



ST. CATHERINE
UNIVERSITY

Institutional Review Board 2009-2010 Application

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. Investigators cannot begin research with human subjects until a complete application has been submitted to the IRB, reviewed and approved.

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.

Instructions for Completing the IRB Application

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.

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

Application Submission:

- Submit a copy of your application via email to **Lynne Linder** <lelinder@stkate.edu> with "Attention IRB" in the subject line **AND**
- Submit **3 copies** of all Exempt and Expedited applications to Lynne Linder in Mendel 112 or to Mailbox #4068 **OR**
Submit **15 copies** of all Full Review applications to Lynne Linder in Mendel 112 or to Mailbox #4068.

Checklist for application submission:

- signed* IRB Application
- 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 APPLICATION FORM**

Human Subjects Code Number: _____
(To be assigned by SCU IRB)

APPLICATION DATA

Date of application:

Indicate type of review: ___ **Exempt** ___ **Expedited** ___ **Full**

For all exempt reviews, indicate which of the following categories apply:

- | | |
|-------------------------------------|--|
| ___ 1. Normal Educational Practices | ___ 5. Secondary Use of Data |
| ___ 2. Educational Tests | ___ 6. Evaluation of Federal Research/Programs |
| ___ 3. Survey/Interview Procedures | ___ 7. Taste Tests |
| ___ 4. Observation | |

Note: There are three levels of IRB Review. You should indicate the level of review you believe is required for your research. The IRB may determine that a different level of review is necessary.

Exempt Status (Level I)

Research is reviewed for Exempt status (Level I review) by an IRB committee member if it involves very minimal or no risk. In general, research which does not propose to disrupt or manipulate the normal life experiences of subjects, incorporate any form of intrusive procedures, or involve deception will be exempt from full Committee review. Projects that involve more than very minimal risk and those that include any degree of deception *do not* qualify for Exempt status. For more information about the types of research listed in the expedited category, visit the IRB website at www.stkate.edu/irb.

Please note that all of the rights and protection afforded to human subjects in research are required in Exempt status cases. Researchers engaged in human subjects research that qualifies for Exempt status **must still complete a full application form and prepare an informed consent statement**. Researchers must engage in practices that minimize risk, maximize benefit and ensure privacy. In short, **research with Exempt status is exempt only from full committee review**.

Expedited Review (Level II)

Expedited review (Level II review), is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the entire IRB. The term "expedited" can be misleading: reviews of this type are *not* "quicker" or conducted with less rigor, but fewer reviewers are required for approval. For more information about the types of research listed in the expedited category, visit the IRB website at www.stkate.edu/irb.

Full Review (Level III)

All research not qualifying for **Exempt status** or **Expedited review** and research involving protected classes of subjects requires Full (Level III) review. In general research requiring Full review places the subject at greater than minimal risk. Full review means that the research protocol is read, discussed and voted upon by the full IRB committee.



APPLICANT DATA

Investigator name(s):
(please list all co-investigators)

Project Title:

Advisor:

Department:

Investigator Mailing Address:

Investigator E-mail Address:

Investigator Telephone:

Dates of Project:

All SCU internally funded research, state, federal and privately funded external grants, and most published research is required to undergo IRB review if human subjects are involved.

Is this research funded by a grant? Yes No
(If YES, please provide name of funding agency) _____

Has this research been reviewed by another IRB? Yes No
(If YES, please provide a copy of the letter of approval, or indicate the status of your application)

Will this research be reviewed by another IRB? Yes No
(If YES, please indicate your plans for review)

RESEARCH SUMMARY

Carefully describe your research project. Include your research question, purpose, subject population, and the procedures you will follow. Do not put "see attached" in your answer to this question. Also, if it applies to your project, you must attach a copy of your thesis proposal, your protocol, your questionnaire, your survey, etc.

Step by step, describe exactly what will happen to your subjects.

SUBJECTS AND RECRUITMENT

Age Range of Subjects:
Number: _____ **Male** _____ **Female** _____ **Total**



Describe how you will recruit your subjects? Be specific and attach a copy of any advertisement, flyer, letter, or statement that you will use to recruit subjects.

Will the subjects be offered inducements for participation? If yes, explain.

Please clearly identify any special populations or classes of subjects that you will include and provide a rationale for using them.

RISKS AND BENEFITS OF PARTICIPATION

Check all that apply. Does the research involve:

- Use of private records (medical or educational records)
- Possible invasion of privacy of the subjects and/or their family
- Manipulation of psychological or social variables
- Probing for personal or sensitive information in surveys or interviews
- Use of deception
- Presentation of materials which subjects might consider offensive, threatening or degrading
- Risk of physical injury to subjects
- Other risks

If any of these are checked, describe the precautions taken to minimize the risks.

List any anticipated direct benefits to your subjects. If none, state that here and in the consent form.

Justify the statement that the potential benefits of this research study outweigh any probable risks.

CONFIDENTIALITY OF DATA

How will you maintain confidentiality of the information obtained from your subjects?

Where will the data be kept, how long will it be kept, and who will have access to it?

Will data identifying subjects be made available to anyone other than you or your advisor? Who?

Will the data become a part of the medical or school record? If yes, explain.

INFORMED CONSENT

How will you gain consent? State what you will say to the subjects to explain your research.

Attach the consent form or text of oral statement. (Note: if you propose to work with children ages 7-18 and you are gaining consent from their parents, you must also develop and attach an age-appropriate assent form.) For a template, visit www.stkate.edu/irb.

When will you obtain consent (that day? several days before the project? a week before?)?



How will you assess that the subject understands what he/she has been asked to do?

ASSURANCES AND SIGNATURES

The signatures below certify that:

- The information furnished concerning the procedures to be taken for the protection of human subjects is correct.
- The investigator, to the best of his/her knowledge, is complying with Federal regulations governing human subjects in research.
- The investigator will seek and obtain prior written approval from the Committee for any substantive modification in the proposal, including, but not limited to changes in cooperating investigators, procedures and subject population.
- The investigator will promptly report in writing to the Committee any unexpected or otherwise significant adverse events that occur in the course of the study.
- The investigator will promptly report in writing to the Committee and to the subjects any significant findings which develop during the course of the study which may affect the risks and benefits to the subjects who participate in the study.
- The research will not be initiated until the Committee provides written approval.
- The term of approval will be for one year. To extend the study beyond that term, a new application must be submitted.
- The research, once approved, is subject to continuing review and approval by the Committee.
- The researcher will comply with all requests from the IRB to report on the status of the study and will maintain records of the research according to IRB guidelines.
- If these conditions are not met, approval of this research may be suspended.

PLEASE NOTE: Applications received without signatures will be returned. To avoid delay, please make sure the primary investigator(s), advisor and department chair (if applicable) have signed the application.

As primary investigator(s), I/we understand and will follow the above conditions.

Signature of Investigator

Date

As Advisor or Sponsor, I assume responsibility for ensuring that the investigator complies with College and federal regulations regarding the use of Human Subjects in research.

Signature of Advisor or Sponsor

Date

(Student investigators must have an advisor. Staff and non-SCU applicants must have a departmental sponsor)

As Department Chair, I acknowledge that this research is in keeping with the standards set by our department and assure that the investigator has met all departmental requirements for review and approval of this research.

Signature of Department Chair

Date

(Necessary only for faculty and staff research at the Expedited and Full levels)