

**Trine University**

**Institutional Review Board**

**Investigation Involving Human Participants**

Trine University is committed to safeguarding and respecting the rights and welfare of human participants involved in research. The Trine Institutional Review Board (IRB) is responsible for conducting initial and continuing review of research involving human participants. Research involving: physical or psychological stress, a risk of harm, invasions of privacy, documentation of private information in which participants might be identified, concealment of deception, or any undesirable consequences for the participant, are all subject to IRB review. Investigators cannot begin research with human participants 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 participants 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 participants to make informed decisions. IRB approval not only protects the human participants, 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**

* Submit your application electronically to IRBnet . Accompanying materials (consent forms, surveys, interview questions, recruiting materials, etc.) maybe submitted as PDF, .docx or .doc files.
* 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 and advisors will electronically sign the application for review in IRBnet.

**Checklist for Application Submission**

[ ]  IRB Application

[ ]  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 INFORMATION**

**Date of Application:** Application Date

**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. Use of Existing Data or Specimens

**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 participants, 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 participants in research are required in Exempt status cases. Researchers engaged in human participants 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.

Research that falls under one or more of the following HHS categories may be classified as Expedited.

1. Clinical studies of drugs and medical devices where an investigational drug/device application is not necessary.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture, from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week. Additional restrictions apply for other groups and can be found at <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>
3. Collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

A full list of HHS regulations can be found here: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>

**Full Review**

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

**APPLICANT INFORMATION**

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

Investigator Names & Credentials.

**Advisor:** Advisor, if applicable

**Department and Campus (if not Trine main campus):** Department & Campus

**Investigator Mailing Address:** Primary Investigator Mailing Address

**Investigator Email Address:** Primary Investigator Email Address

**Investigator Telephone:** Primary Investigator Telephone #

**PROJECT INFORMATION**

**Project Title:** Project Title

**Dates of Project:** Project Start DateProject End Date

**FUNDING**

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

**Is this research funded by a grant?** [ ]  Yes [ ]  No

*If YES, provide the name of the funding agency* Funding Agency

**Has this research been reviewed by another IRB?** [ ]  Yes [ ]  No

*If YES, upload a copy of the letter of approval to IRBnet, or indicate the status of you application.*

External IRB Review

**Will this research be reviewed by another IRB?** [ ]  Yes [ ]  No

*If YES, indicate your plans for review.*

Plans for External IRB Review

1. **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.*
2. **Purpose of the Research:** *Provide a clear, concise statement of purpose.*

Purpose of the Research

1. **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.*

Background Information

1. **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*.

Research Questions and Methods

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

Procedures/Expectations for Participants

1. **Estimated Time Commitment for Participants:**

Number of sessions for each participant: # of Sessions/Participant

Time commitment per session for each participant: Time/Session

Total time commitment for each participant: Total Time/Participant

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

Access to Existing Data/Specimens

*You must include a letter(s) of permission to use existing data from the person who currently holds the data with your application.*

1. **PARTICIPANTS:** *Provide your best estimates below.*
2. **Age Range of participants:** Click here to enter text.
3. **Number of participants:**

**Male** # of Male Participants

**Female** # of Female Participants

**Unknown** # of Unknown Participants

**Total** # of Total Participants

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

Target Population Description

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

Specific Exclusions

1. **RECRUITMENT**
2. **Location of Participants** *(Check all that apply)*

[ ]  Trine University Students Main Campus

[ ]  Trine University Students Branch Campus *(specify branch)* Branch Campus

[ ]  School Setting (Pre K – 12)

[ ]  Hospital or Clinic

[ ]  Other Institutions Specify

[ ]  None of the above Describe location

***NOTE: If participants are recruited or research is conducted through an agency or institution other than Trine University, submit documentation of approval through IRBnet.***

1. **Recruitment Method:** *Describe how you will recruit your participants. Be specific and provide a copy of any advertisement, flyer, letter, or statement that you will use for recruitment purposes with your IRBnet package.*

Recruitment Method Description

1. **Incentives:** *Will participants be offered inducements for participation?*

[ ]  Yes (*If yes, explain below.)* [ ]  No

Incentives Offered

**RISKS AND BENEFITS OF PARTICIPATION**

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

[ ]  Use of private records (medical or educational)

[ ]  Possible invasion of privacy of the participants 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 participants might consider offensive, threatening, or degrading

[ ]  Risk of personal injury to participants

[ ]  Other risks

[ ]  None of the above

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

Risk Description

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

Benefits

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

Risks/Benefits Ratio

1. **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 participant’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*.

Rationale for Using Deception

1. **Confidentiality of Data**
2. **Will your data be anonymous?** [ ]  Yes [ ]  No

**Will your data be confidential?** [ ]  Yes [ ]  No

*(Anonymous data means that the researcher cannot identify participants from their data, while confidential data means the researcher can identify a participant’s response, but promises not to do so publicly.)*

1. How will you maintain anonymity/confidentiality of the information obtained from your participants?

Anonymity/Confidentiality

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

Data Storage

1. **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 participant’s identity will be destroyed.*

Data Destruction

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

Availability of Data

1. **Official Records:** *Will the data become part of the medical or school record? If yes, explain.*
2. **INFORMED CONSENT**
3. **How will you Gain Consent?**

 [ ]  Written Consent Document

[ ] Oral Statement of Research Procedures and Risks

 [ ]  Other—Explain

1. **Consent Document:** *Include the consent form or text of oral statement with the documents submitted to IRBnet*.
2. **Timing of Consent Process:** *When will you obtain consent? (That day, several days before the project, a week/month before, etc*)

Consent Process

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

Assurance of Participant Understanding

**ASSURANCES**

By submitting the IRBnet package, I certify that:

* The information furnished concerning the procedures to be taken for the protection of human participants is correct.
* The investigator(s), to the best of his/her knowledge, is complying with Federal regulations governing human participants in research.
* The investigator(s) 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 participant population.
* The investigator 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 investigator will promptly report in writing to the Committee and to the participants any significant findings which develop during the course of the study which may affect the risks and benefits to the participants 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 renewal application must be submitted.
* The research, once approved, is subject to continuing review and approval by the Committee.
* The investigator(s) 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.