

**CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL**

Study Title: *[Insert title of the study.]*

Principal Investigator: *[Insert name.]*

Funding Source: *[Insert name of company or agency.]*

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

Invitation to Participate and Description of Project

Suggested Text:

You are invited to participate in a research study designed to look at *[state what the study is designed to discover or establish.]* You have been asked to participate because *[explain briefly why the prospective subject is eligible to participate]*. *[If appropriate, state the approximate number of subjects or research sites involved in the study.]*

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

Suggested Text:

If you agree to participate in this study, you will be asked to *[describe the study procedures clearly, in roughly chronological order.]*

Guidelines:

- *Describe the procedures using lay language, short sentences and short paragraphs. The use of subheadings may help to organize this section and improve readability.*
- *Define and explain medical and scientific terms in ordinary language (for example, the amount of blood to be drawn should be given in terms of teaspoons, tablespoons, ounces or milliliters). A medical or scientific term, drug name, etc. may be used throughout the consent form once it has been explained in lay language.*
- *Distinguish clearly between any procedures that are experimental and those that are part of subjects' standard clinical care.*

Specify the subject's assignment to study groups, 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 groups, specify (and explain) the randomization procedures.*
- *For research involving the use of placebo, clearly define the term placebo.*
- *For research involving interviews, surveys, questionnaires, etc., clearly describe the content of the instruments. It may also be helpful to provide a representative sample of the types of questions subjects will be asked.*
- *For research involving review of subjects' medical record, the consent form should explain what types of information will be collected, and why.*
- *For research involving genetic or related testing, the consent form should describe the scope of the research that will be performed with subjects' DNA or tissue (e.g., cancer, aging, mental health, etc.) Alternatively, investigators may request completely unrestricted or open-ended current or future use of banked samples. If such a request is made in the application, the consent form should state in easily understood, plain language the wide scope of use that is being proposed.*
- *When relevant, any plans to return information to subjects, to medical records, to primary care physicians, or others must be made explicit in the consent form.*

This study has been/will be (choose whichever applies) registered in an online database for clinical trials that is run by the federal government. The purpose of this database is to allow everyone to see information on what studies are being done, and what studies have been done. The database will expand during the next year to require study results to be posted there as well. If you would like information about this study online or if you would like to see this online database you may view it at clinicaltrials.gov.

>If appropriate, add:

You will be told of any significant new findings that are developed during the course of your participation in this study that may affect your willingness to continue to participate.

Risks and Inconveniences

Guidelines:

- *Identify all reasonably foreseeable risks, discomforts or inconveniences associated with the study, and describe how they will be managed.*
- *When relevant, risks to pregnant women or to a fetus should be explicitly stated.*
- *In addition to physiological risks/discomforts, describe any psychological, social, legal or financial risks that might result from participating in the research.*
- *Risks should be listed in hierarchical order, from most likely to least likely to occur.*
- *Where such information is available, the consent form should state the likelihood of risks occurring. For example, "most subjects in a similar study had headaches and felt nauseous," or "10 out of 100 people who took drug X felt dizzy."*

- *If appropriate (e.g., if the research involves an experimental intervention or therapy), please include the following statement: “Participation in this study may involve risks that are currently not known.”*
- *Include only those risks that are associated with the research. Risks associated with standard clinical procedures that would be done whether or not the patient is in the study should not be listed.*
- *For studies involving investigational drugs or devices, the consent form should describe a means whereby information about the drug or device may be obtained in emergency situations.*
- *For research involving genetic or related testing, subjects must be informed of any risks associated with the genetic information that may result. Such risks could include reduced access to or retention of benefits or entitlements (e.g., insurance, educational opportunities, employment, etc.); stigmatization; psychological distress in response to information; or detection of biological relationships within a family.*

Benefits

Guidelines:

- *Describe any benefits that can be reasonably expected to result from the research. Please note that benefits include those that accrue directly to the subject (e.g., improved health outcomes), to the population the subject represents (e.g., a better understanding of the subject’s condition that may lead to new treatments), or to society at large (e.g., general advancement of scientific knowledge).*
- *If there is no likelihood that subjects will benefit directly from their participation, this should be stated.*
- *Financial rewards for participating in research are not considered a benefit, and should not be included in this section.*
- *Please note that, by definition, the benefits of research are unproven. Therefore, subjects should be told that participation “may,” rather than “will” yield benefit.*

Economic Considerations

Guidelines:

