Basic Elements of Informed Consent

In seeking informed consent the following information shall be provided to each subject:

- It should begin with a concise and focused presentation of key information that includes only the most crucial information from the potential participant's perspective and must not exceed one page. Key Information should include:
  - A brief description of the purpose of the study and procedures to be followed in lay terms,
  - A statement of the most important reason(s) a person may want to volunteer,
  - A statement of the most important reason(s)/risk(s) may not want to volunteer for this study,
  - A statement clarifying that participation is voluntary and that rights and benefits are not dependent on participation, and
  - A contact person for a subject's questions, suggestions, or concerns;
- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- A description of any reasonably-foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected of the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and notes the possibility that the Food and Drug Administration may inspect the records.
- For research involving more than minimal risk, an explanation as to whether any compensation, or any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; contact information for the research team for questions, concerns, or complaints, and for someone independent of the research team for problems, concerns, questions, information, or input; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- For research involving collection of identifiable information or biospecimens, either a statement that identifiers may be removed and after such removal, information and biospecimens could be used for future research or distributed to another researcher for future studies without additional informed consent, or a statement that subject information or specimens collected as part of the research, even if de-identified, will not be used or distributed for future use.

Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- A statement that the results of the research will be posted on clinicaltrials.gov;
- A statement regarding whether clinically relevant research results, including individually relevant results, will be disclosed to the participant and if so, under what conditions;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research; and the amount and schedule of all payments to subjects;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation;
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
- The approximate number of subjects involved in the study;
- A statement that subject's biospecimens, even if de-identified, may be used for commercial profit and whether the subject will or will not share the commercial profit; and,
- For research involving biospecimens, a statement specifying, if known, whether the research will or could include whole genome sequencing.

Drafting and Developing the Informed Consent Form

Prior to implementation of a trial the PI must have IRB approval of the written ICF document and any other written information provided to subjects. Based upon the protocol, the Investigator's Brochure (if applicable), and templates provided by the LSUHSC IRB or alternate IRB of record and the sponsor (if applicable), the PI and delegated research team members will prepare a draft ICF. The PI and delegated research team members should verify that all required and appropriate elements of the ICF are included. These templates should be used to develop the informed consent document or to adapt the sponsor's informed consent document to meet the requirements of the IRB. If it is found that changes to the ICF are necessary, sponsor and/or PI approval are required prior to submitting to the IRB.

LSUHSC prefers use of our local-approved template; however, if the study team wishes to use the Sponsor template, the LSUHSC ICF Cover Letter must be provided along with the Sponsor consent, or the required language must be embedded into the form. If the designated reviewer does not feel that the Sponsor template contains all the appropriate information or that the quality is poor, the reviewer reserves the right to request the team switch to use of the local-approved template.

ClinicalTrials.gov Registration

As required by U.S. law, a description of qualifying clinical trials must be available on the clinical trial registry http://www.ClinicalTrials.gov. Criteria for required inclusion on this website are available at http://www.ClinicalTrials.gov. If required, then a statement that this information is available to subjects (including the National Clinical Trials number for the study) must be included in the informed consent document for the study. Please refer to the LSUHSC-NO informed consent template for this appropriate language.

Posting IRB Approved Consent Forms

No later than 60 days following the last study visit by any participant, a copy of the consent form must be posted to http://www.ClincalTrails.gov, https://www.regulations.gov/, or any other sight specified by the US Federal Government, by the investigator or study team member responsible for maintaining the ClinicalTrails.gov registration.

If an exception to the requirement above is needed, it is the responsibility of the investigator or designated study team member to contact the federal funding agency to make that request.

If confidential commercial information needs to be redacted from the consent form, the investigator or designated study team member must ensure that only the necessary information is redacted.

ICH-GCP Requirements

When following ICH-GCP(E6) guidelines, the consent document contains:

- The approval/favorable opinion of the IRB.
- The probability for random assignment to each treatment.
- The participant's responsibilities.
- When applicable, the reasonably-foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.
- The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the participant.
- When there is no intended clinical benefit to the participant, the participant is made aware of this.
- A statement that the monitors, the auditors, the IRB, and the regulatory authorities will be granted direct access to the participant's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally authorized representative is authorizing such access.
- If the results of the trial are published, the participant’s identity will remain confidential.

