APPENDIX C
Policy 11-152

Clinical Trials[1]	**All Other Clinical Research**[2]
ICH-GCP training[3]	Course on Research Ethics (CORE): (http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/) or ICH-GCP training[3]

[1] By definition of the World Health Organization, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.

[2] All research which requires approval from the *Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board*.

[3] Acceptable examples of ICH-GCP training include online ICH-GCP training programs (i.e. CITI Canada GCP program: www.CITICANADA.org) or one-half or full-day ICH-GCP workshops which issues certificates of completion. Formal GCP training is provided to clinical research persons employed, appointed and/or affiliated with the Kingston General Hospital through the Network of Networks (N2) CITI-Canada GCP online education program. GCP refresher training is required once every five (5) years or earlier at the discretion of the clinical research team's principal investigator, institution and/or funding sponsor. Complete retraining may be required at the request of the principal investigator and/or institution after changes in GCP Guidelines have occurred, after long periods of absence from the clinical research practice (>1yr) and/or when significant non-compliance issues have been identified on monitoring, auditing and/or inspection visits to research sites. Sponsor-specific GCP training will not be required to be completed by the principal investigator/research team at this institution unless the sponsor has evaluated the N2 CITI-Canada GCP education program and has deemed the program unacceptable with written justification provided to the principal investigator and institution that will be kept on file at site.