**Application for IRB Review**

*Projects which involve procedures that pose greater than minimal risk, or in which the principal purpose is to study vulnerable subjects, require additional provisions to ensure that the ethical principles of* ***beneficence****,* ***respect****, and* ***justice*** *are sustained. They also require IRB review to ensure that the additional provisions are adequate and appropriate. The purpose of this form is for investigators to describe these additional provisions for protecting the rights and well-being of the people being studied.*

***Applications for IRB review, together with all attachments, must be submitted electronically by a St. Olaf faculty or staff member via email to*** ***irb-administrator@stolaf.edu******.*** *Applications for review of projects with student investigators must be submitted by the faculty or staff project supervisor, because this significantly reduces the time needed to complete the review. Submission signifies that:*

* *Both the investigator(s) and the faculty/staff supervisor have completed the research ethics training appropriate to the features of the project;*
* *The supervisor has reviewed the ethics plan and accompanying attachments and believes that the project meets the ethical requirements of beneficence, respect, and justice as described in the St. Olaf document* [*Inquiries Involving People: Ethical Principles and Applications*](file:///C%3A%5CUsers%5Cbeld%5CAppData%5CLocal%5CTraining%5CEthicalPrinciplesAndApplications.pdf)*.*

*Investigators (and, in the case of student projects, faculty or staff supervisors) must receive notification that the IRB has reviewed and approved this application before they begin contacting potential participants or gathering data.*

**Project investigator(s)** *(names and email addresses)*:

**Project title:**

**Faculty/staff project supervisor** (for projects with student investigators):

**Course department and number** (if applicable):

**Federal agency, community partnership, or grant funding supporting this project (if applicable):**

**Application for IRB review submitted by:**

**Date(s) application submitted:**

**Certification of research ethics training** *(check all that apply)*:

|  |  |  |
| --- | --- | --- |
| **Documents/CITI Learner Group Courses** | **Investigator** | **Faculty/Staff Supervisor** |
| Inquiries Involving People: Ethical Principles & Applications (St. Olaf statement) | [ ]  | [ ]  |
| Investigations with Greater than Minimal Risk (CITI course) | [ ]  | [ ]  |
| Investigations of Vulnerable Populations (CITI course) | [ ]  | [ ]  |
| Investigations Conducted Abroad (CITI course) | [ ]  | [ ]  |
| Records-Based and Internet Investigations (CITI course)  | [ ]  | [ ]  |

***Attachments*** *(check and attach all that apply)*

[ ]  **Ethics Plan for Inquiries Involving People** (required for all IRB applications)

[ ]  **Data-collection instrument** (written questionnaire, interview questions, test, description of

procedure, observational coding sheet, etc.)

[ ]  **Recruitment/invitation text** (email message, letter, Psych 125 Research Participation study description, flyer, poster, oral announcement, etc.)

[ ]  **Information for Participants document or statement**

[ ]  **Documentation of Consent form or electronic acknowledgment text**

[ ]  **Authorization to Contact Prospective Participants form**, signed by appropriate individual

[ ]  **Other document(s)** *[list if applicable]*:

**1. Please indicate how you expect to interpret and apply the information you gather from or about the people you are studying in the conclusions you draw.** (Your response to this question affects the process the IRB will use to review your project.)

[ ]  **A.** I expect to draw conclusions only about the group from which I recruited potential participants (for example, the participants are St. Olaf students and conclusions will be drawn about St. Olaf students only)

[ ]  **B.** I expect to draw conclusions about a population beyond or in addition to the group from which I recruited potential participants (for example, the participants are students from one or more colleges and conclusions will be drawn about college students in general)

**2. How are you ensuring justice in the selection of potential participants, so that that no one is either unfairly burdened by the risks and costs of project participation, or unfairly excluded from the possible benefits of project participation?** [45 CFR 46.111(a)(3)]

An equitable distribution of the risks and benefits of project participation results from the following characteristics of the subject selection process:

* There is no coercion or undue influence involved in subject recruitment. [45 CFR 46.111(b)]
* The inclusion of a specific subject population, particularly vulnerable subjects who may experience different risks or costs than other subjects, is justified by the purposes and likely benefits of the project.
* The exclusion of a specific subject population is justified by the purposes of the project, is required by their need for greater protection, or will not result in their exclusion from project benefits.

