KINGSTON HEALTH SCIENCES CENTRE

ADMINISTRATIVE POLICY MANUAL

Subject: Research and Clinical Trial Agreement Overhead Number: 11-151

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	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.

It is the responsibility of KHSC to ensure that all direct and indirect costs related to sponsoredresearch are recovered. KHSC cannot absorb any costs of research (e.g. staffing, facilities, testing and procedures, etc.) that are above and beyond those of the standard of care, and research budgets must include complete recovery of all of these direct costs. KHSC will recover indirect costs of research for all sponsored research activity to the extent possible.

Policy Statement

This policy sets out the authority, responsibility and procedures for the recovery of all direct and indirect costs related to sponsored research at the Hospital. This policy applies to all researchers who conduct hospital-based research using patients, patients' families, Hospital facilities (equipment and space), Hospital funding, and/or Hospital staff (collectively "Hospital Resources"), regardless of whether the research funds are administered through the Hospital or our hospital and university partners.

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-6 and Queen's Indirect Costs of Sponsored Research Policy.

Definitions

<u>Direct Costs</u> are Hospital expenses incurred in the conduct of sponsored research projects that are both essential to the conduct of the research and which can be readily attributed and directly charged to specific projects. They include expenditures for such items as personnel (salaries and fringe benefits), supplies, equipment, research and hospital support services (i.e. tests and procedures, storage/dispensing of medications), travel, and other direct costs necessary for conducting the sponsored activity.

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<u>Indirect Costs</u> are Hospital expenses that are necessary to support research. These expenses are commonly referred to as overheads and may not be measurable or directly attributable to any specific research activities but rather provide general support for the Hospital's research environment as a whole (i.e. libraries, computer networks, occupancy costs (such as heat, light, maintenance, and waste management), research and financial administrative support, insurance, security, and human resource management).

<u>Sponsored Research</u> is research undertaken or proposed to be undertaken using financial and/or other in-kind support from a sponsor, whether by participation in a competition, call for proposals, or pursuant to a research agreement or clinical trial agreement.

Procedures

- 1. Researchers must recover all direct costs related to sponsored-research. Research budgets must include a recovery of direct costs that is adequately representative of all associated costs for their project. The Hospital cannot provide financial support for any direct costs related to sponsored-research above and beyond the standard of care.
- Researchers should consult early with the most appropriate Hospital operational director(s)/manager(s) to ensure that their budgets are accurate prior to the signing of research agreements and clinical trial agreements.
- 3. Indirect costs recovery rates will be levied on all research agreements and clinical trial agreements funded by the commercial sector at the Hospital. A minimum of 40% of the direct costs of a research project will be applied to all non-clinical trial research agreements. A minimum of 30% of the direct costs of a research project will be applied to all clinical (drug and/or device) trial agreements.
- 4. Indirect costs recovery rates associated with Tri-Council funds that support sponsored-research will be levied in accordance with the Federal Tri-Council Granting Agencies' (NSERC, SSHRC, CIHR) guidelines. These indirect costs will be recovered through Queen's and distributed according to the Tri-Council Federal Indirect Cost Program and any inter-institutional agreements/memorandum of understanding between the two institutions.
- 5. The Hospital recognizes that special circumstances may arise in research agreement negotiations requiring a variation in the indirect costs recovery rate. Any variation must be reviewed and approved by KHSC's Vice President, Health Sciences Research.
- 6. The distribution of indirect costs related to researchers, researcher's department(s), KHSC, and/or Queen's will be based on affiliation/inter-institutional agreements, memorandums of understanding, internal/external policies, and/or at the discretion of the KHSC Vice President, Health Sciences Research. Any deviation from this sharing formula must be reviewed and approved by KHSC Vice President, Health Sciences Research.

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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: 11-1

- 11-150 Health Research 01-121 Intellectual Property-Employee
- 01-122 Intellectual Property-Queen's Faculty and Staff Members with Hospital Appointments
- 11-012 Research Hospital Appointment
- 03-021 Research Restricted Accounts
- 11-152 Standard Operating Procedures for Clinical Research