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**Ethics Plan for Inquiries Involving People**

**Section 1: All Projects**

*The St. Olaf Ethics Plan is designed to help investigators design and conduct an ethical inquiry that involves gathering information from or about people. Ethics Plans for projects with student investigators must be reviewed and approved by the student’s faculty/staff project supervisor. If the project requires advisory review or review and approval by the St. Olaf Institutional Review Board (IRB),* ***the* *Ethics Plan, together with all attachments, must be submitted electronically by a St. Olaf faculty or staff member via email to*** ***irb-administrator@stolaf.edu******.*** *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, Practical Applications, and Investigator Obligations*](http://wp.stolaf.edu/irb/files/2013/07/EthicalPrinciplesAndApplications.pdf)*.*

Please use and submit this form as a Word document, not a PDF. It will not convert to a Google Doc.

**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):**

**Date of this Ethics Plan submission:**

**Date on which you hope to begin recruitment and/or data collection:**

**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](http://wp.stolaf.edu/irb/files/2013/07/EthicalPrinciplesAndApplications.pdf)) | [ ]  | [ ]  |
| General Social and Behavioral Investigations ([CITI course](https://www.citiprogram.org/Default.asp)) | [ ]  | [ ]  |
| Investigations with Greater than Minimal Risk ([CITI course](https://www.citiprogram.org/Default.asp)) | [ ]  | [ ]  |
| Investigations of Vulnerable Populations ([CITI course](https://www.citiprogram.org/Default.asp)) | [ ]  | [ ]  |
| Investigations Conducted Abroad ([CITI course](https://www.citiprogram.org/Default.asp)) | [ ]  | [ ]  |
| Community-Based, Records-Based, and Internet Investigations ([CITI course](https://www.citiprogram.org/Default.asp)) | [ ]  | [ ]  |

***Reminder:*** *Training must be completed or renewed within 3 years of the project start date.*

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

[ ]  **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 oral statement**

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

[ ]  [*Authorization to Contact Participants*](https://wp.stolaf.edu/irb/files/2013/07/Authorization-to-Contact-Participants.docx) form, signed by appropriate individual (or email/letter from appropriate individual with clear approval)

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

**For deputized reviewers only** *(Deputized = You have had a Type 2 or Type 3 project approved within past 3 years and this is a Type 2 project.):*

[ ]  The faculty/staff project investigator or supervisor is a deputized reviewer for a project of this type and is submitting this Ethics Plan and attachments for IRB Administrator verification and filing.

[ ]  Although the investigator/supervisor is deputized, we would like the IRB to review this plan.

**Affirmations** *(check all that apply; each investigator should read)*

[ ]  I will consider the recommendations of the IRB’s review before I (or, if applicable, any of my student investigators) begin contacting prospective participants or collecting data

[ ]  The project required consultation with one or more individuals familiar with the group being studied, and I/my student investigator(s) sought appropriate advice and incorporated it into the ethics plan.

[ ]  I/my student investigators will carry out the project as described in the ethics plan.

[ ]  I will notify the IRB if the project changes in ways that would require changes to the provisions of the ethics plan.

***Project purpose, participants, and procedures***

1. **Project abstract.** What are the main research questions you are seeking to answer in conducting this investigation?What kind of information will you gather from/about people, and what methods will you use? What makes this project significant or worthwhile?

**2. Whom are you studying in this project?** *Check all that apply, and provide a brief description of the individuals from or about whom you will be collecting data.*

[ ]  **A.** Currently-enrolled St. Olaf students

[ ]  **B.** St. Olaf alumni

[ ]  **C.** St. Olaf faculty or staff

[ ]  **D.** Individuals who are not St. Olaf students, employees, or alumni

***Description of the individuals you will be studying:***

1. **Approximately how many individuals do you hope to gather information from or about in conducting this project?**

1. **How will you gather information from or about these individuals?** *Check all that apply, identify and/or briefly describe each instrument(s) (questionnaire, interview questions, test, etc.), and attach a copy of each you will use to gather information:*

[ ]  **A.** Written questionnaire

[ ]  **B.** Interview

[ ]  **C.** Focus group

[ ]  **D.** Observation of behavior or performance in a private setting

[ ]  **E.** Psychological or cognitive test

[ ]  **F.** Measurement of physical characteristics or administration of physical test

[ ]  **G.** Collection and analysis of physical samples (hair, skin cells, blood, saliva, etc.)

