

Generic Sample Informed Consent

RESEARCH SUBJECT INFORMED CONSENT FORM

Prospective Research Subject: Read this consent form carefully and ask as many questions as you like before you decide whether you want to participate in this research study. You are free to ask questions at any time before, during, or after your participation in this research.

This is a generic sample form to help you address most situations. Please adapt as appropriate for your research protocol and institution. *Pending rulemaking for classified human subject research will require additional elements of consent.*

Project Information	
Project Title:	Project Number:
Site IRB Number:	Sponsor:
Principal Investigator:	Organization:
Location:	Phone:
Other Investigators:	Organization:
Location	Phone:

1. PURPOSE OF THIS RESEARCH STUDY

- Include 3-5 sentences written in nontechnical language (8th grade reading level) *"You are being asked to participate in a research study designed to..."*

2. PROCEDURES

- Describe procedures: *"You will be asked to do..."*.
- Identify any procedures that are experimental/investigational/non-therapeutic.
- Define expected duration of subject's participation.
- Indicate type and frequency of monitoring during and after the study.

3. POSSIBLE RISKS OR DISCOMFORT

- Describe known or possible risks. If unknown, state so.
- Indicate if there are special risks to women of childbearing age; if relevant, state that study may involve risks that are currently unforeseeable, e.g., to developing fetus

- If subject's participation will continue over time, state: *“any new information developed during the study that may affect your willingness to continue participation will be communicated to you.”*
- If applicable, state that a particular treatment or procedure may involve risks that are currently unforeseeable (to the subject, embryo or fetus, for example.)

4. OWNERSHIP AND DOCUMENTATION OF SPECIMENS

- Describe ownership, use, disposal, and documentation (identification) procedures for specimens or samples taken for study purposes.

5. POSSIBLE BENEFITS

- Describe any benefits to the subject that may be reasonably expected. If the research is not of direct benefit to the participant, explain possible benefits to others.

6. FINANCIAL CONSIDERATIONS

- Explain any financial compensation involved or state: *“There is no financial compensation for your participation in this research.”*
- Describe any additional costs to the subject that might result from participation in this study.

7. AVAILABLE TREATMENT ALTERNATIVES

- If the procedure involves an experimental treatment, indicate whether other non-experimental (conventional) treatments are available and compare the relative risks (if known) of each.

8. AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES

- *“This study involves (minimal risk) (greater than minimal risk).”* In the event that greater than minimal risk is involved, provide the subject with the following information.
- If you are injured as a direct result of taking part in this research study, emergency medical care will be provided by [name] medical staff or by transporting you to your personal doctor or medical center. Neither the [your site name] nor the Federal government will be able to provide you with long-term medical treatment or financial compensation except as may be provided through your employers insurance programs or through whatever remedies are normally available at law.

9. CONFIDENTIALITY

- Describe the extent to which confidentiality of records identifying the subject will be maintained.

“Your identity in this study will be treated as confidential. The results of the study, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you.”

“However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor, by any relevant governmental agency (e.g., U.S. Department of Energy), by the(your site name) Institutional Review Board, or by the persons conducting this study, (provided that such inspectors are legally obligated to protect any identifiable information from public disclosure, except where disclosure is otherwise required by law or a

court of competent jurisdiction. These records will be kept private in so far as permitted by law.”

In addition, list steps to protect confidentiality such as codes for identifying data.

10. TERMINATION OF RESEARCH STUDY

You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate. You will be provided with any significant new findings developed during the course of this study that may relate to or influence your willingness to continue participation. In the event you decide to discontinue your participation in the study,

- These are the potential consequences that may result: (list)
- Please notify (name, telephone no., etc.) of your decision or follow this procedure (describe), so that your participation can be orderly terminated.

In addition, your participation in the study may be terminated by the investigator without your consent under the following circumstances. (Describe) It may be necessary for the sponsor of the study to terminate the study without prior notice to, or consent of, the participants in the event that (Describe circumstances, such as loss of funding.)

11. AVAILABLE SOURCES OF INFORMATION

- Any further questions you have about this study will be answered by the Principal Investigator:

Name:

Phone Number:

- Any questions you may have about your rights as a research subject will be answered by:

Name:

Phone Number:

- In case of a research-related emergency, call:

Day Emergency Number:

Night Emergency Number:

12. AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal

fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Participant Name (Printed or Typed):

Date:

Participant Signature:

Date:

Principal Investigator Signature:

Date:

Signature of Person Obtaining Consent:

Date: