide safeguards against the identification, direct or indirect, of an individual who is the subject of the personal health information; (b) use the personal health information only for the purpose of conducting the proposed research; (c) not publish the personal health information in a form that could reasonably enable the identity of an individual who is the subject of the personal health information to be readily ascertained; (d) not make any attempt to contact an individual who is the subject of the personal health information to obtain additional personal health information unless the individual has provided the custodian with the consent referred to in subsection (6); (e) allow the custodian to access or inspect the researcher's premises to confirm that the researcher is complying with the Act and regulations and the conditions and requirements referred to in clause (a); and (f) pay the costs referred to in subsection (5).
Disclosure to researcher	**Prince Edward Island HIA** **S. 32(4):** A custodian may disclose to the researcher the personal health information requested under section 31 or perform data matching or other services to facilitate the research

	(a) with the consent of the individuals who are the subjects of the personal health information, where the research ethics board recommends that consents should be obtained; or (b) without the consent of the individuals who are the subjects of the personal health information, where the research ethics board does not recommend that consents be obtained.

NEW BRUNSWICK • *Personal Health Information Privacy and Access Act*, S.N.B. 2009, c. P-7.05 ("New Brunswick PHIPA"). • *General Regulations*, N.B. Reg. 2010-112 ("New Brunswick Regulation").	
Definition of *research review board*	**New Brunswick Regulation** **S. 17:** For the purposes of subsection 43(2) of the Act, a research review body shall operate in conformity with the Tri-Council Policy Statement.
Definition of *research*	**New Brunswick PHIPA** **S. 1:** "research" means a systematic investigation designed to develop or establish principles, facts or general knowledge, or any combination of them, and includes the development, testing and evaluation of research.*(recherche)*
Definition of *research data centre*	**New Brunswick PHIPA** **S. 1:** "research data centre" means a public body that compiles and links personal information or personal health information for the purposes of research, analysis or evidence-based decision-making.(centre de données de recherche)
Permitted collection of personal health information	**New Brunswick PHIPA** **S. 27(1):** A custodian may collect personal health information relating to an individual if (a) the custodian has the individual's consent under this Act and the collection, to the best of the custodian's knowledge, is necessary for a lawful purpose, or (b) the collection is permitted or required by this Act. **S. 27(2):** Despite paragraph (1)(a), a custodian may collect personal health information relating to an individual without that individual's consent if the individual is incapable of providing consent and (a) consent can not be obtained because (i) there is no substitute decision-maker who can provide consent in a timely manner, or (ii) the individual has been admitted to a psychiatric facility as an involuntary patient under the Mental Health Act, or (b) the collection is necessary for the provision of health care to the individual.
Permitted disclosure for research purposes	**New Brunswick PHIPA** **S. 43(1):** A custodian may disclose personal health information to a person conducting a research project only if the project has been approved under this section. **S. 43(2):** An approval may be given by a research review body that meets the requirements prescribed by regulation.

	S. 43(3): An approval may be given under this section only if the research review body has determined that (a) the research is of sufficient importance to outweigh the intrusion into privacy that would result from the disclosure of the personal health information, (b) the research purpose cannot reasonably be accomplished unless the personal health information is provided in a form that identifies or may identify individuals, (c) the individuals to whom the information relates have consented to its use and disclosure or it is unreasonable or impractical for the person proposing the research to obtain consent from the individuals to whom the information relates, and (d) the research project contains (i) reasonable safeguards to protect the privacy and security of the personal health information, and (ii) procedures to destroy the information or de-identify the information at the earliest opportunity, consistent with the purposes of the project.
Agreement between researcher and custodian	**New Brunswick PHIPA** **S. 43(4):** An approval under this section is conditional on the person proposing the research project entering into an agreement with the custodian, in accordance with the regulations, (a) not to publish the personal health information requested in a form that could reasonably be expected to identify the individuals to whom the information relates, (b) to use the personal health information requested solely for the purposes of the approved research project, and (c) to ensure that the research project complies with the safeguards and procedures described in paragraph (3)(d).
Permitted use of personal health information	**New Brunswick PHIPA** **S. 34(1):** A custodian may use personal health information in its custody or under its control for one or more of the following purposes: (a) for the purpose for which the information was collected or created and for all the functions reasonably necessary for carrying out that purpose, unless the individual expressly instructs otherwise; (b) another use to which the individual who is the subject of the information consents; (c) if the use of the information is authorized by this Act or by an Act of the Legislature or an Act of the Parliament of Canada; (d) to prevent or reduce a risk of significant harm to the health or safety of the public or a group of people, the disclosure of which is clearly in the public interest; (e) if the custodian is a public body, for planning or delivering programs or services that the custodian provides or that the custodian funds in whole or in part, allocating resources to any of those programs or services, evaluating or monitoring any of them or detecting, monitoring or preventing fraud or any unauthorized receipt of services or benefits related to any of them; (e.1) if the custodian is a public body, for planning or delivering common or integrated services, programs or activities;

