RÉSEAU DE SANTÉ Horizon HEALTH NETWORK	**STANDARD OPERATING PRACTICE** **Office of Research Services**

Authority and Scope of Horizon's Human Research Protection Program		
Standards: L1, L3	**SOP No.: 1**	**Effective Date: January 27, 2020**

PURPOSE

To communicate the organizational authority under which Horizon's Human Research Protection Program (HRPP) is established and empowered. This includes statements of the HRPP's mandate, authority and scope, as well as the principles governing the HRPP to assure that the rights and welfare of participants are protected.

DIRECTLY AFFECTED

Unless explicitly stated, this policy applies to the persons or groups listed below exclusively.

- Researchers, Research Coordinators, and Research Assistants
- Research Ethics Board
- Regional Director Research Services
- Regional Director Ethics Services
- Office of Research Services (ORS)
- Vice-President Medical, Academic and Research Affairs

PROCEDURE

Institutional Authority

Through its Executive Leadership Team, Horizon Health Network (Horizon) has established a Human Research Protection Program (HRPP). The HRPP is an institution-wide program for protecting Horizon's human research participants, effective as of July 1, 2018.

Mandate

The mandate of the HRPP is to:

- Safeguard and promote the health and welfare of human research participants by ensuring that their rights, safety and well-being are protected
- Provide guidance and support to the research community in the conduct of research with human participants
- Assist the research community in ensuring compliance with relevant regulations
- Provide timely and high-quality review and oversight of human research projects
- Promote a culture of research excellence through a systemic approach that places great value on the conduct of scientifically sound and ethically acceptable human participants research.

For those interested, this Mandate has been translated into French (Appendix A).

Organizational Structure of the HRPP

The HRPP consists of individuals, departments and committees with responsibilities for human research protection: Horizon executive leadership; the Offices of Research Services and of Research Ethics; the Regional Director of Research Services; the Regional Director of Ethics Services; the members of the Research Ethics Board; staff with assigned responsibilities for HRPP operations; investigators; research staff; and others.

Vice President Medical, Academic and Research Affairs

The Vice-President (VP) Medical, Academic and Research Affairs is the Institutional Authority for the HRPP, and as such:

- Fosters a culture that supports the ethical conduct of research.
- Is responsible for ensuring that the HRPP has adequate resources to the support size and complexity of the research conducted as well as support necessary to comply with all organizational policies, laws, and regulations that govern human participant research.
- Ensures that the HRPP is adequately insured and has access to legal counsel.
- Ensures that the REB functions independently from Horizon with respect to its deliberations and decisions.

As the HRPP's Institutional Authority, the VP has the appropriate training in human research protection and the legal authority to represent the HRPP. Further, the VP has the authority to suspend, terminate, or disapprove research or take other actions, such as sanctions or restrictions of research privilege or uses of research data, as necessary, to ensure the proper conduct of research, the protection of human participants, the autonomy and authority of the REB, compliance with regulation or policy, or to protect the interests of Horizon. However, the VP may not approve research that has been disapproved (or not yet approved) by the REB.

HRPP Director

The VP also has the authority to delegate the performance of certain oversight and operational duties to an HRPP Director, if such delegation is not contrary to HRPP policies and procedures. This Director must be qualified through education and training in human research protection.

Reporting indirectly to the VP through the Regional Director of Research Services, the HRPP Director is responsible for the day-to-day operation of the HRPP. This includes:

- Fostering a culture that supports the ethical conduct of all human research and adherence to all regulations, guidelines and policies listed in the Mandate.
- Facilitating the regulatory and methodological components of the institutional review process for all research studies submitted to the HRPP.
- Ensuring that there are sufficient resources for auditing and conducts regular auditing activities to evaluate compliance of both individual research studies and of the HRPP overall.
- Ensuring that any corrective or preventative actions, or areas for improvement, identified in an audit are addressed in a timely manner.
- Ensuing that Investigators/Researchers under the HRPP are fulfilling their responsibilities.
- Conducting an annual, formal, and documented review of the HRPP and makes adjustments, as required.

If operations require, the Director will delegate some or all of their responsibilities to another HRPP member. However, the Director maintains responsibility for the conduct of their

delegates, and ensures that all HRPP members have the appropriate education and training before undertaking their delegated responsibilities.

Regional Director, Research Services

Through the Regional Director of Research Services who reports directly to the VP Medical, Academic and Research Affairs, the Office of Research Services (ORS) provides support to the HRPP by working collaboratively with the HRPP Director to assist in implementation of the program.

Regional Director, Ethics Services

Reporting directly to the VP Medical, Academic and Research Affairs, the Regional Director oversees the operations of the Research Ethics Board. The Director is also a member of the REB and has extensive knowledge and experience in the area of ethics of human participants research. The Regional Director will work collaboratively with the Regional Director of Research Services and the HRPP Director to ensure that:

- A culture is fostered that supports the ethical conduct of all human research;
- The REB members have access to applicable education and training;
- Any corrective or preventative actions, or areas for improvement, identified in an audit are addressed in a timely manner and;
- That Investigators/Researchers under the HRPP are fulfilling their responsibilities.

Research Ethics Board

Horizon's Research Ethics Board (REB) reviews and advises on all ethical aspects of proposed research. The REB functions independently of, but in coordination with, other committees and officials with responsibilities related to human participant research. However, the REB makes its independent determination whether to approve or disapprove research, based upon whether or not human participants are adequately protected and, whether the proposed research is scientifically valid and has social and clinical value.

