**GUIDANCE FOR PREPARING CONSENT DOCUMENTS (consent form and/or information letter)**

*Note: it is not possible to address all scenarios for all types of studies conducted by AU researchers. This sample is designed to assist you in creating your consent document. It is intended to provide language preferred by the AU IRB to address the required elements of informed consent. In many cases, sample language will require modification, deletion, or expansion for your particular study.*

IF USING THIS GUIDANCE FOR THE FIRST TIME, READ ALL SHADED AREAS FIRST, AS THE FORMAT AND CONTENT OF THE DOCUMENT CAN VARY.

**Shaded paragraphs like this once are instructions for you, the writer. Do not include shaded sections in the document you submit. If instructions indicate specific language applies to your study, the specific language will be shown below the instructions outside the shaded paragraph.**

**Formatting Instructions**

* **Use 11 or 12 pt font.**
* **Write in 2nd person (i.e., you) and keep pronoun usage consistent.**
* **Use Page x of y on each page if this is a stand-alone document. Page numbers are not needed if the information is provided in the form of an email, etc.**

**Use understandable, non-technical language at an 8th-grade or lower reading level.**

* **Readability information can be displayed in Microsoft Word. Use Microsoft Office Help for “readability statistics” for further instructions.**

**Adaptation of content**

* **Consent in research takes many forms. This document provides content and formation for a physical (hard copy) document; however, researchers can use this sample to adapt the document to fit other common forms of obtaining participant consent such as an email, letter, telephone script or the landing page of an online survey hosting site.**

**Consent Form vs Information Sheet:**

* **If the research requires a written signature, the document should be labeled CONSENT FORM and include a signatures section.**
* **If NO written signature is required, the document should be labeled INFORMATION SHEET with no lines for participants’ initials and no signatures section. When an information letter is used, the application should include a waiver of consent documentation request.**
* **If adapting this sample for use as an email to participants, remove the document label and include the information and an introduction from the sender in the first section.**

**CONSENT FORM (or INFORMATION SHEET**)

**Title of Research:**

**Principal Investigator:**

**Faculty Principal Investigator: (if PI a student):**

**Sponsor (if externally funded):**

**RESEARCH INVOLVING CHILDREN – WHEN TO INSERT “FOR CHILDREN…” BOX:**

* When a parent or guardian is providing consent ONLY for a minor participant (17 years and younger) and that minor participant will sign the assent section of the consent form, do not use “you/your child” throughout the form. Instead, use “you” and insert the following text before the Purpose of the Research section.

|  |
| --- |
| **For children (persons under 18 years of age) participating in this study, the term “you” addresses both the child participants (“you”) and the parent of legally authorized representative (“your child”).** |

**RESEARCH INVOLVING CHILDREN – WHEN NOT TO INSERT “FOR CHILDREN…” BOX:**

* **When a parent or guardian is providing consent only for a child participant and that child participant will sign a separate assent form or will not provide written assent, use “your child” throughout the form.**
* **When a parent or guardian is providing consent form both him/herself and a child participant, specify throughout the document when the parent is referred to and when the child is referred to. This allows the use “you,” “your child,” and “you and your child” throughout the form when appropriate.**

**General Information**

**CONTENT GUIDANCE: *Review of a consent document by a potential participant is one part of the consent process; be concise and use more than one paragraph, if needed, to provide details of the study.***

**INTRODUCTORY PARAGRAPH**

* Introduce the Principal Investigator and (if applicable), Faculty Principal Investigator.
* Describe why the participant is being invited to join the study.
* In non-technical language, explain the purpose of the study.
* Give some background information so participants understand what issue(s) the research is attempting to solve or learn more about.
* State that the activities are for a research study; use the word “research” specifically.
* If collaborating with other institutions, provide information about that collaboration, including what, if any, data will be shared and how the data will be shared.
* Remind participants they may ask study staff questions at any time about any part(s) of the study.