	(e.2) if the custodian is a health care provider, for delivering common or integrated services, programs or activities; (f) for the purpose of risk management, error management or for the purpose of activities to improve or maintain the quality of care or to improve or maintain the quality of any related programs or services of the custodian; (g) for educating agents of the custodian to provide health care; (h) for the purpose of disposing of the information or de-identifying the information; (i) for the purpose of seeking the individual's consent, or the consent of the individual's substitute decision-maker, when the personal health information used by the custodian for this purpose is limited to the name, contact information and registration information of the individual and the name and contact information of the substitute decision-maker, if applicable; (j) for the purpose of a proceeding or contemplated proceeding in which the custodian or the agent or former agent of the custodian is, or is expected to be, a party or witness, if the information relates to or is a matter in issue in the proceeding or contemplated proceeding; (k) if the custodian is a Minister of the Crown, for the purpose of recovering health care costs; (l) for the purpose of obtaining payment for or processing, monitoring, verifying or reimbursing claims for payment for the provision of health care or related goods and services; (m) for a research project approved by a research review body under section 43; (m.1) for a research project approved in accordance with an agreement referred to in paragraph 43.1(a); (m.2) if the custodian is the Minister or a researcher, to perform data matching for the purpose of a research project approved by a research review body under section 43; (m.3) if the custodian is the Minister or a research data centre, to perform data matching for the purpose of a research project approved in accordance with an agreement referred to in paragraph 43.1(a); (n) subject to any requirements and restrictions prescribed by regulation, if permitted or required by law or by a treaty, agreement or arrangement made under an Act of the Legislature or the Parliament of Canada; (o) if the custodian is a regional health authority, the board of directors or management personnel of a regional health authority or any member of any administrative or advisory committee established in accordance with the by-laws of a regional health authority for the following functions within the geographic area in which the custodian has jurisdiction: (i) planning and resource allocation; (ii) health system management; (iii) public health surveillance; and (iv) health policy development; (p) paragraph (o) also applies to a custodian who is a Minister of the Crown for the purposes set out in that paragraph when engaged in a function related to the delivery or administration of health care in the Province; and (q) to produce de-identified information that does not, either by itself or in combination with other information in the custody of or under the control of the custodian, permit an individual to be identified.

Disclosure for research purposes	**New Brunswick PHIPA** **S. 43(1):** A custodian may disclose personal health information to a person conducting a research project only if the project has been approved under this section. **S. 43(2):** An approval may be given by a research review body that meets the requirements prescribed by regulation.
Conditions for approval by a research review body	**New Brunswick PHIPA** **S. 43(3):** An approval may be given under this section only if the research review body has determined that (a) the research is of sufficient importance to outweigh the intrusion into privacy that would result from the disclosure of the personal health information, (b) the research purpose cannot reasonably be accomplished unless the personal health information is provided in a form that identifies or may identify individuals, (c) the individuals to whom the information relates have consented to its use and disclosure or it is unreasonable or impractical for the person proposing the research to obtain consent from the individuals to whom the information relates, and (d) the research project contains (i) reasonable safeguards to protect the privacy and security of the personal health information, and (ii) procedures to destroy the information or de-identify the information at the earliest opportunity, consistent with the purposes of the project. **S. 43(4):** An approval under this section is conditional on the person proposing the research project entering into an agreement with the custodian, in accordance with the regulations, (a) not to publish the personal health information requested in a form that could reasonably be expected to identify the individuals to whom the information relates, (b) to use the personal health information requested solely for the purposes of the approved research project, and (c) to ensure that the research project complies with the safeguards and procedures described in paragraph (3)(d).