**Please discuss the extent to which these characteristics are reflected in the criteria for subject selection:**

***For projects with greater than minimal risk***

*The purpose of this section is to supplement the information provided in the ethics plan concerning the way the project upholds the ethical principle of* ***beneficence****. The content of this section is guided by federal regulations at 45 CFR 46.111(a)(1) and (2). If the Ethics Plan indicates that this project poses no greater than minimal risk in any of the three categories discussed below (psychological, social/legal, or physical – Items 4-6), proceed to Item 8.*

**3. Please provide a brief summary of the scholarly research literature you reviewed in designing the procedures described in your ethics plan and this application for IRB review.** Include citations for your most important sources.

**4. In what ways does the project design minimize potential psychological risks to project participants?** Please check all that apply below and explain in the text box (4 I).

[ ]  **A.** Not applicable; this project poses no greater than minimal psychological risks.

[ ]  **B.** Questions or other procedures that pose psychological risk are limited to those essential to accomplishing the purposes of the project and warranted by the likely benefits of the project.

[ ]  **C.**  Questions are phrased to cause as little psychological disturbanceas possible.

[ ]  **D.** The method of data collection minimizes psychological disturbance (e.g., data are being collected through survey rather than through face-to-face interviews, the participants’ information will be anonymous, etc.).

[ ]  **E.** The Information for Participants statement indicates that some questions or other procedures may cause psychological disturbance (anxiety, depression, stress, feelings of guilt, feelings of shame, or loss of self-esteem)and that they are free to not answer them.

[ ]  **F.** The Information for Participants statement describes resources to alleviate any psychological disturbance attributable to project participation.

[ ]  **G.** Participants are debriefed *[describe if applicable]*:

[ ]  **H.** Other steps taken to minimize psychological risks *[describe if applicable]*:

**I. Please explain or elaborate on your responses to Item 4; you must show that you have checked the appropriate box(es) above:**

**5. In what ways does the project design minimize potential legal, social, academic, or economic risks to project participants?** Please check all that apply below and explain in the text box (5 G).

[ ]  **A.** Not applicable; this project poses no greater than minimal legal, social, academic, or economic risks.

[ ]  **B.** Information that could embarrass or harm a participant, or private information, is collected only insofar as such information is essential to accomplishing the purposes of the project and warranted by the likely benefits of the project.

[ ]  **C.** Identifiers (e.g., names, identification numbers, etc.) or identifying information (e.g., detailed demographic descriptors) are collected only insofar as such information is essential to accomplishing the purposes of the project and warranted by the likely benefits of the project.

[ ]  **D.**  Identifiers such as names, ID numbers, etc. are not recorded or are removed from other data about the participants, so the data in project records is anonymous.

[ ]  **E.** Identifiable information about individual participants will not be disclosed during any phase of the project without the participant’s consent, and the procedures for obtaining and documenting the participants’ consent assure that the investigator will honor the participants’ wishes.

[ ]  **F.** Other steps taken to minimize legal, social, academic, or economic risks *[describe if applicable]*:

**G. Please explain or elaborate on your responses to Item 5; you must show that you have checked the appropriate box(es) above:**

## **6. In what ways does the project design minimize potential physical risks to project participants?** Please check all that apply below and explain in the text box (6 G).

[ ]  **A.** Not applicable; this project poses no greater than minimal physical risks.

[ ]  **B.** Study procedures involving physical risk are limited to those essential to accomplishing the purposes of the project and warranted by the likely benefits of the project.

[ ]  **C.** The Information for Participants statement indicates that some study procedures may result in physical discomfort or injury and that participants are free not to participate.

[ ]  **D**. The Information for Participants statement describes resources to alleviate any physical discomfort or injury attributable to their participation.

[ ]  **E**. The investigator has completed appropriate safety and/or emergency training to enable study procedures to be carried out as safely as possible.