When following ICH-GCP (E67) (R2) guidelines, documentation of the consent process must include:

- The person who conducted the informed consent discussion must sign and personally date the consent. This must be completed prior to subject’s participation in the trial.
- If either the subject or the legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion.
    - After the informed consent has been read and explained to the subject or the legally acceptable representative, and after the subject or the legally acceptable representative have orally consented to participation in the trial, and if capable of doing so, have signed and personally dated the consent, the witness should sign and personally date the consent as well.
    - The signature line for the witness should include a statement where the witness attests that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject or the legally acceptable representative, and that consent was freely given by the subject or the legally acceptable representative.

Researchers and research staff provide all the disclosures and follow the requirements pertaining to

consent covered by ICH-GCP (E6).

FDA Requirements

When a subject withdraws from a clinical trial:

- The consent document does not give the subject the option of having data collected on the subject up to this point removed. It must remain part of the study database.
- A researcher may ask a subject who is withdrawing if they wish to provide continued follow-up and further data collection subsequent to their withdrawl from the intervention portion of the study. This discussion must distinguish between study-related interventions and follow-up associated only with clinical outcome information. Maintenance of privacy and confidentiality of the subject's information, such as medical course or laboratory results obtained through chart review must be addressed.
    - If the subject agrees to this limited participation, the researcher must obtain consent from the subject (assuming this situation was not described in the original consent). The IRB must approve the new consent form prior to use.
    - If the subject does not consent to limited participation, the investigator may not access for purposes related to the study the subject's medical or other confidential records. However, a researcher may review study data related to the subject collected prior to subject's withdrawl. Investigator may also consult public records such as those establishing survival status.

Waiver or Alteration of Informed Consent

Federal regulations at 45CFR46.116(c) & (d) and LSUHSC-NO policies allow for waiver of informed consent when the following conditions are met. The IRB may waive parental permission by determining that the criteria for waivers or alterations are met. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
- The research could not practicably be carried out without the waiver or alteration, even if the research involves use of identifiable private information or identifiable biospecimens.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration, even if the research involves use of identifiable private information or identifiable biospecimens; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation

The issue of the test of practicability can be met, for example, by:

- The need for a large numbers of subjects
- A presumed or demonstrated inability to contact subjects for whom contact information may not be accurate
- The fact that many of the subjects may have died, or
- The fact that a lack of data from a few subjects may make the number of subjects available for the study too few to make the study valid

To request a waiver of informed consent, each of the above questions must be addressed in the request.

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

Documentation of Informed Consent

Except as provided in the following section on Waiver of Documentation of Informed Consent, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

The consent form may be either of the following:

- A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
- A short-form written consent document in the language of the subject stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form. When a short form is used for a subject that does not speak English, the IRB must determine that the witness present is conversant in both English and the language of the subject.

Waiver of Documentation of Informed Consent

Federal regulations at 45CFR46.117(c) and LSUHSC-NO policies allow for a waiver of documentation of informed consent when the following conditions are met.

For research not regulated by the FDA, an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds :

- That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the

subject's wishes will govern;

- 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 of the research context;
- The researcher will obtain information through oral or written communication with the prospective participant or legally authorized representative; or
- The Researcher will obtain identifiable private information or identifiable biospecimens by accessing records or stored biospecimens.

For research that involves distinct cultural groups and is not regulated by the FDA, an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds:

- The research presents no more than minimal risk of harm to subjects;
- The subject or their legally authorized representative is a member of a distinct cultural group or community in which signing informed consent documents is not the norm;
- There is an appropriate, alternate mechanism for documenting that informed consent was obtained; and
- The oral or written information provided to the subject includes all required and appropriate additional elements of consent disclosure.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

For studies regulated by the FDA, regulations at 21CFR56.109(c)(1) also allow for a waiver of documentation of informed consent if the research presents no more than minimum risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. When following FDA regulations and guidance, the IRB is prohibited from waiving or altering the consent process.

For studies involving randomization, the researcher must follow the clinical trial's randomization procedures, if any, and ensure that the code is broken only in accordance with the protocol. If the clinical trial is blinded, the researcher must promptly document and explain to the Sponsor any premature unblinding.

The researcher must inform the participant’s primary physician about the participant’s participation in the clinical trial if the participant has a primary physician and if the participant agrees to the primary physician being informed.

Although a participant is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the researcher must make a reasonable effort to ascertain the reason, while fully respecting the participant’s rights.

Genetic studies

Informed consent must be obtained for all studies conducting genetic analysis of tissue. This requirement must be followed even if no personal identifiers related to the tissue are collected or maintained.