KINGSTON HEALTH SCIENCES CENTRE

ADMINISTRATIVE POLICY MANUAL

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Preamble
The Kingston Health Sciences Centre (KHSC), together with its sole agent for research, the Kingston General Health Research Institute ("KGHRI"), 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.

The KHSC Board is ultimately responsible for all aspects of the operation of the Hospital and it is essential that the Hospital administration have adequate information and proper documentation of research projects that may involve patients, patients' families, Hospital facilities (equipment and space), Hospital funding, and/or Hospital staff (collectively "Hospital Resources"). It is also essential that the Hospital administration be assured that all research projects have been reviewed, approved and have met due diligence compliance specifically relating to ethical, legal, and financial oversight.

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

KHSC works collaboratively with its partners, Queen's University at Kingston (Queen's) and Providence Care Centre (PCC). 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-1.

Procedure

1. The use and disclosure of personal health 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 human participant data will be subject to the PHIPA provisions in accordance with Hospital policy. See KHSC Administrative Policy #09-055 Personal Health Information Protection.

2. If the research involves the use of human participant data, individual medical records should be accessed in accordance with the Accessing Medical Records for Research roadmap [Appendix A]. For other data needs for research beyond the individual medical record level, the Decision Support Services for Research roadmap (Appendix B] should be used as a guideline..

3. Participants' right to refuse inclusion in research must be respected in accordance with PHIPA and the KHSC public written statement on Personal Health Information practice (see Appendix C "Our Privacy Commitment to Patients"). Researchers must verify within each

Hospital medical record that consent to be contacted for research or the use of PHI for research has not been withdrawn by a patient. This procedure for verifying in the medical record is described in Appendix A "Accessing Patient Data for Research Roadmap"

4. Researchers are responsible for developing a 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 participants, human biological materials, or human participant data, which includes data received directly from individuals and/or their medical records, will require prior clearance in writing from one of the following research ethics boards: the Health Sciences and Affiliated Teaching Hospitals Research Ethics Board Research Ethics | Vice-Principal Research (queensu.ca) , Clinical Trials Ontario (CTO) or the Ontario Cancer Research Ethics Board (OCREB) . Projects requiring the use of animals will require clearance by the Queen's University Animal Care Committee). Researchers must also ensure that appropriate clearance from Queen's University Radiation Safety Committee and Queen's University Biohazards Committee) are obtained, as needed. All the indicated Boards and Committees have their own online application/submission forms with instructions for completion and submission. Researchers are responsible for ensuring that they have received all appropriate approvals (clearance) prior to initiation of their 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 KHSC's Medical Affairs Office prior to submission. See KHSC Administrative Policy #11-012.

6. All project team members on research projects involving the use of human participants, human biological materials, or human participant data, which includes data received directly from individuals and/or their patient/medical charts, must have completed the "Course on Research Ethics" (CORE) as per HSREB requirements. Each team member's copy of the certificate of completion must be attached to the HSREB application for the research project.

7. A Research Hospital Appointment is required for any individual from another institution who will be carrying out research at KHSC. This includes researchers from another hospital, Queen's University, St. Lawrence College (SLC) or any other academic institution who are 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 KHSC 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 or St. Lawrence College are entitled to complete fewer Research Hospital Appointment application requirements if their research activities are only part of their regular academic programs (e.g. undergraduate project or graduate thesis), as the Hospital has written affiliation agreements with both institutions. If

the research being conducted is not part of their regular academic program, a Research Hospital Appointment is required. See KHSC Administrative Policy #11-012.

8. Information regarding the impact of a research project on the operations of the Hospital will be collected through Queen's University Research Services' Tools for Research at Queen's (TRAQ) via their application portal (TRAQ DSS FORM). Impact is defined as any procedure or research protocol which uses Hospital Resources, including impacting the flow of standard patient care operations in the Hospital. Examples 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. Supporting documents for hospital-based research are available at: http://www.queensu.ca/traq/awards-grants-contracts/supportive-documents or http://www.kgh.on.ca/research/researchers-staff-trainees. 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 DSS FORM 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 and budget are prepared. The TRAQ DSS FORM application must be submitted at least 15 business days in advance of the funding agency deadline. It is also recommended that researchers consult with Hospital Operational Director(s)/Program Manager(s) well in advance of the deadline (> 1 month) to discuss any issues involving impact on patient flow, budgeting for hospital services and cost recovery, preparing a human ethics review submission, etc. to ensure all Hospital approvals are in place. Researchers are responsible for ensuring all appropriate approvals through the TRAQ application portal 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 (TRAQ DSS FORM). Researchers are responsible for uploading a completed Hospital Departmental Impact and Information Form to the TRAQ DSS FORM application.

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 for their research activities. Approval is obtained through the TRAQ application portal (TRAQ DSS FORM).

