

## INSTRUCTIONS FOR CUSTOMIZING THE CONSENT FORM TEMPLATE

### For Use with the CMU IRB Consent Form Template

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Consent form templates are updated from time to time. Please check the Regulatory Compliance website (<http://www.cmu.edu/osp/regulatory-compliance/index.html>) for the most recent version of the template *before* submitting your IRB application.

The template includes the elements that are required to create a consent form for a minimal risk study. Standard language is in black text and should not be changed unless otherwise indicated. You may change the format of the consent document as long as the required elements are included.

Instructions for each section are provided below and provided on the template in [brackets and blue text] (please delete or type over all of the blue text before submitting your IRB application).

If you have any questions concerning the completion of this template or if your study involves special circumstances not addressed in this template please contact the Research Regulatory Compliance Office at 412-268-1901 or 412-268-5460.

**Please provide the IRB your proposed consent form electronically in Word format.**

#### Elements

- 1. Title:** This should match your project title. If the study has more than one consent form, please indicate here which group of participants the consent is for. It is important to be able to easily distinguish between the multiple consents.
- 2. Principal Investigator:** Insert the name and title of the principal investigator.
- 3. Faculty Advisor:** If the PI is a student, insert the name of the faculty advisor. Otherwise delete this section.
- 4. Other Investigators:** Insert the name and titles of other investigators involved in the study. If there are no other investigators, delete this section.
- 5. Purpose:** Provide a brief but detailed description of the purpose / goal of the study.
- 6. Procedures:** Describe the procedures to be followed in the study. Provide a detailed description of the procedures expected to be performed on or by the participants. Be sure to discuss any audio and/or video recording. Include the expected duration of the study and the location.
- 7. Participation Requirements:** List the requirements for participation in the study. For example, list the age range of participants, required physical conditions, required professional or educational credentials, etc. If your study involves minors, pregnant women, prisoners or any other protected class, please contact the Regulatory Compliance Administration at 412-268-1901 or 412-268-5460.
- 8. Risks:** All minimal risk studies involve risks and discomforts which are no greater than those ordinarily encountered in daily life or during the performance of routine physical or

psychological examinations or tests. Insert a description of the specific risks and discomforts associated with participation in the study.

9. **Benefits:** Describe any benefits the subject may receive from participation in the study. Describe direct benefits first, then include societal benefits if any.
10. **Compensation & Costs:** List any compensation provided. If applicable, list any costs to subjects that may result from participation in the research. If the study will continue over time, payments must be pro-rated. Describe the payment schedule here.
11. **Confidentiality:** Please confirm that the study complies with the standard language in this section. Describe any other affirmative measures taken to protect the participant's privacy and the confidentiality of research data. If applicable, explain how audio and/or video recordings will be kept confidential. If audio and/or video recordings will be shared with other investigators this must be done in a de-identified manner unless the optional permission discussed below is granted.
12. **Optional Permission:** Use this section only if you wish to present the audio and/or video recordings at a convention, in the classroom, or in some other public setting. Be sure the language covers all your intended uses. Delete this entire section if you do not plan to use audio and/or video recordings in this manner, or if there will not be audio or video recording in your study.
13. **Rights:** This is standard language for all consent forms. Do not alter this language.
14. **Right to Ask Questions:** Insert contact information for the principal investigator.
15. **Conflict of Interest:** In this section, disclose any conflict of interest, including but not limited to, financial conflicts of interest, which any researcher may have with the study. If there are none, please delete this section.
16. **Signature of participant:** If you are using this consent online, please remove the signature line and replace with an "accept or agree button". The consent should be written in a manner that tells the potential participant that by clicking the button, s/he acknowledge reading the consent and agree to participate in the study.
17. **Approval Footer:** (Study number, approval date, expiration date, and modification date): Please include this footer in your document. It will be populated by the IRB Office.