NEWFOUNDLAND AND LABRADOR • *Personal Health Information Act*, S.N.L. 2008, c. P-7.01 ("Newfoundland and Labrador PHIA"). • *Personal Health Information Regulations*, N.L.R. 38/11 ("Newfoundland and Labrador Regulation").	
Definition of *research ethics board* and *research ethics body*	**Newfoundland and Labrador PHIA** **S. 1:** (w) "research ethics board" means the research ethics board appointed by the Health Research Ethics Authority for Newfoundland and Labrador under the Health Research Ethics Authority Act ; (x) "research ethics body" means a research ethics body approved by the Health Research Ethics Authority for Newfoundland and Labrador under the Health Research Ethics Authority Act ;
Definition of *research* and *researcher*	**Newfoundland and Labrador PHIA** **S. 1(v):** "research" means a systematic investigation designed to develop or establish principles or facts or to generate knowledge, or any combination of principles, facts and knowledge, and includes the development, testing and evaluation of research; **S. 1(y):** "researcher" means a person who conducts research;
Permitted disclosure for research purposes	**Newfoundland and Labrador PHIA** **S. 44:** A custodian may disclose personal health information without the consent of the individual who is the subject of the information for research purposes but only where the research project has been approved by a research ethics board or research ethics body under the Health Research Ethics Authority Act.
Permitted collection of personal health information from a source other than the individual	**Newfoundland and Labrador PHIA** **S. 31:** A custodian may collect personal health information from a source other than the individual who is the subject of the information where (d) the custodian collects the information from a person who is not a custodian for the purpose of carrying out a research project that has been approved by the research ethics board or a research ethics body;
Permitted use of personal health information	**Newfoundland and Labrador PHIA** **S. 34:** A custodian may use personal health information in its custody or under its control for one or more of the following purposes: (j) for an approved research project in accordance with section 44;

NOVA SCOTIA • *Personal Health Information Act*, S.N.S. 2010, c. 41 ("Nova Scotia PHIA"). • Personal Health Information Regulations, N.S. Reg 217/2012 ("Nova Scotia Regulations").	
Definition of *research*	**Nova Scotia PHIA** **S. 52 (c):** "research" means a systematic investigation designed to develop or establish principles, facts or generalizable knowledge, or any combination of them, and includes the development, testing and evaluation of research;
Definition of *data matching*	**Nova Scotia PHIA** **S. 52(a):** "data matching" means the creation of individual identifying health information by combining individual identifying or non-identifying health information or other information from two or more databases without the consent of the individuals who are the subjects of the information;
Definition of *research ethics board* ("REBs")	**Nova Scotia PHIA** **S. 52(d):** "research ethics board" means a research ethics board established and operating in conformity with the Tri-Council Policy Statement; **S. 52(e):** "Tri-Council Policy Statement" means the Tri-Council Policy Statement "Ethical Conduct for Research Involving Humans" adopted in August 1998 by the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada, and includes any amendments or successor statements.
Compliance requirements for personal health information use	**Nova Scotia PHIA** **S. 55:** A custodian may use personal health information for research if, before commencing the research, the custodian (a) prepares a research plan that meets the requirements in Section 59; (b) repealed 2012, c. 31, s. 6. (c) receives the approval of a research ethics board; and (d) meets any conditions imposed by the research ethics board.
Compliance requirements for personal health information disclosure to researcher	**Nova Scotia PHIA** **S. 56:** A custodian may disclose personal health information about an individual to a researcher if the researcher, (a) submits to the custodian (i) an application in writing, (ii) a research plan that meets the requirements of Section 59, and (iii) a copy of the submission to and decision of a research ethics board that approves the research plan; and (b) enters into the agreement required by Section 60.

