KINGSTON GENERAL HOSPITAL

ADMINISTRATIVE POLICY MANUAL

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Prepared/Reviewed by: Vice President, Health Sciences Research
President, KGH Research Institute

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Preamble

The Kingston General Hospital (KGH) 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. Because the Hospital Board is ultimately responsible for all aspects of the operation of the Hospital, it is essential that the administration have adequate information and proper documentation of research projects that may involve patients, patients' families, Hospital facilities and/or Hospital staff. It is also essential that the Hospital administration be assured that all projects have been reviewed and approved from an ethical, organizational, and financial point of view.

Policy Statement

The procedures set out below apply to all research projects within the Hospital, whether the projects are funded or not.

KGH works 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. Thus elements of this policy are similar to those found in the policies of HDH (Policy #430) and PC (Policy #ADM-RES-1).

Procedure

1. The use and disclosure of patient health and medical information is subject to compliance with applicable privacy laws and regulations, including the Personal Information Protection and Electronic Documents Act (PIPEDA) and the Personal Health Information Protection Act (PHIPA). All research based on patient data will be subject to the PHIPA provisions in accordance with Hospital policy. See KGH Administrative Policy #09-055 Personal Health Information Protection.

2. If the research involves the use of patient data, a “KGH/HDH Data Request” form (see Appendix A) and a confidentiality statement (see Appendix B) must be completed as required by KGH’s Department of Patient Records and Health Information Services.

3. Patients’ right to refuse inclusion in research must be respected in accordance with PHIPA and the public written statement on Personal Health Information practice (see Appendix C “Our Privacy Commitment to Patients”).

4. The researcher is responsible for developing a satisfactory research proposal, which meets the guidelines of the funding agency for financial support (if applicable) and the ethical standards for clinical research adopted by the Hospital. All projects requiring the

use of human subjects or their personal health information will be reviewed and approved by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) (http://www.queensu.ca/ors/researchethics/REB.html). Projects requiring animals will be reviewed by the Queen's University Animal Care Committee (http://www.queensu.ca/uvet/index.html). The researcher must ensure that appropriate approvals of the Queen's University Radiation Safety Committee (http://www.safety.queensu.ca/gi_rad.htm), Queen's University Biohazards Committee (http://www.safety.queensu.ca/biocom/approval.htm) are obtained, as needed. All the indicated Boards and Committees have their own online application/submission forms with instructions for completion and submission. The researcher is responsible for ensuring that they have received all appropriate approvals prior to initiation of the research project.

5. All research staff, medical, undergraduate, and graduate students, post-doctoral fellows, residents, and trainees require a supervisor for their research project when applying to HSREB. If the supervisor does not hold Hospital privileges or a Research Hospital Appointment, the supervisor must obtain an appointment through KGH's Medical Affairs Office prior to submission. See KGH Administrative Policy #11-012.

6. All students with research projects involving the use of human subjects or their personal health information must have completed the "Course on Research Ethics" (CORE) (http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/). Copies of the completed course (passed certificate) must be attached to the HSREB application for their student research project.

7. A research hospital appointment is required for any individual from another institution who will be carrying out research at KGH. This includes researchers from another hospital, Queen's University, St. Lawrence College or any other academic institution who is not otherwise hired, appointed or authorized by the Hospital to carry out research on site. A research hospital appointment is also required for any individual working at KGH who becomes involved in research activities that are not part of their usual employment or appointment activities in the Hospital. Students enrolled at Queen's University, St. Lawrence College or any other school, university or college do not need this appointment for research activities required by their regular academic programs, providing that there is a written agreement between the institutions. If the research being conducted is not part of their regular academic program, a research hospital appointment is required. See KGH Administrative Policy #11-012.

8. Information regarding the impact of a research project on the operations of the Hospital will be collected on the Queen's University Research Services' Tools for Research at Queen's (TRAQ) via their application portal. Impact is defined as any procedure or research protocol which uses Hospital resources above those normally required for standard clinical practice and care. This may include extra tests or procedures, preparation/dispensing/storage of medications used in studies, additional staff time, educational preparation, and/or other ancillary costs covered by the Hospital. The Hospital cannot absorb research costs associated with research projects above and beyond the standard of care. These extra costs must be clearly indicated within the TRAQ application and researchers must have funding to support these activities. Researchers are advised to seek early consultation with the appropriate Hospital operational director(s)/manager(s) from the appropriate department(s)/program(s) to ensure that a feasible proposal budget is prepared. Consultation should occur within 2-4 weeks of funding deadlines to ensure all Hospital approvals are in place. The researcher is responsible for ensuring all appropriate approvals are obtained prior to initiation of the research project.

9. Research projects must be approved by hospital operational director(s)/manager(s) from the appropriate department(s)/program(s) where the research will be conducted. Approval is obtained through the TRAQ application portal.

10. Research projects must be approved by the Queen's University's Department Head or University/Hospital administrator to whom the researcher is most responsible for reporting to for their research activities. Approval is obtained through the TRAQ application portal.

11. The researcher is responsible for ensuring that all clinical trials are registered on the Hospital affiliated clinical trials registry (http://clinicaltrials.gov/) prior to the enrollment of subjects into a clinical trial. Clinical trials only need to be registered once. Consequently, if a clinical trial has been registered by a sponsor, the researcher does not need to register the trial. Contact KGH's Office of Health Sciences Research for further details if necessary.

