Human Research Protection Program (HRPP)
Frequently Asked Questions

What is the Human Research Protection Program (HRPP)?
The Human Research Protection Program (HRPP) is a new institutional approval process for research, effective as of July 1, 2018. Horizon Health Network will review all final, completed applications for new research studies and amendments to ensure they meet requirements for methodology, regulatory compliance & privacy, and ethical research conduct.

What Does the HRPP Not Cover?
If you are in the early stages of developing your project, and require feedback on your protocol and study documents, you should contact the Office of Research Services (ORS) to schedule a consultation meeting with one of our staff.

How Do I Submit a Project for HRPP Review and Approval?
All projects are submitted by emailing the study package to ResearchServices@HorizonNB.ca.

What is Involved in an HRPP Review?
Research Services will first review the package for Methodology and Regulatory Compliance. (This review occurs simultaneously to facilitate an expeditious process.)

| HRPP Regulatory Review | • Reviews study for compliance with national, provincial and local regulations, policies, and guidelines, including but not limited to:  
| | o International Conference on Harmonization Good Clinical Practices (ICH GCP)  
| | o Health Canada’s Food and Drug Act  
| | o U.S. Food and Drug Administration  
| | o Personal Health Information Protection and Access Act (PHIPAA)  
| | o Other relevant legislation. When applicable, Research Study and Clinical Trial Agreements and budgets will be reviewed for adherence to industry best practices and compliance with allowances and/or restrictions established by HIROC and CMPA. |
| HRPP Methodology Review | • Review will focus on ensuring that:  
| | o For quantitative methods, there is a testable and unambiguous research question;  
| | o For qualitative methods, the research purpose is clear;  
| | o The study is properly designed to produce data suitable for analysis;  
| | o The results/conclusions directly address the questions being asked. |

Once complete, the HRPP coordinator forwards the study package and ORS Evaluation to the Research Ethics Board (REB) for either delegated or full board review. When the ethics review is complete, the REB then returns its comments to the HRPP Coordinator for the Institutional Approval letter to be drafted and sent to the applicant.
Who is the HRPP?
The HRPP is comprised of staff from the Office of Research Services, staff from the Office of Research Ethics, and the Horizon Health Network REB.

Regulatory Compliance
These requirements are reviewed by ORS staff with significant research and nursing backgrounds, and with certifications in clinical research coordination and/or privacy information management from national accrediting bodies.

Jacquelyn Legere, BN, CIPPc
As the Regulatory Compliance Manager – responsible for the regional regulatory compliance program for the conduct of clinical trials – Jacquelyn Legere is well positioned to be the director of our HRPP as well as the Lead Regulatory Reviewer in the program. Over the past 23 years in research, she has built her career in various roles throughout Horizon Health Network where she began as a staff nurse with the internal medicine program in 1989. Her adventure into the research world began with clinical trials in 1995 as a clinical trials nurse and evolved into a position in Research Ethics held until 2013. She held a VP position with CAREB (Canadian Association of Research Ethics Boards) for four years and was recently appointed to the Accreditation Council for Orion HRA (Orion Human Research Accreditation Inc.) which is an independent, not-for-profit accrediting body for human research; the first and only in Canada. Jacquelyn received her diploma in nursing in 1988 from the Saint John School of Nursing, her Bachelor of Nursing degree from UNBSJ in 2011, and her Certification as an Information Privacy Professional (CIPPc) in 2016.

Pat Shea, RN, CCRP
As a Clinical Trial Manager with Research Services, Pat is responsible for research training and assisting new coordinators, completing submissions to Horizon’s Research Ethics Board, and assisting clinical investigators with their research studies. Prior to assuming her current role, Pat was a study coordinator in geriatric research, during which time she completed her Certified Clinical Research Professional (CCRP) designation. Graduating from the Saint John School of Nursing, she has had a diverse clinical career, working in Labour and Delivery, Surgery, Surgical and Medical ICU, Neuro ICU, the Eye Clinic, Geriatric Medicine Clinic, Psychiatry, and Community Nursing. Pat is a native of Saint John; however, early in her career worked as a registered nurse in Maine and at the University of Alberta Hospital in Edmonton. With 18 years’ experience in clinical care and research, Pat is ideally suited to support our HRPP as an Alternate Regulatory Reviewer.
Methodological Review

These requirements are reviewed by ORS staff with significant research experience (i.e., PhDs, or PhD candidates finishing their dissertations, in health-related disciplines).

Donaldo Canales, MA, PhD(c)
Donaldo Canales is our HRPP’s Lead Methodology Reviewer, using his 9 years’ experience in quantitative research design/analysis to provide consultations to Horizon clinicians, academic faculty and students engaged in research (e.g. Dalhousie Medicine New Brunswick). Donaldo holds a Bachelor of Arts with Honours in Psychology (University of Saskatchewan ’08), a Master of Arts degree (UNB ’11), and is currently a Ph.D. candidate in Experimental/Applied Psychology at the University of New Brunswick; he received both Masters and Doctoral Social Sciences and Humanities Research Council (SSHRC) Graduate Scholarships to support his work. Throughout his graduate academic career, he has developed expertise in forensic psychology, and has conducted research related to offender risk assessment, recidivism prediction, mental health and offending, mental health courts, psychopathy, and police psychology. Donaldo has also served as a stipend instructor at UNB Saint John’s Psychology Department, and has taught courses related to behaviour modification, dementia, criminal behaviour, and statistics.