Permitted collection of personal health information directly from individual	**Nova Scotia PHIA** **S. 30:** A custodian may collect personal health information, (a) for a lawful purpose related to the authority of the custodian; or (b) if it is expressly authorized by this Act or another Act of the Province or of the Parliament of Canada. **S. 31:** A custodian shall collect personal health information directly from the individual about whom the information is being collected, except in the following circumstances: (h) the custodian collects the information from a person who is not a custodian for the purpose of carrying out a research project that has been approved by the research ethics board or a research ethics body, except if the person is prohibited by law from disclosing the information to the custodian.
Permitted disclosure of personal health information without individual consent	**Nova Scotia PHIA** **S. 58:** A custodian may disclose personal health information about an individual to a researcher without the consent of the subject individual if (a) the researcher has met the requirements in Section 56; (b) a research ethics board has determined that the consent of the subject individuals is not required; (c) the custodian is satisfied that (i) the research cannot be conducted without using the personal health information, (ii) the personal health information is limited to that necessary to accomplish the purpose of the research, (iii) the personal health information is in the most deidentified form possible for the conduct of the research, (iv) the personal health information will be used in a manner that ensures its confidentiality, and (v) it is impracticable to obtain consent; and (d) the custodian informs the Review Officer. 2010, c. 41, s. 57;
Research plan requirements	**Nova Scotia PHIA** **S. 59(1):** Before commencing research, a researcher seeking to conduct research utilizing personal health information shall submit a research plan to a research ethics board. **S. 59(2):** The research plan must be in writing. **S. 59(3):** In order to meet the requirements for a custodian under this Act, the research plan must include (a) a description of the research proposed to be conducted; (b) a statement regarding the duration of the research; (c) a description of the personal health information required and the potential sources of the information;

	(d) a description as to how the personal information will be used in the research; (e) where the personal health information will be linked to other information, a description of the other information as well as how the linkage will be conducted; (f) where the researcher is conducting the research on behalf of or with the support of a person or organization, the name of the person or organization; (g) the nature and objectives of the research and the public or scientific benefit anticipated as a result of the research; (h) where consent is not being sought, an explanation as to why seeking consent is impracticable; (i) an explanation as to why the research cannot reasonably be accomplished without the use of personal health information; (j) where there is to be data matching, an explanation of why data matching is required; (k) a description of the reasonably foreseeable risks arising from the use of personal health information and how those risks are to be mitigated; (l) a statement that the personal health information is to be used in the most de-identified form possible for the conduct of the research; (m) a description of all individuals who will have access to the information, and (i) why their access is necessary, (ii) their roles in relation to the research, and (iii) their qualifications; (n) a description of the safeguards that the researcher will impose to protect the confidentiality and security of the personal health information; (o) information as to how and when the personal health information will be destroyed or returned to the custodian; (p) the funding source of the research; (q) whether the researcher has applied for the approval of another research ethics board and, if so, the response to or status of the application; and (r) whether the researcher's interest in the disclosure of the personal health information or the conduct of the research would potentially result in an actual or perceived conflict of interest on the part of the researcher.
Agreement between researcher and custodian	**Nova Scotia PHIA** **S. 60(1):** Where a custodian discloses personal health information to a researcher, the researcher shall enter into an agreement with the custodian to adhere to the requirements in subsection (2). **S. 60(2):** An agreement referred to in subsection (1) must include a commitment by the researcher (a) to comply with any terms and conditions imposed by a research ethics board; (b) to comply with any terms and conditions imposed by the custodian;

	(c) to use the information only for the purposes outlined in the research plan as approved by a research ethics board; (d) not to publish the information in a form where it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual; (e) to allow the custodian to access or inspect the researcher's premises to confirm that the researcher is complying with the terms and conditions of this Act and of the agreement between the custodian and the researcher; (f) to notify the custodian immediately and in writing if the personal health information is stolen, lost or subject to unauthorized access, use, disclosure, copying or modification; (g) to notify the custodian immediately and in writing of any known or suspected breach of the agreement between the custodian and the researcher; and (h) not to attempt to identify or contact the individuals unless the custodian or researcher has obtained prior consent by the individuals.

