Guidelines for Preparing Consent Form(s)

Carefully read this document prior to creating your consent form(s) using the templates provided.

On the template, follow the instructions in the gray, bracketed areas and fill in your information. After adding your information, remove both the brackets and the shading. Save your consent form as a Word document and make sure to have your last name and a description of the document in the title, e.g., Smith Consent Form.

The new federal guidelines require that informed consent must begin with a "concise and focused presentation of the key information" that will help assist subjects in understanding the reason why they may or may not participate in the research. It needs to be organized and presented in a way that facilitates comprehension and ideally appear all on the first page. Include the following:

- *A statement that the project is research and participation is voluntary*
- *A summary of the research, including:*
  - *Purpose*
  - *Duration*
  - *List of procedures*
  - *Reasonable, foreseeable risks or discomforts*
  - *Reasonable, expected benefits to the participant*
  - *Alternative procedures or course of treatment, if any*

How a study team applies the "key information" requirement, and to what level of detail, will depend on the complexity of the research project. OHRP (2019) has stated that information included in the key information section does not need to be repeated later in the body of the informed consent form.

ADDITIONAL INFORMED CONSENT REQUIREMENTS:

1. A statement that the project is research and participation is voluntary (above, in Key Information)
2. Statement that the research is being conducted through St. John Fisher College.
3. Official name of any institution fully spelled out.
4. Explanation of the purpose of the research and the expected duration of the participant's involvement (e.g., how long will it take to complete the survey and number of questions).
5. Description of the procedures to be followed and identification of any procedures which are experimental.
6. Alternative procedures or course of treatment, if any.
7. Description of any benefits to the participant or to others which may reasonably be expected from the research. If there are no benefits to the participant, this should be stated.
8. Description of any reasonably foreseeable risks and discomforts to the participant, including loss of time.
9. Statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained, stored for how long, and how destroyed.
10. When your project will involve the collection of identifiable private information, the informed consent must include a statement indicating whether identifiers may be removed and de-identified information may or may not be used or shared for future research. Please note some professional organizations and/or journals now require indefinite, de-identified data sharing prior to submission for publication. If this applies to your research study, you must indicate this on the consent form.

11. For research involving more than minimal risk, an explanation as to whether any medical treatment is available if injury occurs; or counseling available for questions that might be sensitive, and if so, what they consist of, or where further information may be obtained.
12. Statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
13. Statement that participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
14. Name, phone number, and email information of whom to contact for answers to pertinent questions about the participant's rights, and whom to contact in the event of a research-related injury to the participant.
15. Statement that participant should keep a copy of the informed consent.

Please note the following items that should be included in any consent form if applicable to your project:

1. **Studies conducted in classrooms/school settings/institutions** When appropriate, include a statement that participation in the research will not affect participants' grades, services or class standing.
2. **Recording (audio and video)** If you are audio- or video-recording, you have two options.
   a) If you require participants to consent to the recording in order to participate, you should clearly state this in the consent form in the study description section.
   b) If it is acceptable for participants to refuse recording and still participate, you should include a separate section for recording information at the end of the consent form with a separate signature line for consent to the recording, as well as a description of how you will collect information without recording.
3. **Compensation for participation** Include the type and description of the compensation and the procedures to obtain compensation. Please note whether participants will receive compensation even if they don't complete the study.
4. **Referrals** If the study has the potential to cause physical or emotional distress, then you must direct participants to seek out an appropriate provider. If participants are SJFC students, then refer them to the SJFC Health and Wellness Center (385-8280). If participants are not SJFC students, then refer them to their healthcare provider or an appropriate agency.
5. **Focus Groups** Please include the following statement: "Confidentiality cannot be guaranteed in group situations. Other participants in your group will know how you answer questions. While we will discourage anyone from sharing this information outside of the group, we cannot guarantee confidentiality by other group members**.** We will do our best to keep all of your personal information private and confidential but absolute confidentiality cannot be guaranteed."

When working with minors:
If you will be working with minors, you must provide two separate forms: 1) an informed consent for parent/guardians; 2) a statement of assent for minors (17 years of age and younger).

If your proposed research can only be completed by waiving or altering the requirements above, please explain why in your proposal and include a debriefing procedure.