KINGSTON HEALTH SCIENCES CENTRE

ADMINISTRATIVE POLICY MANUAL

Subject: Standard Operating Procedures for Clinical Research	**Number:**	**11-152**
Prepared by/Reviewed by: Vice President, Health Sciences Research	Page:	1 of 2
	Original Issue:	2017.04
Issued by: President and Chief Executive Officer	Revised:	NEW

Preamble

The Kingston Health Sciences Centre (KHSC), together with its sole agents for research, the Kingston General Health Research Institute ("KGHRI") and the Hotel Dieu Hospital Kingston Research Institute ("HDHKRI"), endorses and supports research that advances knowledge and brings evidence into practice for the benefit and empowerment of our patients, their families and our medical community. KHSC consists of two hospital sites: Kingston General Hospital site and Hotel Dieu Hospital site. The Hotel Dieu Hospital site conducts all research consistent with the history, traditions, mission and Catholic faith and in accordance with the Catholic Health Ethics Guide published by the Catholic Health Alliance of Canada.

Regulatory authorities require that clinical research sites utilize standard operating procedures (SOPs) (see Appendix A) to ensure that clinical research is conducted in a manner that protects the rights and safety of human participants partaking in research and simultaneously guards the integrity of the research human participant data being collected. Because the Hospital Board is ultimately responsible for all aspects of the operation of the Hospital, it is essential that the Hospital administration be assured that all clinical research conducted in the Hospital is adhering to systems and SOPs. The Network of Networks (N2) has developed a national standardized set of SOPs that are applicable to any therapeutic area of research and are compliant with Health Canada, the United States Food and Drug (FDA) regulations, the International Conference on Harmonization-Good Clinical Practice Guidelines (ICH-GCP), and the Canadian Tri-Council Policy Statement on Research Involving Human Subjects (TCPS-2). KHSC has adopted these SOPs as our institutional SOPs for conducting clinical research.

Policy Statement

The procedures set out below are to ensure that all clinical research, whether it is funded or not, is conducted within the Hospital in accordance with federal regulations, good clinical practice guidelines (GCP), and Hospital policies to protect the rights and welfare of human participants by ensuring that systems and procedures that assess the quality of every aspect of clinical research are implemented.

KHSC works collaboratively with its partners, Queen's University at Kingston (Queen's) and Providence Care Centre (PC). To the extent possible, attempts have been made to harmonize policies and procedures for issues of common interest, such as research, with our partners. The elements of this policy are similar to those found in the PC Policy #ADM-RES-2.

Procedures

1. All researchers, research staff, medical and graduate students, post-doctoral fellows, volunteers, and trainees conducting research within the Hospital will adopt and adhere to the SOPs outlined by the N2 organization (see Appendix B).

2. The SOPs are designed to reflect '"how" a procedure is done, not "why" it is done. It is the ultimate responsibility of the researcher to provide training to their research staff, medical and graduate students, post-doctoral fellows, volunteers, and trainees in order to ensure that all study team members understand the "why" concepts in order to be deemed suitably trained to perform these SOPs.

3. All researchers, research staff, medical and graduate students, post-doctoral fellows, volunteers, and trainees conducting research on human participants must be trained in GCP. To determine the appropriate GCP training and frequency of training, please see Appendix C. GCP online training is available through the KHSC's Office of Health Sciences Research.

4. The Hospital will routinely consult with the N2 organization to ensure the SOPs are up-to-date. The N2 will ensure that the SOPs are externally reviewed by an independent expert every two years or sooner, if dictated by changes in regulations or guidance documents mentioned in the preamble or referenced in Appendix D.

5. All researchers will keep a copy of these SOPs in their research area that can be easily accessible to any sponsor, research ethics board, or regulatory authority, if requested.

Adherence to the foregoing procedures will ensure efficient administration of research within the Hospital.

Authorizing Signature

_____

Dr. David Pichora
President and Chief Executive Officer

Related Documents:
03-021 Research Restricted Accounts
01-121 Intellectual Property-Employee
01-122 Intellectual Property-Queen's Faculty and Staff Members with Hospital Appointments
11-012 Research Hospital Appointment
11-150 Health Research
11-151 Research and Clinical Trial Agreement Overhead