Grinnell College IRB Proposal Form

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Assigned ID Number: Please fill in the appropriate sections for exempt, expedited, or committee review and email to IRB@grinnell.edu

##  A. Review Dates

Date of Initial Submission:

If this is a revision of a reviewed but not yet approved project, date of revision submission:

##  B. Project Information

Project Title: Principal Investigator:

* ***Category of Project:***
	+ [ ] Faculty or Staff Research; Department:
	+ [ ] Student Research Project, this includes MAP projects affiliated with faculty research.
		- Course # and name, if applicable:
		- Name of Professor/Staff: Proposed duration of the project:

How many participants are required to meet the study goals?

Specify the age range of participants: to or [ ] N/A (e.g., biospecimens, data sets)

##  C. Funding

Do you have funding from a source other than Grinnell College? [ ] Yes [ ] No If *yes,* Funding Sponsor:

##  D. Performance Sites

 [ ] Grinnell College [ ] Other sites (please list):

If your project takes place at another site besides the College, please note whether the proper permissions have been obtained?

[ ] Yes [ ] No

Please indicate the individual who has provided approval, and document the nature of the permissions granted:

 **E. Study Personnel** Please provide the following information for all personnel working on the project (e.g., Grinnell College faculty, staff, students). *If additional lines are needed, attach a document describing those additional personnel.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Role of Personnel** | **List date of completion of ethics training and****specific training program (e.g., CITI, NIH)** | **Qualifications (i.e., special****training, degrees, coursework, etc.)** | **Conflict of Interest related to the research?** |
|  |  |  |  | [ ] Yes [ ] No |
|  |  |  |  | [ ] Yes [ ] No |
|  |  |  |  | [ ] Yes [ ] No |
|  |  |  |  | [ ] Yes [ ] No |

***Please note:*** The IRB will not proceed with a review of this protocol without all of the above information provided. ***Also,*** all ethics training expires after four years, and the local Grinnell College ethics training is no longer available. You may obtain updated training from [www.citiprogram.org.](http://www.citiprogram.org/)

Describe any conflicts of interest related to this research here:

Are any researchers from organizations other than Grinnell College engaged in research? [ ] Yes [ ] No

If *yes*, please list the names of those researchers, their organization affiliation, their qualifications, and information related to the completion of human subjects protections training:

##  F. Does the project meet the federal (and Grinnell College) definition of human subjects research?

1. Does the activity involve a systematic investigation? [ ] Yes [ ] No *Systematic investigations* include the use of a predetermined, organized, and objective set of procedures that allow researchers to collect data, to answer research questions, or test hypotheses. Examples include most experiments, observational studies, interviews and focus groups, surveys, analysis of data and specimens, and epidemiological studies.
2. Is the activity designed or intended to develop or contribute to generalizable knowledge? [ ] Yes [ ] No The *generalizable knowledge* criterion reflects a design and an intention on the part of the researcher(s) so as to have an impact on others beyond the individual, group or situations being studied. The actual sharing of results is not required.

Examples of activities that are not generalizable are biographies, oral histories, course evaluations, classroom exercises solely to fulfill course requirements or train students in the use of particular research methods or devices, and program evaluation or quality assurance activities designed to improve the quality or performance of a program or department.

1. Are you seeking to obtain private information about participants? [ ] Yes [ ] No *Private information* includes information about the individual participant (e.g., behavior, attitudes, opinions) that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). If you are collecting ***facts*** that are not particularly sensitive or private from participants you may check “No” for this question.
2. Are you collecting data through intervention or interaction with participants? \* [ ] Yes [ ] No *Intervention* includes both physical procedures by which data are gathered and manipulations of the participant or the participant’s environment that are performed for research purposes (e.g., experiments). *Interaction* includes communication or interpersonal contact between investigator and participant (e.g., interviews, focus groups, questionnaires, participant observation).

*\** If you are not obtaining data directly from a person but instead are working with a dataset from which you can identify a person, please check “Yes” for this question.

If you checked “**Yes**” for F.1, F.2, F.3, and F.4, proceed to Section G. Exemption Categories.

If this project is being submitted for evaluation for determination of **Not Human Subjects Research** (“No” checked for any of F.1, F.2, F. 3, or F.4), please briefly describe the purpose of the study, its procedures, and why this study should not be considered human subjects research (i.e., why “No” was checked above). Then, proceed to section I. Assurances prior to submission.

