

## Schedule 07

### Harmonization of Research Policies

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## Schedule 3H

### HARMONIZATION OF RESEARCH POLICIES

#### 1. Preamble

University and hospitals are jointly committed to excellence in teaching, research, community service and care, and to working together in order to achieve that aim and to achieve goals that are beyond the capacity of any one institution to accomplish.

University and hospitals are committed to the highest standards of ethical conduct and public accountability in research.

University faculty members working part- or full-time in hospitals are expected to familiarize themselves with both University and hospital policies. They are expected to follow the policy in effect at the institution where the work is being carried out. If doing so puts them in substantive conflict with the policy of the other institution, they should consult the appropriate officials and seek clarification of their responsibilities.

University respects the hospitals' role in overseeing the rights and responsibilities of their staff, including those who hold academic appointments at the University.

University acknowledges the fiduciary obligation of the hospitals with respect to the protection of patients and the maintenance of the highest ethical and clinical standards, pursuant to each hospital's mission and values.

#### 2. Publication

University and hospitals are committed to the concept that review by scholarly peers is the cornerstone of excellence in research, and that researchers should have the right to publish or otherwise disseminate the results of their research.

University and hospitals agree that they will not enter into agreements that allow research sponsors to suppress or censor research results. University and hospitals agree that, in agreements with sponsors, delays in the publication of research results will normally be limited to a maximum of six months and in no case will exceed twelve months.

University and hospitals agree that agreements with sponsors shall have provisions to permit the public disclosure of research results if required to protect the health of patients. University and hospitals agree that all contracts with sponsors will contain provision for the effective resolution of disagreements between the sponsor and the researchers.

#### 3. Ethical Conduct in Research

University and hospitals agree to adopt policies and procedures to effectively address allegations of ethical misconduct in research at their institutions and will consult with one

another to ensure the greatest possible degree of compatibility of those policies and procedures.

University and hospitals agree that, when conduct of clinical research raises questions about an investigator's fitness for clinical/professional practice, the hospitals have the right to pursue allegations through the Medical Advisory Committee or other appropriate mechanisms.

4. Conflict of Interest

University and hospitals agree to adopt policies and procedures to address real and potential conflicts of interest in the conduct of research at their institutions, and will consult with one another to ensure the greatest possible degree of compatibility of those policies and procedures.

University and hospitals agree that such policies and procedures shall require investigators to disclose all relevant information necessary to permit a determination by the responsible officials whether a real or potential conflict of interest exists. Such disclosures include, but are not limited to, funding sources for the research, investigators' direct or indirect financial interests in the outcomes of the research, and any past or ongoing direct financial relationships between the sponsor of the research and the investigators.

5. Working Group on Ethical Conduct of Research

University and hospitals agree to collaborate in the creation and support of a Working Group on Ethical Conduct of Research, which shall report to the Research Committee of the Toronto Academic Health Sciences Council (TAHSC). The mandate of this Working Group will be to establish (insofar as is feasible) common standards for ethical conduct of research, including policies on disclosure of conflicts of interest and procedures for investigating research misconduct.

6. Use of Human Subjects in Research

University and hospitals agree to adopt policies and procedures that are consistent with the Tri-Council Policy Statement on "Ethical Conduct for Research Involving Humans." University and hospitals agree to implement the Tri-Council Policy Statement through the establishment of appropriately constituted University and Hospital Research Ethics Boards.

University and hospitals agree to collaborate in the creation and support of a Working Group on Research Involving Human Subjects, which shall report to the Research Committee of the Toronto Academic Health Sciences Council (TAHSC). The mandate of this Working Group will be to establish (insofar as is feasible) common standards and procedures for, and facilitate the coordinated delivery of, ethics review of all research projects in clinical settings. Institutions shall have in place mechanisms for resolving disputes arising from REB decisions; these mechanisms must include an appeal process, and may include provision for referral to the Working Group for advice and mediation.

7. Use of Animals in Research

University and hospitals agree that the care and use of animals in connection with research projects shall be in accordance with the standards established by the Canadian Council on Animal Care.

University and hospitals agree to collaborate in the creation and support of a Working Group on Research Involving Animals, which shall report to the Research Committee of TAHSC. The mandate of this Working Group will be to share information regarding relevant policies and procedures with the aim of improving standards and enhancing collaboration insofar as it is feasible.

8. Graduate Students, Postdoctoral Fellows, and Research Associates

University and hospitals agree that all graduate students are subject to the policies and regulations of the School of Graduate Studies.

University and hospitals agree that all graduate students, postdoctoral fellows, and other research associates being supervised and/or working in hospitals shall be bound by all applicable hospital policies and regulations.

9. Research Administration

University and hospitals agree to share information and best practices in research administration, and to cooperate in the development of consistent approaches to liability management, indirect cost recovery and other issues, where consistent with the mission and values of the involved institutions.

University and hospitals agree that when there is doubt as to which institution should administer a research grant or contract, the appropriate officials of the institutions will consult with one another and make a determination.

10. Research Coordination

Through joint standing committees and other consultative mechanisms, University and hospitals agree to exchange information on their strategic research goals and strive, where appropriate, to develop coordinated research programs and shared research facilities.

11. Revisions to this Schedule

Revisions to this Schedule will be made by mutual agreement of the Parties, normally upon recommendation of the Research Committee of TAHSC, which will have a number of joint University-Hospital Working Groups, including ones on Research Involving Human Subjects, Research Involving Animals, Intellectual Property and Technology Transfer, and Ethical Conduct of Research.