



DEVELOPMENT OF A HUMAN RESEARCH PROTECTION PROGRAM (HRPP)



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Foreword

The Digital Governance Standards Institute (DGSI) develops digital technology governance standards fit for global use. The Institute works with experts, as well as national and global partners and the public to develop national standards that reduce risk to Canadians and Canadian organizations adopting and using innovative digital technologies in today's digital economy.

DGSI standards are developed in accordance with the *Requirements & Guidance – Accreditation of Standards Development Organizations*, 2019-06-13, established by the Standards Council of Canada (SCC).

Attention is drawn to the possibility that some of the elements of this Standard may be the subject of patent rights. DGSI shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of this Standard are included in the Introduction.

For further information about DGSI, please contact:

Digital Governance Standards Institute

500-1000 Innovation Dr.

Ottawa, ON K2K 3E7

www.dgc-cgn.org

A National Standard of Canada is a standard developed by a Standards Council of Canada (SCC) accredited Standards Development Organization in compliance with requirements and guidance set out by SCC. More information on National Standards of Canada can be found at www.scc.ca.

SCC is a Crown corporation within the portfolio of Innovation, Science and Economic Development (ISED) Canada. With the goal of enhancing Canada's economic competitiveness and social well-being, SCC leads and facilitates the development and use of national and international standards. SCC also coordinates Canadian participation in standards development and identifies strategies to advance Canadian standardization efforts.

Accreditation services are provided by SCC to various customers, including product certifiers, testing laboratories, and standards development organizations. A list of SCC programs and accredited bodies is publicly available at www.scc.ca.

HRSO is a Canadian, not-for-profit, standards development organization that develops standards of relevance to Canadians conducting, overseeing, and participating in human research.

Human research standards ensure that the rights and welfare of research participants are safeguarded, and that human research is conducted in an environment that promotes efficiencies, mitigates risks, and produces reliable, verifiable, and credible data. The adoption of standards for human research ensures harmonization, partnership, and economic growth of this activity within Canada and internationally.

HRSO adheres to the World Trade Organization (WTO) Agreement on Technical Barriers to Trade: Code of Good Practice for the Preparation, Adoption, and Application of Standards in the development of service and management standards for human research.

The timeline for development of NSC HRSO-100.01 “The Development of a Human Research Protection Program (HRPP)” was as follows:

Notice of Intent Publication: 2020/02/25
First Meeting of Technical Committee: 2020/06/11
Public Consultation Period: 2020/08/24 – 2020/10/31
Final Meeting of Technical Committee: 2020/11/12
Publication of First Edition: 2020/11/27
First Revision: 2024/09/09.

The revised version incorporates the following amendments:

- Added terms and definitions
- Revised wording to provide additional clarity on requirements

This Standard is subject to technical committee review beginning no later than one year from the date of publication. The completion of the review may result in a new edition, revision, reaffirmation or withdrawal of the Standard.

Technical Committee Members

Members and Contributors

Clarissa Alberti Fleck, BSc; Quebec
Fern Brunger, BA, MA, PhD; Newfoundland and Labrador
Julie Bull, MAHS, PhD; Prince Edward Island
Natalie Comeau, MHSc, CIPP/C; Ontario
Denis Cournoyer, MD, FRCPC; Quebec
Pierre Deschamps, BCL, CM; Quebec
Rosie Goldstein, BSc, MD, CM, FRCPC; Quebec
Ann Munro Heesters, BEd, BA, MA, PhD; Ontario
Michal Helbin, MSc Pharm; Ontario
Daniel Houde, BSc, MBA, LLB; Quebec
Linda Hunt, Hons BSc, MSc, CCRA; Ontario
Murray Jensen, BSc, MSc; Quebec
Martin Letendre, BA, LLB, LLM; Quebec
Alex Karabanow, BSc, BAA; Ontario
Lynn Lavalee, MSc, PhD; Ontario
Jacquelyn Legere, RN, BN, CIPP/C; New Brunswick (Leader)
Linda Longpre, CCRP; Alberta
Debbie Martin, MA, PhD; Nova Scotia
Michael McDonald, BA, MA, PhD; British Columbia
Pertice Moffitt, BScN, MN, PhD; Northwest Territories
Melanie Nguyen, BSc, MSc; Quebec
Janice E. Parente, BSc, PhD; Quebec
Bryn Robinson, BA, PhD; New Brunswick
Barbara von Tigerstrom, BA, MA, LLB, PhD; Saskatchewan
Michael Walker, BSc, MSc, PhD; Ontario
Sheri Webb, BSc; Ontario

Standards Officer

Darryl Kingston, BA; Ontario (DGSI)

Introduction

One of the primary ethical justifications for conducting human research is to benefit society. Because human research seeks to understand something not yet known, participation in human research is not without risks. Given the fundamental importance of human research, society must ensure that research is conducted ethically, rigorously, safely, and in a manner that safeguards the rights and welfare of Research Participants.

A Human Research Protection Program (HRPP) is an organization-wide program composed of a network of interdependent entities that share the responsibility for Research Participant protection and interact in a system that promotes a culture of research integrity, quality, efficiency, accountability and evidence-based practices. An HRPP can exist in any for-profit or not-for-profit, public or private organization where human research is conducted and/or overseen.

An HRPP is composed of individuals or entities within an organization whose actions directly or indirectly affect research data integrity and/or the health, welfare, interests, or rights of Research Participants, such as the Leader or Leadership, Investigators/ Researchers, research personnel, REB members, and administrative and ancillary personnel.

