

CONSENT FORM – GENERAL INSTRUCTIONS

- A. Consent Forms may be written in first, second or third person consistently throughout the form, with the exception of the signature section, which must be written in the first person (use language provided in the “Sample Consent Form”)
- B. When investigational drugs or therapies are used in a study, they must be referred to as investigational drugs or therapies. Include the IND number on the application. If experimental devices are used, an IDE must be included.
- C. Consent forms must be written in a manner comprehensible to someone with 9th grade reading skills. Technical terms and jargon must be reduced to lay language. No scientific or technical symbols can be used without explanation. The style must be similar to that used in popular news magazines and newspapers.
- D. "Louisiana State University Health Sciences Center Informed Consent Form" must appear at the top of the first page. The header must include "LSUHSC-N.O.," the IRB study number, the page number: "page x of x," and a version number or date that will clearly identify that version of the consent form since several revisions may occur over the course of the study. Use the header format with a smaller size font than the text. Footers must provide a line for subject's initials & study ID number. Examples of the header and footer format are included in the ICF template.
- E. Consent forms must be in the format provided, with section headings numbered and capitalized and in the order presented. If a section is not applicable to your study, indicate this by marking (N/A).
- F. Translations (for non-English speaking subjects) should be submitted after IRB approval of the final version of the English consent. The non-English version of the consent form must be accompanied by certification from a reliable source that this is a true translation of the LSUHSC-NO-approved consent form.
- G. The IRB may, for some or all subjects, waive the requirement that the subject or the subject's legally authorized representative must sign a written consent form if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. The exception to the informed consent process or a request to waive some or all of the elements of informed consent must meet all of the federal requirements for such exception or waiver. An investigator planning to request such an exception should refer to “Waiver of Informed Consent and Waiver of Documentation, Section 5.5, [IRB Policies and Procedures Guidebook](#)”. The request should be made separately in memo form. LSUHSC-NO does not participate in studies that require a waiver of informed consent for planned emergency research.

FORMAT INSTRUCTIONS – CONSENT FORM

1. **STUDY TITLE:** The complete title of the study must be used and must be identical to that of the research protocol. Indicate the protocol number and IND or IDE number if applicable.
2. **PERFORMANCE SITES:** Include the names of all institutions where LSUHSC-NO personnel will enroll subjects into the study.
3. **NAMES AND TELEPHONE NUMBERS OF INVESTIGATORS:** All investigators involved in the study, along with their telephone numbers, must be listed. Designate a 24-hour phone number and label it as such. Pager use must be explained.
4. **PURPOSE OF THE STUDY:** The first sentence must clearly state that this is a research study. There must be a clear statement that describes the difference between being a research subject and a person not involved in this study. State clearly what the study is designed to investigate. Provide the FDA status of any drug(s) or devices. Provide a rationale that explains why this therapy, research, survey, etc. is being done. Include a description of the type of subject that would be included; e.g., adult diabetics with hypertension. This section is a critical portion of the informed consent process as this conveys the essence of what is being studied and why. The importance of the research should not be overstated or exaggerated. It should inform the subject of the extent of the study, e.g., city-wide, state-wide, national or international. The total number of subjects to be entered must be included, with the locally anticipated number noted as well.
5. **DESCRIPTION OF STUDY PROCEDURES:** This section must contain a complete description of the procedures that are necessary to complete the study. All experimental procedures must be described and any related but non-experimental procedures must be stated. The subject's time commitment must be explained in terms of the length of time of the study, number of visits, and any other activities, e.g., diaries, telephone follow-up, etc., that the study will encompass. Use lists, tables and charts to show complex schedules and study designs. Provide the subject with the sequence of events for the study. This should be a chronology of the events that will take place from the subject's point of view. Describe the procedures to be followed, including their purpose, duration, frequency, and recovery time, if applicable. All drugs or devices must be described. Procedures for randomization of subjects should be explained, if applicable; this must include the chances of being assigned to a particular arm or strategy. If the study is to utilize a placebo, this information must be included, though individual subjects need not be informed as to whether they will actually receive the placebo. The term placebo must be defined in lay terms. Quantities of specimens such as blood should be described in terms familiar to the subject, such as teaspoons. If the study involves a survey, indicate that subjects may skip any questions which they do not want to answer.

