Trine University
Institutional Review Board
Investigation Involving Human Subjects
Application Form 2015 - 2016

Trine University is committed to safeguarding and respecting the rights and welfare of human subjects involved in research. The Trine Institutional Review Board (IRB) is responsible for conducting initial and continuing review of research involving human subjects. Research involving: physical or psychological stress, a risk of harm, invasions of privacy, documentation of private information in which subjects might be identified, concealment of deception, or any undesirable consequences for the subject, are all subject to IRB review. Investigators cannot begin research with human subjects until a completed application has been submitted, reviewed and approved by the Trine IRB.

The purpose of this application is to ensure that human research subjects are protected. It is the task of the researcher to minimize the negative consequences of any research, justify any negative consequences that cannot be eliminated, and to provide adequate information for subjects to make informed decisions. IRB approval not only protects the human subjects, but also protects the researcher, the advisor, and Trine University.

Instructions for Completing the IRB Application

You must complete the application in its entirety. Information and other relevant materials must be submitted in the designated area. Do not insert "see attached" in any of the application blanks. You may excerpt material from other sources and may expand on the space provided in the document, but the application should be relatively concise.

Application Submission

- Please submit your application electronically as a Word™ document. All submissions should be sent to the IRB Chair (email address contact info here …) with "Attention IRB or similar" in the subject line.
- Applications that lack clarity due to excessive errors or incomplete information may be returned to the investigator. This will delay the review process. Please spell and grammar check your document before submission.
- Investigators will electronically sign the application for review.

Checklist for Application Submission

☐ IRB Application with an electronic signature
☐ Informed consent form
☐ Recruiting materials (phone script, fliers, ads, etc.)
☐ Survey/questionnaire(s), focus group or interview questions (if applicable)
☐ Conflict of interest/financial interest disclosure (if applicable)
☐ Letter(s) of support (if conducting research at another agency, school, etc.)

APPLICATION DATA

IRB No. _____
(To be assigned by TU IRB)

Date of Application: _____

Indicate type of review: ☐ Exempt ☐ Expedited ☐ Full

For Exempt Reviews please indicate which of the following apply:

☐ 1. Normal Educational Practices

☐ 2. Educational Tests

☐ 3. Survey and/or Interview Procedures

☐ 4. Observation

☐ 5. Secondary use of Data

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
Research is reviewed for Exempt status by an IRB 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 sensitive topics, or involve deception will be exempt from full IRB review. Projects that involve more than very minimal risk and those that include any degree of deception *do not* qualify for Exempt status.

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 IRB review.

Expedited Review
Expedited 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
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.

APPLICANT DATA

Investigator name(s) and credentials (eg. Ph.D., RN, PE etc) ***(Please list all co-investigators):***

Project Title:

Advisor:

Department and Campus (if not Trine main campus):

Investigator Mailing Address:

Investigator Email Address:

Investigator Telephone:

Dates of Projects:

All 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 the name of the 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 you application.

Will this research be reviewed by another IRB? ☐ Yes ☐ No

If YES, please indicate your plans for review.

I. RESEARCH SUMMARY: *Please complete each section in clear, easy to read language that can be understood by a person who is unfamiliar with your research and field of expertise.*

a. **Purpose of the Research:** *Provide a clear, concise statement of purpose.*

b. **Background:** *Provide a concise summary in 1 to 2 brief paragraphs to explain the importance of the research and how it fits with previous research.*

c. Research Methods and Questions: *Give a general description of the study design, and specific methods you will use in your investigation. Specify all of your research options and/or hypotheses. Reviewers will consider whether the information you are gathering from participants is necessary to answer your research question(s), so this should be clear in your application.*

d. Expectations of Participants: *Give a step by step description of all procedures that you will have participants do. Attach any surveys, tests, instruments, interview questions, data, collection forms, etc. that you will use with participants.*

e. Estimated Time Commitment for Participants:

Number of sessions for each participant: _____

Time commitment per session for each participant: _____

Total time commitment for each participant: _____

f. **Access to Existing Data:** *If you are analyzing existing data, records, specimens, explain thye source, type, means of access, and permission(s) to use them.*

II. SUBJECTS: *Provide your best estimates below.*

a. **Age Range of subjects:**

b. Number of subjects: _____ **Male** _____ **Female** _____ **Total**

c. **Target Population:** *Describe your target population (eg. Seniors, children ages 9 – 12, healthy adults 18 or over, etc)*

d. **Specific Exclusions:** *If women and/or minorities are to be excluded from the study, clear rationale should be provided in section "f"* below.