Adherence to this NSC ensures that an organization has the necessary structure, oversight capabilities, and documented procedures in place to safeguard the rights and welfare of Research Participants, safely conduct research, and produce reliable, verifiable, and credible research data in an environment that promotes efficiencies and mitigates risks.

Consistent application of this NSC will ensure that human research is conducted uniformly from one organization to another, and from one province to another, enabling harmonization, collaboration, and economic growth of this activity within Canada and internationally.

It is the responsibility of the user of this NSC to judge its suitability for the user's intended purpose. This NSC may be used for conformity assessment.

CETTE NORME NATIONALE DU CANADA EST DISPONIBLE EN VERSIONS FRANÇAISE ET ANGLAISE.

ICS Code 03.100.30

1. Scope

This NSC applies to all individuals, as well as all for-profit and not-for-profit, public and private organizations engaged in the conduct and/or oversight of human research. By reducing the variability of interpretation of regulations, policies and guidelines, this NSC provides a basis for the establishment of unambiguous documented procedures that adhere to Canadian and international normative references.

Human research incorporates various types of qualitative and quantitative methods, disciplines (e.g. health, social sciences and humanities, arts, engineering), and approaches (e.g. interventional, observational) conducted in a variety of domains (e.g. biomedical, social, legal, behavioural). Human research may involve the use of existing or prospectively collected data or specimens.

“Shall” vs “Should”

In this NSC, “shall” indicates that the requirement is mandatory and is supported by normative references, whereas “should” indicates that the requirement is recommended, or a best practice statement.

2. Normative References

This NSC was developed in direct accordance with the normative documents listed below, all of which are publicly available. The user of this NSC should refer to the latest edition or revision of the normative documents.

2.1 Canadian Legislation

Health Canada Food and Drugs Act <https://laws-lois.justice.gc.ca/eng/acts/F-27/page-1.html>

Personal Information Protection and Electronic Documents Act (PIPEDA) <https://laws-lois.justice.gc.ca/ENG/ACTS/P-8.6/page-1.html>

Office of the Privacy Commissioner of Canada: Provincial and Territorial Privacy Laws and Oversight <https://www.priv.gc.ca/en/about-the-opc/what-we-do/provincial-and-territorial-collaboration/provincial-and-territorial-privacy-laws-and-oversight/>

2.2 Canadian Regulations

Health Canada Food and Drugs Regulations, Part C, Division 5 <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-drugs-clinical-trials-human-subjects-gui-0100.html>

Health Canada Natural Health Products Regulations, Part 4 <https://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/page-5.html#h-700807>

Health Canada Medical Device Regulations, Part 3 <https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-9.html#h-1021976>

2.3 Policies and Guidelines

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 (2018) https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html

Interpretations - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 (2018) Interpretations https://ethics.gc.ca/eng/policy-politique_interpretations.html

Material Incidental Findings - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 (2018) https://ethics.gc.ca/eng/incidental_findings.html

International Council for Harmonization (ICH) of Technical Requirements for Pharmaceuticals for Human Use Good Clinical Practice Guideline <https://www.ich.org/page/efficacy-guidelines>

The First Nations Principles of Ownership, Control, Access, and Possession OCAP® <https://fnigc.ca/ocap-training/>

2.4 National Standards of Canada and Global Standards

CAN/HRSO-200.01-2021 Ethical Review and Oversight of Human Research <https://www.hrso-onrh.org/standards/published-standards/>

CAN/HRSO-300.01-2022 Conduct of Human Research <https://www.hrso-onrh.org/standards/published-standards/>

HRSO-100.02-2023 Development of a Training Program for Human Research Protection <https://www.hrso-onrh.org/standards/published-standards/>

2.5 Other Regulations

US Code of Federal Regulations Title 21 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

US Code of Federal Regulations Title 45 https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45tab_02.tpl

3. Terms and Definitions

Community: A group of people with a shared identity or interest that has the capacity to act or express itself as a collective. A Community may be territorial, organizational, or defined by a shared interest. A Community may have governance processes that affect human research such as leadership engagement, recruitment, consent, and dissemination and ownership of research results.

Conflicts of Interest: A set of conditions or factors (such as money, friendship, reputation) in which professional judgment concerning a primary interest (such as the welfare of a Research Participant) could be reasonably expected to be influenced by a secondary interest (such as financial gain). Conflicts of interest have the following components:

- a relationship - one party (the trustor) is entitled to trust that the other (the trustee) will promote or protect their interests in relation to matters within that relationship
- an influence that tends to make the trustee's judgment on a given decision less reliable in promoting or protecting the trustor's interests than it would normally be
- an exercise of judgment - the trustee must be able to make a decision that affects the trustor's interests.

Conflicts of interest may be actual, when a secondary interest is currently influencing professional judgment, potential, when there is a risk that it could influence future decisions; or perceived, when it appears to others that professional judgment may be compromised, even if no actual influence exists.

Conflicts of Roles: A situation that occurs when competing demands are placed on an individual relating to their job or position, such as conflicting responsibilities (e.g. an Investigator/Researcher reviewing her own research while serving on an REB).

Conformity Assessment: Processes used to demonstrate that a product, service, management system or body meets specified procedures or requirements.

Data: Any set of values of qualitative or quantitative variables. Data may be recorded in any format (e.g. electronic, paper) and include *de novo* collections or secondary use of existing data.

Essential Documents: A term usually associated with clinical research, essential documents are those documents which individually and collectively permit evaluation of the conduct of research and the quality of the research data produced.

