



ST. CATHERINE
UNIVERSITY

Institutional Review Board 2009-2010 Renewal Application & Completion Form

St. Catherine University is committed to safeguarding and respecting the rights and welfare of human subjects involved in research. In order to carry out this obligation, the University, through its Institutional Review Board (IRB), is responsible for conducting initial and continuing review of *all* research that involves human subjects.

The purpose of this application is to ensure that human research subjects are protected. This includes protecting the privacy of subjects, respecting the autonomy of subjects, preserving the dignity of subjects, minimizing risks while maximizing benefits to subjects, and providing adequate information for subjects to make informed decisions. In addition to promoting quality research, protecting human subjects also protects the researcher, the advisor, and the University.

Renewal Application

Annual IRB review is required for ongoing human subjects research. Researchers continuing with recruitment of human subjects and/or data analysis must apply for renewal using this application. Researchers with ongoing human subjects projects will receive email notification two months prior to the renewal deadline. **If a researcher does not file for renewal by the project's one year deadline, he/she will be required to resubmit his/her project through the entire IRB application process as a new project.**

Project Completion Form

Once the project is complete, researchers must fill out the research project summary section of the IRB Renewal Application & Completion Form. Researchers should complete the form through question #5, noting the number of subjects recruited and summarizing any subject complaints, early withdrawals, adverse events, injuries or problems with the research study. **This form is required to finalize the St. Catherine University IRB process.**

Instructions for Completing the IRB Renewal Application & Completion Form

Complete the following application in its entirety. Do not insert "see attached" in any of the application blanks. You may excerpt material from your thesis or grant proposal, but your application should be relatively concise.

Note: If you have made changes to any of supporting documents such as your informed consent, child assent form (if applicable), recruiting materials, or survey/interview questions, submit copies of the new documents with your renewal application.

Formatting: All applications must be **word processed**. Please **spell- and grammar-check** your document.



Renewal Application Submission:

- Submit your **Renewal Application & Completion Form** via email to **Lynne Linder** <llinder@stkate.edu> with "Attention IRB" in the subject line

Checklist for application submission:

- signed* IRB Renewal Application & Completion Form

If any changes have been made, also submit:

- informed consent form
- child assent form (if applicable)
- recruiting materials (phone script, fliers, ads, etc)
- survey/questionnaire, focus group or interview questions (if applicable)
- conflict of interest/financial interest disclosure (if applicable)
- letters of support (if you are conducting research at another agency, school, etc).

Questions? Visit the St. Catherine IRB website at www.stkate.edu/irb for additional information and for a list of contacts.



REQUEST FOR THE APPROVAL FOR THE USE OF HUMAN SUBJECTS IN RESEARCH 2009-2010 RENEWAL APPLICATION/COMPLETION FORM

Human Subjects Code Number: _____ (assigned by IRB)

RENEWAL DATA

Date of Last Approval:

Indicate type of review: ___ Exempt ___ Expedited ___ Full

APPLICANT DATA

Investigator name(s):

Project Title:

Department:

Investigator Mailing Address:

Investigator E-mail Address:

Investigator Telephone:

1. What is the status of this study:

- Recruiting subjects
Recruitment complete; following subjects
Data collection complete; Data analysis only
Study not begun
Completed/Discontinued. If checked, should the IRB deactivate this study?
Other (please explain):

2. What is the total number of subjects approved for this study (if this is a multi-site study, please indicate)

Male _____ Female _____ Total _____

3. Currently, how many subjects have been enrolled?

Male _____ Female _____ Total _____

4. Is this project funded? _____



- a. If yes to # 4, what is the funding agency and grant number (not all grants have grant numbers; if you have received an internal grant or a corporate/foundation grant, please indicate the source of funding)?
 - b. If yes to #4, are there any conflicts of interest between the investigator(s) and the funder?
5. Describe any subject complaints, early withdrawals, adverse events, injuries or problems with the research study: (If none, simply write “none.”)
6. Have there been changes in principal investigator, co-investigators, or research staff? _____
- a. If yes, please explain
 - b. If there have been no changes, indicate “none”
7. Given any preliminary results, have there been any changes that would affect a subject’s decision on whether to participate in this study? _____
- a. If yes, please explain
 - b. If there have been no changes, indicate “none”
8. Has the risk/benefit relationship for subjects changed since the initiation of the study? _____
- a. If yes, how?
 - b. If there have been no changes, indicate “none”
9. List previous changes in the study and dates approved by the IRB (if none, put “none”).
10. Have there been any changes to the consent/assent forms since the last IRB approval? _____
- a. If yes, please attach all current consent/assent forms. Highlight any changes from the originally approved version. Explain any changes here.
 - b. If there have been no changes, indicate “none”

ASSURANCES AND SIGNATURES

As principal investigator (s), I (we) assure that the information contained on this form is accurate.

Signature of Principal Investigator (s) Date

Signature of Principal Investigator (s) Date

Signature of Principal Investigator (s) Date