[ ]  **H.** Collection and analysis of artifacts (students’ written assignments, personal or educational journals, etc.)

[ ]  **I.** Analysis of information that was previously gathered by someone else, requiring no additional interaction with the individuals you are studying

[ ]  **J.** Observation of behavior or performance in a public setting (e.g., in a shopping mall)

[ ]  **K.** Other *(please describe)*:

***Beneficence: Protecting the well-being of the people you are studying***

1. **What risks, if any, could your method(s) of gathering information pose to the people you are studying?**  *Think carefully about the individuals who will be participating in your project, since different people may respond in different ways to the same question, test, or other procedure. Which of the following types of risks might your project pose for these individuals? Check all that apply and explain below:*

**Psychological risks** – *Make a selection if your method(s) of gathering information may cause participants to experience more stress, anxiety, depression, or feelings of guilt or shame than they would ordinarily experience in daily life. Please indicate whether your project includes:*

[ ]  **A.** Questions about personally-traumatic events

[ ]  **B.** Offensive or threatening questions

[ ]  **C.** Questions about attitudes, behaviors, experiences, or circumstances that may prompt strong feelings of fear, guilt, sadness, or shame

[ ]  **D.** Exposure to offensive, degrading, or frightening material

[ ]  **E.** Manipulation of the participants’ environment – isolation, negative messages, etc.

[ ]  **F.** Deception that causes distress once the subjects are debriefed

[ ]  **G.** Other

***If you checked any of the above boxes (5 A-G), please elaborate on the psychological risks posed by this project:***

**Legal, academic, or social risks** – *Make a selection if the information you are gathering is* ***not anonymous****, and the findings, if disclosed, could put a participant at risk of civil or criminal liability, or damage his or her financial standing, academic standing, employability, or reputation. Legal, academic, or social risks are posed by procedures that gather individually-identifiable information (that is, information that can be traced to a specific individual) about:*

[ ]  **H.** Illegal activities

[ ]  **I.** Activities or behaviors that violate institutional policies

[ ]  **J.** Activities or behaviors that violate social norms

[ ]  **K.** Activities, opinions or beliefs that could invite retaliation or other repercussions from others

[ ]  **L.** Circumstances that could harm a participant’s employability, such as a previous job loss or a health problem

[ ]  **M.** Behaviors that could harm a participant’s reputation, such as alcohol use or sexual behaviors

[ ]  **N.** Other

***If you checked any of the above boxes (5 H-N), please elaborate on the legal, academic, or social risks posed by this project:***

[ ]  **O. Physical risks** – *Select if your method(s) of gathering information may cause injury or physical discomfort beyond what would be experienced in normal daily activities.*

***If you checked Box 5 O, please elaborate on the physical risks posed by this project:***

[ ]  **P. None of the above** – *Select if your method of gathering information is unlikely to pose psychological, legal, academic, social, or physical risks of harm or discomfort beyond what people are likely to experience in normal daily activities.*

**If you checked any box in Item 5 other than 5 P, complete *Section 2: Type 3 Projects* below.**

1. **How much time will your project require from the people you are studying?** Please discuss any other costs they will incur from participation.
2. **What direct or indirect benefits, if any, will participants experience as a result of their participation?** Check all that apply and explain briefly below.