 **G. Exemption Categories** Eight categories of human subjects research are not subject to the requirements of the federal regulations. Research activities that ***only*** involve participants in one or more of the following categories may qualify for exemption.

* The word ***only*** means that non-exempt activities are not involved. Research that includes exempt and non-exempt activities is **not** exempt.
* Studies involving prisoners cannot be exempt. Studies involving children may not be exempt under Category 2 when the studies involve interviews, surveys, or educational testing.

## Please check any/all that may apply: Category 1

The research is conducted in established or commonly accepted educational settings ***and*** is studying normal educational practices, such as (i) research on instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research must not adversely impact students' opportunity to learn required educational content.

|  |  |
| --- | --- |
| 1. Does this exemption apply? [ ] Yes [ ] No |  |
| **Category 2** |
| **I will be conducting surveys on adults.** | [ ] Yes | [ ] No |
| **I will be conducting interviews with adults.** | [ ] Yes | [ ] No |
| **I will be observing people at a public place/venue.** | [ ] Yes | [ ] No |
| **I will be administering standardized educational tests on adults.** | [ ] Yes | [ ] No |

## If yes is checked for one or more of the above, please read and answer the question for the exemption:

Exemption category 2 exempts research that includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if *at least one* of the following criteria is met:

* 1. The information obtained is received and recorded by the investigator in such a manner that the identity of the human subjects ***cannot*** readily be ascertained, directly or through identifiers linked to the subjects; or
	2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
	3. The information obtained is received and recorded by the investigator in such a manner that the identity of the human subjects ***can*** readily be ascertained, directly or through identifiers linked to the subjects, but there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
1. Does this exemption apply? [ ] Yes [ ] No
	1. Which Roman numeral category are you relying on? [ ] (i) [ ] (ii) [ ] (iii)
	2. Is your data? [ ] Level 1 (Not sensitive) [ ] Level 2 (Mildly or somewhat sensitive) [ ] Level 3 (Sensitive) [ ] Level 4 (Extremely Sensitive)
	3. Who will serve as the data steward?
	4. If Roman numeral (iii) is checked, please describe how you will secure all research data:

## Category 3

The research involves the use of “benign behavioral interventions” on adults. They must be brief in duration, harmless/painless, not physically invasive, not offensive nor embarrassing. Examples might include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

1. Does this exemption apply? [ ] Yes [ ] No

## Category 4

The research is “secondary research,” i.e., the study of identifiable data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

1. Does this exemption apply? [ ] Yes [ ] No

**Note:** Grinnell College does not normally/regularly use exemptions 5-8. These include directly working with a federal agency to examine one of its programs (exemption 5), food tasting (exemption 6), or the establishment, management, or use of a data or biospecimen archive at the College (exemptions 7 & 8). If you believe one of these exemptions may apply to your research, please contact the Grinnell College IRB.

*If none of the Exempt categories apply, proceed to Section H. Protocol Information.*

If one or more of the Exempt categories apply, describe your study procedures and the risks of participation. Please also attach any relevant study materials (e.g., surveys, interview questions) and consent documents. Then, proceed to Section I. Assurances.

##  H. Study information for non-exempt studies

1. Study Overview*. Please give information about the purpose, rationale, and scientific or disciplinary significance for the project, including background and references.*
2. Study Procedure*. Please briefly describe the procedure that the participant will experience, from start to finish. Provide a description and copies of stimuli, tasks, or interview questions, where appropriate.*
3. Study participants.
	1. Describe and justify participant inclusion and exclusion criteria.
	2. Will any special populations be involved?

Prisoners [ ] Yes [ ] No

Adults unable to consent [ ] Yes [ ] No

Cognitively impaired [ ] Yes [ ] No

Pregnant women [ ] Yes [ ] No

Wards of the state [ ] Yes [ ] No

Individuals who are not yet adults (infants, children, teenagers) [ ] Yes [ ] No Victims of sexual assault and/or abuse (\*see waiver info below) [ ] Yes [ ] No Other vulnerable populations (specify): [ ] Yes [ ] No

*\*For a waiver of the mandatory reporting requirement for victims of sexual assault and abuse, review the policy titled,* Research Exemption to the Reporting Responsibility of Employees*. Then, complete submit the form* Application for Waiver of Mandatory Reporting Requirement *along with this protocol proposal*.

