**Application of the Use Of Human Subjects**

**Part A: Application Information**

1. **Title of Study:**
2. **Principal Investigator**

**Name:** **Title:**

**Phone:** **Email:**

**Campus Address:**

1. **Research Personnel**

Please list all individuals that will have contact with human subjects or identifiable data. The principal investigator and all personnel must have completed CITI training within the last 3 years prior to submission.

|  |  |  |
| --- | --- | --- |
| **Name:** | **Role** | **Citi Training Date** |
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1. **Funding**

Note: If this research is associated with an active or pending research grant, attach a copy of the methodology section of the grant with this application.

How will this research be funded?

If the research is funded by an external sponsor, please complete the following information:

 Name of Funding Source:

 Status:

 If, funded, grant ID#

 Grant/Contract Title:

 Principal Investigator listed on Grant/Contract:

1. **Research Duration**

Estimated start date :

Estimated completion date :

**Part B: Research Overview**

1. **Brief Research Summary (please limit to one page)**

Please provide a brief (no more than one page) summary for a general lay audience that includes background, rationale, and hypothesis for the proposed research.

1. **Research Categorization**
2. Will the proposed research be conducted in a typical educational setting, involving normal educational practices, such as:

- research on regular and special education instructional strategies, or

- research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

If yes, please list the activities below

1. Are there activities (questionnaires, procedures, etc.) that subjects will perform regardless of their enrollment as a subject in the proposed research?

If yes, please list the activities below

1. Will the proposed research gather data using educational tests, survey procedures, interview procedures, or observation of public behavior in such a way that investigators will be able to identify subjects? (Either directly or indirectly)

If yes, please list the activities below

1. Are the subjects elected or candidates for public office?

If yes, please list the activities below

1. Will the research involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens that are publicly available or where the information is recorded by the investigator in such a manner that subjects cannot be identified by the investigators?

If yes, please list the activities below

1. **Location of Research**

Please indicate all locations where the proposed research will be conducted (i.e., room numbers, local address, institution, city, state, country, etc.)

1. **Research Subject Information**
	1. Number of Subjects
	2. Gender of Subjects
	3. Ages of Subjects
	4. Identify any of the following vulnerable populations that will be included in the proposed research.

|  |  |
| --- | --- |
| [ ]  Individuals under the age of 18 | [ ]  Institutionalized |
| [ ]  Pregnant Women | [ ]  Students Enrolled in Your Class(es) |
| [ ]  Prisoners | [ ]  Mentally Disabled Persons |
| [ ]  Economically Disadvantaged Persons | [ ]  Educationally Disadvantaged Persons |

* 1. If the proposed research will include a vulnerable population, as identified above, please provide justification for their inclusion.

* 1. Please provide a description of the subject population. Specifically explain the criteria that will be used to include or exclude potential subjects from participating in the proposed research.

* 1. Please provide an explanation and justification for the number of subjects (Part B, 4a) to be enrolled in the proposed research (e.g., power/sample size analysis, citation of comparable studies from the literature).

1. **Non-English Speaking Subjects**

In accordance with federal regulations, subjects cannot be excluded from research on the basis of race, sex, age, language, or disability status.

1. Will the proposed research likely recruit and/or involve subjects or parents/guardians of subjects who are not fluent in English?

If yes, please list the languages:

If yes, please submit an English version of the consent form AND a version of the consent form translated into the appropriate language(s) as attached documents in part E.

1. If you believe the proposed research requires the exclusion of a particular non-English speaking subject population please provide a justification and explanation below. (Note: investigator inconvenience and/or additional effort associated with producing bilingual documents will not be considered as an appropriate justification)

1. **Subject Compensation**
	1. Will subjects be compensated for participation?

If yes, please describe the form of compensation (i.e., cash, check, gift certificate, voucher, 1099, etc.) :

* 1. If compensation is monetary please provide the amount of compensation.

* 1. Please provide a brief justification for the form and amount of compensation provided to subjects.

* 1. Please describe when and how compensation will be provided to subjects.

* 1. Will compensation be prorated?

If yes, please describe how proration will occur.

* 1. For research involving students, will compensation be provided in the form of class credit to students that choose to participate?

If yes, describe how students who choose not to participate in the research may earn class credit. The alternative method to earn class credit should be comparable in time and effort required for research subjects to complete study tasks.

**Part C: Research Proposal**

1. **Research Question**

What do you intend to measure, observe, describe, demonstrate, confirm, etc. from the proposed research?

1. **Hypothesis**

If applicable, state your hypothesis for each of the research questions listed in Part C, 1

1. **Background and Significance (please limit to 1 page)**

This section should provide clear, logical and sufficient support from the scientific literature that provides a rationale for the proposed aims and hypotheses stated above.

1. **Subject Recruitment and Informed Consent**
2. Which of the following tools will be used to recruit subjects? (Check all that apply)

|  |  |
| --- | --- |
| [ ]  Posted/Distributed Flyer | [ ]  Third party/Non-Study Personnel/ Professional recruiters |
| [ ]  Classroom Announcement | [ ]  Website/Social Media/Online |
| [ ]  Email to Subjects | [ ]  Other:       |

1. Please describe the initial contact with potential subjects and the process to obtain their consent.

1. Have you attached the necessary consent forms with the application?

1. Have you attached a copy of all recruitment materials (i.e., scripts, flyers, screen shots of online material, etc.) with the application?