11. Researchers are responsible for ensuring that all clinical trials are registered on the Clinical Trials Registry prior to the enrollment of participants 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. Principal Investigators are responsible for updating their clinical trials records annually until the project has been completed and the

results approved, released by the PI and posted by the Clinicaltrials.gov administrators (PRS). Clinicaltrials.gov accounts are administered by Kingston General Health Research Institute. Please contact KGHRI for further details.

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), 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 KHSC Vice President, Health Sciences Research who reports to the KHSC President and Chief Executive Officer. As required by the guidelines of the Canadian Council on Animal Care (CCAC); 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 KHSC Department of Pharmacy Services must approve all clinical drug trials when the study medication is prepared, dispensed, and/or stored in the KHSC Department of Pharmacy Services. Approvals are obtained through the Queen's TRAQ application portal (TRAQ DSS FORM). Researchers are responsible for consulting with the KHSC Department of Pharmacy Services' Research Office for all associated costs and uploading a completed KHSCs Pharmacy Services Study Request Form to the TRAQ DSS FORM application.

14. The KHSC Department of Laboratory Services must approve all services for any biological samples/specimens that are processed, analyzed, and/or stored by the KHSC Department of Laboratory Services. Approvals are obtained through the Queen's TRAQ application portal (TRAQ DSS FORM). Researchers are responsible for consulting with the KHSC Department of Laboratory Services' Research Office for all associated costs and uploading a completed Laboratory Services Study Request Form to the TRAQ DSS FORM application.

15. Medical equipment (*Hospital-owned, researcher-owned, and/or industry-owned*) used for research at the Hospital must have an electrical inspection completed by KHSC Clinical Engineering Services, to ensure CSA codes and standards are upheld. Approvals are obtained through the Queen's TRAQ application portal (TRAQ DSS FORM). Government regulatory authorities have annual preventative maintenance requirements for equipment used for research (beyond standard of care) that need to be assessed for cost recovery. Researchers are responsible for consulting with the KHSC Department of Clinical Engineering Services for all associated costs and uploading a completed Clinical Engineering Services Study Request Form to the TRAQ DSS FORM application when using hospital-owned equipment for regulated clinical trials

16. All needs for specifically assigned research space must be reviewed with the KHSC Vice President, Health Sciences Research. Applications (space request form) for research space within the hospital must be submitted to the KHSC Vice President, Health Sciences Research via the researcher's Department Head. See KHSC Administrative Policy 05-135 and Research Space Allocation Policy 11-154.

17. 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 human participants or the Hospital, the researcher will, first, attempt to resolve the issue directly with the Hospital department or program involved. If the issue is not resolved to the agreement of all parties, the KHSC Vice President, Health Sciences Research, with consultation, will submit recommendations for continuance or discontinuance of the project.

18. 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 KHSC and/or KGHRI in any public presentation or publication.

19. 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 KHSC Vice President, Health Sciences Research must be notified in advance of the audit and provided with a copy of the final report. Further details are described in the Audits and Inspections roadmap Appendix D.

20. 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, KGHRI must be notified in advance of the monitoring visits. A research team member is responsible for sending an email to KGHRI and KHSC Protection Services including the monitoring date(s) and name(s) of the individual(s) attending the 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 research team member must meet the individual at the main entrance and escort them to the KHSC Protection Services office on Dietary 1 to obtain their visitor's pass and then escort them to the monitoring space. Further details are described in the Visitor's Pass for Research roadmap (Appendix E). When remote monitoring is required, please contact KGHRI for details.

21. Researchers are responsible for keeping their research data intact for the mandated amount of time and destroying the data by confidential means once the retention period has been attained. 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 5 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 15-25 years,

according to Health Canada regulations. Further details are described in the Archiving roadmap (Appendix F) and Long Term Storage of Clinical Trials Records Policy 11-153. 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. Although KHSC Health Information Services delineates medical record retention periods in its administrative policy #01-220, each funding agency/oversight authority will have their own guidelines, so researchers are encouraged to verify these and retain their research data in the original format for the maximum time period. For retention of paper medical records for research beyond the hospital medical record retention period, researchers must contact the Medical Records Department for arrangements. Reimbursement to the Medical Records Department will be required.

22. Off-site (remote) access to medical records (PCS Clinical Desktop) will only be granted to research staff, undergraduate, medical and graduate students, post-doctoral fellows, volunteers and trainees under exceptional circumstances,. Please direct all inquiries to KGHRI.

23. The KHSC 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 KHSC and have e-mail messages in their KHSC mailbox that need to be retained as part of their research activity, for longer than one year. Please contact KGHRI and the KHSC 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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Dr. David Pichora
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
01-226 Privacy Breach in Research
03-021 Research Restricted Accounts
05-135 Facility Planning
09-050 Disclosure of Personal Health Information
09-055 Personal Health Information Protection
09-140 Access to, Correction and Use of Personal Health Information
11-012 Research Hospital Appointment
11-151 Research and Clinical Trial Agreement Overhead
11-152 Standard Operating Procedures for Clinical Research
11-153 Long term Storage of Clinical Trial Records
11-154 Research Space Allocation