If the study includes photography, video-taping, audio-recording, or use of other media the subjects must be told how their identity will be protected. Define permitted usages and detail disposition of these materials at the end of the study. Insert a signature block thus:

"I give my permission to be {photographed, video-taped, recorded}
___ Yes ___ No"

Insert a statement permitting the subject to review and edit the media. The subject must be told that the materials can be withdrawn by submitting a request in writing to the researcher.

The use of lay language is essential. The subject and the family must be able to get an overall picture of what will happen during the study, when it will happen and how long they could be involved.

6. **BENEFITS TO SUBJECT:** A fair, reasonably detailed and easily comprehensible description of any potential benefits that may result from the research should be simply stated. If the subject will receive no direct benefit, this should be explicitly stated. Stating that there is the possibility for future benefits to others is permitted. It is also permissible to state that a project may yield results that could possibly benefit a sub-population, e.g. HIV/AIDS patients, low-birth weight babies, etc.
7. **RISKS TO THE SUBJECT:** This section must include an adequate description of the risks so that subjects and their families can decide if they are willing to participate. Provide a fair, reasonably detailed and comprehensible description of any physical, psychological, and/or social risks or discomforts that might occur to the subjects as a result of the study. Potential behavioral and psychological risks, such as evocation of disturbing memories, being informed that one has a disabling condition, etc. must be listed. Indicate that counseling or a referral for counseling will be provided should a subject experience emotional distress.

Legal and social risks, risks to privacy, and the risk of breach of confidentiality must be stated, especially if positive results of HIV testing, genetic testing or confirmation of other health statuses are required for entry or as part of the study.

For clinical drug studies, the side-effects of each drug, device or procedure must be listed separately with the medical consequences of such an effect, e.g. lowering of white blood cell count that may result in an increase in infections. All known side-effects must be listed. It must also be pointed out that there is always the risk of previously unknown side-effects occurring.

The risk of blood draws, including pain or bruising at the site where the blood is taken, can occur. It must also be stated that some people feel lightheaded and may even faint. There is also a slight risk of infection.

Subjects must be warned that their condition may not improve or may worsen. If differences exist in risks between the treatment groups, these risks must be explained to all subjects. A statement must be included that participation in the study may involve unforeseen risks.

8. **ALTERNATIVES TO PARTICIPATION IN THE STUDY:** The following language is suggested:

"The alternative is not to participate."

Describe the alternative procedures or treatments that are available to individuals if they choose not to participate in the study. Any standard treatment that is available must be disclosed, with its relative risks and

benefits. The "option of no treatment" must be candidly presented to potential subjects if the research protocol is considered to be hazardous, unpleasant, or may cause a worsening of the quality of prolonged life. If no alternative treatment is available, this must be stated. If a drug or device is available for use outside the proposed protocol, that must be stated.

For studies that propose non-clinical protocols, state if there are other alternative actions such as private weight loss clinics, private counseling, special courses, etc.

9. SUBJECT REMOVAL: Subjects must be informed about the circumstances under which they might be removed from the study against their wishes. This includes, but is not limited to:
 - a. The subject's condition worsening, or the investigator feeling that the subject remaining in the study is not in their best interest
 - b. The subject being unable to keep appointments for study visits
 - c. Failure of the subject to complete study activities, e.g. keeping study diaries
 - d. The study being canceled by the investigator or by the company, etc

If subjects could be put at special risk by removal, they must be informed about those risks. This is particularly important in studies where discontinuation of therapy will likely result in continuation or progression of the disease.

