Institutional Review Board
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CONSENT FORM GUIDE

NOTE: The consent forms in your approved IRBNet PACKAGE must be used. When creating or editing your consent form, please provide the most recent IRBNet package number at the bottom, right corner of the consent form. This ensures you are using the most "up-to-date" version of the form.

To find your IRBNet package number, go to the MY PROJECTS tab and click on the title of your project. In the PROJECT OVERVIEW page, your IRBNet package number will be listed at the top, next to your project title.

INSTRUCTIONS:

Please use the Consent Form Template to prepare your Informed Consent Form. The Consent Form Template includes prompts and guidance for all regulatory requirements for obtaining informed consent.

Italicized text found throughout the Consent Form Template offers guidance for completion. Edit this text with the appropriate wording for your project. When you are satisfied with your edits, highlight the entire text and click Ctrl + i to remove the italics.

PROJECT TITLE:

- This title should be the same as the project title used in the Initial Application.
- If there are multiple groups or phases to the study that will require more than one Consent Form, please add a sub-title, such as: Phase II, Focus Group, Survey Group, Pilot Study, etc. This will help the IRB during the review process and will help the PI and research team keep accurate research records.

PURPOSE:

- This section should clearly explain why this research is being conducted.
- Describe why the person reading the consent form is a possible research participant.
- Describe the knowledge or information that is being sought and explain why you are seeking the knowledge or information.

PROCEDURES:

- Describe the procedure(s) chronologically using lay language and short sentences.
- State the location where the study will be conducted.
- Explain medical and other technical terminology using simple language.
- State the overall duration for the subject's participation and, if appropriate, how long each procedure will take.
- If the research involves surveys or interviews, please include one or more sample questions.

POTENTIAL RISK/DISCOMFORTS:

- Describe any known or foreseeable risks including physical, psychological, social, emotional, legal and financial risks that may result from participating in the research.
- Risks should be stated by likelihood and severity or compared with natural risks that are understood by most participants. Use categories such as likely, less likely, unlikely, and/or rare.
- Some studies include risks that may be better described as things that could make the subject feel uncomfortable such as *fear*, *embarrassment* or *fatigue*. These are also examples of risks that should be included.
- If you will be asking the subject any sensitive questions (e.g. drug abuse, criminal or sexual activity), please indicate this and provide information on the topics that will be covered. In this circumstance, state: *You do not have to answer any question that makes you uncomfortable*.
- Do not describe risks as minimal and do not state that there are no risks beyond everyday life.
- Risks must be consistent with the risks described in the protocol.
- Unforseeable Risks: If applicable include a statement that the research (or a particular procedure) may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant) that is currently unforeseeable.
- All consent forms should list the risk of the *potential for the loss/breach of confidentiality.*
    - No Known Risks: If applicable, state the following: *There are no known risks associated with participating in this research project.*

POTENTIAL BENEFITS:

- List any direct and reasonably expected benefits to the subject.
- If no direct benefits, use the following language: *This research is not designed to help you personally, but the results may help the investigator learn more about….*
- Describe the overall potential benefits to science or society expected from the research, if any.
- **NOTE:** Monetary compensation and extra credit for courses are **NOT** benefits and must be described in the Procedures section.

CONFIDENTIALITY:

- Include a description of the procedures to maintain the confidentiality of the data, e.g. having locked filing cabinets and storage areas, coding collected data, using password-protected computer files, etc.
- For anonymous surveys, state that “the surveys are anonymous and will not contain information that may personally identify you.”
- For coded identifiable information, state the following, if applicable (1) your name will not be included on the surveys and other collected data; (2) a code will be placed on the survey and other collected data; (3) through the use of an identification key, the researcher will be able to link your survey to your identity; and (4) only the researcher will have access to the identification key.
- State who will have access to the research data.
- If there is a possibility that you will collect information on child abuse or neglect, abuse or neglect of the developmentally disabled or other vulnerable adults, danger to the subject or others, or similar types of information that may need to be disclosed to comply with

legal requirements, professional standards, etc., the possibility of such disclosure must be included in the consent form.

- Sample Text: *In accordance with legal requirements and/or professional standards, we will disclose to the appropriate individuals and/or authorities information that comes to our attention concerning child abuse or neglect or potential harm to you or others.*

MEDICAL TREATMENT:

- Please only include this section for research presenting greater than minimal risk. If you are keeping this section, delete the italicized text by right clicking on it and selecting "Delete Content Control".
- Remove this section for research involving no greater than minimal risk. To remove this section, first highlight the entire row, right click, and select "delete content control". Then, highlight the entire row again, right click, and select "Delete Row."

COMPENSATION:

- Please only include this section for participants receiving monetary compensation (not class credit).
- If participants refuse compensation, they may still participate.
- Remove this section if no compensation will be provided. To remove this section, first highlight the entire row, right click, and select "delete content control". Then, highlight the entire row again, right click, and select "Delete Row."

RIGHT TO WITHDRAW AND QUESTIONS:

- If applicable, include an explanation of any circumstances under which a subject's participation may be terminated by the investigator without regard to the subject's consent.
- If applicable, include an explanation of the consequences of a subject's decision to withdraw from the research and any procedures for orderly termination of a subject's participation.
- If applicable, please state the following: *"You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study."*
- If the study includes students, staff or faculty, please include the following*: "If you are an employee or student, your employment status or academic standing at UMD will not be positively or negatively affected by your participation or non-participation in this study."*

PARTICIPANT RIGHTS:

- Please do not modify this section.

STATEMENT OF CONSENT:

- If obtaining Written Informed Consent, please do not modify this section.
- If obtaining Online Informed Consent, please modify the following statements: "*You will receive **[may print]** a copy of this consent form. If you agree to participate, please sign your name **[type/click "I Agree/Consent"]** below."*
- If using the Consent Form Template as an Information Sheet, please remove this section.

SIGNATURE AND DATE:

- Please modify this section as it applies to your study.
- If obtaining Parental Consent for a Minor, please add a row to print the minor's name.
- If using the Consent Form Template as a combination Parent Consent/Minor Assent Form, please add rows to capture the minor's printed name, signature and date.
- If obtaining consent from a Legally Authorized Representative, please capture the printed name of the participant and include rows to capture the LAR's printed name and signature.

****If using fMRI, please download the fMRI Consent Form Template and fMRI Initial Application Template.**