

Purpose

The purpose of this SOP is to ensure that all staff involved in clinical research receive basic training in research ethics issues.

Policy

Effective November 2005, Canadian research ethics training is mandatory for all Sick Kids clinical investigators. Studies will not receive REB approval or reapproval without written evidence that all study investigators have successfully completed training.

Effective November 2006, mandatory training will be expanded to include all other key study personnel.

Research ethics training is also required for all REB members and REB staff.

Definitions

Clinical Research: This refers to any research involving human subjects, data, tissue or waste eg., urine, excreta for which the REB provides ethical review.

Canadian research ethics training: The Introductory Tutorial for the Tri Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS). This online tutorial has log-on, log-off capability, can be completed in less than 2 hours, and issues a printable certificate at completion.

Key personnel: Sick Kids staff who have contact with research subjects or who have access to identifying personal health information. In addition to investigators this could include research managers, coordinators, research nurses, assistants, students, and trainees.

Certification: A personalized TCPS certificate of completion issued by the TCPS introductory tutorial.

Procedures

1. Clinical research staff must complete the Canadian online tutorial which can be accessed at www.pre.ethics.gc.ca/english/tutorial/
2. Upon successful completion, a TCPS certificate of completion is issued and must be submitted to the REB office via email or surface mail. The information will then be entered into the Research Operations (IDA) database.
3. New applications and study renewals without documentation of TCPS training *for each of the study investigators* will be returned to the primary investigator as incomplete and will not be processed by the REB office.

4. While research ethics training is not mandatory for co-investigators who are not Sick Kids staff, they are encouraged to complete the TCPS tutorial as well.
5. It is the responsibility of the primary investigator to ensure that their other key personnel obtain certification and submit their certificates to the REB office for data entry.
6. Written evidence of successful completion of in-house training programs offered by the REB Chair *prior to the launch of the TCPS online tutorial* will also be accepted.
7. For US funded research, investigators may also wish to complete the NIH training course through www.nihtraining.com/ohsr/site/cbt/cbt.html. This course is not mandatory.
8. Refresher training at periodic intervals following initial training is not required at this time.

Appendices

None

Responsibility

Research Ethics Manager or designee

Reference Documents

- * June 1, 2006 Letter of support issued by Chief of Research & Chair, Medical Advisory Committee
- * Tri Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)
- * NIH Office of Human Subjects Research: Researcher Computer-Based Training

Related Documents

Ethical Conduct of Research policy
Research Involving Human Subjects policy

Authority

REB Chair

Version Date

June 1, 2006