GEORGE & FAY YEE
Centre for Healthcare Innovation

Investigator Initiated Clinical Trial Roadmap

There are 10 steps required to move your research from an idea to approval to conduct your research at a public institution or site in Manitoba.

After your research is approved, you will need to ensure your records continue to meet all regulatory requirements. Information about continuing review and post-approval activities can be found here.

Please review all steps on the website before proceeding as the order of the steps can be changed to accommodate your needs, many steps can be completed concurrently, and updates may occur.

#	STEP	INFORMATION
1	Protocol	Protocol templates for various organizations and trial types are available on the George and Fay Yee Centre for Healthcare Innovation (CHI) website. CHI staff can help with planning your research project. If you would like to arrange a meeting, please email info@chimb.ca
2	Planning & Budget	• Develop the operational plan to include location and space for the study, staffing needs and Data and Safety Monitoring Board (DSMB)(see # 9) • Budget for staffing, space, pharmacy assistance, laboratory testing, diagnostic imaging, blood collection, IV starts, chart reviews, data management, supplies, study monitoring, and archiving (as per funding organization requirements) • Unless the above services are part of standard of care, they must be paid for from study funds • Many of these services are specific to the site where the research will be conducted and the site determines the costs of these services. **Contact the following for cost estimates:** Staffing - CHI at 204-787-8707 or email info@chimb.ca Pharmacy – consult with site Blood collection/lab tests – Diagnostic Services of Manitoba at 235-3935; except for HSC contact 204-787-4968

		IV starts – consult with your site Diagnostic imaging – consult with site Health Information Services - consult with site for access to medical records Monitoring services - under development Archiving – consult with site Supplies – check with your department **Contact information for budget planning and site specific requirements:** Cancer Care Manitoba – Clinical Trials and Research Unit – ph 204-787-2127. Concordia Hospital – Research Ethics Committee – ph 204-661-7160 Deer Lodge Centre – Research Review Committee – ph 204-831-3422 Grace General Hospital - Executive Assistant to CMO – ph (204) 837-0588 Health Sciences Centre – Adult or Pediatric– HSC Research Impact Committee – ph 204-787-4968 Manitoba Adolescent Treatment Centre – Quality Evaluation & Research Committee – ph 204-958-9600 Manitoba Institute of Child Health – ph (204) 480-1348 or email Pan Am Clinic – Albrechtsen Research Chair – ph 204-927-2665 Rehabilitation Centre for Children – Research Development – ph 204-453-9844 Riverview Health Centre – Riverview Research Committee – ph 204-478-6215 St. Boniface General Hospital – Office of Clinical Research – ph 204-258-1044 Victoria General Hospital – Research & Evaluation – ph 204-477-3372 Other - contact the Centre for Healthcare Innovation – ph 204-787-8707 or email info@chimb.ca A budget template and detailed list of budget requirements can be obtained by emailing info@chimb.ca
3	Peer Review	You are strongly encouraged to have your completed protocol and budget undergo peer consultation and

		review.
4	Funding Application (if applicable)	For all research funds that will be managed by the University of Manitoba, the funding application and contract proposal must be reviewed by the Office of Research Services (ORS) prior to submission to the funding agency. The office can be reached by calling the Contracts Coordinator at (204) 474-6681. For research funds that will be managed at your site, refer to site specific contact information (Step # 2 Budget).
5	Ethics Application Site Impact Health Canada **Complete Concurrently**	**Ethics Application** Any research to be conducted at a Winnipeg Regional Health Authority institute, site or hospital requires approval from one of the University of Manitoba Research Ethics Boards. For specific instructions, click here. NOTE: As a condition of final ethical approval/clearance the PI must complete the 2nd edition of *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* TCPS2 course and Personal Health Information (PHIA) training. Consultation with the appropriate community in the design and conduct of the study will also be required where the interpretation or analysis of research results refer to Aboriginal (Inuit, Metis and members of First Nations) peoples. For questions regarding the Ethics application contact Bannatyne Campus at 204 789-3255 or Fort Garry Campus at 204 474-7122. Please contact the CHI Intake Coordinator at info@chimb.ca for research that will be conducted outside of Winnipeg. Note: All approved studies are subject to auditing by the University of Manitoba Research Quality Management (RQM) office. Contact RQM at ResearchQualityManagement@umanitoba.ca **Site Impact** Each site has specific requirements that must be met before research can be conducted. Site specific impact forms can be obtained by contacting the site as per the site specific contact information listed in Step # 2 Budget. **Health Canada** Information on trials that require Health Canada approval and data safety monitoring information can be found here.

6	Finances and Contract	A research account must be set-up to manage trial expenses and income (if applicable). This application should be started as soon as possible. If the trial is being funded by a sponsor or granting agency, the contract must be reviewed and signed off by the university or site as appropriate. Contact the U of M Contracts Coordinator at (204) 474-6681 or the site as per the specific contact information listed in Step # 2 Budget. For clinical trials that will be managed by the University of Manitoba, the investigator must contact the Office of Research Services (ORS) to ensure all needed paperwork is in place for the establishment of a research fund. The office can be reached by calling the Contracts Coordinator at (204) 474-6681. Once the contract has been signed, the institution (University or site) will inform the researcher how the account will be established.
7	Clinical Trial Registration	All trials that assign participants to a health-related intervention must be registered with a clinical trial registry. Information about clinical trial registries can be found here. NOTE: Registration must be completed before the first participant is enrolled.
8	Document Management	Case report forms (CRFs), a procedure manual and a regulatory binder are needed for all research studies. A case report form (CRF) is a paper or electronic document used to collect information about each study participant. The information to be collected is informed by the protocol to answer the research question. The data collected is usually de-identified to protect the participant's anonymity. A procedure manual provides instructions to research staff on the conduct of the clinical trial. The instructions clarify and itemize the information in the protocol. A regulatory binder contains the essential documents for conduct of a clinical trial. This binder will be reviewed by monitors, auditors, the Research Ethics Board, and other regulatory authorities (e.g. Health Canada). CRF templates and regulatory document requirements and templates can be found on the CHI website. NOTE: Standard Operating Procedures (SOPs) and training in good clinical practice (GCP) regulations and guidelines can be obtained from CHI. Email info@chimb.ca for information. NOTE: REDCap (Research Electronic Data Capture) is a secure web-based application for research data collection.

		Contact info@chimb.ca for more information.
9	Clinical Trial Operations	The following should be considered in planning your research: • Establish standard operating procedures (SOPs) for the trial • Establish a Data and Safety Monitoring Board (DSMB). A DSMB is an independent group of experts who oversee and evaluate the data and safety of the trial. As the researcher is responsible to develop an acceptable plan for monitoring the trial to ensure the safety of participants, it may be necessary to establish a DSMB. • Determine space for storing documents during the trial and when the trial is completed • Determine data management requirements • Hire and train staff on GCP and the protocol • Develop paper or electronic CRFs • Understand reporting requirements for the Research Ethics Board, the site(s) where the research will be conducted, the sponsor and Health Canada. The University of Manitoba Research Quality Management :RQM) office is available for consultation anytime Contact RQM at ResearchQualityManagement@umanitoba.ca
10	Approvals	Screening, recruitment, participant consent, visits, interventions and data collection may only begin : • after the contract is signed; • after the University of Manitoba Research Ethics Board approval is received; • after the site(s) where the trial will be conducted approves the study; • after receiving Health Canada approval (as applicable); • and after receipt of the clinical trial registration number