[ ]  **A.** Opportunity to reflect on or discuss significant issues

[ ]  **B.** Enhanced self-understanding

[ ]  **C.** Awareness of resources or opportunities

[ ]  **D.** Other benefits to participants

***Please elaborate:***

1. **What benefits to individuals or groups other than the participants may result from your project?**

[ ]  **A.** Contribution to the investigator’s knowledge and/or research abilities

[ ]  **B.** Contribution to organizational knowledge (for projects with organizational or institutional clients)

[ ]  **C.** Contribution to scholarship

[ ]  **D.** Other contributions *(please describe)*:

***Please elaborate.*** *For example, if you are surveying the clients of a community organization and are sharing results with the organization, you could discuss the value of the results to the organization’s work. If there are no direct benefits, consider indirect or community benefits, such as your own willingness to participate in other investigators’ projects in the future.*

1. **Review the information you provided above about the risks (if any), costs, and benefits (if any) of participation in your project, as you have described them above. Explain briefly why it is appropriate to ask others to participate in your project in view of these potential risks, costs, and benefits.** *For example, you can discuss the steps you took to minimize or eliminate potential harms and to limit the time commitment necessary to participate. You can indicate that gathering information directly from people is critical to answering the research questions you are investigating. You can discuss the nature of St. Olaf as a community of inquiry.*

     ***Respect: Honoring people’s rights to privacy, freedom, and self-determination***

1. **Please indicate whether a principal purpose of your investigation is to study any of the following categories of persons.** *The study of some of these categories of persons may involve additional measures for protecting their rights to privacy, freedom, and self-determination. Please check all that apply:*

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

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

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

[ ]  **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)

[ ]  **F.** Not applicable; my investigation is not focused on any of the above categories of persons

**If you checked any box in item 10 other than 10 F, complete *Section 2: Type 3 Projects* below.**

1. **How will you invite people to participate in your project?** *Check all that apply and explain briefly below:*

[ ]  **A.** Not applicable, because I am analyzing data that has already been gathered.

[ ]  **B.** I will use public venues (e.g., posters or flyers in public spaces, ads in newspapers) to distribute information about the project and recruit participants

[ ]  **C.** I will post a description of my study on the Research Participation Sign-Up Sheet on the Psychology 125 Subject Pool Moodle site

[ ]  **D.** A third party (someone other than I) will provide prospective participants with information about the project

[ ]  **E.** I will send information about the project directly to the individuals I am inviting to participate, using email, campus mail, US mail, telephone, social media, or some other means of direct contact

[ ]  **F.** Other:

***Please elaborate on your method of recruitment, and be sure to attach the text of the email message, letter, Psych 125 Research Participation sign-up sheet, flyer, poster, oral announcement, or other communication you or your third-party contact will use to invite people to participate.***

1. **If you are contacting individuals directly with an invitation to participate, through email, campus mail, telephone, or some other means of direct communication, how will you make sure you do not violate their privacy in the method you use to contact them*?*** *In other words, what are you doing so that prospective participants don’t wonder how you got their email address or telephone number, and so you don’t share the prospective participants’ contact information with one another? Check all that apply and explain:*

[ ]  **A.** Not applicable, because I am analyzing data that has already been gathered, a third party is contacting prospective participants on my behalf, or I am recruiting participants in person.

[ ]  **B.** I will use contact information that is publicly available (a publicly-available directory, a list of individuals and contact information on a publicly-available website, etc.)

[ ]  **C.** I will use contact information that is not publicly-available, but that I am authorized to use (for example, you are the instructor of a course and you are administering a questionnaire to your students, or you are a member of an organization and you are interviewing other members of the organization, or I am enrolled in a psychology course and will seek approval to post a Research Participation sign-up sheet on the Psychology 125 subject pool Moodle site).

[ ]  **D.** I will use contact information that is not publicly-available, but that I have been given appropriate permission to use (for example, a course instructor has given permission to contact students in her course and has supplied a course email alias, or a non-profit organization staff member has collected names and telephone numbers from interested clients of the organization and, with their permission, has provided them to you).

[ ]  **E.** Other:

***Please describe your method of contacting prospective participants and how you will ensure that their contact information is not shared with anyone else*** *(for example, if you are using email, you will create an email alias rather than using individual usernames). If you checked Box 12 D, attach a completed Authorization to Contact Prospective Research Participants form.*

1. **Will participants receive incentives, inducements, or rewards for participation** (e.g., satisfaction of a course requirement, extra credit, refreshments, gift certificates, monetary compensation)?

