

Informed Consent Guidance: Behavioral & Social Science Research

- **Study Title:** Title of the study must match the title provided on the IRB application.
- **Researcher:** Provide the name of the Principal Investigator.
- **Sponsor:** If applicable, provide the name of the sponsor funding the research study.
- **Purpose of the study:** Provide a brief non-technical explanation of the purposes of the research. Explain why the subject is being asked to participate in the study (e.g., you are being asked to participate in this research study because...).
- **Study tasks or procedures:** Provide a complete description of procedures, including the order in which they occur, and specifically identify and distinguish any procedures that are “experimental” or being performed solely for research purposes from activities that would otherwise occur. Specifically state if the participants will be audio or videotaped, or if their educational or medical records will be accessed. Describe what the participant will be expected to do and fully explain any abbreviations or scientific terminology.
- **Duration of participation and study withdrawal:** Provide expected duration of the subject’s participation. Ensure that the proposed duration is realistic for the procedures to be performed (e.g., time required to complete surveys).

Indicate that the subject may choose to discontinue participation without penalty or prejudice.

Note: Standard language is provided on the consent template.

Explain potential outcomes of a participant’s decision to withdraw from the research (e.g., a participant who is an Ohio State student will receive extra credit for enrolling in the study even if he/she withdraws).

Note: Do not state that the investigator may withdraw participants if they do not follow study procedures, as participants are not in a position to know all of the study procedures.

- **Description of risks and benefits:** Provide a description of any reasonably foreseeable risks, stress, or discomforts. Explain the likelihood and seriousness of the risks, including potential physical, social, economic, psychological, and legal harms. Describe the precautions that are being taken to minimize the risks. Include additional resources (e.g., counseling centers) available for the participants.

When appropriate (e.g., for studies involving genetic testing), include the following language:

There is a small risk of health insurance discrimination based on genetic testing; however, per the Genetic Information Nondiscrimination Act of 2008 (GINA), group and individual health insurers may not use your genetic information to set insurance eligibility, premiums, or contribution amounts, nor can they request or require that you take a genetic test. In addition, employers with 15 or more employees may not use your genetic information to make decisions regarding hiring, firing, job assignments, or promotions, nor can they request, require, or purchase your genetic information. In Ohio, there is a similar state law that also provides some protection for private health insurance plans. GINA does not protect you against genetic discrimination by companies that sell life, disability, or long-term care insurance.

Provide a description of any benefits to the participant or to others that may reasonable to expect from the research, distinct from benefits subjects may receive if not participating. Consider potential benefits that may accrue to science or society in general as a result of the planned research. Assess the likelihood of benefits based on the protocol and ensure they are realistic for the research. Do not overstate potential benefits.

If applicable, insert the following language when no direct benefits to participants are expected:

You will not benefit directly from participating in the study.

Note: Describe any payments to participants in the incentives section.

- **Confidentiality of participants' records:** Add the following to the standard language on the consent template: A statement describing the extent, if any, to which the confidentiality of records identifying the participant will be maintained. Do not interchange the terms "confidential" and "anonymous." Discuss the disposition of participants' records following conclusion of the research. For research involving protected health information (e.g., medical records), provide a HIPAA research authorization or request for waiver.
- **Incentives provided:** Explain payments or other incentives (e.g., class credit) to participate, including amount and schedule of payments. Compensation should be pro-rated (e.g., per session) and not contingent upon study completion.

If payments will be offered, include the following language:

By law, payments to subjects are considered taxable income.

If payments will not be offered, insert the following language:

You will not be paid to participate in the study.

- **Participants' rights:** State that participants do not give up any personal legal rights by agreeing to participate. The following must also be included: participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled *and* subjects may discontinue participation at any time without penalty or loss of benefits.

Note: Standard language is provided on the consent template.

- **Contacts and Questions:** Provide contact information for the principal investigator and/or research staff for questions, concerns, or complaints about the study and for information about the availability of compensation. The person(s) listed should be knowledgeable about the research. As appropriate, provide provisions for emergency or after-hours contact.

Note: Add information to the standard language on the consent template.

Provide ORRP contact information for questions about participant rights and as a contact not part of the study team for participant concerns or complaints about the research. For research involving international participants, provide the ORRP toll number (614-688-4792) rather than (or in addition to) the toll-free telephone number, as appropriate.

Note: Standard language is provided on the consent template.

When appropriate, include one or more of the following elements:

- A statement that the treatment or procedure may involve risks (to the participant and/or embryo or fetus if the participant is pregnant) that are currently unforeseeable
- Anticipated circumstances under which participation may be terminated by the investigator without regard to the participant's consent
- Any additional costs to the subject that may result from participation
- Consequences of a participant's decision to withdraw from the research and procedures for orderly termination from participation
- A statement that significant new findings developed during the course of the research that may relate to subjects' willingness to continue participation will be provided
- The approximate number of participants involved in the study
- An explanation as to whether any compensation and whether any medical treatments are available if harm occurs, and, if so, what they consist of or where further information may be obtained (for greater than minimal risk research)
- Disclosures of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the participant (include the full range of available options for the participant, including the option of choosing not to participate)