

TAHSN Research Committee Response to the Report from the TASK FORCE ON HUMAN SUBJECTS RESEARCH

Administrative Response to the Task Force on Human Subjects Research

In April 2006, on the advice of the TAHSN Research Committee, the Vice-Provost Relations with Health Care Institutions struck a Task Force on Human Subjects Research with the purpose of identifying common challenges among the TAHSN hospitals and the University in the management of clinical studies. On behalf of the TAHSN Research Committee, thanks very much to the Task Force co-Chairs, Paula Rochon and Valerie Sales for their leadership in this process. Also, many thanks go to all of the members of the Task Force who worked diligently for many months with the co-Chairs in successfully developing a useful analytical process and report. The faculty survey that was undertaken as part of the internal scan attests to the commitment of the Task Force in seeking reliable evidence relevant to our investigators. Input from the Research Ethics Boards (REBs) was also very useful and helped to identify the widening gaps between their function and the identified need for human subjects research management support within our institutions.

The following responds to the recommendations of the Task Force and provides discussion about next steps in meeting the identified challenges.

Information Technology Support for REB Applications and Review

The TAHSN Research Committee recognizes the importance of enabling the process of ethics review including the necessity for timely turn around of both single and multi-sited trials with improved information technology support. A secure, portal-based, web-enabled review system applied across the TAHSN hospitals and the University would enhance the ability of faculty and students to submit their requests on-line. Common application forms and instructions would further enable the application and review process. All of the harmonized human subjects research ethics policies and guidelines including the most up-to-date regulatory requirements could also be accessed through the same portal. At present, there is no collective organization of REB function across TAHSN, nor assignment of information technology personnel within to create and maintain a central portal system and liaise with external groups on national and international initiatives. The TAHSN Research Committee will request that the TAHSN Research Ethics Committee Limited Term strike a steering group, including institutional senior administrative personnel in information technology to advise TAHSN and the University about next steps in establishing appropriate information technology infrastructure.

Human Subjects Research Management

The Task Force identified that the work of the REBs has escalated in the past decade as the amount of human subjects research conducted by faculty and students has increased. Further, the complexity of research and the requirements of granting agencies and journals have intensified the review process. The recognition that the role of the REB should be limited to review and not oversight of management of process issues (including those surfacing at the REB level) arising from research proposals is important. The TAHSN Research Committee will create a framework for addressing this matter in each institution through the Vice-Presidents Research with a view to harmonizing policies and guidelines across the TAHSN member institutions.

TAHSN Research Ethics Committee - Limited Term

During the work of the Task Force, the TAHSN Research Committee recognized the need to establish a working group to address the issues that would arise from the Task Force deliberations as well as immediate issues, such as, handling of human subject data. Therefore, the TAHSN Research Ethics Committee Limited Term was established with approval of TAHSN (see attached terms and membership). This committee is now engaged fully in addressing immediate, intermediate and long-term issues related to human subjects research, providing expert advice to the TAHSN Research Committee.

New Budget for Human Subjects Research Infrastructure within TAHSN

The University and the TAHSN hospitals are committed to enabling state-of-the-art human subjects research to be conducted by our investigators. The Faculty of Medicine is investing in leadership for TAHSN to build on the existing human subjects research infrastructure including human resources in research ethics and provide integration among our institutions facilitating multi-site research within Toronto and across Ontario. Sources of funding will be sought through partnership with Cancer Care Ontario, the relevant Ministries of the Ontario Government, national agencies and the private sector.

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June 2007