Thesis & Select Publications:


Supporting our Lead Methodology Reviewer are two more Research Services staff, who review HRPP applications as required:

Natasha Hanson, PhD
As part of Horizon’s SOAR (Support Opportunities & Assistance for Research) program, Natasha Hanson relies on 16 years’ research experience to manage SOAR projects as well as provide qualitative methods support and consultation regarding research documents, grant writing, and results publications. Natasha worked previously as a Research Grants Assistant at Dalhousie Medicine New Brunswick, as well as a private qualitative research consultant. She is originally from New Brunswick, having earned her Bachelor of Arts
degree in Anthropology (St. Thomas, ‘01). Natasha then obtained her Master’s (Carleton ‘06), her PhD in Social Anthropology (Dalhousie ‘13), and a Postdoctoral Fellowship at the University of Prince Edward Island. For our HRPP, Natasha serves as the Qualitative Methods Expert to review incoming applications using qualitative and mixed methodologies.

Dissertation & Select Publications:


Bryn Robinson, PhD
Bryn Robinson is our Research Engagement Manager, developing and supporting research collaborations, knowledge translation, and education with Horizon’s researchers, patients, families and community members. Previously, she was Clinical Research Manager as part of the Maritime SPOR SUPPORT Unit (MSSU) grant, supporting patient-oriented research and access to administrative data. Prior to joining Horizon Health, she was a senior policy analyst with WorkSafeNB for 6 years, conducting strategic planning research, as well as the vice-president of the Canadian Mental Health Association’s Saint John Branch. Bryn has a BA Honours in psychology and major in French (UNB ‘03), and a PhD in experimental and applied psychology (UNB ‘10) – the latter supported through a Social Sciences and Humanities Research Council (SSHRC) Canada Graduate Scholarship (‘04) and a SSHRC Doctoral Fellowship (‘06). With 14 years’ research experience supporting a breadth of disciplines, Bryn serves our HRPP as its Coordinator for all applications, and as an Alternate Methodology Reviewer as needed.

Dissertation & Select Publications:


Ethical Review
For a review of ethical research conduct, the REB membership is comprised of experts in ethics, medicine, law, and methodology, as well as having representation from the non-scientific community. For a complete list of its current membership, please visit their Skyline page.

What Does a “Complete” Study Package Contain?
At a minimum, your submission should contain the following documents.

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<tr>
<th>New Study Submissions</th>
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<tbody>
<tr>
<td>• A complete REB application for your clinical trial or non-clinical research;</td>
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<tr>
<td>• A study protocol appropriate to the methodology (contact us if you need support);</td>
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<tr>
<td>• Informed consent forms appropriate to the methodology selected (or if applicable,</td>
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<td>information in the REB application on seeking a waiver of consent)</td>
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<tr>
<td>Other documents may also be relevant to include, such as: Clinical Trial Agreements,</td>
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<td>Data Sharing Agreements, Privacy Impact Assessments, Certificates of Training, study</td>
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<td>budgets.</td>
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<th>Amendments</th>
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<tr>
<td>• Complete REB amendment form</td>
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<td>• All documents impacted by amendment (e.g., new consent form, changes to protocol)</td>
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If you ever have questions prior to submission, please contact ResearchServices@HorizonNB.ca.

I Want to Submit to REB Meeting in [Month]. When Should I Submit My Package for Review?
Timelines are dependent on several factors, such as: the completeness of the study package; whether there are any questions that need to be addressed prior to the REB review; and the number of other submissions currently under review. While our office aims to have your methodology and regulatory review completed within one week, we cannot guarantee a date because of such factors as those noted above. As such, it is the researcher’s responsibility to plan their submission accordingly, and to get in touch with our office if there are any questions or concerns.

What Happens if My Submission is Not Approved?
You will be provided with feedback from each stage of review, and will have the opportunity to address the concerns raised, as well as the option to go through the Research Services consultation process.
I Have an Industry Clinical Trial – Does It Need to Go Through HRPP?
Yes, but the methodology and regulatory review process may take less time, as industry clinical trials are subject to considerable review by both the sponsor and Health Canada (via the No Objection Letter or NOL).

Why did Horizon Health Network initiate an HRPP? / Doesn’t REB do a privacy and methodology review?
An HRPP represents best practices that are being adopted by other institutions in Canada, the United States, and internationally. There are many parts to protecting participants’ rights in research, each requiring its own expertise. Although members of the REB might have interest or knowledge in privacy, privacy remains an obligation of Horizon Health as a custodian of personal health information. The Personal Health Information Privacy and Access Act (PHIPAA) is complex, and often needs the involvement of our Chief Privacy Officer. The same is also true for research methodology.

With this new process, any privacy or methodology issue will be addressed before it goes to REB for its ethical review. Experts will continue to hold seats on our REB to look at privacy and methodology – to ensure that the methodology does not impact the ethical value of the project, or does not “hide” something from the patient that could make his or her consent void.

Will There Be an Electronic Submission Portal?
Yes. The HRPP team is currently working with the platform team at Process Pathways on developing Horizon Health Network’s ROMEO Submission Portal. It is expected that the portal will be officially live in winter 2019, and will significantly improve processing time for all involved. Once we can confirm the date that the software will “go live”, we will begin scheduling training for all staff, as well as revising this FAQ to reflect the new SOP.

What if I Have Questions Not Answered in This FAQ?
Please contact us with your questions, and/or to set up a time for an in-person or Skype meeting.