APPENDIX C
Policy 11-152

Clinical Trials[1]	**All Other Clinical Research**[2]
ICH-GCP training[3]	TCPS 2 Tutorial 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 either: (1) Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB); (2) Clinical Trials Ontario (CTO); or (3) Ontario Cancer Research Ethics Board (OCREB).

[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 free online GCP training is provided to clinical research persons employed, appointed and/or affiliated with the Kingston Health Sciences Centre 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. The N2 CITI-Canada GCP education program has been deemed acceptable by the TransCelerate (http://www.transceleratebiopharmainc.com/gcp-training-attestation/).