

Human Subject Research at CMU

Ethics Protocol Submissions Guidelines for Submissions & Reviews

SUBMISSION GUIDELINES:

1. Applications are to be submitted to the Research Ethics Board (REB) For collaborative studies, the protocol submission form should be submitted by the Principal Researcher. Submit via the online form on the Research Ethics webpage. Attachments can be sent to the Chairperson, Dr. Heather Campbell-Enns (hcampbell-enns@cmu.ca).
2. Grant Proposals: The REB will not normally provide ethics reviews of research grant proposals; in other words, the project should generally be funded before submission for ethics review. However, where researchers require an ethics certification as a condition for applying for funding, REBs will provide a review of grant applications.
3. Sponsored Programs of Research: If a researcher is applying for a multi-year research program, or he/she must submit a Research Ethics Protocol Submission for **each project** involving human subjects to be funded by that grant. Ethical approval for one project involving human subjects does not apply to related projects.
4. Student projects: Graduate and undergraduate students should not submit ethics applications before their proposals have been reviewed and approved by their project advisors. (Premature submission of an ethics protocol for a project often only delays approval for the project. Each new submission requires a completely new review).
5. It is the applicant's responsibility to ensure that all application materials are complete in order to facilitate the review of a submission. In no circumstance will an application be reviewed if the file is incomplete or not in the required format.

REVIEW PROCESS:

1. The Chair of the REB will determine the appropriate method of review based on the following:
 - Studies that use anonymous/anonymized data, mail returned surveys (with minimal risk and no identifying information), secondary analysis may qualify for Expedited Review. As well, studies which have been approved at other Canadian universities may qualify for Expedited Review (with submission of approval letter).
 - All other studies will undergo a Full Review.
2. In cases of Expedited Review, the review process will produce one of five possible outcomes. Research will be judged to be: ethically acceptable as is; acceptable, with conditions; in need of clarification or further information; in need of full review; or unacceptable: revise and resubmit.
3. In cases of Full Review, the review process will produce one of four possible outcomes. Research will be judged to be: ethically acceptable as is; acceptable, with conditions; in need of clarification or further information; or unacceptable: revise and resubmit.
4. Negotiated revisions: Where changes are required by the ethics review process, these will be negotiated by the researcher(s) and the Chair of the REB, acting on behalf of the reviewers and/or the REB. Once agreement has been reached, the Chair shall issue a letter indicating ethics approval for the research.
5. Reconsideration: If there is no agreement between the REB and researcher on the changes recommended by the REB, a study does not pass ethics review. The researcher may request reconsideration by the REB of this decision. This request should be accompanied by a detailed explanation of the reasons why the suggested procedure is unacceptable, and preferably a suggestion of an alternative procedure. If requested, the REB will allow the researcher to make his/her case before the REB; however after presenting the case the researcher must leave to allow the REB to deliberate its decision *in camera*. The REB decision following reconsideration is final.
6. Appeals: Appeals may be made on procedural or substantive grounds. The researcher(s) may appeal a decision by submitting their appeal in writing to the Chair of the Main Campus Academic Council (copy to Chair of REB).