* 1. If you checked “yes” for any special population listed in question H.3.c, please describe additional protections that will be put into place to ensure that the rights and welfare of such groups are protected. CITI training modules are available and may be required to assist researchers in considering the special needs of vulnerable populations.
	2. Will identifiers be collected and recorded in your research notes? [ ] Yes [ ] No Check the box next to each identifier you will be collecting for the research.

[ ] Name [ ] First Name Only [ ] Last Name Only [ ] First and Last Name

(Select for name only when it is linked to or stored with other study data. If names are collected and stored in a separate location from study data, do not select name above.)

 [ ] Unique ID numbers: Student ID, Health Plan Beneficiary or Medical Record Number

[ ] Account Number, etc. [ ] Certificate/License Number
[ ] Address [ ] Vehicle Identifiers

[ ] City [ ] Device Identifiers

[ ] County [ ] Web Universal Rouse Locators (URL)

[ ] Precinct [ ] Internet Protocol (IP) Address Numbers

[ ] Zip Code [ ] Biometric Identifiers (including finger or voice prints)
[ ] Telephone Number [ ] Full Face Photographs and Comparable Images

[ ] Fax Number [ ] Other Unique Identifying number, characteristic or code

[ ] Email Address [ ] All dates that are directly related to an individual (e.g., date [ ] Social Security Number of birth, graduation date, admission/ discharge date)

* 1. Is there a reasonable possibility that participants’ identities could be ascertained from any combination of information in the data? [ ] Yes [ ] No

If yes, please describe:

* 1. Will participants’ identities be kept confidential when results of the research are disseminated? [ ] Yes [ ] No
1. Recruitment procedure. *Check and include all that apply.*

[ ] Advertisement [ ] Flyer [ ] Telephone script [ ] Recruitment letter
[ ] Invitation to participate [ ] Questionnaire (including orally administered) or surveys
[ ] Interview/focus group guide [ ] Posting on bulletin board (e.g., PSELL) [ ] Other (describe below):

* 1. Description of recruitment procedure:

*Provide attach any oral or written recruitment information (e.g., flyers, email, oral script) that you will use.*

1. Incentive, compensation, and reimbursement. Please describe your incentive, compensation, and reimbursement strategies (e.g., nature of payment, method, timing, restrictions). Please note that credit or payment should accrue as the study progresses and not be contingent upon the participant completing the entire study. Also note that incentives and compensation may be considered taxable income (see Grinnell College IRB policy for *Incentives, Compensation, and Reimbursement of Expenses Associated with Participation*).
2. Risk. *Minimal risk means that the probability and magnitude of harm, hazards or discomfort anticipated in the research is not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Consider physical, psychological, social, legal and economic risks when making this determination.*

Do you consider risks to the participants to be minimal? [ ] Yes [ ] No Please address the issue of risks to the participant. Discuss how you are guarding against any harm that might come to the participants.

1. Deception. If your project uses deception, how do you justify this practice? How will you debrief the participant? Note: not disclosing the hypotheses before data collection is not considered deception, but presenting a different hypothesis than the one actually being tested is considered deception. [Attach all debriefing materials.]
2. Benefits. Discuss the benefits (to participants, you, or the research field) resulting from your project. Because we are an educational institution, please describe educational benefits (as in debriefing participants about your hypotheses or methodology, research issues, or findings) that you will give to participants. Please note that incentives, compensation, and reimbursement are not considered benefits of participation.
3. Data Security. The Grinnell College IRB instituted a data security policy and will make a determination of the types of harms associated with a breach of security of your data. The IRB also will recommend minimum levels of data security protections upon approval of this research protocol. The data security levels are as follows.
* Data Security Level 1 (Public): Information that if disclosed would not harm participants. Examples: benign research information, research data that has been de-identified in accordance with applicable rules/laws, published research, etc.
* Data Security Level 2 (Sensitive): Information that if disclosed could cause risk of material harm to individuals if disclosed. Examples: personnel records, financial information, personally held attitudes and beliefs, some performance metrics, etc.
* Data Security Level 3 (Extremely Sensitive): Information that would likely cause serious social, psychological, reputational, financial or legal harm to individuals if disclosed. Examples: individually identifiable educational records, medical information, genetic information, information on legal/immigration status, social security number, etc.

