RITHIM

Research Improvement Through Harmonization In Manitoba

Background

Clinical research helps to inform policy development and best practices, and provides numerous opportunities for patients to access innovative treatments and procedures which would otherwise not be available to them. Canada ranked among the "top-tier countries as a location for industry-sponsored clinical trials", yet between 2002 and 2006 it yielded "a marked decline in its relative growth rate for industry-sponsored clinical trials"[i]. This trend has been continuing, with Health Canada and local Research Ethics Boards yielding progressively lower numbers, reflecting in an estimated 2.6% decline of clinical trials activity per year[ii]. Time-to-conduct has been identified by industry as one of the main issues central to this decline in investing in Canada and moving to emerging countries like Russia and Japan.

Data intensive research also helps to inform policy and practice and improves health services for and health outcomes of Manitobans. Data access is the main issue identified by industry in a survey done by the Life Sciences Association of Manitoba in 2016.[iii] Survey respondents indicated that the process was slow, time consuming and even painful and frustrating.

The provinces of British Columbia, Alberta, Ontario, and Quebec have responded to this issue by harmonizing their research administrative and regulative processes to coordinate research review and improve efficiency, resulting in improved time-to-conduct in their respective jurisdictions. The current state of clinical and data research administration in Manitoba has not kept pace with these other jurisdictions, resulting in a competitive disadvantage.

Currently, there are approximately 25 bodies responsible for providing ethical, institutional and data access approvals in Manitoba, each having their own submission, review and approval processes and each operating autonomously. This fragmented and uncoordinated approach significantly increases researcher burden and results in lengthy approval delays as researchers and industry are required to navigate through the complexities of each body's submission process. These delays in approval negatively impact time-to-conduct, progressively making Manitoba less attractive to industry for sponsorship investments, partnerships, and research collaborations, and further paints the research landscape in Manitoba as bureaucratic to innovative researchers looking to relocate their operations. Manitoba competes for the 13.7% of industry investments in clinical trial research in Canada[iv]. As significant cost recoveries are obtained from these industry investments, attracting industry-sponsored investment is critical to the ongoing operational funding of agencies that support clinical research in Manitoba.

To continue to promote Manitoba as an attractive province to invest in and undertake clinical research, and to remain economically and intellectually competitive as a province, improvements in the coordination and efficiency of the research administrative and regulative processes are required. Recognizing this need, Research Manitoba has undertaken a project to a) define the current state of research administrative and regulative processes in Manitoba; b) engage stakeholders to help identify

barriers and inefficiencies in these processes; and c) provide recommendations that will improve the efficiency and coordination of these processes while balancing privacy protection for Manitobans.

Project Goals

- To develop recommendations for administrative and regulative processes of clinical research in Manitoba that are comprehensive, integrated and collaborative, to improve efficiency (time-to-conduct) and increase capacity, allowing Manitoba researchers to engage in practice-changing, patient-oriented research.

- To establish recommendations for the best mechanisms and practices to build investment potential and administer partnerships with industry.

Project Objectives

- Map the existing state of research administration and regulative processes for human clinical and data intensive research in Manitoba, to identify strengths and opportunities for integration between each of the sites;

- Environmentally scan for best practices in research administrative and regulative processes and inter-agency coordination/harmonization in Canada and internationally;

- Engage human clinical research stakeholders to assist in identifying barriers (navigation / time-to-conduct/cost/burden) and establishing recommendations for improvement in the efficiency and coordination of research access, administration, review and approval processes in Manitoba;

- Establish recommendations that conform to and balance privacy protection for human participants in Manitoba; and,

- Engage industry to foster a rapport and identify competitive disadvantages to research investment and partnerships within Manitoba and establish industry lead recommendations on the best mechanisms to improve industry investment and partnership potential.

Issues identified

There is a lack of a systematic approach to support the approval and undertaking of clinical and data intensive research in Manitoba. While there are pockets of efficiency and effectiveness within the system, the processes become cumbersome when research is done across several different organizations, requiring numerous institutions to provide approvals.

Over the course of the last year, the Working Group and Steering Committee have met to understand the issues and discuss options for improvement. The following provides a summary of the key issues identified.

1) **Uncoordinated Authority and Governance**

a. Unclear governance around research taking place across multiple institutions and by researchers with multiple affiliations within the health system and academia.

b. Approval authority is poorly defined and communicated. Researchers struggle with identifying the right approval authority for accessing, using, disclosing and sharing data.

c. Overlaps in authority or perceived responsibility which has led to duplication of review (e.g. privacy and ethics).

