Skidmore College
Institutional Review Board
Informed Consent Guidelines

Prior to conducting research with human participants (except when the research involves only anonymous surveys, naturalistic observations, or similar procedures), researchers enter into a social contract with participants, clarifying the nature of the research and what participants can expect to experience during the course of the study. Participants are informed of all features of the research that might influence their decision to participate. Researchers are to respect participant decisions to decline or discontinue participating in the research at any time for any reason and without penalty. Where possible, researchers make reference to participants' rights along these lines in their consent forms.

The IRB may approve a consent procedure that does not involve a written consent procedure when:

1. The research involves no more than minimal risk

2. The waiver does not adversely affect the rights and welfare of the participants

3. The research could not be carried out in any other way practically

4. Whenever possible, participants will provide additional information and/or consent after participating (e.g., releasing use of video)

Whether or not a written consent form is required by the IRB, it is the researchers' responsibility to protect human participants' rights and welfare at all times, including their right to have enough information about the study to make an informed decision as to whether or not they want to participate.

Websurveys: Some research may meet the above conditions, but utilize a websurvey for data collection. In those cases, a brief statement of how confidentiality and privacy will be handled must appear in a concise consent statement at the beginning of the survey. Implied consent (i.e., consent given by completing the survey) is acceptable for low-risk research.

Except under the conditions above, researchers are required to obtain written informed consent from all adult participants. Investigators are required to provide potential adult participants with sufficient information and opportunity to consider that information. Every written consent form should obtain a statement of participant rights.

Basic elements of consent forms are summarized below:

1. Introduction: This should include an invitation to the participant to participate, a statement that the study involves research, and who is conducting the study.

2. Background: This should include the purpose of the study, relevant research questions, and brief background information on research that has been done in the area. All research terms should be well defined, the key elements of the research process indicated, and any experimental drugs or devices explained (if applicable).

3. Duration: Participants should be informed of an estimate of the total amount of time the participant would expect to be involved in the study.

4. Procedures: Explain tasks and procedures from the participant's point of view. Describe what the participant will be required to do in lay terms. If applicable, explain how participants are assigned to groups, including an explanation of the term "random assignment." For survey research, indicate that not all questions have to be answered If applicable, identify additional procedures due to "research" participation (e.g., data collection instruments) separate from "treatment" (e.g., intervention) procedures. Be sure all procedures are explained and terms defined at an eighth-grade level. Note: if data are collected through a websurvey, set up the survey so that questions can be skipped (i.e., it is not acceptable to require a response before moving on to the next question). This can be handled by offering an alternative response category of "I choose not to answer".

5. Risk/Benefits: Honestly explain risks, hazards, or discomforts, including the likelihood of risk. Describe any benefits to the participant and to society. If there are significant risks in participation, tell participants under what conditions the study will be terminated. If applicable, identify the risks associated with being in the control group. Describe any inducement/compensation the participant will receive for participation.

6. Confidentiality: Indicate how the data will be kept confidential and limitations to confidentiality. Specify how long data will be retained until they are destroyed. If tape recordings or videotapes are to be made, explain who will have access and if they will be used for educational purposes, and when they will be destroyed.

   Websurveys: If data are collected through a websurvey, be careful not to guarantee confidentiality or anonymity. Online transmissions do have the potential for security breaches. Researchers who use websurveys should explain to participants that e-mail and the Internet is not 100% secure and that all reasonable measures have been taken to protect their identity and responses (e.g., the highest level of encryption available such as SSL encryption, which is what is used by financial institutions, IP addresses are not collected). Researchers should encourage participants to (1) use a private computer instead of a public one, and (2) clear the cache and browser history to protect their privacy after completing the websurvey. Finally, for websurveys, researchers should explain to participants how the data will be stored (e.g., in a password protected database).

7. Voluntary Nature of the Study: A statement that participation is voluntary, and that refusal to participate (or the decision to discontinue participation) will not lead to any penalty or loss to which participants are otherwise entitled. This section should specify that the participant may discontinue participation at any time without penalty.

   Websurveys: Web-based surveys must allow participants to withdraw from the study at any time. At the end of the survey, offer participants the choice to submit their responses or not. If they choose not to submit their responses, the websurvey should be set up so those responses are not saved to the server.

8. Contacts and Questions: An explanation of whom to contact for answers to relevant questions about the research and/or participants' rights, and whom to contact in the event of an injury related to the research.

9. Compensation: Include a statement regarding compensation for injuries for studies involving physically invasive procedures.

10. Statement of Consent: Provide a signature line for the participant and the person who is consenting the participant. Add a signature space to document assent of children to participate in the study. Parental signatures are still required. Give participant a copy of the signed consent form.

    Websurveys**:** If data are collected through websurvey, state that completion and return of the survey indicates consent to participate. In low-risk research, it is acceptable for participants to be instructed to click on a link if they give their consent to participate in the study.

Additional elements of the informed consent form might include the following:

a. A statement that the procedure(s) may involve risks that are not currently anticipated;

b. References to circumstances under which the researcher may discontinue the participant's involvement without consulting the participant himself or herself;

c. Reference to any additional cost to the participant that may result;

d. A statement that significant new findings developed during the course of the study may relate to the participant's willingness to continue involvement.