*See the Grinnell College IRB Data Security policy for additional details and definitions.*

1. Is your data? [ ] Anonymous (no identifiers collected) [ ] Non-Anonymous
2. Is your data? [ ] Level 1 (Public) [ ] Level 2 (Mildly or somewhat sensitive) [ ] Level 3 (Sensitive) [ ] Level 4 (Extremely Sensitive)
3. Who will serve as the data steward?
4. Please describe how you will secure all research data.
5. Informed Consent. Please attach your informed consent document(s) to this proposal or as a separate attachment and describe your procedures for obtaining informed consent below.

*The Office of Human Research Protections requires certain elements for fully informed consent (CFR 45 §46.116). They also require that the participant or the participant’s legally authorized representative provide written consent (CFR 45 §46.117). Please document by checking the boxes below that your informed consent document has these elements. If you would like to request a waiver of informed consent for any of these elements, please provide your rationale below.*

[ ] A statement that the study involves research
[ ] An explanation of the purposes of the research

[ ] The expected duration of the participant’s participation
[ ] A description of the procedures to be followed

[ ] A description of any foreseeable risks or discomforts to the participant

[ ] A description of benefits to the participant or others that may reasonably be expected from the research

[ ] A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
[ ] For research involving more than minimal risk, an explanation as to whether any compensation will be provided and an

explanation as to whether any medical treatments are available, if injury occurs, and, if so, what they consist of or where further information may be obtained

[ ] An explanation of whom to contact for answers to pertinent questions about the research (typically the PI) and research participants’ rights (typically the IRB), and whom to contact in the event of a research-related injury to the participant

[ ] A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits, to which the participant is otherwise entitled

As appropriate:

[ ] Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent

[ ] The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant

[ ] Any additional costs to the participant that may result from participation in the research [ ] Identification of any procedures that are experimental

[ ] A disclosure of the appropriate alternative procedures or courses of treatment, if any,that might be advantageous to the participant

[ ] A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable

[ ] A statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation, will be provided to the participant

1. Waivers Associated with Informed Consent Process: If you are applying for a waiver of informed consent or a waiver of documenting the informed consent process, please complete the following.
2. *CFR 45 §46.116c:* An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:
	1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
	2. The research could not practicably be carried out without the waiver or alteration.
3. Does this waiver apply? [ ] Yes [ ] No
4. If “Yes,” provide your rational for this waiver of informed consent.
5. *CFR 45 §46.116d:* An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
	1. The research involves no more than minimal risk to the subjects;
	2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
	3. The research could not practicably be carried out without the waiver or alteration; and
	4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
6. Does this waiver apply? [ ] Yes [ ] No
7. If “Yes,” provide your rational for this waiver of informed consent.
8. *CFR 45 §46.117c:* An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
	1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
	2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

1. Does this waiver apply? [ ] Yes [ ] No
2. If “Yes,” provide your rational for this waiver of documenting informed consent.

**PLEASE PROOFREAD YOUR PROTOCOL BEFORE SIGNING BELOW.**

 **I. Assurances** Submission of a proposal to the Grinnell College IRB requires that the **principal investigator and research mentor** (required when PI is a student) **sign this** page indicating that they have read the definitions of “scientific misconduct” (below) and agree to the continuing responsibility for the ethical conduct of this research.

Scientific Misconduct

Scientific Misconduct shall be considered to include:

1. Fabrication, falsification, plagiarism or other unaccepted practices in proposing, carrying out, or reporting results from research;
2. Material failure to comply with Federal requirements for the protection of human subjects;
3. Failure to meet other material legal requirements governing research;
4. Failure to comply with established standards regarding authorship or publications;
5. Failure to adhere to issues of confidentiality as provided in the informed consent document, the study protocol, and as outlined in the Code of Federal Regulations (45 CFR 46) and Food and Drug Administration regulations (21 CFR 50).

## Investigator Responsibility

**The research will be carried out in accordance with the ethical principles from the Belmont Report, specifically with respect for persons, beneficence (kindness), and justice. I have completed all required training and I will conduct my study in compliance with all federal, state, and local laws and policies.**

**The information provided is a complete and objective representation of the research that I plan to undertake. If I want/need to make changes to my research plan, I will contact the IRB prior to making them.**

**I have read the definition of scientific misconduct and my continuing responsibilities to conduct the research as described. My signature attests to my agreement to conduct this study in such a manner that acts of scientific misconduct and conflicts of interest will not be committed, and I will adhere to the responsibilities described above.**

Electronic Signature of Principal Investigator Date Electronic Signature of Research Mentor (if student PI) Date