

# Sample Informed Consent Form

(Include or exclude the following information as applicable)

## INFORMED CONSENT STATEMENT

[List title of project here]

### INTRODUCTION

State that participants are invited to participate in a research study. State the purpose/objectives of the study.

### INFORMATION ABOUT PARTICIPANTS' INVOLVEMENT IN THE STUDY

List all procedures, preferably in chronological order, which will be employed in the study. Point out any procedures that are considered experimental. Clearly explain technical and medical terminology using non-technical language. Explain all procedures using language that is appropriate for the expected reading level of your participants.

State the amount of time required of participants per session and for the total duration of study.

If audio taping, videotaping, or film procedures are going to be used, provide information about the use of these procedures. (If applicable, please review the document entitled Videotape Guidelines.)

If you plan to include children in your study, please review the document entitled Special Considerations for the Protection of Children Participating in UT-Sponsored Research.

### RISKS

List all reasonably foreseeable risks, if any, of each of the procedures to be used in the study, and any measures that will be used to minimize the risks.

### BENEFITS

List the benefits you anticipate will be achieved from this research, either to the participants, others, or the body of knowledge.

### CONFIDENTIALITY

State that the information in the study records will be kept confidential. Data will be stored securely and will be made available only to persons conducting the study unless participants specifically give permission in writing to do otherwise. No reference will be made in oral or written reports which could link participants to the study.

\_\_\_\_\_ Participant's initials (place on the bottom front page of two-sided consent forms)

**COMPENSATION** *(If applicable to your study, add compensation information here)*

Indicate what participants will receive for their participation in this study. Indicate other ways participants can earn the same amount of credit or compensation. State whether participants will be eligible for compensation if they withdraw from the study prior to its completion. If compensation is pro-rated over the period of the participant's involvement, indicate the points/stages at which compensation changes during the study.

**EMERGENCY MEDICAL TREATMENT**

The University of Tennessee does not "automatically" reimburse subjects for medical claims or other compensation. If physical injury is suffered in the course of research, or for more information, please notify the investigator in charge (list PI name and phone number).

**CONTACT INFORMATION**

If you have questions at any time about the study or the procedures, (or you experience adverse effects as a result of participating in this study,) you may contact the researcher, [Name], at [Office Address], and [Office Phone Number]. If you have questions about your rights as a participant, contact the Office of Research Compliance Officer at (865) 974-3466.

**PARTICIPATION**

Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed your data will be returned to you or destroyed.

[**Note:** Please delineate the "Consent" section of the Informed Consent Form by drawing a line across the page. This delineation is especially important when your consent form grammar shifts from second person to first person, as shown in this example.]

**CONSENT**

I have read the above information. I have received a copy of this form. I agree to participate in this study.

Participant's signature \_\_\_\_\_ Date \_\_\_\_\_

Investigator's signature \_\_\_\_\_ Date \_\_\_\_\_

**Additional Notes to Investigators:**

1. Researchers are urged by the Committee to use the wording at the reading level of the participant and follow the format in the sample, unless researcher supported reasons are provided for alternative wording. Use of alternative wording or different format may slow down the review process. All sections of the consent form, except the "Consent Section" should be written in second person ("You are invited..."). Use of first person ("I") can be interpreted as suggestive and coercive.
2. Be sure to follow the directions for preparing the signature lines. Separate forms should be prepared when minors are used; one for the minors and one for the parents.
3. If your form is more than one page, there should be a line at the bottom of each page for the subject's initials, except for the last page where the signature is obtained.
4. Be sure to include any basic elements of informed consent that are appropriate to your study. If they apply to your study, they must be included. If you have any questions contact the Office of Research Compliance Officer at 1534 White Avenue or by calling (865) 974-3466.