QUEBEC • *An Act respecting Health Services and Social Services*, c. S-4.2 ("Quebec Health Services Act"). • *Bill 3: An Act respecting health and social services information and amending various legislative provisions*, 1st Sess, 43rd Leg, Quebec, 2023 (assented to 4 April 2023), SQ 2023, c 5 ("Bill 3").	
Definition of *research project*	**Bill 3** **S. 3:** "research project" means a process aimed at developing knowledge, in particular for innovation purposes, by means of structured study or systematic investigation;
Request for personal information for research purposes	**Bill 3** **S. 44:** A researcher attached to a body referred to in Schedule I, to a public institution or to a private institution under agreement that operates a hospital centre may be informed of the existence of and have access to information held by a body and necessary for carrying out a research project, unless the person concerned has refused access to the information under subparagraph 3 of the first paragraph of section 8, if so authorized by the person exercising the highest authority within the body to which the researcher is attached. To that end, the researcher must submit a written request for authorization to the person exercising the highest authority and enclose the following documents: (1) a detailed presentation of the activities related to the research project setting out, in particular, (a) the objectives pursued; (b) all the information necessary for achieving those objectives; and (c) the intended pairing of such information; (2) a report containing a privacy impact assessment; and (3) the documented decision of a research ethics committee formed or designated by the Minister under article 21 of the Civil Code with regard to the research project.
Authorization to examine a record for study, teaching or research purposes	**Quebec Health Services Act** **S. 19.2:** The director of professional services of an institution or, if there is no such director, the executive director may authorize a professional or a researcher attached to a public body to examine the record of a user or obtain communication of all or part of such a record for study, teaching or research purposes. Before granting such authorization, the director must, however, ascertain that it is consistent with sections 67.2.1 to 67.2.3 of the Act respecting Access to documents held by public bodies and the Protection of personal information (chapter A-2.1). If the director is of the opinion that the project of the professional or of the researcher attached to a public body is not in compliance with generally accepted standards of ethics or scientific integrity, the director must refuse to grant the authorization.

	The authorization must be granted for a limited period and may be subject to conditions. It may be revoked at any time if the director has reason to believe that the authorized professional or the authorized researcher attached to a public body is violating the confidentiality of the information obtained or is not complying with the conditions imposed or with generally accepted standards of ethics and scientific integrity. For the purposes of this Act, a researcher is attached to a public body in the cases described in paragraph 2 of section 2.2 of the Act respecting the Institut de la statistique du Québec (chapter I-13.011).
Requirements for privacy impact assessment	**Bill 3** **S. 45:** The privacy impact assessment referred to in subparagraph 2 of the second paragraph of section 44 must be proportionate to the sensitivity of the information concerned, the purposes for which it is to be used, the quantity and distribution of the information and the medium on which it is stored. Moreover, where the research project involves the communication of information outside Québec, the assessment must take into account (1) the sensitivity of the information; (2) the purposes for which it is to be used; (3) the protection measures, including those that are contractual, that would apply to it; and (4) the legal framework applicable in the State in which the information would be communicated, including the rules for the protection of health and social services information applicable in that State
Affiliated research body compliance requirements	**Bill 3** **S. 46:** The person exercising the highest authority within the body to which the researcher is attached must, before granting the request, consult each of the bodies that hold information covered by the request, which then have 10 days to submit observations. **S. 47:** The person exercising the highest authority within the body to which the researcher is attached may authorize the researcher to be informed of the existence of and to have access to the information, if the person considers that the following criteria are met: (1) it is unreasonable to require obtaining the consent of the person concerned; (2) the objective of the research project outweighs, with regard to the public interest, the impact of using or communicating the information on the privacy of the person concerned; (3) the security measures that will be in place for the carrying out of the research project are suitable for ensuring the protection of the information and comply with the information governance rules referred to in section 90 and the special rules defined by the network information officer under section 97; and

