KINGSTON GENERAL HOSPITAL

ADMINISTRATIVE POLICY MANUAL

Subject: Standard Operating Procedures for Clinical Research

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Preamble

Regulatory authorities require that clinical research sites utilize standard operating procedures (SOP's) (see Appendix A) to ensure that clinical research is conducted in a manner that protects the rights and safety of human subjects participating in research and simultaneously guards the integrity of the research data being collected. Because the Kingston General Hospital (KGH) Board is ultimately responsible for all aspects of the operation of the Hospital, it is essential that the Board be assured that all clinical research conducted in the Hospital is adhering to systems and SOP's. The Network of Networks (N2) has developed a national standardized set of SOP's 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). KGH 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 subjects by ensuring that systems and procedures that assess the quality of every aspect of clinical research are implemented.

KGH is working collaboratively with its partners, including Hotel Dieu Hospital (HDH) and Providence Care (PC), and to the extent possible attempts to harmonize policies and procedures for issues of common interest, such as research, have occurred. The elements of this policy are similar to those found in the policies of HDH (Policy #7190) and 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 SOP's outlined by the N2 organization (see Appendix B).

2. The SOP's 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 SOP's.

3. All researchers, research staff, medical and graduate students, post-doctoral fellows, volunteers, and trainees conducting research on human subjects 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 KGH Office of Health Sciences Research.

4. The Hospital will routinely consult with the N2 organization to ensure the SOP's are up-to-date. The N2 will ensure that the SOP's 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 SOP's in their research area that can be easily accessible to any sponsor, research ethics board, or regulatory authority, if requested.

Related Documents:
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

Authorizing Signature

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