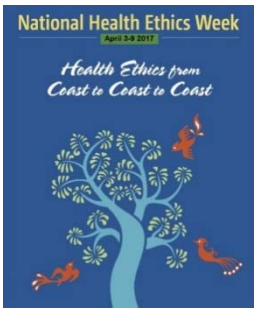

National Health Ethics Week 2017: April 3-9th

Research Ethics Bulletin #2: HREB Reporting Requirements

Once a study has received ethics approval from the Health Research Ethics Board (HREB), there are still requirements to report any changes to the approved research to the HREB.[1] In the conduct of approved research, researchers should be aware of this requirement to report to the HREB, in a timely manner, proposed changes from approved research that affect participants at any stage of the process including, but not limited to, changes to the consent form, changes to the tasks or interventions involved in the research, or changes to measures to protect privacy and confidentiality.

Any substantive change to the research should not be implemented prior to documented approval by the HREB, except when necessary to eliminate an immediate risk(s) to the participants. Below are examples of post approval documentation that must be submitted to the HREB:

Amendments

Any proposed change in the conduct of a study must be submitted to the HREB, and approved, before the change may be implemented. Such changes might include modification of recruitment procedures or inclusion or exclusion criteria, revised sample size, addition or deletion of study sites, changes to an intervention, consent forms, and questionnaires or scripts, etc. Amendments to the approved study which request major changes or contain new information that could increase the risk to participants are referred to the HREB subcommittee (HREB-CT or HREB-NCT) that approved the original study, for review and vote. If there are changes in project team members or changes to funding source(s) and/or the sponsor of a project, there are specific forms to complete to report this to the HREB (personnel change notification form and sponsor and/or partner change notification form, respectively).

Adverse Events

Serious and unanticipated adverse events that occur within Newfoundland and Labrador (i.e. locally) are required to be reported to the HREB. Such an event may occur in both clinical trials and in other types of research, e.g. collapse during a rehabilitation program, emotional breakdown requiring follow up care during an interview, breach of privacy during correspondence in a genetics study. Serious adverse events that are fatal or life-threatening are required to be reported to the HREB as soon as becoming aware of the event.

Protocol Deviations

Any deviation of an approved study protocol must be reported to the HREB. Deviations from or protocol changes to eliminate immediate hazards to study participants do not require prior approval but must be reported to the HREB as soon as reasonably possible.

Safety Reports

Safety reports providing information on all serious adverse events (SAEs) occurring in a clinical trial must be provided by the sponsor to the HREB normally on a three or six monthly basis (i.e. in accordance with the specified reporting timelines that were outlined in the approved ethics application).

Investigator Brochure (IB) and Product Monograph (PM)

Throughout the course of a clinical trial, changes may be implemented to study documents (such as the IB or PM) by the study sponsor. All revisions to approved study documents must be submitted to the HREB to ensure the record is up to date. If the revisions include new risk or safety information there may be a requirement to notify research participants via a consent addendum to ensure ongoing consent has been obtained.

Ethics Renewal/Study Closure

Ethics approval lasts for one year. Ethics renewal is required annually, on the anniversary of the date of the HREB notification of approval. Once data collection is no longer ongoing, or once the study is complete, a study closure form is required to be submitted to the HREB for the study to be closed in good standing.

NEWFOUNDLAND AND LABRADOR HREA HEALTH RESEARCH ETHICS AUTHORITY

[1] ***Articles 2.8 and 6.16 of TCPS2 2014, Section 9 of the HREB Policy Manual, Section 4.5.4 of the ICH GCP and sections 10 and 12 of the Health Research Ethics Authority (HREA) Act.***