

Application for Review

For IRB use only

Sub date:

Submit Only use <u>Adobe Acrobat</u> to fill out this form.

Save your application BEFORE submitting. When you select Submit, you will be taken to a secure login where

you can upload your saved application, along with any other documentation.

Submit electronic versions of this *Application for Review*, and all following material(s) that will be required to conduct your project by using the "submit" button. Incomplete applications will be returned.

- Recruitment Materials: Posters, fliers, and verbatim text/scripts that will be used to recruit potential participants
- Informed Consent, Parental Permission or Assent Forms
- Surveys, questionnaires, interview questions, measurement instruments, etc.
- CITI Completion report

Please email all questions to: irb@humboldt.edu

| PROJECT TITLE: |
|--|
| Proposed start date: |
| Responsible Faculty or Staff Member: |
| Name: Department: |
| Phone Number: E-mail: |
| CITI Training Complete / Date Completed |
| Student Investigator: (if student is primary investigator) |
| Name: Department: |
| Phone Number: E-mail: |
| Qualifications: |
| Responsibilities: |
| CITI Training Complete / Date Completed |
| Purpose of Project: (check all that apply) |
| Faculty Research Staff Research Graduate Research Undergraduate Research |
| Funded Research - Funding Agency: |
| Do you or anyone else plan on disseminating the information acquired from this project outside of the specified course classroom or the University? ONO OYES |
| If yes, please explain: |

Personnel: Please list **ALL** additional personnel who may interact with human subjects or have access to subjects' information or responses.

- Any student who may use the data for a thesis or project must be listed, if not student listed above.

- ALL personnel listed are required to complete the <u>CITI training</u> prior to submission.

| · . | | | | |
|---|--|--|--|--|
| Faculty Staff Student | Name: E-Mail: | | | |
| Qualifications: | | | | |
| | | | | |
| Responsibilities: | | | | |
| | CITI Training Complete / Date Completed | | | |
| Faculty Staff Student Qualifications: | Name: E-Mail: | | | |
| Qualifications. | | | | |
| Responsibilities: | | | | |
| | CITI Training Complete / Date Completed | | | |
| C Faculty C Staff | Name: E-Mail: | | | |
| O Student Qualifications: | | | | |
| Qualifications. | | | | |
| Responsibilities: | | | | |
| | CITI Training Complete / Date Completed | | | |
| For additional personnel please provide information in a similar format in an attached word document. | | | | |
| | Responsible Faculty or Staff Member Assurances | | | |
| The faculty or sta | aff primary investigator, or the faculty or staff member supervising student research is responsible for: | | | |
| □ Ensuring tha □ applicable; | t permission from outside institutions (e.g., tribes, hospitals, prisons, or schools) is obtained, if | | | |
| Ensuring the | e quality and accuracy of the written materials included in the Application for Review; | | | |
| · · · · · · | man Subjects in Research Training for all personnel who may interact with human subjects or have bjects' information or responses; | | | |
| Supervising | the conduct of research protocols submitted under their direction; | | | |
| | mpliance with all federal, state and local regulations, as well as Humboldt State University Irding the protection of human subjects in research; | | | |
| | any stipulations imposed by the Humboldt State University IRB; | | | |
| _ • | research data, including informed consent documentation of participants, in accordance with | | | |
| - | local, state and federal regulations; | | | |

Reporting to the Humboldt State University IRB immediately if there are any adverse events and/or unanticipated problems involving risks to subjects or others.

ACKNOWLEDGEMENT: By submitting this *Application for Review*, I verify that the information provided is complete and correct, and I accept the faculty and staff responsibilities listed above.

