

SAMPLE INFORMED CONSENT FORM

CONSENT TO PARTICIPATE IN RESEARCH

[Insert title of the study.] [If the study involves using different consent forms for different populations, identify the population group as the subtitle of the study.]

Suggested text:

You are asked to participate in a research study conducted at the *[Insert the study site]* by *[name(s) of investigator(s)]*. Your participation in this study is voluntary. You should read the information below and ask questions about anything you do not understand before deciding whether or not to participate.

Guidelines:

- *Use simple language.*
- *Be concise.*
- *Use the pronoun “you” consistently throughout*

(except for the signature of the subject on the last page).

PURPOSE OF THE STUDY

[State what the study is designed to discover or establish.]

PROCEDURES

Suggested text:

If you volunteer to participate in this study, we would ask you to do the following things:

Guidelines:

- *Describe the procedures chronologically using lay language, short sentences and short paragraphs. The use of tables or flow diagrams will help to organize this section and increase readability. Distinguish which procedures are experimental and which are standard clinical treatments. Include screening evaluations and a listing of inclusion/exclusion criteria. Define and explain medical and scientific terms in ordinary language (for example, describing the amount of blood to be drawn in terms of teaspoons or tablespoons).*
- *Specify the subject's assignment to study groups, the number of subjects expected to be enrolled, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of the procedures to be done, etc.*

- *For research involving randomization of subjects into different arms of studies, specify the randomization procedures.*
- *For research involving the use of placebo, describe “placebo” in lay terms*

POTENTIAL RISKS AND DISCOMFORTS

Guidelines:

- *Identify each procedure and then describe any reasonably foreseeable risks, discomforts, inconveniences, and how these will be minimized. Quantify risks using understandable comparisons.*
- *In addition to physiological risks/discomforts, describe any psychological, social, or legal, risks that might result from participating in the research. If screening involves drug screening, serologic HIV or hepatitis C testing, explain the extent to which data will be kept confidential. Address local or federal reporting requirements, if any. Inform the subjects about availability of follow up or referral for treatment.*

ANTICIPATED BENEFITS TO SUBJECTS

Suggested text:

[Describe the anticipated direct benefits to subjects resulting from their participation in the research. If consent will be obtained from a legal representative of the subject, the direct benefit to the subject must be elaborated in the consent form.]

Guidelines:

- *If there is no likelihood that participants will benefit directly from their participation in the research, state as much in clear terms. For example: “You should not expect your condition to improve as a result of participating in this research” or “This study is not being done to improve your condition or health. You have the right to refuse to participate in this study.”*
- *Do not include payment for participating in this section.*

ALTERNATIVES TO PARTICIPATION

Guidelines:

- *Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subjects decide whether or not to participate in the study. If there are no efficacious alternatives, state that an alternative is not to participate in the study.*

- *If the prospective subjects are suffering from a terminal illness, and there are no alternative treatments available, you should say so; but add that treatment of symptoms and pain control are available through supportive care. In other words, avoid suggesting that participation in the research is the only way to obtain medical care and attention.*
- *If prospective subjects have a chronic, progressive disorder, for which no treatment had been demonstrated to be safe and effective, say that, as well. But also describe opportunities for managing symptoms, improving ability to function, etc. so that it does not appear that the patient will be abandoned if he/she does not agree to participate.*

PAYMENT FOR PARTICIPATION

Guidelines:

- *Federal law, 24 USC 30, permits compensation for blood draws, not to exceed \$50 per blood draw, to be paid to “**On-Duty**” service members. A service member who is participating while “**On-Duty**” may only be compensated for blood draws, and may be otherwise compensated for research participation.*
- *Federal law, 24 USC 30, provides an exception to the Dual Compensation Act, which prohibits service members from being paid by any source other than regular military salaries while “**On-Duty**”. “**Off-Duty**” service members may be compensated in the same manner as non-military research subjects. “**Off-Duty**” service members therefore may be paid more than \$50 per blood draw, and may be compensated for research participation generally (not only for blood draws). *Note: Payment to “**Off-Duty**” service members for research participation other than blood draws must **not** be directly from a federal source (payment from a contractor or other non-federal source is permissible).*
- *Service members need to have Command permission to participate in research while “**Off-Duty**”. “**Off-Duty**” research participation may affect a service member’s ability to perform his/her military duties. Principal Investigators should confirm that a service member’s Commander supports the service member’s research participation.*
- *State whether the subject will be paid or offered other benefits (e.g., free care). If not, state so.*
- *If the subject will receive payment, describe remuneration amount, when payment is scheduled, and prorated payment schedule should the subject decide to withdraw or be withdrawn by the investigator.*
- *If the subject will be reimbursed for expenses such as parking, bus/taxi,, etc., state so*

MEDICAL CARE FOR RESEARCH RELATED INJURY

Note: The following is a required element of informed consent for research involving greater than minimal risk.

Suggested text:

For greater than minimal risk research involving private citizens, include the following statement: Other than medical care that may be provided, there is no compensation available for your participation in this research study; however, you understand this is not a waiver or release of your legal rights.

CONFIDENTIALITY

Suggested text:

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiotape recordings of you will be used for educational purposes, your identity will be protected or disguised. [*Describe how personal identities will be shielded, disguised, etc.*]

[When the research records may be subject to inspection by FDA, a funding agency, or an industrial sponsor, you must add:]

Authorized representatives of the CG, FDA, and the manufacturer of the drug [*or device*] being tested [*insert name of company*] may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

Guidelines:

- Give a brief description of how personal information, research data, and related records will be coded, stored, etc., to prevent access by unauthorized personnel.
- Explain how specific consent will be solicited, if any other uses are contemplated.
- If applicable, state if and when individual responses to survey questionnaires will be destroyed, following analyses of the data.

PARTICIPATION AND WITHDRAWAL

Suggested text:

Your participation in this research is voluntary. If you choose not to participate, that will not affect your relationship with (enter study site) or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice.

CONSEQUENCES OF WITHDRAWAL

(Note: If this does not apply to your research, please omit this entry and delete the heading.) [*Explain the consequences of a subject's decision to withdraw from the research and any follow up the subject may be asked to complete, for reasons of safety.*]

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

Suggested text:

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If you experience any of the following side effects [*list and describe*] or if you become ill during the research, you may have to drop out, even if you would like to continue. The investigator will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

NEW FINDINGS

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

IDENTIFICATION OF INVESTIGATORS

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact [*Identify the point of contact. Include the daytime telephone numbers and addresses.*]

For greater than minimal risk studies, include night/emergency telephone numbers.]

VOLUNTEER REGISTRY DATA BASE REQUIREMENTS

For all studies involving greater than minimal risk to subjects, the Volunteer Registry Data Base must be included in the consent form (see Commandant (CG-113) website – <http://www.uscg.mil/hq/cg1/cg113/default.asp>).

RIGHTS OF RESEARCH SUBJECTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the [*Insert name, address, and telephone number of the point of contact.*]

SIGNATURE OF RESEARCH SUBJECT

I have read the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

Name of Subject

Signature of Subject

Date

Address

SIGNATURE OF WITNESS

My signature as witness certifies that the subject signed this consent form in my presence as his/her voluntary act and deed.

Name of Witness

Signature of Witness

Date