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**Project Information for Participants Worksheet**

In order to give “informed” consent to participate in a human subjects project, prospective participants need to know a number of things about a proposed project and their anticipated role in it. Federal regulations, as well as the [St. Olaf statement of ethical principles for Inquiries Involving People](http://wp.stolaf.edu/irb/files/2013/07/EthicalPrinciplesAndApplications.pdf), require investigators to **provide basic information about the project in an accurate and understandable way** [[45 CFR 46.116(a)]](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116). This basic information is provided in a Project Information statement, which is shared either verbally or (more often in writing) with each prospective participant before he or she consents to participate.

Since you can inform your participants in a variety of ways (i.e., in a written Project Information Statement, in the introductory paragraphs of a written questionnaire, in a verbal statement prior to an interview, etc.) this worksheet, in its current form, does not need to be given to your participants**.** Completing the worksheet will help you prepare the information you need to provide in whatever form you provide it, and will ensure that the information tells the participants everything they need to know.

Your Project Information statement should include the following (even for projects with minimal risk):

1. *Project purpose:* Provide a brief explanation of the purposes of the project (which may include fulfillment of a course requirement for student projects).

1. *Supervising faculty:* If the project is being conducted by students, provide information to that effect, along with the name and department of the faculty member under whose supervision the project is being conducted.

1. *Procedures:* Include a description of what the participants will be asked to do (complete a questionnaire, participate in a focus group, taste food substances, answer oral questions, etc.) and/ or how information will be collected about them (weighing, specimen collection, observation, etc.).

1. *Costs to the participants:* Write a description of likely costs, particularly the length of time participants will be asked to commit to the project, or other inconveniences they may experience.

1. *Risks to the participants:*If the project involves more than [minimal risk](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102), include a description of any reasonably foreseeable risks or discomforts the participant may experience. If there are no such risks or discomforts, no statement is necessary, although some investigators choose to include a statement indicating that there are no risks or discomforts anticipated.

1. *Audiences for dissemination:* Write a statement describing the audience(s) with whom project results will or may be shared. (If you are not sure whether results will be shared outside St. Olaf, you can use tentative language – “Results may be shared at professional conferences or in publications.”)

1. *Whether and to whom the participant’s involvement in the project would be disclosed:*If participation in a project would be disclosed to any others (even if personally identifiable information provided by the participant is not disclosed), write a statement describing such disclosure. Many investigators include an assurance of non-disclosure if no disclosure is planned.

1. *Whether the participant’s information will be identifiable and if so, to whom:*  Participants need to know whether anyone, including the investigator, will be able to determine who said or did what, or who experienced what. If so, participants will need to know which others, and how they will know (examining the original data? reading or listening to reports?). In general, project information should include a version of one of the following statements about the identifiability of the subject’s information. **Select the most appropriate statement from the list below and apply it to your human subjects project.**
   1. *The participants will provide their information anonymously.* If data are collected with no identifying information at all included with the participant’s data, so that *even the investigator cannot link the participant’s data to the participant’s identity*, then the project statement should indicate that participants will provide their information anonymously.
   2. *The participant’s information will not be anonymous, but will be protected/confidential.* This means that only the investigators and any affiliated researchers will be able to link the identity of a participant to his or her data, and they promise not to disclose the participants’ identities or information that could be linked with the participants. If the data collected from the participants include any identifying information (such as name, ID number, social security number, etc.) or demographic information that, when combined with other information, could permit participants to be identified, the project statement should describe how the investigator will ensure that no one else will be able to link the participant’s identity to the participant’s data. For example, the statement could indicate that all potential identifiers will be removed when the data are collected and/or reported, or that no individual-level data, or data from small groups with distinctive demographic features, will be reported.
   3. *The participant’s information will be identifiable to others, with the participant’s permission.* Some kinds of projects are designed so that participants’ identities may be disclosed to others, or linked with their information. In these cases, the project information statement must indicate that clearly and explain how and why that is likely to occur.

1. *Project benefits:*Include a description of any benefits to the participants (such as the chance to reflect on important topics), and/or to the wider community, which may reasonably be expected from the project.

1. *Voluntary nature of initial decision to participate:* Write a statement stating that the participant is free to choose to participate, or not to participate, in the project, and that the participant will not be penalized or lose any benefits to which the he or she may otherwise be entitled if the subject chooses not to participate.

1. *Voluntary nature of continued participation:* Include a statement that the participant is free to discontinue participation at any time over the course of the project, or to participate only in part (e.g., by choosing not to answer selected questions), even after having initially consented to participate, without any penalty or loss of benefits.

1. *Investigator contact information:*Finally, you must include complete contact information (name, telephone, email address at a minimum) for the investigator and, if appropriate, the investigator’s supervisor, for questions or concerns about the project.

1. If you have questions regarding your rights as a research subject, you may contact the St. Olaf College Institutional Review Board at [irb-administrator@stolaf.edu](mailto:irb-administrator@stolaf.edu). You may also contact the Institutional Review Board about any problems, complaints, or concerns you may have about this research study.