**Instructor’s checklist for review of informed consent document**

To accompany student’s informed consent document

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 Code of Ethics, 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.htm#46.116). This basic information is provided in a Project Information statement, which is shared either verbally or (more often) [in writing](http://www.stolaf.edu/academics/irb/Examples/WrittenConsent.htm) with each prospective participant before he or she consents to participate. An Information for Participants document should include the following:

* ***Project purpose:*** A brief explanation of the purposes of the project (which may include fulfillment of a course requirement for student projects).
* ***Supervising faculty:*** If the project is being conducted by students, a statement to that effect. The name and department of the faculty member under whose supervision the project is being conducted should also be provided.
* ***Procedures:*** A description of what the subjects 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 the subject (weighing, specimen collection, observation, etc.).
* ***Costs to the subjects:*** A description of likely costs, particularly the length of time subjects will be asked to commit to the project, or other inconveniences subjects may experience.
* ***Risks to the subjects, if any:***If the project involves more than minimal risk (see above), a description of any reasonably foreseeable risks or discomforts the subject 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.
* ***Audiences for dissemination:*** A statement describing the audience(s) with whom project results will be shared.
* ***Whether and to whom the subject’s participation in the project would be disclosed:* I**f the subject’s participation in a project would be disclosed to any others (even if personally identifiable information provided by the subject is not disclosed), a statement describing such disclosure. Many investigators include an assurance of non-disclosure if no disclosure is planned.
* ***Whether the subject’s information will be identifiable and if so, to whom:*** Subjects need to know whether anyone, including the investigator, will be able to determine who said or did what, or who experienced what. If so, subjects 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:
  + ***That the subject’s information will be anonymous:***If data are collected with no identifying information at all included with the subject’s data, so that even the investigator cannot identify the subject’s data as belonging to the subject, then the project statement should indicate that subjects will provide their information anonymously.
  + ***That the subject’s information will be confidential:***Although the subject’s information will not be anonymous, only the investigators will be able to link the identity of the subject to the subject’s data. If the data collected from the subjects include any identifying information (such as name, ID number, social security number, etc.) or demographic information that, when combined with other information, could permit subjects to be identified, the project statement should describe how the investigator will ensure that no one else will be able to link the subject’s identity to the subject’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.
  + ***That others may be able to link the subject’s identity to the subject’s information.***Some kinds of projects are designed so that subjects’ identities may be disclosed to others. In these cases, the project information statement must indicate that clearly and explain how and why that is likely to occur.
* ***Project benefits:***A description of any benefits to the subjects (such as the chance to reflect on important topics), and/or to the wider community, which may reasonably be expected from the project.
* ***Voluntary nature of initial decision to participate:*** A statement that the subject is free to choose to participate, or not to participate, in the project, and that the subject will not be penalized or lose any benefits to which the subject may otherwise be entitled if the subject chooses not to participate.
* ***Voluntary nature of continued participation:*** A statement that the subject 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.
* ***Investigator contact information:***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.