Human Research: A systematic, rigorous investigation involving human beings that includes, but is not limited to, the following disciplines: health research, social sciences and humanities research, creative and arts-based research, and engineering research, and includes, but is not limited to, the following methods:

- interventional research, observational research
- qualitative research, quantitative research
- social and behavioural research, health services research, public health research, educational research
- research involving existing human data and human biological materials and their derivatives
- research involving living or deceased individuals.

Human Research Protection Program (HRPP): An organization-wide program composed of a network of interdependent entities that share the responsibility for Research Participant protection and interact in a system that promotes a culture of research integrity, quality, efficiency, accountability and evidence-based practices. An HRPP can exist in any for-profit or not-for-profit, public or private organization where human research is conducted and/or overseen.

Indigenous Peoples: In the context of Canada, persons of First Nations, Inuit, or Métis descent, regardless of where they reside and whether their names appear on an official register.

Individuals Who Play a Role in the HRPP: Any individual or entity within an organization whose actions directly or indirectly affect research data integrity and/or the health, welfare, interests, or rights of Research Participants, such as the Leader or Leadership, Investigators/ Researchers, research personnel, REB members, and administrative and ancillary personnel.

Investigator/Researcher: For this NSC, an individual who carries out human research.

Leader or Leadership: An individual or group of individuals representing the highest authority within the HRPP. The Leader or Leadership is responsible for oversight of the HRPP and is legally authorized to represent it.

National Standard of Canada (NSC): A NSC is a standard developed by a Standards Council of Canada (SCC) accredited Standards Development Organization, in compliance with requirements and guidance set out by SCC.

Negative Impact: Any event, whether anticipated or not, that does or could adversely affect research data integrity; the health, welfare, interests or rights of Research Participants, Investigators/Researchers, and third parties such as families and communities; or the conduct of the research.

Organization: In the context of an HRPP, an entity, such as an institution or corporation, that, as part or all of its activities, conducts and/or oversees human research.

Performance Indicators: A type of measurement used to evaluate the success of an organization or particular activity in which it engages.

Personal Associate: An individual with whom a relationship, other than a professional or business relationship, exists. Examples of a personal associate include, but are not limited to, a relative by birth, adoption, marriage, domestic partnership or civil union, as well as anyone who currently is a member of one's household.

Documented Procedures: A collective term used to describe policies, procedures (such as standard operating procedures), and guidelines.

Publicly Accessible Registry: In the context of clinical research, the publication of an internationally agreed set of information about the design, conduct and administration of clinical trials. These details are published on a publicly accessible website managed by a registry conforming to World Health Organization standards (e.g. www.clinicaltrials.gov).

Publicly Declared Emergency: A situation that has been proclaimed an emergency due to the extraordinary risks it presents, by an authorized public official in accordance with legislation and/or public policy. Publicly declared emergencies arise suddenly or unexpectedly and require urgent or quick responses to minimize devastation. Examples include, but are not limited to, natural disasters, large communicable disease outbreaks, catastrophic civil disorders, bio-hazardous releases, environmental disasters, and humanitarian emergencies.

Research Data: Data used for research purposes. For this NSC, the term "research data" is restricted to data about humans, including their biological materials.

Research Ethics Board (REB): A REB is an appropriately constituted group that applies ethical principles in its review and ongoing evaluation of research involving humans. A REB is also known as an independent or institutional review board (IRB), independent ethics committee (IEC), a research ethics review committee (RERC), a research ethics committee (REC), or ethical review board (ERB).

Research Participant: An individual whose data, biological materials, or responses to interventions, stimuli, or questions may be used to answer the research question(s).

Vendors and Sub-Contractors: Entities that sell products and services to the HRPP (Vendors) or provide services under contract to the HRPP (Sub-Contractors). Some important examples of Sub-Contractors include, but are not limited to, external REBs, external Investigators/Researchers, external biobanks, and contract research organizations.

4. Technical Requirements

4.1 HRPP Mandate

The Organization shall have a written Mandate that describes the structure, leadership, culture, and overall applicability of the Human Research Protection Program (HRPP).

The Mandate shall:

- 4.1.1 describe its origins, and the processes for its approval, updates, and revisions.
- 4.1.2 outline the structure of the HRPP and its reporting relationship(s), if any, within the Organization and outside the Organization.
- 4.1.3 outline the individuals and groups who play a role in the HRPP including, but not limited to, the REB, Investigators/Researchers, and administrative personnel.
- 4.1.4 list the relevant regulations, guidelines, policies, and standards governing the HRPP.
- 4.1.5 outline the function, responsibility, jurisdiction and authority of the HRPP.
- 4.1.6 describe the culture of the HRPP, particularly the core organizational values with respect to the ethical conduct of its human research, and its adherence to regulations, guidelines, policies, and standards listed in the Mandate.
- 4.1.7 describe how the HRPP will operate in a multi-centre and multi-jurisdictional research environment.
- 4.1.8 outline the process that ensures that the deliberations and decision making of the REB are free from any outside influences or biases.
- 4.1.9 outline the process for ensuring responsible conduct of research by the HRPP's Investigators/Researchers.
- 4.1.10 be available in the working languages of the Individuals Who Play a Role in the HRPP.
- 4.1.11 ensure that Individuals Who Play a Role in the HRPP are aware of who the HRPP Leader or Leadership is and have direct access to the HRPP Leader or Leadership.
- 4.1.12 appoint a Leader or Leadership of the HRPP that is responsible for its oversight and has the legal authority to represent it.