12. Animal research will be conducted on hospital premises only after review and approval of both the animal-based research and the designated space for that research by the University Animal Care Committee (UACC) (http://www.queensu.ca/uvet/index.html), which reports to the Queen's University Principal via the Queen's University Vice Principal (Research). Animal research on hospital premises must also be approved by the KGH Vice President, Health Sciences Research who reports to the KGH President and Chief Executive Officer. As required by the guidelines of the Canadian Council on Animal Care (CCAC; http://www.ccac.ca/) and the Animals for Research Act, research

animals may not be housed overnight in research space, but must be housed in approved housing facilities. There are several such facilities at Queen's University and one on Hospital premises. Animals may be brought from, and returned to, approved housing facilities only after approval of the relevant animal-use protocol by the UACC.

13. The KGH's Department of Pharmacy Services must approve all clinical drug trials when the study medication is prepared, dispensed, and/or stored in the KGH Department of Pharmacy Services. Approvals are obtained through the Queen's TRAQ application. The researcher is responsible for consulting with the KGH's Department of Pharmacy Services' Research Office for all associated costs.

14. All needs for specifically assigned research space must be reviewed with the KGH Vice President, Health Sciences Research. Applications (space request form) for research space within the hospital must be submitted to the KGH Vice President, Health Sciences Research via the researcher's Department Head. See KGH Administrative Policy #05-135.

15. If, during the conduct of the project, the study is not being conducted according to the approved method or the project is causing undue stress to the subjects or the organization, the researcher will, first, attempt to resolve the issue directly with the department or program involved. If the issue is not resolved to the agreement of both parties, the KGH Vice President, Health Sciences Research, with consultation, will submit recommendations for continuance or discontinuance of the project.

16. Researchers are encouraged to share their results within the Hospital, and especially with those who may be contributing to or supporting this research. Researchers must acknowledge the support of KGH in any public presentation or publication.

17. If, during the conduct of the project, the study undergoes an internal or external audit (i.e. local research ethics board, government regulatory authorities including Health Canada, the US Food and Drug Administration (FDA), any other foreign regulatory agencies, the sponsor of the project), the KGH Vice President, Health Sciences Research must be notified in advance of the audit and provided with a copy of the final report.

18. If, during the course of performing the project, the study is monitored by individuals who are either employed or engaged under contract by the sponsor of the project, the KGH Vice President, Health Sciences Research must be notified in advance of the monitoring visits. Upon notification of the monitoring date(s) and name(s) of the individual(s) attending the visit, the KGH Office of Health Sciences Research will send an email to KGH Security authorizing the monitoring visit so that the monitor(s) can obtain a visitor pass in order to access the hospital. On the day of the monitoring visit, the individual must report to the

KGH Security Desk in the front lobby to obtain their visitor's pass prior to entry into the hospital.

19. Researchers are responsible for keeping their research data intact for the mandated amount of time. The time frame is dependent on the research study type, funding agency conditions, and local research ethics board/governing oversight authority requirements. Funding agencies such as CIHR require grant recipients to retain original data sets for a minimum of five years (or longer if other policies apply) after the end of the grant. Industry studies (drug trials) generally require original data to be maintained for a minimum of 25 years, according to Health Canada. The HSREB requires that research records are retained for a minimum of 5 years from the date of publication or other form of presentation or longer if mandated by a legal requirement or an applicable funding or oversight agency. Remember: each funding agency/oversight authority will have their own guidelines, so researchers are encouraged to check with them and keep their research data in the original format for the greatest time period.

20. The KGH Department of Patient Records and Health Information Services have their own policies on how long medical records are retained. Most Hospital policies only call for a record retention period of 10 years. For clinical trials, researchers need to inform KGH's Department of Patient Records and Health Information Services about their study in order to ensure that the paper and electronic records that are part of their source documents are retained past the 10 year limit of Hospital policy. Health Canada requires that all source/study documents be kept for a minimum of 25 years for drug trials.

21. Off-site (remote) access to medical records (PCS Clinical Desktop) will not be granted to research staff, undergraduate, medical and graduate students, post-doctoral fellows, volunteers and trainees, all of whom are currently able to gain access to this database from within the hospital firewall.

22. KGH's Department of Information Management has created an e-mail repository specifically to address the e-mail retention needs of the research community. Research email domains can be obtained by researchers, research staff, and trainees if they conduct research at KGH and have e-mail messages in their KGH mailbox that need to be retained as part of their research activity, for longer than one year. Please contact KGH Help Desk to open a research e–mail domain.

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

Authorizing Signature

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Leslee J. Thompson
President and Chief Executive Officer

Related Documents:
01-121 Intellectual Property-Employee
01-122 Intellectual Property-Queen's Faculty and Staff Members with Hospital Appointments
05-135 Facility Planning
09-050 Disclosure of Personal Health Information
09-055 Personal Health Information Protection
09-140 Access to Personal Health Information
11-012 Research Hospital Appointment
11-151 Research and Clinical Trial Agreement Overhead
11-152 Standard Operating Procedures for Clinical Research