Trine University
Institutional Review Board
Renewal 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 Research 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.

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.

> ***Note:*** *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.*

Instructions for Completing the IRB Renewal 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.

> ***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.*

Checklist for application submission:

☐ *Signed* IRB Renewal Application (Typed name in signature section will constitute an electronic signature)

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).

Renewal Application Submission:

Submit your Renewal Application via email to Alison Witte (wittea@trine.edu).

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IRB Number (as 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
☐ 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? ☐ Yes ☐ No

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?
(If yes, please explain) ☐ Yes ☐ 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?
(If yes, please explain) ☐ Yes ☐ None

8. Has the risk/benefit relationship for subjects changed since the initiation of the study?
(If yes, explain how) ☐ Yes ☐ None

9. List previous changes in the study and dates approved by the IRB. (If there were changes list them below) ☐ Yes, changes ☐ None

10. Have there been any changes to the consent/assent forms since the last IRB approval?
☐ Yes ☐ None
If yes, please attach all current consent/assent forms. Highlight any changes from the originally approved version. Explain any changes here.

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 Advisor/Supervisor Date

Signature of Department Chair Date