2) **Varying Processes for Submission, Review and Approval Across the System**

a. Varying submission process institution to institution – each organization has its own unique submission form, submission criteria and submission process.

b. Varied Impact Committee Review within the WRHA affiliated institutions: Some Impact Committees have dedicated monthly committee meetings while others receive materials for review and comment without the requirement of attending a meeting. Some institutions perform delegated review for low impact, low risk studies while others send all studies to the committee or review committee meeting. These scheduled monthly meetings cause batching of submissions resulting in unnecessary delay.

c. Signatory requirements vary institution to institution; significant delays (several weeks) in obtaining signatures have been reported. Some sites require only one signature, while others require multiple signatures to execute the approval.

3) **Lack of Sufficient Human Resources**

a. Lack of staffing resources (based on current sate) to adequately monitor submission workflows; - Large volumes, complex submissions - compounded by the lack of available technology – current staffing resources having difficulty managing all of the work in an efficient manner

Steering Committee Recommendations

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1) **Improving the Process**

a. Creation of the Manitoba Research Ethics and Review Committees (MRERC) which would be responsible, and have the authority, for final approval of research to be undertaken in Winnipeg. This encompasses the ethics, impact and privacy reviews of clinical and data intensive research done at any relevant institution in Winnipeg.

The MRERC would encompass two review committees:

- **BioMedical Research Review Committee** which reviews interventional studies under Health Canada/FDA authorization such as drug, device or natural health product where committee membership must comply with regulations.
- **Health Research Review Committee** which reviews all other types of research studies which require ethics approvals.

In this model, impact and feasibility of the project is assessed prior to the committee meeting (within 10 business days) and the results are submitted to the committee for their review. To expedite the process, the electronic application would be sent to an organization designate to ensure the assessment is complete and submitted in time to be considered by the review committee during their meeting.

b. Establish an Organizational Designate as a specific individual who represents a specific approving organization (e.g. a specific person at SOGH) who acts to:

- Be the central/single point of contact for the MRERC Coordinator;
- facilitate the timely review, approval, and contract process at the approver's institution (e.g. HSC);
- bestow final approval judgment on behalf of the institution he/she represents;
- be the principal signatory authorizing the research (i.e. for conduct or for access to data).

c. Establish a standardized online submission and review process which supports online intake of research submissions, efficient document management and project workflow, time stamps, monitoring response timelines and reporting; facilitates inter-agency collaboration and use and has in-platform communication. Such a system should allow for continued quality improvement and sustainability.

d. Establish a single application form within the electronic system.

2) Enhance the System Wide Culture to Undertake Research

a. Training - Establish Investigator and Research Personnel training - Mandatory orientation to all first-time submitters to the REB/Institutional Impact focused on process and submission quality. A dedicated individual or agency to monitor and deliver the training is recommended.

b. Establish Sustainable Working Groups - To create bodies of knowledge and act as a forum for discussion around interpretation and application of legislation and the development of provincial working rules and SOPs. Groups would create bodies of knowledge around:
   - ***PHIA:*** Create a working group comprised of Privacy Officers, Research Administrators, Researchers and Patients/Citizens to have an ongoing dialogue around the interpretation and application of PHIA as it applies to research. The working group will also support the education and dissemination of knowledge around PHIA.

- ***LEGAL:*** to develop standardized and agreed upon language and templates for research agreements and data sharing agreements (particularly between WRHA and UofM) – to liaise/participate with national initiatives to develop standardize agreement language and model clinical trial agreements.

c. Connect with national initiatives, such as the Canadian Clinical Trials Coordinating Centre and the Canadian Clinical Trials Asset Map, to ensure that Manitoba's activities are best practices in Canada and that we take advantage of collective efforts to improve the environment for clinical trials in Canada.

3) Investments in Infrastructure

a. The First Nations Health and Social Secretariat of Manitoba Health Information Governance Committee (HIRGC) reviews the ethics and benefits of any research proposals by academics regarding First Nations health. They also offer advice to university researchers on how to engage First Nations partners. Additional support to this group would increase their capacity to review proposals in a timely fashion and support their ability to respond to increased demand for advice.

b. Following process improvement, should staffing resources continue to be an issue, staffing resources should be conservatively increased.

c. Consider technological investments which could enhance the use of data from a variety of data sets, while improving security and privacy concerns.

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[i] Leclerc et al., Metrics Survey of Industry Sponsored Clinical Trials In Canada, Health Care Policy Vol.8, No2, 2012

[ii] Leclerc et al., Metrics Survey of Industry Sponsored Clinical Trials In Canada, Health Care Policy Vol.8, No2, 2012

[iii] Life Sciences Association of Manitoba, Forum Report, Real World Evidence, 2016.

[iv] Leclerc et al., Metrics Survey of Industry Sponsored Clinical Trials In Canada, Health Care Policy Vol.8, No2, 2012