4.1.13 outline the Leader or Leadership's authority and responsibilities, including the following:

- (a) The Leader or Leadership should have training in human research protection.
- (b) The Leader or Leadership shall foster a culture that supports the ethical conduct of all human research and adherence to relevant regulations, guidelines, policies, and standards listed in the Mandate.
- (c) The Leader or Leadership shall ensure that the HRPP has resources to support the size and complexity of the research conducted, such as qualified personnel, space, equipment, materials and technology.
- (d) The Leader or Leadership should ensure that the HRPP is insured to fulfill its mandate and has access to independent legal counsel.
- (e) The Leader or Leadership may delegate parts of its authority to other qualified Individuals Who Play a Role in the HRPP but shall be solely responsible for their conduct.
- (f) The Leader or Leadership shall ensure that the HRPP has sufficient resources for internal compliance auditing, and that activities of the HRPP are audited on a regular basis.
- (g) The Leader or Leadership shall ensure that findings stemming from internal or external compliance auditing are addressed in a timely manner, including corrective and preventative actions, and effectiveness verification, as required.
- (h) On an annual basis, the Leader or Leadership shall conduct a formal and documented review of the HRPP and make adjustments, as required. The scope of the review can be found in Annex A.
- (i) The Leader or Leadership shall ensure that the documented procedures of the HRPP will be reviewed at least every two years and revised where necessary.

4.2 Human Research Determination

The HRPP shall have documented procedures that determine what constitutes human research and falls under the auspices of the HRPP.

Documented procedures shall include:

- 4.2.1 a process for the determination of what constitutes research involving humans and falls under the auspices of the HRPP.

- 4.2.2 a designation of whom, within the HRPP, is authorized to make determinations of what constitutes research involving humans.

4.3 Obtaining Approvals to Conduct Human Research

The HRPP shall have documented procedures to ensure that proposed human research attains all levels of approval that are required prior to commencement of any research. Examples of research activities requiring approval prior to their commencement can be found in Annex B.

Documented procedures shall ensure that, before the commencement of any research:

- 4.3.1 a review(s) shall be conducted, as appropriate, within or outside the HRPP, to determine that the proposed research is scientifically valid and has value to affected communities.
- 4.3.2 approval by a properly constituted REB shall be received for the proposed research.
- 4.3.3 where required, approval(s) from committees or individuals within or external to the Organization shall be received for the proposed research.
- 4.3.4 where required, written authorization from the appropriate regulatory authorities shall be received for the proposed research.
- 4.3.5 where required, approval from the appropriate community or external organization shall be received for the proposed research.

Documented procedures shall ensure that:

- 4.3.6 where required, after receiving all required approvals, the proposed research shall be entered into a publicly accessible registry.

Documented procedures should ensure that:

- 4.3.7 an internal registry of the HRPP's research studies shall be created, maintained, and be available to the public.

4.4 Qualification and Training of Individuals Who Play a Role in the HRPP

The HRPP shall ensure that Individuals Who Play a Role in the HRPP are qualified for their roles, are trained in human research protection, and that a program is in place for ongoing training.

Documented procedures shall:

- 4.4.1 ensure that a training program exists for human research protection and that all Individuals Who Play a Role in the HRPP have participated in the training program prior to performing their roles (e.g. HRSO-100.02-2023 Development of a Training Program for Human Research Protection).
- 4.4.2 ensure that all Individuals Who Play a Role in the HRPP have relevant credentials, education and are trained for their roles within the HRPP.
- 4.4.3 ensure that Investigators/Researchers that play a role in HRPP will only be approved to conduct human research in their specific areas of expertise for which they have relevant credentials, education and experience. Examples of acceptable credentials for Investigators/Researchers can be found in Annex C.
- 4.4.4 describe the plan for ensuring ongoing training and continuing education for all Individuals Who Play a Role in the HRPP, including training and continuing education from external sources.
- 4.4.5 outline the process for the creation and maintenance of training files for all Individuals Who Play a Role in the HRPP.

4.5 Compliance with the HRPP

The HRPP shall have documented procedures for assessing compliance with the HRPP.

- 4.5.1 Documented procedures shall describe the process for assessing compliance with the HRPP including, but not limited to:

- (a) the frequency, number, and level of scrutiny of compliance assessments commensurate with the size of the HRPP, and the complexities and risks associated with the human research.
- (b) the methods for data collection.
- (c) the metrics employed in order to conduct an analysis of compliance with the HRPP.

Documented procedures should ensure that:

- 4.5.2 a report will be prepared at least annually that summarizes all of the compliance and non-compliance assessment findings for presentation to the HRPP Leader or Leadership.

4.5.3 the HRPP Leader or Leadership will ensure that the report summarizing all of the compliance and non-compliance assessment findings will be shared with the highest authority of the Organization.

4.6 Non-Compliance with the HRPP

The HRPP shall have documented procedures for managing incidents of non-compliance with the HRPP.

Documented procedures shall:

- 4.6.1 define non-compliance, serious non-compliance, and continuing non-compliance with the HRPP.
- 4.6.2 outline the process for managing incidents of non-compliance with the HRPP including, but not limited to, how they are identified, received, reviewed, and investigated.
- 4.6.3 outline the process for reporting incidents of non-compliance, serious non-compliance, and continuing non-compliance with the HRPP including, but not limited to, the following:
 - (a) the timeline for reporting,
 - (b) the format for reporting,
 - (c) to whom the incidents of non-compliance shall be reported (e.g. HRPP Leader or Leadership, REB, study sponsor, regulatory authorities, Research Participants).
- 4.6.4 outline the ways that Individuals Who Play a Role in the HRPP shall mitigate future incidents of non-compliance, serious non-compliance, and continuing non-compliance.

4.7 Continuous Quality Improvement of the HRPP

The HRPP should have documented procedures for continuous quality improvement of the HRPP in order to fulfill 4.1.13 (h).

Documented procedures should:

- 4.7.1 describe the process for continuous quality improvement of the HRPP that includes, but is not limited to, the following:
 - (a) the individuals responsible for continuous quality improvement of the HRPP and a delineation of tasks for which these individuals are responsible.

- (b) a plan to assess the performance of the HRPP.
 - (c) a schedule of the performance indicators that will be monitored in order to routinely evaluate improvement efforts and outcomes. Examples of performance indicators can be found in Annex A.
 - (d) the methods for assessing, measuring, monitoring and analyzing the performance indicators.
 - (e) an evaluation of the results and determination of subsequent actions.
 - (f) a process by which to improve on items that emerge.
- 4.7.2 ensure that all Individuals Who Play a Role in the HRPP understand the performance indicators and are empowered to improve efforts and results.
- 4.7.3 ensure that stakeholders outside the HRPP, especially Research Participants, are involved in continuous quality improvement activities.
- 4.7.4 describe the process for receiving and addressing complaints including anonymous complaints (a whistle-blower provision) from Individuals Who Play a Role in the HRPP, and from stakeholders outside the HRPP.
- 4.7.5 describe how the HRPP will protect complainants from reprisal and how information about this protection will be disseminated to those that play a role in the HRPP and stakeholders outside the HRPP, in order to promote a culture of responsible research.
- 4.7.6 include a process to report on the results of the performance of the HRPP, and what, if any, procedures or changes in practice emerged due to the continuous quality improvement activities.

4.8 Selection of Vendors and Sub-Contractors

The HRPP shall have documented procedures for selecting Vendors and Sub-contractors and assessing their compliance with the HRPP.

Documented procedures shall describe the process for:

- 4.8.1 the selection of Vendors and Sub-contractors hired to fulfill a role(s) within the HRPP. The process should ensure that the HRPP's preferred option is to select Vendors and Sub-contractors that hold proof of third-party conformity assessments such as certification, qualification or accreditation.

- 4.8.2 assessing the documented procedures of Vendors and Sub-contractors that do not hold proof of third-party conformity assessments to ensure that they are in compliance with the HRPP. The process shall include the criteria upon which the selection decision is made and any training or other measures that are required in order to ensure compliance with the HRPP.

Documented procedures should describe the process for:

- 4.8.3 conducting for-cause and random audits of all Vendors and Sub-contractors hired to fulfill a role(s) within the HRPP in order to ensure compliance with the HRPP.

4.9 Negative Impacts of Research

Where there are NSCs dealing with negative impacts of research on affected parties and the conduct of research, the HRPP shall recognize and follow them. If NSCs do not exist, the HRPP shall ensure that it has documented procedures for dealing with negative impacts of research on affected parties including Research Participants, Investigators/ Researchers, and third parties such as families and communities, and on research data integrity and the conduct of research.

Documented procedures shall:

- 4.9.1 include a plan for identifying, monitoring, mitigating, assessing, managing, and reporting negative impacts for the particular types of research under the auspices of the HRPP.
- (a) The plan shall include specific reference and adherence to applicable organizational, regional, provincial, national or international guidelines and regulations regarding negative impacts and their reporting requirements.
- Examples of applicable guidelines and regulations can be found in Annex D.
- (b) The plan shall include provisions for negative impacts that are unanticipated.
- 4.9.2 ensure that all Individuals Who Play a Role in the HRPP are aware of the above-mentioned plan and have been appropriately trained on its implementation.
- 4.9.3 outline the process for the review and management of emerging information or other findings of consequence to affected parties that could adversely affect their health, welfare, interests, rights, or impact the conduct of the research.
- 4.9.4 include provisions for monitoring and managing heretofore unrecognized or emerging negative impacts including the process, timeline and format for reporting, and to whom they are reportable. An example would be the implementation of a data and safety monitoring board (DSMB), or its equivalent.

Such provisions shall include measures to ensure meaningful input from Research Participants and/or their representatives.

4.10 Privacy and Data Governance

Where there are NSCs dealing with privacy and data governance as they relate to human research, the HRPP shall recognize and follow them. If NSCs do not exist, the HRPP shall ensure that it has documented procedures to protect the privacy interests of Research Participants and to maintain the confidentiality and security of personal information (personal data) and research data.

Documented procedures shall:

- 4.10.1 define the terms personal information (personal data), privacy, and confidentiality in accordance with applicable laws, regulations, policies, and guidelines and in relation to their impact on Research Participants and research activities.
- 4.10.2 outline the process for assessing risks that may impact the privacy interests of Research Participants and the maintenance of confidentiality and security of personal information (personal data) and research data, including, but not limited to, the following:
 - (a) the criteria that will be considered in the risk assessment. Examples of risk assessment criteria related to privacy and data security can be found in Annex E.
 - (b) a determination of who within the HRPP is responsible for conducting the risk assessment.
 - (c) to whom the risk assessment findings will be reported.
- 4.10.3 ensure that an assessment of risks that may impact the privacy interests of Research Participants and the maintenance of confidentiality and security of personal information (personal data) and research data will be conducted prior to the initiation of research and will be reviewed and updated on an ongoing basis throughout the research.
- 4.10.4 ensure that all Individuals Who Play a Role in the HRPP are aware of the above-mentioned risk assessment process and have been appropriately trained on all documented procedures related to protecting the privacy interests of Research Participants and to maintaining the confidentiality and security of personal information (personal data) and research data.