[ ]  **F**. Other steps taken to minimize physical risks *[describe if applicable]*:

**G. Please explain or elaborate on your responses to Item 6; you must show that you have checked the appropriate box(es) above:**

**7. Please review your responses to Items 4-6 in this application, and your response to Item 9 in your Ethics Plan. Is there anything you wish to add about the way in which your project design ensures that the risks of participation have been minimized and are reasonable in relation to project benefits?**

***For projects focused on the study of vulnerable subjects***

*The purpose of this section is to supplement the information provided in the Ethics Plan concerning the way the project upholds the ethical principle of* ***respect.*** *The content of this section is guided by federal regulations at 45 CFR 46, Subparts C and D. If your Ethics Plan indicates that this project is not focused on the study of any categories of vulnerable subjects, proceed to Item 15.*

**8. Please indicate which categories of persons you are studying in this investigation.** Check all that apply:

[ ]  **A.** Minors (children and adolescents under age 18)

[ ]  **B.** Adults (age 18 or older) whose decision-making may be compromised for reasons of mental illness, developmental disability, age-related dementia, or other condition

[ ]  **C.** Individuals who may be economically or educationally disadvantaged (e.g., recent immigrants, low-income persons, persons of color)

[ ]  **D.** Individuals in correctional institutions, health care facilities, or long-term care facilities

[ ]  **E.** Persons with physical conditions that may make some types of procedures riskier for them (e.g., pregnant women, persons with food allergies)

**9.** **Does your project require that you secure the informed consent of a parent, guardian, or other legally-authorized representative for some or all of the project participants?**

[ ]  **A.** Yes, because some or all of the participants will be one or more of the following:

* Minors (children and adolescents under age 18)
* Adults (age 18 or older) whose decision-making may be compromised for reasons of mental illness, developmental disability, age-related dementia, or other condition

[ ]  **B.** No, because minors and adults whose decision-making may be compromised are excluded from participation in this project. (If you checked this response, please skip to Item 14).

**10.** **If you checked Box A (“Yes”) in your response to Item 9, please describe below your procedures for securing and documenting the informed consent of parents, guardians, or other legally-authorized representatives** for those project participants for whom such consent is required. Address the following in your response:

* How you will determine which participants will require the informed consent of a legally-authorized representative
* How, in what form, and how long in advance, the legally-authorized representatives will receive project information
* How the informed consent of the legally-authorized representative will be documented
* The policies of the host organization (e.g., school, retirement community, or other institution), if any, concerning procedures for notifying and securing the informed consent of legally-authorized representatives, and how you ensured that your proposed procedures are consistent with these policies.

**11. Please indicate the documents you are attaching in support of your response to Item 10.** Check and attach all that apply:

[ ]  **A.** Project Information Statement for parents, guardians, or other legally-authorized representatives

[ ]  **B.** Documentation of Consent form for parents, guardians, or other legally-authorized representatives

[ ]  **C.** A copy of any policies of the host organization concerning procedures for securing informed consent of legally-authorized representatives

[ ]  **D.** A letter of support from an appropriate official or staff member in the host organization concerning the consistency of your proposed consent procedures with organizational policy or practice.

[ ]  **E.** Other documentation *[describe if applicable]*:

**12.** **If you checked Box A (“Yes”) in your response to Item 9, please describe below your procedures for securing and documenting the informed assent of project participants who cannot provide legally-effective consent.** Address the following in your response:

* How you will determine which participants should provide informed assent
* How, in what form, and how long in advance, the participants will receive project information, and how you will ensure that the information is comprehensible to them (e.g., you will ask a professional who works with this population to review your draft information)
* How you will document the informed assent of project participants who cannot provide legally-effective consent.
* The policies of the host organization (e.g., school, retirement community, or other institution), if any, concerning procedures for securing informed assent, and how you ensured that your proposed procedures are consistent with these policies.

**13. Please indicate the documents you are attaching in support of your response to Item 12.** Check and attach all that apply:

[ ]  **A.** Project Information Statement for participants who cannot provide legally-effective informed consent

[ ]  **B.** Documentation of Assent form for participants who cannot provide legally-effective informed consent

[ ]  **C.** A copy of any policies of the host organization concerning procedures for securing informed assent

[ ]  **D.** A letter of support from an appropriate official or staff member in the host organization concerning the consistency of your proposed assent procedures with organizational policy or practice

[ ]  **E.** Other documentation *[describe if applicable]*:

**14. Federal regulations state that when investigators study groups of people who may be “vulnerable to coercion or undue influence,” such as children, prisoners, or economically disadvantaged persons, the study should include additional safeguards to protect the rights and welfare of these individuals** [45 CFR 46.111(b); see Item 8 for a complete list of potentially-vulnerable subjects]. Please review your Ethics Plan and the additional information you have provided in this Application for IRB Review, and indicate below any additional safeguards other than those you have already described in those documents.

***All projects***

**15. Please use this space to provide any additional information not provided elsewhere in this application or in the project Ethics Plan.**