[ ]  **A.** No

[ ]  **B.** Yes *[describe if applicable]*:

1. **Does your project require you to secure the informed consent of the people you are studying?** *To answer this question, please review your response to Item 4.*

[ ]  **A.** No; I am analyzing data that has already been gathered (Box 4 I) or observing public behavior (Box 4 J). *If you checked this box, skip to Item 17.*

[ ]  **B.** Yes; I am administering a survey or test, conducting interviews or focus groups, observing private behavior, or engaging project participants in some other way.

1. **If you checked Box 14 B, you need to provide specific information about your project to your prospective participants so they can make an informed decision about whether to participate. Please indicate below how you will provide this information to your prospective participants, and make sure that the information is incorporated in the attachments to this Ethics Plan.** Please use the [Project Information for Participants worksheet](http://wp.stolaf.edu/irb/files/2013/07/ProjectInformationForParticipantsWorksheet.docx), available on the Research Ethics website, to prepare this information for your participants.The project information needs to address all the items in the worksheet, and it needs to be in language that your prospective participants can understand.

[ ]  **A. Orally:** I will provide the Information for Participants orally *[please attach the Information for Participants statement you will provide orally].*

[ ]  **B. In writing** *[required for projects with greater than minimal risk]***:** I will include the Information for Participants material in the following documents *[please check and attach all that apply]:*

[ ]  **1. In my written recruitment/invitation message**

[ ]  **2. In my data-collection instrument (survey, test, etc.)**

[ ]  **3. As a stand-alone document:** I will provide an Information for Participants document separately from the recruitment message but before participants begin participating (answering questions, taking tests, etc.)

[ ]  **C. Other** *(please describe)*:

**16. How will you document that your participants have received and understood the project information and consent to participate?**  *The requirements for documenting consent depend on the characteristics of your investigation. Please check the appropriate box and attach your Documentation of Consent form or statement, if applicable.*

[ ]  A. No documentation: If a project poses no greater than minimal risk (indicated by checking Box 5 P, “none of the above”), no documentation of consent is required (though participants will still receive project information as described in my response to Item 15 above). Those who participate after receiving project information are assumed to have consented.

[ ]  B. Electronic documentation: When data are being gathered entirely through electronic means, the process requires participants to confirm electronically, prior to their participation, that they have read the project information, had the opportunity to receive answers to any questions, and consent to participate. [Required for electronic data collection procedures that include items posing greater-than-minimal risk.]

[ ]  C. Paper documentation: Prior to their participation, participants will indicate that they have read the project information, had the opportunity to receive answers to any questions, and consent to participate by signing two copies of a consent form and keeping one copy for themselves (attach Documentation of Consent form). [Required for greater-than-minimal risk projects involving face-to-face interaction between the investigator and the participants; paper documentation also may be helpful for recording participants’ preferences with respect to the sharing of individually-identifiable information.]

[ ]  D. Oral documentation: If a signed Documentation of Consent form could increase risk for participants (by providing an identifiable record of participation or particular responses), consent may be provided orally and will not be documented in writing. [May be desirable in some greater-than-minimal risk projects.]

**17. How will you keep the data you are gathering secure while you are conducting your investigation, so that others who are not conducting or supervising this project will not have access to it?** *In order to protect the privacy of your participants, you need to ensure that no one other than you, your co-investigators (if any), and your instructor or supervisor (if applicable) will have access to the raw data (survey or interview responses, test results, etc.) as you are gathering it.**Please check all that apply:*

[ ]  **A.** Paper records (e.g., handwritten notes from interviews) will be kept in a locked file or room

[ ]  **B.** Electronic records will be stored on the St. Olaf network with restricted access (e.g., a shared drive or personal drive)

[ ]  **C.** Electronic records will be stored in a web-based “cloud” system (such as Google drive) with restricted access

[ ]  **D.** Electronic records will be stored on the hard-drive of a password-protected personal or office computer in a locked room (IT does not recommend storing sensitive data on any form of portable device, including USB flash drives, laptops, or other devices)

[ ]  **E.** Other (*please explain):*

**18. How will you keep the data secure after you have completed your project or report?** *What will you do with the raw data at the conclusion of your project?*

[ ]  **A.** I will shred or delete the raw data as soon as I have completed my project.