4.11 Operations during Disruptive Events and Publicly Declared Emergencies

Where there is a NSC for operations during disruptive events and publicly declared emergencies, the HRPP shall recognize and follow it. If a NSC does not exist, the HRPP shall ensure that it has documented procedures for operations during disruptive events and publicly declared emergencies.

Documented procedures shall:

- 4.11.1 define disruptive events and publicly declared emergencies.
- 4.11.2 describe how essential activities will be maintained during disruptive events and publicly declared emergencies.
- 4.11.3 outline the process for ensuring the safety and wellbeing of the following during disruptive events and publicly declared emergencies:
 - (a) Research Participants.
 - (b) Individuals Who Play a Role in the HRPP.
- 4.11.4 outline the process for ensuring the integrity of the following during disruptive events and publicly declared emergencies:
 - (a) essential documentation.
 - (b) research data.
 - (c) biological samples.
 - (d) investigational product.
- 4.11.5 describe the process for how operations will resume as the disruptive event or publicly declared emergency subsides.
- 4.11.6 describe the process for assessing and documenting the response to the disruptive event or publicly declared emergency and any lessons learned for the future.

4.12 Conflicts of Interest and Conflicts of Roles

The HRPP shall have documented procedures to identify, disclose, review and manage conflicts of interest and conflicts of roles of Individuals Who Play a Role in the HRPP and their personal associates.

Documented procedures shall:

- 4.12.1 identify which aspects of conflicts of interest (e.g. monetary, reputational, or institutional) and conflicts of roles (e.g. having a care role as well as a research role) are relevant to the HRPP (e.g. situational and structural), in particular, those that involve conflicts with the responsibilities of the Individuals who Play a Role in the HRPP with respect to Research Participants, and the achievement and communication of research results.
- 4.12.2 outline the process for Individuals Who Play a Role in the HRPP, as well as Vendors and Sub-contractors, to disclose conflicts of interest and conflicts of roles that may affect any aspect of their human research responsibilities.
- 4.12.3 describe how the identification and disclosure of conflicts of interest and conflicts of roles will be documented, managed, and reported.
- 4.12.4 ensure that Individuals Who Play a Role in the HRPP are trained on how to identify and disclose conflicts of interests and conflicts of roles.

4.13 Undue Influence

The HRPP shall have documented procedures to ensure that Individuals Who Play a Role in the HRPP, as well as Vendors and Sub-contractors, function independently and free from undue influence.

Documented procedures shall:

- 4.13.1 include a definition of undue influence as it pertains to Individuals Who Play a Role in the HRPP, as well as Vendors and Sub-contractors, and their human research responsibilities and activities. The definition shall describe the various sources of possible undue pressure such as those that may be perceived from owners, shareholders, board members, community members, institutional officials of the Organization, study sponsors, or government.
- 4.13.2 ensure that Individuals Who Play a Role in the HRPP, as well as Vendors and Sub-contractors, shall function independently and free from any undue influence that may affect their human research responsibilities.
- 4.13.3 describe the process for Individuals Who Play a Role in the HRPP, as well as Vendors and Sub-contractors, to identify and disclose incidents of undue influence.
- 4.13.4 describe how the identification and disclosure of incidents of undue influence will be documented, managed, and reported.
- 4.13.5 describe how the HRPP will protect individuals who disclose incidents of undue influence from reprisal and how information about this protection will be

disseminated to those that play a role in the HRPP, as well as Vendors and Sub-contractors, in order to promote a culture of responsible research.

4.14 Dissemination of Research Results

The HRPP shall have documented procedures to ensure and monitor that the results of human research are responsibly disseminated in a timely manner, without undue restrictions, and, where applicable, in compliance with funding and public registry requirements.

Documented procedures shall ensure that:

4.14.1 Investigators/Researchers will have timely and unrestricted access to their original research data for the duration of the research to ensure that they can report findings accurately in order to make informed decisions regarding research participation.

(a) The documented procedures shall include a provision for timely and unrestricted access to original research data for the duration of the research from all Investigators/Researchers involved in multi-site research.

4.14.2 the results (data analyses, interpretation of data, findings) of research will be responsibly disseminated to Investigators/Researchers, Research Participants, and the public in a timely manner.

4.14.3 no undue restrictions will be placed on Investigators/Researchers regarding what research data they can publish or responsibly disseminate.

4.15 Community and Research Participant Engagement

Where there is a NSC for engaging the public in the research enterprise, the HRPP shall recognize and follow it. If a NSC does not exist, the HRPP shall ensure that it has documented procedures to support a program that engages the public in the research enterprise.

Documented procedures should:

4.15.1 describe the elements and tools of a program designed to engage the community and Research Participants in the research enterprise, and the process for the program's implementation.

4.15.2 ensure that the program involves all stages of research and all Individuals Who Play a Role in the HRPP.

4.15.3 describe the plan for communicating and publicizing the program to the community and Research Participants, including the method of accessing the program.

4.16 Research Participants' Inquiries and Concerns

The HRPP should have documented procedures to address inquiries and concerns of Research Participants.

Documented procedures should describe:

4.16.1 the plan for communicating to Research Participants that a process is in place to address their inquiries and concerns.

4.16.2 the process for addressing inquiries and concerns of Research Participants in a manner that is inclusive and respectful of their rights and privacy.

4.16.3 the process ensuring that Research Participants' inquiries and concerns will be addressed in a timely and efficient manner.

Documented procedures shall describe:

4.16.4 who within the HRPP is responsible for addressing inquiries and concerns of Research Participants and describe how their contact information will be conveyed to Research Participants.