1. Lay Abstract of Proposed Research:

The abstract should be written in a manner that can be easily understood by someone who has no training in science, medicine or research. Avoid or define technical terminology. (2000 maximum characters)

| 2. Type of Data to be Collected: (check all that apply) | | | | | | |
|---|-------------|-------------|--------------------------------------|--|--|--|
| Interview Survey / Questionnaire | Focus Group | Observation | Experimental / Physical Intervention | | | |
| Secondary / Existing Data or Records | | | | | | |
| List Source(s): | | | | | | |
| Other: | | | | | | |

| 3. <u>Subjects:</u> | | | | | | | |
|---|---------------------------|--|--|--|--|--|--|
| Type of Subjects: | | | | | | | |
| Estimated number of Subjects: | Expected Age of Subjects: | | | | | | |
| Approximate total time commitment required from subjects: | | | | | | | |
| Will subjects be compensated? NOO YESO | | | | | | | |
| If yes, please describe the nature of the compensation and its influence on subject participation. Course credit, extra credit or payment are compensation, not a benefit. | | | | | | | |
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- 4. Description of Proposed Project: (no more than one page):
 Provide the scientific rationale and significance for conducting the project
 Provide the Research Question, Purpose or Hypothesis

5. Subject Recruitment and Selection:

- Describe how you will invite potential participants to volunteer for your project.
 - Submit all texts/scripts of oral or written invitations/explanations to recruit potential participants.
 - Submit all flyers and posters to recruit potential participants.
- Describe all characteristics that are relevant to being selected as a potential participant.
- Identify the source(s) from which potential participants will be recruited.
 - (e.g., hospitals, institutions, schools, classes, shopping malls, etc.)

6. <u>Vulnerable Subjects</u>: Select which, if any, of the following vulnerable subjects will be involved in your research.
 Pregnant women, human fetuses, neonates (see Federal Guidelines, <u>45CFR46 subpart B</u>)

Prisoners (see Federal Guidelines, <u>45CFR46 subpart C</u>)

Children (see Federal Guidelines, <u>45CFR46 subpart D</u>)

Not applicable to this project

If vulnerable subjects are involved, describe safeguards for each population.

7. Documentation of Consent: Indicate the type of documentation of consent. (check all that apply)

Informed Consent is obtained from the subject or the subject's legally authorized representative, and is required to be written at a 7th to 8th grade reading level.

- Submit Consent form with application.

Parental Permission: agreement of parent(s) or guardian(s) to the participation of their child or ward in the project.

- Submit Parental Permission form with application.

Assent: A child's affirmative agreement to participate in the project. Failure to object should not be construed as assent. Adequate provisions must be made for soliciting the assent of the children.

- Submit documentation of assent form with application.

Waiver of Documentation of Informed Consent. Under certain circumstances, an IRB may waive the requirement for the investigator to obtain a signed consent form.

- Provide your rationale for requesting this waiver in Consent Process.

Waiver of Informed Consent. Under certain circumstances, an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent.

- Provide your rationale for requesting this waiver in Consent Process.

8. Consent Process: Explain the process to obtain a legally effective informed consent of potential participants.

For Written Consent, Parental Permission or Assent: explain the consent process of potential participants.
 To request a waiver, explain the rationale for a waiver.

| 10. Benefits: D |)escribe any | benefits to the | PARTICIPANT | S which may | reasonably | be expected | from the proje | ect. |
|-----------------|-------------------------------|-----------------|------------------|--------------|----------------|------------------|----------------|------|
| - Course credit | t <mark>, extra credit</mark> | or payment are | a compensation a | nd should be | listed under I | Nill subjects be | compensated | ? |

11. Potential Risks: Describe any reasonably foreseeable risks or discomforts to the participants.

12. <u>Risk Management Procedures</u>: Describe procedures for minimizing potential risks.
 - Ensure that each potential risk listed above is addressed in this section.

- 13. Anonymity and Confidentiality: Explain how anonymity or confidentiality will be maintained.
- Anonymity: information obtained from participants in such a manner that subjects cannot be identified, directly or through identifiers linked to the participants, even to the person collecting the information.
- Confidentiality: intent to keep information obtained from participants secret

14. Data Storage, Security and Destruction: Describe the data security and storage process. - Indicate length of time data will be maintained, and how data will be disposed of.

15. Informed Consent Storage: Explain where Documentation of Consent will stored.

- Faculty or staff are required to retain Consent Documentation.
- Consent Documentation shall be retained for at least 3 years after completion of the research.
- All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner (see 45 CFR 46.115 (b)).