[ ]  **B.** I will shred or delete the raw data at the end of the academic year; in the meantime, I will keep the data secure as described in the preceding item.

[ ]  **C.** I will shred or delete the raw data when I am no longer a St. Olaf student or employee; in the meantime, I will keep the data secure as described in the preceding item.

[ ]  **D.** The data will not be destroyed, but will be archived in a secure location *(please explain)*:

[ ]  **E.** Other *(please explain)*:

**19. With whom will project results be shared?** *Check all that apply and provide a brief description of the dissemination plan. Please discuss tentative or aspirational prospects for dissemination as well as plans that are more certain.*

[ ]  **A.** Results will be shared only with St. Olaf College faculty, staff, and/or students.

[ ]  **B.** Results will, or may, be shared with audiences outside St. Olaf College (linked on a website, reported to an external organization, presented at a conference, submitted for publication, etc.)

***Please describe your dissemination plan:***

**20. What agreement are you making with your participants about whether others will be able to identify them in your reports about the results of your project?** *Review your document for informing your participants’ consent and check one of the following:*

[ ]  **A.** My participants will be asked to **permit their information to be identifiable** (so others may be able to identify them in any reports I disseminate), and I will secure their written or electronic consent to this identifiability.

[ ]  **B.** My participants will **provide their information** **anonymously**, so I will be unable to tell whose information is whose when I analyze and report the data, and I will be unable to provide identifiable information in any reports I disseminate.

[ ]  **C.** My participants will be asked to **provide their information confidentially**, so that even though I may be able to tell whose information is whose, I will not share that information with others; and I will agree to protect their identities in any reports that I disseminate.

[ ]  **D.** My participants will be invited to **choose whether their information will be identifiable or confidential**; each participant’s decision will be recorded in their written or electronic consent document, and I will honor each participant’s decision.

[ ]  **E.** Other *(please explain)*:

**21. How will you carry out the agreement(s) you are making with your participants about whether others will be able to identify them in your reports?** *Check all that apply:*

[ ]  **A.** I will only use identifiable information from participants from whom I have documented agreement to identifiability.

[ ]  **B.** My participants’ information is anonymous (see definition for Box 20 B), so I will be unable to provide identifiable information in any reports I disseminate.

[ ]  **C.** If I include any individual-level information in my paper, poster, presentation, or other reporting (for example, quotes from interviews or responses to survey questions), I will remove any potentially-identifying information for participants who have requested confidentiality

[ ]  **D.** Before analyzing the data, I will discard all identifying information from my records

[ ]  **E.** When analyzing the data, I will keep identifying information separate from the other information I gather from the participants

[ ]  **F.** I will not report any individual-level information (such as quotes) at all; results will be reported in aggregated (grouped) form only

[ ]  **G.** I will remove potentially-identifying information (e.g., demographic descriptors) from aggregated (grouped) data (particularly important for small and distinctive groups)

[ ] **H.** *(For student investigators)* I will ask my project supervisor to read a draft of my report or my presentation outline before sharing it with anyone else, to make sure that my report respects the agreements I made with my participants about the identifiability of their information.

[ ]  **I.** I will take the following additional steps *[please describe]*:

***Justice: Accounting for social patterns of power and privilege***

1. **Are persons from any of the following categories of “vulnerable populations” likely to participate in your investigation, even if they are not the principal focus of your project?** *For example, if you are administering a survey to college students or interviewing people who live in Hennepin County, your participants may include people who are not yet age 18, low-income people, or people whose native language is not English. Social patterns of power and privilege mean that such persons are considered “vulnerable” to additional risks, unfair pressure to participate in burdensome research, or agreement to participate without fully understanding what is being asked of them. Please indicate whether your participants may include any of the following by checking all that apply:*

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

[ ]  **B.** Individuals who may be economically or educationally disadvantaged

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

[ ]  **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)