	(4) where the research project involves the communication of information outside Québec, the privacy impact assessment referred to in subparagraph 2 of the second paragraph of section 44 establishes that the information would receive adequate protection, in particular in light of generally recognized principles regarding the protection of personal information. An unfavourable decision must give reasons and be notified in writing to the researcher who submitted the request.
Written agreement between researcher and affiliated institution	**Bill 3** **S. 48:** The authorization is made official by a written agreement between the researcher and the body to which the researcher is attached. The agreement must stipulate, among other things, that information covered by the authorization (1) may be used only by persons who need to examine it to exercise their functions and who have signed a confidentiality agreement; (2) may not be used for purposes other than those specified in the detailed presentation of the activities related to the research project; (3) may not be paired with any information other than information mentioned in the detailed presentation of the activities related to the research project; and (4) may not be communicated, published or otherwise distributed in a form allowing the person concerned to be identified. The agreement must also (1) specify the information that must be communicated to the persons concerned if information concerning them is used for the purpose of soliciting their participation in the research project; (2) specify that the information may be used or communicated only in a form not allowing the person concerned to be identified directly, where it is possible to carry out the research project by using or receiving the information in such a form; (3) specify the security measures that will be in place for the carrying out of the project; (4) determine a preservation period for all the information; (5) set out the obligation to inform the person exercising the highest authority within the body to which the researcher is attached of the destruction of the information; and (6) set out the obligation to inform without delay the person exercising the highest authority within the body to which the researcher is attached and the Commission d'accès à l'information (a) of non-compliance with any condition set out in the agreement; (b) of any failure to comply with the security measures provided for in the agreement; and (c) of any event that could breach the confidentiality of information. Where the research project involves the communication of information outside Québec, the agreement must take into

	account, in particular, the results of the privacy impact assessment referred to in subparagraph 2 of the second paragraph of section 44 and, if applicable, the terms agreed on to mitigate the risks identified in the assessment. A copy of the agreement must be sent to each body consulted under section 46 and to the Commission d'accès à l'information

SASKATCHEWAN	
• *Health Information Protection Act*, S.S. 1999, c. H-0.021 ("Saskatchewan HIPA"). • *Health Information Protection Regulations*, R.R.S. c. H-0.021 Reg. 1 ("Saskatchewan Regulation").	
Definition of *personal health information*	**Saskatchewan HIPA** **S. 2(1)(m):** "personal health information" means, with respect to an individual, whether living or deceased: (i) information with respect to the physical or mental health of the individual; (ii) information with respect to any health service provided to the individual; (iii) information with respect to the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily substance of the individual; (iv) information that is collected: (A) in the course of providing health services to the individual; or (B) incidentally to the provision of health services to the individual; or (v) registration information
Permitted use and disclosure of personal information with consent	**Saskatchewan HIPA** **S. 29(1):** A trustee or a designated archive may use or disclose personal health information for research purposes with the express consent of the subject individual if: (a) in the opinion of the trustee or designated archive, the research project is not contrary to the public interest; (b) the research project has been approved by a research ethics committee approved by the minister; and (c) the person who is to receive the personal health information enters into an agreement with the trustee or designated archive that contains provisions: (i) providing that the person who is to receive the information must not disclose the information; (ii) providing that the person who is to receive the information will ensure that the information will be used only for the purpose set out in the agreement; (iii) providing that the person who is to receive the information will take reasonable steps to ensure the security and confidentiality of the information; and (iv) specifying when the person who is to receive the information must do all or any of the following: (A) return to the trustee or designated archive any original records or copies of records containing personal health information;

	(B) destroy any copies of records containing personal health information received from the trustee or designated archive or any copies made by the researcher of records containing personal health information received from the trustee or designated archive.
Permitted use and disclosure of personal health information without consent	**Saskatchewan HIPA** **S. 29(2):** Where it is not reasonably practicable for the consent of the subject individual to be obtained, a trustee or designated archive may use or disclose personal health information for research purposes if: (a) the research purposes cannot reasonably be accomplished using de-identified personal health information or other information; (b) reasonable steps are taken to protect the privacy of the subject individual by removing all personal health information that is not required for the purposes of the research; (c) in the opinion of the research ethics committee, the potential benefits of the research project clearly outweigh the potential risk to the privacy of the subject individual; and (d) all of the requirements set out in clauses (1)(a) to (c) are met. **S. 29(3):** This section does not apply to personal health information disclosed in accordance with section 29 of The Archives and Public Records Management Act .