Research that has been reviewed and approved by the REB may be subject to review and disapproval by officials of the organization. However, those officials may not approve human research that has not been approved or has been disapproved by the REB.

Components of Institutional Review

The components of institutional review ensure that no research study can commence without:

- Meeting institutional requirements for compliance and methodology (which includes evidence of authorization from the appropriate regulatory authority if applicable, and evidence of support from the organizations impacted departments)
- Final REB approval.

Regulatory Review

Research Services staff with significant clinical research experience and certifications in clinical research coordination, and/or privacy information management from national accrediting bodies, are assigned by the HRPP Director to review projects for regulatory compliance with federal regulations, provincial law, and organizational policies.

Research using an investigational product or device is subject to:

- **Health Canada's Food and Drug Act**
  - Regulations Part C Division 5
  - Medical Device Regulations Part 3
  - Natural Health Product Regulations Part 4

- If involving the United States, **FDA regulations** including, but not limited to, 21 CFR 50, 21 CFR 56, 21 CFR 312 and 21 CFR 812.

- **International Conference on Harmonization ("ICH") Good Clinical Practices ("GCP") Guidelines** (sometimes referred to as "ICH-GCP" or "E6 R2)

- Research involving the use of Personal Health Information is reviewed and conducted in accordance with the New Brunswick's **Personal Health Information Privacy and Access Act** (PHIPAA) (2009)

- **Federalwide Assurance (FWA) and IRB Registration**: The federal regulations require that federally-funded human subject research only be conducted at facilities covered by a Federalwide Assurance (FWA) approved by the DHHS Office for Human Research Protections (OHRP). An FWA is an organization's assurance to the federal government that human participant research conducted at that site complies with federal regulations pertaining to the protection of human participants.

Methodology Review

ORS staff with significant experience in research methodology and design at the doctoral level are assigned by the HRPP Director to review and evaluate research projects for scientific validity of the proposed research. This review considers whether:

- There is a testable and unambiguous research question (for quantitative methods)
- The research purpose is clear (for qualitative methods)
- The study is properly designed to produce data suitable for analysis
- The results/conclusions directly address the questions being asked

Research studies that meet regulatory and methodologic requirements are forwarded to Horizon's Research Ethics Board (REB) for review and approval. If there is disagreement between Investigators/researchers or Sponsors, and those reviewing the project for regulatory compliance or methodology, the Project will be forwarded to the Research Ethics Board with comments appended for the REB's review and consideration.

Research Ethics Board Review

The membership of Horizon's Research Ethics Board will ensure a competent and independent research ethics review

The REB upholds and adheres to the principles of *Tri Council Policy Statement*: *Ethical Conduct for Research Involving Humans* by the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada (2018):

- *Respect for Persons*, which involves obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations.

- *Concern for Welfare*, which involves ensuring that possible benefits are maximized, and possible risks are minimized to all human participants.
- *Justice*, which refers to the obligation to treat people fairly and equitably

The REB has the authority to:

- Approve, require modifications to secure approval, or disapprove human participants research.
- Require that informed consent be obtained and documented in accordance with regulatory requirements, unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the REB.
  - The REB may require that information, in addition to that specifically mentioned in the regulations, be given to the participants when, in the REBs judgment, the information would meaningfully add to the protection of the rights and welfare of participants.
- Conduct continuing review of research at intervals appropriate to the degree of risk of the research, but not less than once per year.
- Suspend or terminate approval of research not being conducted in accordance with the REB's requirements or that has been associated with unexpected serious harm to participants.
- Observe, or have a third party observe, the consent process
- Observe, or have a third party observe, the conduct of the research.

Board members will have the qualifications, expertise and training necessary to review the ethical issues raised by research proposals that fall within the jurisdiction of research conducted in Horizon. There is a strict selection process for members of the REB and nominations must be approved by the President and Chief Executive Officer, upon recommendation of the VP Medical, Academic and Research Affairs.

As per recommendations from the International Committee of Medical Journal Editors (ICMJE), all eligible studies are required to be registered on a publicly accessible website.

Multi-Centre Research Studies

Multi-centre research studies are subject to Horizon's Institutional Review process. The Horizon REB conducts its own independent research ethics review of multi centre research projects and the level of ethics review for research that involves multiple REBs and/or institutions is proportionate to the risk involved in the research.

Contact Horizon's HRPP

As of January 1, 2020, the HRPP Director is *Jacquelyn Legere, Office of Research Services*. If there are questions or concerns about the HRPP, or to schedule a meeting, the HRPP Director can be contacted directly by email: ROMEO@HorizonNB.ca.

RELATED DOCUMENTS

HRPP Organizational Chart

REFERENCE(S)

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2018.

Health Canada, *Guidance Document (GUI-0100): Part C, Division 5 of the Food and Drug Regulations: Drugs for Clinical Trials Involving Human Participants*, August 2019.

International Committee of Medical Journal Editors, *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*, December 2018.

International Conference on Harmonization, Guidance E6 R2: *Good Clinical Practice (GCP) Guideline*, November 2016.

United States Department of Health and Human Services: Code of Federal Regulations. *Title 45 Public Welfare Part 46, Protection of Human Participants*, current as of July 2018.

Unites States Food and Drug Administration: Code of Federal Regulations. *Title 21, Food and Drugs Part 56.107, Institutional Review Boards*, current as of November 2019.

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