[ ]  **F.** Not applicable; none of the above categories of persons will be included among my participants

1. **How does your investigation avoid unfair treatment of any of the vulnerable persons who may participate in your project?** *Check all that apply and explain as needed below.*

[ ]  **A.** Not applicable; none of the above categories of vulnerable persons will be included among my participants

[ ]  **B.** I evaluated and, if necessary, adjusted my project procedures (interview questions, test procedures, etc.) so they would not affect vulnerable persons any differently than they affect any other participants

[ ]  **C.** I made sure my Project Information was understandable for people of varying ages and backgrounds

[ ]  **D.** I conferred with an advisor with expertise or experience working with the types of vulnerable populations included in my study

[ ]  **E.** I made sure that any incentives included in my study are fairly available to all prospective participants and don’t create undue influence to participate

[ ]  **F.** Other:

***Please elaborate as needed:***

1. **Please provide any other information about the ways in which your project reflects the ethical principles of beneficence, respect, and justice.** If you are studying Individuals who are not St. Olaf students, employees, or alumni, please describe any assistance you received in planning your project from persons who are familiar with the group(s) you are studying and who could help you develop appropriate protections. You may also use this space to explain anything in your ethics plan that is not otherwise addressed.

**If any of the following apply, continue to Section 2. If not, please send this form and attachments to** **irb-administrator@stolaf.edu****. The email for student projects must be sent by the supervisor.**

* **Something other than 5 P is checked in Item 5.**
* **Something other than 10 F is checked in Item 10.**
* **This project has funding from an agency in** [**this list**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html)**.**

**Section 2: Type 3 Projects**

*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. (This review is also required for certain federally funded projects.) The purpose of this section is for investigators to describe these additional provisions for protecting the rights and well-being of the people being studied.*

**Federal agency, community partnership, or grant funding supporting this project (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)](https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-A/part-46#p-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)](https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-A/part-46#p-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***

(Complete if [Section 1, Item 5](#Item5) has a checkmark next to a letter other than P. If only 5 P is selected, skip to Item 8.)

*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)*](https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-A/part-46#p-46.111(a))*(1) and (2).*

**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. (Select only if Section 1, Items 5 A-G are unchecked.)

[ ]  **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. (Select only if Section 1, Items 5 H-N are unchecked.)

[ ]  **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. (Select only if Section 1, Item 5 O is unchecked.)

[ ]  **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 Section 1. 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***

(Complete if [Section 1, Item 10](#Item10) has a checkmark next to a letter other than F. If only 10 F is selected, skip the remaining questions.)

*The purpose of this section is to supplement the information provided in Section 1 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*](https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-A/part-46#p-46.301(a)) *and* [*D*](https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-A/part-46#p-46.401(a))*.*

**8.** **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? (Note: A and B may both apply.)**

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

* minors (children and adolescents under age 18)

*and/or*

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

 *Answer the remaining questions if A is checked.*

[ ]  **B** No, because minors and adults whose decision-making may be compromised are excluded from participation in this project.

 *Skip to item 13 if B is checked.*

**9.** **If you checked Box A in your response to Item 8, 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.

**10. Please indicate the documents you are attaching in support of your response to Item 9.** 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]*:

**11. If you checked Box A in your response to Item 8, please describe below your procedures for securing and documenting the informed assent of project participants who cannot provide legally-effective consent.** (For example, while parents or guardians provide informed *consent* for minors to participate, children may be expected to *assent* to participate. See [45 CFR 46.408](https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-A/part-46#p-46.408(a)).). 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.

**12. Please indicate the documents you are attaching in support of your response to Item 11.** 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]*:

**13. Federal regulations state that when investigators study groups of people who may be “vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons,” the study should include additional safeguards to protect the rights and welfare of these individuals** [[45 CFR 46.111(b)](https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-A/part-46#p-46.111(b))]. Indicate below any additional safeguards other than those you have already described.

**Thank you. Please send this form and attachments to** **irb-administrator@stolaf.edu****. The email for student projects must be sent by the supervisor.**