

FACULTY OF MEDICINE / AFFILIATED INSTITUTIONS
LETTER OF AGREEMENT ON THE APPEALS PROCESS FOR REVIEW OF HUMAN SUBJECT
PROTOCOLS

Procedure

The institutions comprising TAHSC (Bloorview MacMillan Children's Centre, Baycrest Centre for Geriatric Care, Centre for Addiction and Mental Health, Hospital for Sick Children, Mount Sinai Hospital, St. Michael's Hospital, Sunnybrook and Women's Health Sciences Centre, Toronto Rehabilitation Institute and University Health Network) have entered into an agreement for a mechanism to deal with decisions of TAHSC Research Ethics Boards (REBs).

The TAHSC Committee on Human Subjects Research Review will act as the REB Appeals Committee. This committee is comprised of the Chairs of all TAHSC REBs and a representative of the University. Additional members with specific expertise will be added if necessary, and members of the Appeals Committee will be excluded if in a conflict of interest.

In the event of an appeal, the Committee will decide if sufficient grounds exist for a formal review of a REB decision. If so, a hearing will be held and investigators, the responsible REB and experts with specific content expertise will be invited to provide opinions on the review process.

The committee may dismiss the appeal or direct the responsible REB to reconsider the original decision. The Appeals Committee will review the appeal in light of the process issues identified, but may not overturn the decision of the responsible REB.

The full text of the Policy may be found below.

For further information, contact either of the Co chairs of the Committee:

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Policy

Toronto Academic Health Sciences Committee on Human Subjects Research Review

Letter of Agreement on the Appeal Process

The institutions comprising TAHSC (Bloorview MacMillan Centre, Baycrest Centre for Geriatric Care, Centre for Addiction and Mental Health, Hospital for Sick Children, Mount Sinai Hospital, St. Michael's Hospital, Sunnybrook and Women's Health Sciences Centre, Toronto Rehabilitation Institute and University Health Network) hereby enter into an agreement for a mechanism designed to appeal of decisions of TAHSC Research Ethics Boards (REBs).

In the event that a TAHSC REB rejects a submission by an investigator, the investigator may appeal this decision to the TAHSC Committee on Human Subjects Research Review which will act as the REB Appeal Committee. This REB Appeal Committee membership includes the Chairs of all TAHSC REBs and a representative of the University of Toronto. The Chair of the REB Harmonization Committee will act as the Chair of the REB Appeal Committee or designate an alternate Chair from the membership. Any member(s) of the REB Appeal Committee that is (are) in a perceived conflict of interest will be excused from deliberations. The REB at the institution at which the original decision was made may nominate up to two (2) individuals (one of whom may be from the institution itself) to participate in the proceedings. The REB Appeal Committee will choose one individual from the nominations. At the discretion of the REB Appeal Committee, content or ethics experts from the TAHSC community will be utilized as determined by content of the REB appeal submission and the judgement of the REB Appeal Committee.

In the event of an appeal, the REB Appeal Committee will first decide whether or not the appeal merits review by the REB Appeal Committee by a preliminary poll of its members, and, if appropriate, review the process by which the responsible REB(s) reached its decision. If there is sufficient concern over the REB process with regard to the specific protocol review, the REB Appeal Committee will hold a formal hearing and invite members of the investigative team, responsible REB(s), and TAHSC-community members with specific expertise to provide opinion on the merits of the review process. The REB Appeal Committee may dismiss the Appeal or direct the responsible REB(s) to reconsider its decision. The Committee may not overturn the decision of the responsible REB(s).

The investigative team, responsible REB(s) and the TAHSC Research Sub-Committee will receive written comments and recommendations for actions from the REB Appeal Committee. Appeals will be heard within 60 days and written comments and recommendations will be received by the interested parties within 30 days of the termination of the hearing. Subsequent action will be at the discretion of the responsible REB.

Approved by the TAHSC Research Committee April 7, 2003