10. SUBJECT'S RIGHT TO REFUSE TO PARTICIPATE OR WITHDRAW: The following language is suggested:

"Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You may refuse to participate or withdraw from the study at any time without jeopardizing, in any way, your medical treatment at this institution in the present or future. Tell the researcher if you are thinking about withdrawing from the study so that you may do so safely. If you decide not to continue participation in the study you should seek medical advice for alternatives. Should significant new findings take place during the course of the research that may relate to your willingness to continue participation that information will be provided to you."

Study subjects are free to withdraw at any time and cannot be required to provide a reason. They cannot be required to come for follow up visits. They should be informed that a reasonable effort will be made to contact them for a "close-out visit" for safety reasons. If subjects could be put at special risk by withdrawing, they must be informed of those risks.

If the study includes collection of samples from the subject, the subjects must be told whether their sample will be stored for future testing. Define permitted usages, length of time samples will be stored, and detail disposition/destruction of these materials. Insert a signature block thus:

"I give my permission for my samples to be stored
___ Yes ___ No"

Insert a statement permitting the subjects to withdraw their consent for storage of their samples by submitting a request in writing to the researcher.

11. SUBJECT'S RIGHT TO PRIVACY: The following language is suggested:

"The results of the study may be released to the funding agency. *[provide the name of the funding agency, if known]* If the results of the study are published the privacy of subjects will be protected and they will not be identified in any way. Your personal information may be disclosed if required by law."

12. RELEASE OF INFORMATION: The following language is suggested:

"Organizations that may inspect and/or copy your study-related medical records for quality assurance and data analysis include: the sponsor *[provide the name of the sponsoring agency, if known]*, the LSUHSC-NO Institutional Review Board, and the doctors listed on page 1 of this consent form and their staff. While every effort will be made to maintain your privacy, absolute confidentiality cannot be guaranteed. Records will be kept private to the extent allowed by law."

13. FINANCIAL INFORMATION:

- a. The subject must be informed as to who is responsible for all costs, which include drugs, visits, procedures, and complications both related, and unrelated, to participation in the study. If the sponsor is responsible for providing study drugs and will pay for office visits and procedures, this should be clearly stated. If not, the following language is suggested:

"The costs of all drugs, visits, procedures and study related and unforeseen complications must be met by the subject. The treatments required are felt to be a part of good medical care and are for the most part covered by most insurance companies. The principal investigator will arrange for medical care for any emergency medical problem that you may experience as a direct result of your participation in this research. This will be provided on a fee-for-service basis. There {are/ are not} funds available to pay for any disability that results or for damages such as lost wages, etc."

- b. If additional costs are to be incurred through participation in the study, the subject must be informed. If not, the following language is suggested,

"Participation in this study will not result in any extra charges above and beyond those routinely incurred by patients with similar conditions."

- c. If subjects are to be paid for their participation as reimbursement for their time and travel, or reimbursed for other expenses, the amount and conditions for payment must be stated. Payments must be made in equal amounts at each visit throughout the course of the study. Payment must be based on a prorated system. Since subjects can withdraw from a study at any time they cannot be required to complete the study to receive payment. Payment must not constitute an undue inducement to participate.

14. **SIGNATURES:** The section must be submitted in the format provided on the sample consent form without exception. A copy of the signed consent form must be given to the subject according to federal regulations. A legal guardian must give informed consent for minors. Particular attention must be paid to obtaining assent from children. The following must be adhered to:
- a. The investigator is required to obtain assent from children 12 years of age or older
 - b. The investigator must make every attempt to obtain assent of children 7 years to 12 years of age
 - c. The investigator is not required to obtain assent of children below 7 years of age, however, it is recommended as good practice whenever possible
 - d. Documentation of required assent by children will be by signature of the child, whenever practical, or by signature of the parent, or legal guardian, attesting to such assent
 - e. If a decision is made to include children in a study without their assent, the reasons must be documented and constitute proper justification for such action. The signature section must include the person who should be contacted for additional information regarding the study, and for injuries. This is usually the principal investigator

All questions regarding the subject's rights as a research subject must be answered by the Chancellor. The specific language regarding this is provided in the [Consent Form Template](#).