1. **Research Methods**
2. Write a complete description of all procedures involving human subjects in the proposed research. This description should encompass the experimental course of a subject from their entry into the study to their completion of the study.

1. Many studies use multiple instruments/questionnaires/surveys as part of the research methodology. If applicable to the proposed research, list each instrument/questionnaire/survey that will be administered to subjects and provide a rationale for the inclusion of each one.

1. Please indicate how many times human subjects will perform research activities.

1. How much time will each visit take?

1. What is the total time required for a subject to complete the proposed research?

1. Will the research include the use of existing data, research records, patient records, and/or human biological specimens?

If yes, please provide a description of the data and the source of the data

If the data has identifiable subject information associated with it, please describe how the data will be de- identified.

1. Will the research involve deception or less than full disclosure?

If yes, please justify the need for deception in the proposed research.

1. Will the research require accessing student educational records?

If yes, please describe the procedures you will employ to access the information. Specify the information you will request

1. Does the research involve audio/video recording or photography?

If yes, please describe how and in what situations the recordings/images will be used. If applicable, attach the video/photographic release form

1. Will subjects be followed after completion of the proposed research?

If yes, please explain.

1. Have you included a copy of all instruments, questionnaires, surveys, and/or interview questions to be used for this research in Part F of the application?

1. **Data Analysis**

Whether quantitative or qualitative, please provide a detailed description of the research design/statistical design and data analysis plan for the proposed research.

1. **Benefit to Subjects and Society**
	1. Please describe any benefits that research subjects will receive as a direct result of their participation in the proposed research. (Note: compensation is not considered a benefit)

* 1. Please describe how this research may provide benefit to scientific knowledge, a specific discipline, and/or society in general.

1. **Risks**

Generally, risk assessment in research considers the harm, trauma, discomfort, stress, or any other undesirable or untoward consequence of being a research subject whether anticipated or unexpected. Risk may take the following forms: physical, psychological, emotional, financial, and/or social. This list is representative but not comprehensive.

Please consider the following questions based on the experiences that subjects might encounter through participation in the proposed research.

1. Whether great or small, please describe the potential risks to subjects that participate in the proposed research.

1. What steps will be taken by investigators to reduce the aforementioned risks?

1. **Confidentiality**

The following questions address your efforts to maintain subject confidentiality in the proposed research. Protecting hard copy data may involve de-identification of data and secured storage locations and conditions. Protecting electronic data may involve a secure network, password access, and data de-identification/encryption.

1. Describe what type of hard copy data will be generated by the proposed research (i.e., notes, audio/video tapes, questionnaires, etc.).

1. Where will this hard copy data be stored and how will it be protected?

1. Describe what type of electronic data will be generated by the proposed research (i.e., computer files/ spreadsheets, questionnaires, images, video, audio/mp3 files, etc.).

1. Where will this electronic data be stored and how will it be protected?

1. How long will data from this study be maintained by the principal investigator?

1. Will raw data be made available to anyone other than the principal investigator and the immediate study personnel?

If yes, describe the rationale and procedure for sharing study data. Include a description of what will be shared and with whom. Specify the protections in place to transfer the data.

**Part. D Researcher Agreement and Signature Page**

 (A scanned copy of this page maybe submitted separately)

 The research study involves the use of human subjects. I understand the university's policy concerning research involving human subjects and by submitting this application I agree to:

[ ]  Obtain voluntary and informed consent of subjects who are to participate in this project.

[ ]  Report to the IRB any unanticipated effects on subjects which become apparent during the course of, or as result of, the experimentation and the actions taken.

[ ]  Cooperate with members of the committee charged with continuing review of this project.

[ ]  Obtain prior approval from the committee before amending or altering the scope of the project or implementing changes in the approved consent document.

[ ]  Maintain the documentation of consent forms and progress reports as required by institutional policy for three years.

[ ]  Safeguard the confidentiality of research subjects and the data collected when the approved level of research requires it.

Signature of the Principal Investigator­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_

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Investigator/Student Researcher’s Name Signature Department/Affiliation

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Investigator/Student Researcher’s Name Signature Department/Affiliation

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Investigator/Student Researcher’s Name Signature Department/Affiliation

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Investigator/Student Researcher’s Name Signature Department/Affiliation

*(Please add lines as needed)*

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Department Chair’s Name Department Chair’s Signature Date Telephone

# Additional Parts

Please attach the appropriate Parts as described below.

Applications that do not contain all of Parts A-D and all necessary Additional Parts will be returned to the applicant without a review.

Forms are available at <http://www.weber.edu/irb>

## Part E

* Consent documents
* Assent documents
* Parental permission documents
* Request for Waiver or Modification of Consent form
* Faculty Sponsor Form (If student lead research)

## Part F

* All questionnaires, surveys, interview questions, discussion questions

## Part G

* Letters of support from sponsoring institutions/organizations, if applicable
* Photographic Release
* Video Release
* Recruiting Materials (including scripts, flyers/posters, letters, screen shots of online recruiting materials, etc.)
* A copy of research grant methodology section, if applicable