**REQUIREMENT FOR A CONCISE SUMMARY: Mandated by revisions to the Common Rule, for studies reviewed via the Expedited Process and by the Convened IRB, the concise summary must include 7 elements that should allow a potential participant (a “reasonable person”) to review the summary and decide whether the study sounds like something they wish to participate. IF APPLICABLE, insert the Concise Summary table.**

|  |  |
| --- | --- |
| **General Information** | You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form. |
| **Purpose** | The purpose of the research study is… |
| **Duration of Procedures** | You will be in this study for… |
| **Overview of Procedures** | This study will include… |
| **Risks** | The most common risks include… |
| **Benefits** | You may or may not benefit… |
| **Alternatives** | If you do not want to take part in the study… |

**Purpose**

* In nontechnical language, explain the purpose of the research study.
* Describe why potential participants are being asked to enroll (why they are eligible).
* State the study involves research.
* State the total number of participants (individuals, records, specimens) to be enrolled by the AU investigator and, if a multi-site study, the total number.
* If a drug or device will be used, indicate whether they are FDA approved or investigational.

**Explanation of Procedures**

* In nontechnical language, describe study procedures, identify which procedures are for research purposes and which are for routine standard of care or educational procedures. Describe the procedures in chronological order, including the location of procedures, and, for example, if applicable, if “loose” clothing should be worn.
* If the research includes deception, describe general aspects of the deception and the de-briefing session to explain the true nature of deceptive procedures.
* To ensure ease of understanding, it is useful to bullet lists and to break long descriptions to smaller paragraphs.
* Include the anticipated time of involvement, for individual activities and for activities as a whole (exclude routine standard of care or educational procedures in the estimate).

**Incidental Findings**

* If imaging is included as part of the research, describe whether the imaging is solely for research purposes. If yes, then describe that the imagining is not intended for diagnostic or therapeutic purposes and researchers will not interpret the imaging or comment medically. If an electronic copy will be provided to participants, describe that option.

**Risks and Discomforts**

* Include any foreseeable risks or discomforts to participants (physical, social, financial, loss of employment, reputation, and breach of confidentiality).
* When possible, quantify the risks involved (frequent, common, occasional, rare, or percentages).
* To make information easier to read, use bulleted lists.
* If randomization to groups is part of the study, describe the randomization process and describe that being randomized to a group by chance may prove to have more or fewer benefits than the other study group.

**Confidentiality**

* Participants must be told the steps to protect their confidentiality (study data), including how data will be stored.
* Advise participants and who might receive study data (the AU IRB, sponsor (if applicable), FDA (if the study includes a drug or device) and any other(s).
* If the research will be covered by a Certificate of Confidentiality (CoC) from National Institutes of Health (NIH), a description of CoC protections for the research must be described.
* If the study procedures meet the definition of a clinical trial and will be registered at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), a description must be included.

**Benefits**

* Describe any potential benefits to participants or others that can reasonably expected from the research.
* Do not overstate benefits.
* If there is no potential for direct benefit to participants, that should be stated.

**Voluntary Participation and withdrawal**

* Include procedures for how participants can withdraw.
* If applicable, describe circumstances that would prompt PI to withdraw the participant (if study procedures are not followed, for example).
* Remind participants their choice to withdraw will not affect their relationship with AU, the department, etc.

**Compensation**

* If no compensation will be provided, state, “You will not be compensated for your participation.”
* If compensation is part of the study, provide specifics of the compensation (i.e., extra credit in an AU course, participation in a raffle, gift card, etc.) including how compensation will be distributed and when.
* If compensation will be prorated based on specified procedures, describe proration of compensation.
* If minors are participants, specify whether minors or parents/guardians will be compensated.

**Costs**

* If participants will not incur costs, state, “You will have no costs associated with participating in the study.”
* If participants may or will incur costs (i.e, data usage, etc), describe the costs and refer participants to contact their cellular provider or health insurance company, as applicable.

**Research-Related Injuries**

* Include this section only if the research involves greater than minimal risk or procedures or interventions that could result in harm or injury.

**Questions**

* Include the name of the Principal Investigator and their contact phone number and email address for participants to contact.
* If the Principal Investigator is a student, include contact information for the student PI and the faculty PI.
* For greater than minimal risk studies, include after hours contact information.

**Legal Rights**

* State that no legal rights are waived when a consent form is signed and/or participation is implied by participating.

**Signatures**

*It is not possible to address all scenarios for signature requirements needed for various types of research. In some cases, the Signatures section will require customization for the particular study population.*

* Requirements for signature lines depend on how the consent process is described in the application form.
* The entire signature section must appear on the same page; however, the signatures page does not need to be on a separate page, with no other information.
* If the research intends to obtain consent from the participant **OR** the Legally Authorized Representative (LAR), add “legally Authorized Representative” after “Signature of Participant.”