- *Describe any compensation that will be made to subjects (including direct monetary payment, payment in the form of a gift, or reimbursement for costs such as travel, parking, childcare, etc.), and the conditions for receiving this compensation.*
- *If payment will be prorated for subjects who do not complete the study, this should be clearly explained. If payment is conditional on completing the study, this should be clearly explained.*
- *Clearly describe the subject’s costs associated with participation in the research. If it is possible that research procedures or tests will not be covered by the subject’s insurance, health plan benefits, or other third party payers, this should be indicated.*
- *Clearly describe the parts of the research (drugs, tests, procedures, etc.) that will be provided at no cost to the subjects.*

- *Subjects may be offered an estimate of the charges they will be expected to cover.*

Treatment Alternatives/Alternatives

(Note: This paragraph is a required element of informed consent for all research involving treatment or therapeutic intervention. Certain non-treatment protocols may also require an “Alternatives” section detailing appropriate treatment or procedures that are available outside of the research. Investigators may also choose to state that the only alternative is to decline participation in the study. If the “Alternative Treatments” section does not apply to your study, you may omit this entry and delete the heading.)

Guidelines:

- *Describe any appropriate alternative therapeutic, diagnostic or preventive procedures that should be considered before the subject decides whether or not to participate in the study.*
- *Please note that alternatives are not limited to curative procedures. For chronic or terminally ill subjects, alternatives may include procedures for symptom management, improving the ability to function, or palliative care.*

Confidentiality

Suggested Text:

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. [*Describe the methods used to safeguard the confidentiality of subjects’ data (e.g., coding data or samples with numbers, storing research materials in locked cabinets, password-protecting data stored on a computer, etc.)*] When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

Representatives from the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

Guidelines:

- *Please state how long subjects’ data will be kept before it is destroyed or de-identified.*
- *If information will be released to any other party for any reason, identify the person/agency to whom the information will be furnished, the nature of the information, and the purpose of the disclosure. Examples include legal reporting requirements for child or elder abuse, or identification of reportable infectious diseases.*

- *When the research records may be subject to inspection by FDA, a funding agency, or an industrial sponsor, the following must be included: “Authorized representatives of the Food and Drug Administration (FDA) [or a funding agency, such as the National Institutes of Health] and the manufacturer of the [drug/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.”*
- *If the research involves audio or videotaping, describe the subject’s right to review or edit the tapes, and indicate when they will be erased.*

In Case of Injury

(Note: This paragraph is a required element of informed consent for all research presenting greater than minimal risk. It should also be used for minimal risk research that presents the potential for physical harm (e.g., research involving blood draws). If the “In Case of Injury” section does not apply to your study, please omit this entry and delete the heading.)

Suggested Text:

If you are injured as a result of your participation in this study, [*indicate whether treatment will be made available, and who will be responsible for its cost.*]

Guidelines:

- *For studies sponsored by for-profit entities, the sponsor is encouraged to provide funds for the treatment of injuries sustained as a direct result of participation in the research. Per HIC policy, sponsors should not agree to cover only those expenses not paid for by the subject’s insurance.*
- *Yale School of Medicine and Yale-New Haven Hospital do not provide funds for the treatment of research-related injury. If the study is sponsored by a non-profit entity (e.g., investigator’s own funds, federal funding, or a private non-profit organization), the following paragraph should be used: “If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.”*

Required Text: You do not give up any legal rights by signing this form.

Voluntary Participation and Withdrawal

Suggested Text:

You are free to choose not to participate and if you do become a subject you are free to withdraw from this study at any time during its course. If you choose not to participate or if you withdraw it will not harm your relationship with your own doctors or with Yale-New Haven hospital. [*If applicable: “We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment.”*]

The researchers may withdraw you from participating in the research if necessary. [*Describe the conditions under which a subject might be withdrawn from the research (e.g., progression of disease/poor response to treatment, development of serious side effects, or subject non-compliance).*].

Guidelines:

- *Subjects should be informed whether they will have the ability to withdraw their data from the research once it is collected, unlike tissue samples, which often can be withdrawn and destroyed, data derived as part of the research usually will not be covered by an option for withdrawal. If data or samples will be unable to be withdrawn (for example, if they have been anonymized), subjects should be apprised of this fact in the consent form.*
- *If there are medical needs required by the subject upon withdrawal, these should be stated. Any follow-up procedures or assessments accompanying the withdrawal should be clearly explained.*

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject: _____

Signature: _____

Relationship: _____

Date: _____

Signature of Principal Investigator

Date

or

Signature of Person Obtaining Consent

Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator [*cite name and full telephone number*]. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

*THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX
HAS BEEN COMPLETED BY THE HIC OFFICE*

<p>THIS FORM IS VALID ONLY THROUGH: _____.</p> <p>HIC PROTOCOL #: _____</p> <p>INITIALED: _____</p>
