Continuing Review and Post-approval Activities – Version 1

Below are activities you will need to consider after your study/trial receives all required approvals.

Continuing Review Requirements	All research is subject to continuing research ethics review from the date of initial approval throughout the life of the study/trial. The Research Ethics Board (REB) will make the final determination as to the nature and frequency of continuing research ethics review.	
	Annual Review	***REB Approval is limited to one year*** for all research studies/trials. Requests for annual re-approval must be made by completing either the: • Bannatyne Campus Research Ethics Boards Annual Study Status Report and submitting it to the REB 4 weeks prior to the expiry date on the last approval certificate. The renewal form can be accessed at http://umanitoba.ca/faculties/medicine/ethics/2689.html • Fort Garry Campus Research Ethics Board Renewal/ Amendment Form. The renewal form can be accessed at http://umanitoba.ca/research/orec/ethics/human_ethics_REB_forms_guidelines.html **NB**: Annual renewal is a regulatory requirement (e.g. Tri Council Policy, Health Canada) and is the Principal Investigator's responsibility. Serious consequences, such as funding withdrawal, data compromise and enrollment hold may occur if annual renewal is not obtained.
	Amendments	All planned changes to a study protocol must receive approval prior to implementation and must be submitted to the REB on an amendment request form and to Health Canada as applicable. If a change was implemented to ensure safety of participants, the amendment must be submitted to the REB and to Health Canada as soon as possible. Notify all affected sites of the amendment (e.g. any departments participating in the study, study site(s), DSM, Pharmacy, etc.) and provide a copy of the REB amendment approval.
	Funding source	A change in the study funding source or amount is considered an amendment and will require approval from the REB (e.g., funding is secured from or withdrawn by a sponsor after study commencement). Research administration must also be notified about any budget amendments. U of M managed funds, contact ORS at 204 474-6681
	Adverse Event and Safety Data Reporting	Researchers shall adhere to an acceptable plan for monitoring the safety of participants, which should include a plan for: • tabulation, analysis and reporting of safety data as per REB and Health Canada (as applicable) regulations • sharing of other new information in a form that permits REBs to interpret and respond appropriately • removing participants for safety reasons • stopping or amending the clinical trial if it is found to be unsafe, or for reasons of futility (e.g. it is determined that the trial is unlikely to produce valid results) or efficacy (e.g. one or more interventions are found to be successful) • a Data & Safety Monitoring Board (DSMB) or Data & Safety Committee (DSC)as per REB or HC regulations Contact the U of M REB if you have any questions: Bannatyne Campus at 204 789-3255 or Fort Garry Campus at 204 474-7122.
	Protocol Deviation Reporting	Protocol deviation - is any action or inaction that does not correspond to the approved protocol. A protocol deviation may include accidental/unintentional or intentional changes, including changes made to eliminate an immediate hazard to participants or others. Protocol deviations may be major or minor. Major protocol deviation - adversely affects the rights and welfare of participants, the safety of participants, the integrity of the study data and/or the participant's willingness to continue study participation. Minor protocol deviation - does not impact participants' rights and welfare, participant safety, the integrity of the study data and/or the participant's willingness to continue study participation. Review the regulatory requirements and REB guidelines for protocol deviation reporting , which can be searched at http://umanitoba.ca/research/orec/ethics/human_ethics_index.html

	Study Closure/Termination and/ or Study Suspension	Upon closure of the study, study termination, or when the study has been prematurely suspended, researchers are required to: 1) Submit a Final Study Status Report to the REB – forms for the Fort Garry and Bannatyne Ethics Boards are available at http://www.umanitoba.ca/research/orec/ethics/human_ethics_index.html 2) Notify Health Canada, as applicable 3) Notify research institution where study was conducted and ensure each site notifies their REB 4) Update the clinical trial registry, and 5) Notify any department that has been involved in the study. Plans must be in place for archiving all study related documents.
Clinical Trial Registry Updates (e.g. Clinical Trials.gov)	An affirmative verification or update of the data in protocol record(s) that have not been closed or terminated must be completed every 6 months. Failing to login to the Protocol Registration System (PRS) and confirm or update your record(s), regardless of whether there has been a change to the trial or not, may result in a loss of funding and/or the inability to publish the results of a trial in an International Committee of Medical Journal Editors (ICMJE) associated journal. Information about clinical trial registries can be found at http://www.umanitoba.ca/medicine/ethics/media/Clinical_Trial_Registration_July_2012.doc. Also keep the "Protocol Record" up to date with all amendments.	
Monitoring	Monitoring of study activities is the act of overseeing the progress of a clinical trial, and ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirement(s) (ICH Guidelines for Good Clinical Practice 5.18 Monitoring) The researcher must ensure that appropriate monitoring is in place. This includes monitoring safety of participants and monitoring of study activities. The researcher is responsible to ensure risks to participants remain in the acceptable range, and the safety of participants is monitored (TCPS2: Monitoring Safety and Reporting New Information, Article 11.7). For more information on your responsibilities please contact the University of Manitoba (RQM) office at ResearchQualityManagement@umanitoba.ca	
Audits	An audit is a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's SOPs, GCP and the applicable regulatory requirements (ICH Guidelines for GCP 5.19 Audit) All studies/trials may be subject to audits by the University of Manitoba (UM) Research Quality Management (RQM) office and/or site-specific research institutions and granting agencies. Such audits may be random or for cause or as requested by the institution, researcher or REB. For more information on your responsibilities please contact the UM Research Quality Management (RQM) office at ResearchQualityManagement@umanitoba.ca	
Heath Canada Requirements	Clinical trials conducted under a Clinical Trial Application (CTA) or Investigational Testing Authorization(ITA) are required to submit all amendments to Health Canada (HC) for review and approval prior to implementation. The CTA or ITA must adhere to the Post Authorization Requirements as outlined on the Health Canada website at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cta_post_approval-eng.php#adr	
Health Canada Inspections	An inspection is conducted by The Health Products and Food Branch Inspectorate or by the FDA with the main objective to reduce risks to participants enrolled in clinical trials, to verify the accuracy and reliability of clinical trial data and to assess compliance with regulations governing the conduct of clinical trials. CTAs and ITAs studies/trials may be subject to random or for cause regulatory inspections by Health Canada or the USA Food and Drug Administration inspections. As soon as you receive notification of an inspection, notify the trial sponsor, the REB, the Institution (Research Office*),* study site(s) and any department participating in the study such as DSM, Pharmacy, etc. and Health Records. RQM is also available for consultation should a site require this before the inspection. Review the Health Canada Pre-Inspection Package that includes Fact sheets, FAQs, a checklist for your organization to prepare for inspection, and a checklist of the required documents that are reviewed at an inspection. There is a summary report that outlines findings that are common in an inspection. Visit Health Canada's Good Clinical Practice and Inspection Strategy for Clinical Trials	