4.17 Research with Individuals in Situations of Vulnerability

The HRPP shall have documented procedures to identify and consider situations where Research Participants may be vulnerable in the context of the proposed research.

Documented procedures shall:

4.17.1 outline the process for determining which situations and criteria render a Research Participant vulnerable in the context of the proposed research. For example, there are situations in which Research Participants are confined or lack accessibility in relation to study participation requirements, situations that disadvantages Research Participants economically or socially, and situations that place Research Participants in a relationship of power imbalance with the Research Team.

4.17.2 ensure that individuals placed in situations of vulnerability are neither inappropriately included (e.g. over-researched populations), nor excluded from research (e.g. avoiding research addressing individuals in situations of vulnerability). The selection of Research Participants should be guided first and foremost by the goals of the research.

4.17.3 outline the process for ensuring ethical oversight of research involving Research Participants in situations of vulnerability, including consultation with affected Research Participants, referral to support services, or applying safety protections, where appropriate.

4.18 Respecting Research Participants' Culture, Beliefs, and Social Identity

The HRPP shall have documented procedures that describe how the HRPP will respect the culture, beliefs and social identity of Research Participants.

4.18.1 Documented procedures shall outline the process for ensuring that the culture, beliefs and social identity of Research Participants will be respected by all Individuals Who Play a Role in the HRPP and apply throughout the entire research process. This includes, but is not limited to, the building and fostering of relationships with, and inclusion of, culturally- and socially-identifiable individuals in the entire research process.

4.19 Research with Indigenous Peoples

Where there is a NSC for research with Indigenous Peoples, the HRPP shall recognize and follow it. If a NSC does not exist, the HRPP shall ensure that it has documented procedures that describe how the HRPP will promote a respectful research environment when conducting research with Indigenous Peoples.

Documented procedures shall describe the process for ensuring that:

- 4.19.1 an authentic partnership with the Indigenous Community is established, including, but not limited to, how the Investigators/Researchers will:
- (a) demonstrate that they entered into a voluntary and mutually beneficial relationship with the Indigenous Community prior to designing the research;
 - (b) continue to develop the relationship; and
 - (c) sustain the relationship throughout the research process and thereafter.
- 4.19.2 Indigenous research governance processes are adhered to, including, but not limited to, describing how:
- (a) Indigenous governance structures and REBs will intersect (e.g. ensuring that the Indigenous community's process is followed in terms of the order of REB review and approval in relation to Indigenous community review and collective consent).
 - (b) collective consent will be obtained from the Indigenous Community; and

(c) ongoing collective acceptability of the research to the Indigenous Community will be monitored.

4.19.3 the HRPP promotes Indigenous sovereignty over research data, including a process for ensuring:

(a) Indigenous ownership of research data.

(b) Indigenous control of research data.

(c) that organizational structures within the HRPP (e.g. legal requirements, financial policies) do not unduly burden or restrict Indigenous sovereignty over research data.

4.19.4 research funding respects the infrastructural needs of Indigenous communities, including, but not limited to, the following:

(a) how the organization will ensure that Investigators/Researchers do not unduly burden Indigenous communities.

(b) how Research Participants and community leaders are appropriately compensated for engagement in research.

4.19.5 Individuals Who Play a Role in the HRPP and plan to conduct research with Indigenous Peoples have been appropriately trained on research with Indigenous Peoples before any elements of research are undertaken.

Documented procedures should describe the process for ensuring that:

4.19.6 Indigenous research governance processes are adhered to, including describing how the research partnership would be dissolved and the Investigators/ Researchers' involvement in the research terminated, should collective consent no longer apply.

4.19.7 research funding respects the infrastructural needs of Indigenous communities, including how the HRPP will support a goal of having research funds managed by the Indigenous Community rather than the research institution, whenever possible.

4.20 Research with Other Communities

The HRPP shall ensure that it has documented procedures that describe how it will promote a respectful research environment when conducting research with humans based on their membership in specific communities. Examples of communities include, but are not limited to, individuals who have the shared experience of a common

impairment (e.g. hearing, vision), disease (e.g. HIV AIDS, breast cancer, Alzheimer's Disease), genetic history, cultural history, social relationship, or marginalization. In developing its documented procedures, the HRPP shall consider the relevant requirements described in section 4.19 - Research with Indigenous Peoples.

Documented procedures shall describe the process for ensuring that:

- 4.20.1 an authentic partnership with the Community is established, including, but not limited to, how Investigators/Researchers will:
 - (a) identify and consult with the Community leadership, or if such leadership does not exist, identify and consult with individuals who represent various groups within the Community;
 - (b) demonstrate that they entered into a voluntary and mutually beneficial relationship with the Community; and
 - (c) continue to develop the relationship and sustain the relationship throughout the research process and thereafter.
- 4.20.2 the Community is engaged in the human research from design to completion.
- 4.20.3 research funding respects, and where possible enhances, the infrastructural needs of the Community, including, but not limited to, the following:
 - (a) how the HRPP will ensure that Investigators/Researchers do not unduly burden or over-solicit communities; and
 - (b) how Research Participants and Community leaders are appropriately compensated for engagement in research.
- 4.20.4 the research is likely to generate knowledge that could benefit the Community (e.g. to increase the understanding of causal factors, to contribute to the health or well-being of Community members).
- 4.20.5 where appropriate, approval from the Community is granted prior to the commencement of any human research activities (see section 4.3 – Obtaining Approvals to Conduct Human Research).
- 4.20.6 where appropriate, Community research governance processes are adhered to, including, but not limited to, describing how:
 - (a) collective consent will be obtained, if required; and
 - (b) ongoing collective acceptability of the research to the Community will be monitored.