III. RECRUITMENT: LOCATION OF SUBJECTS *(Check all that apply)*

☐ Trine University Students Main Campus

☐ Trine University Students Branch Campus *(specify branch)* _____

☐ School Setting (Pre K – 12)

☐ Hospital or Clinic

☐ Other Institutions (Specify) _____

☐ None of the above (Describe location of subjects) _____

NOTE: If subjects are recruited or research is conducted through an agency or institution other than Trine University, submit either written or electronic documentation of approval.

a. **Recruitment Method:** *Describe how you will recruit your subjects. Be specific and attach a copy of any advertisement, flyer, letter, or statement that you will use for recruitment purposes.*

b. **Incentives:** *Will subjects be offered inducements for participation? If Yes, explain.*

RISKS AND BENEFITS OF PARTICIPATION

a. Does the research involve: *(check all that apply)*

☐ Use of private records (medical or educational)
☐ Possible invasion of privacy of the subjects and/or 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 personal injury to subjects
☐ Other risks
☐ None of the above

b. Risks: *Briefly describe the risks of participation in your study, if any. Describe the precautions to minimize these risks.*

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

d. Risks/Benefit Ratio: *Justify the statement that the potential benefits of this study outweigh any probable risks.*

e. Deception: *The use of deception in research poses particular risks and should only be used if necessary to accomplish the research and when risks are minimized. The researcher should not use deception when it would affect the subject's willingness to participate in the study.*

Will you be using deception in your research? ☐ Yes ☐ No

If yes, justify why deceptive techniques are necessary in terms of the study's scientific, educational, or applied value. Explain what alternatives were considered that do not use deception and why they did not meet the researcher's objective.

IV. CONFIDENTIALITY OF DATA

a. Will your data be anonymous? ☐ Yes ☐ No

Will your data be confidential? ☐ Yes ☐ No

(Anonymous data means that the researcher cannot identify subjects from their data, while confidential data means the researcher can identify a subject's response, but promises not to do so publicly.)

b. How will you maintain anonymity/confidentiality of the information obtained from your subjects.

c. Data Storage: *Where will the data be kept, and who will have access to it during that time?*

d. Data Destruction: *How long will the data be kept? What is the date when the original data will be destroyed? All studies must specify a date when original data that could be linked back to a subject's identity will be destroyed.*

e. Availability of Data: *Will data identifying subjects be made available to anyone other than you or your advisor? If yes, please explain who will receive the data, and justify the need.*

f. Official Records: *Will the data become part of the medical or school record? If yes, explain.*

V. INFORMED CONSENT

a. How will you Gain Consent? *State what you will say to the subjects to explain your research.*

b. Consent Document: *Attach the consent form or text of oral statement.*

c. Timing of Consent Process: *When will you obtain consent? (That day, several days before the project, a week/month before, etc)*

d. Assurance of Participant Understanding: *How will you assess that the subject understands what he/she has been asked to do? (A simple yes/no answer from the subject is not sufficient. The subject should be able to explain the purpose of the study, the procedures, what happens if they elect to withdraw, etc.)*

VI. 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 instructor, to the best of his/her knowledge, is complying with Federal regulations governing human subjects in research.
- The instructor 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 instructor and/or student 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 instructor 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 IRB 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 instructor 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.

Note: Applications received without (applicable) signatures will be returned.

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 University and federal regulations regarding the use of Human Subjects in research.

Signature of Advisor/Sponsor Date

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 department requirements for review and approval of this research.

Signature of Department Chair Date