- 4.20.7 results and knowledge derived from the human research are transferred, translated, and exchanged (e.g. Knowledge Translation and Exchange, Knowledge Mobilization) with the Community.
- 4.20.8 where applicable, any agreements with the Community include details for ownership of, access to, and use of data and include arrangements for co-authorship in situations where Community members are collaborators or partners in the research.

Informative Annexes

Annex A: Scope of the Annual HRPP Review (Informative)

The scope of the annual review of the HRPP should include, but not be limited to, the following performance indicators:

General Performance of the HRPP

- Feedback from Investigators/Researchers, REB members, research sponsors, Research Participants
- Research Participant outreach and engagement initiatives
- Findings from internal compliance assessments, corrective and preventative actions, effectiveness verification
- Findings from external audits (e.g. sponsor, regulatory), corrective and preventative actions, effectiveness verification
- Incidents of non-compliance and resolutions
- Research Participant complaints and resolutions
- Comparative efficiency metrics analyses (prior years)
- Quantity, complexity, risks of research undertaken
- Vendor and sub-contractor audits

Review of Resources

- Space
- Equipment, materials, technology
- Investigators/Researchers, REB members, administration
- Training
- Quality Assurance
- Legal (conflicts of interest, contracts)
- Funding

Actions Required

- Add, modify, remove or reallocate resources
- Arrange for repeat or new training
- Modify or add internal compliance assessments
- Modify or add documented procedures
- Modify Research Participant outreach and engagement initiatives

Annex B: Examples of Research Activities Requiring Approval Prior to their Commencement (Informative)

Examples of research activities requiring approval prior to their commencement include, but are not limited to, the following:

- Research Participant recruitment activities
- review of a potential Research Participant's clinical chart
- collection of any research data
- access to research data
- collection of human biological materials

Annex C: Examples of Acceptable Credentials for Investigators/Researchers (Informative)

Examples of acceptable credentials for Investigators/Researchers are as follows:

- Curriculum vitae demonstrating education, training and experience to assume responsibility for the intellectual direction of the research or research-related activity, and to assume administrative responsibility for the grant, award or contract, if applicable.
- If the research involves restricted activities regulated by a professional licensing and regulating body, a valid professional license issued by the professional licensing and regulating body from the province where the research will be conducted.
- If the research involves a therapeutic product for medical or dental purposes, a valid licence issued by a medical or dental professional licensing and regulating body from the province where the research will be conducted.

Annex D: Examples of Applicable Guidelines and Regulations Referenced in a Plan for Negative Impacts of Research Participation (Informative)

Examples of applicable guidelines and regulations that should be referenced in relation to a plan for identifying, monitoring, mitigating, assessing, managing, and reporting negative impacts for the particular types of research under the auspices of the HRPP include, but are not limited to, the following:

- authorship guidelines
- biological safety (biosafety)
- collection and use of human biological materials
- commercialization of research
- conflicts of interest in research
- intellectual property
- privacy and data governance
- radiation safety
- research integrity
- research involving controlled goods
- responsible conduct of research
- transportation of dangerous goods

Annex E: Examples of Risk Assessment Criteria Related to Privacy and Data Security (Informative)

Criteria that shall be considered in an assessment of risks by the HRPP that may impact the privacy interests of Research Participants and the maintenance of confidentiality and security of research data include, but are not limited to, the following:

Research Participants

- the methods that will be used to identify and contact potential Research Participants
- the settings in which potential Research Participants and Research Participants will interact with Individuals Who Play a Role in the HRPP
- the appropriateness of each individual who plays a role in the HRPP to be present for research procedures

Research Data

- the process for obtaining consent from Research Participants or their representatives in order to collect, use and/or disclose research data
- the methods that will be used to collect research data
- the nature of the research data to be collected
- how the research data will be used
- for what purposes the research data will be collected and used
- the methods, such as data encryption, that will be used to protect the identity of Research Participants
- the methods that will be used to secure stored research data including paper, electronic, or any other medium
- the process for determining which Individuals Who Play a Role in the HRPP will be authorized access to the research data
- the process for granting and removing authorized access to research data and how this access will be tested and removed
- the process for ensuring that appropriate agreements are in place for sharing research data within the HRPP and externally
- the process for the secure transmission of research data within the HRPP and externally
- the timeline and process for the destruction of research data

Annex F: Informative References

The following Informative documents are meant to help with the conceptual understanding of this NSC. The user of this NSC should refer to the latest edition or revision of these informative documents.

Institute of Medicine - Preserving Public Trust: Accreditation and Human Research Participant Protection Programs
<https://www.nap.edu/catalog/10085/preserving-public-trust-accreditation-and-human-research-participant-protection-programs>

Report on the Evaluation of Control Mechanisms in Clinical Research in Quebec (The Deschamps Report), authored by Pierre Deschamps, BCL, CM
<https://www.hracanada.org/hra/wp-content/uploads/2022/04/Deschamps-Report-EN.pdf>

The Governance of Health Research Involving Human Subjects (HRIHS), authored by Michael McDonald, BA, MA, PhD
https://epe.lac-bac.gc.ca/100/206/301/law_commission_of_canada-ef/2006-12-06/www.lcc.gc.ca/pdf/macdonald%20eng%20oct%2017%202000%20final.pdf

World Health Organization - Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants
https://apps.who.int/iris/bitstream/handle/10665/44783/9789241502948_eng.pdf

World Medical Association - Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects
<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>