Consent Form Template

Supplemental Instructions

General Instructions

This **Supplemental Instructions** document, along with the **LSUHSC-NO Consent Form Template**, provide clear consent information to increase potential research participant understanding of research studies. Follow these general instructions to help facilitate better informed decision-making by participants:

- ☐ **Recommended Formatting**: Use reader-friendly formatting so the consent form looks easy to read.
  - Leave a 1-inch margin around the entire document.
  - Leave ample white space between headings and paragraphs, but do not double space within paragraphs.
  - Use subheadings, bullet lists, tables and/or illustrations when appropriate.
- ☐ **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.
- ☐ **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 5.8, 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.
- ☐ **Genomic Research Studies:** Genome.gov is an excellent resource for creating genomic research consent forms.
- ☐ **Department of Defense (DOD) Sponsored Project:** If DOD is the sponsor of your project, you must incorporate DOD-required language in your informed consent. See the "Elements to Include in the Informed Consent Document" section of the Guidelines for Investigators, available at https://mrmc.amedd.army.mil/assets/docs/orp/guidelinesForInvestigators.doc.

Section by Section Instructions

Suggested/sample text for use in consent forms are italicized and in blue text.

MAIN HEADING (Required Section)

The following heading is required for all LSUHSC-NO consent forms:

Louisiana State University Health Sciences Center in New Orleans

Consent to Participate in Research

STUDY TITLE & OTHER IDENTIFIERS (Required Section)

- ☐ Include the ***complete title of the study***; it must be identical to that of the research protocol.
- ☐ Indicate ***who is conducting the research*** (name and degrees of the PI). Do not list a co-investigator or other investigators here. The IRB does not require that all investigators be listed in the consent form—only in the IRB application.
- ☐ If this is a greater than minimal risk study, include an ***emergency contact number*** identical to the "research injury" number listed later in the form.
- ☐ Name the ***study sponsor*** (if any)—use the same information as in the application.

INVITATION TO BE PART OF A RESEARCH STUDY (Required section)

- ☐ Investigators may be from different departments; use the ***department affiliation of the PI***.
- ☐ Explain to potential participants ***why the research team is asking them to take part*** in the study. Identify the most basic and important qualification for participation. **Do not** discuss detailed inclusion/exclusion criteria here.

Example statements:

The research team is asking you to be in this study because

- ✦ *…you are a healthy person between the ages of 18 and 40.*
- ✦ *…you have tried to quit smoking in the past but have not been successful.*
- ✦ *…you are undergoing surgery and will be given a general anesthetic.*
- ✦ *…you have leukemia and other standard medical treatments have not been successful.*

- ☐ When preparing ***a consent form for parental permission,*** clarify that "you" refers to the child as a prospective participant. Also do not use "your child" in the form. Consider replacing the last paragraph of this section with something similar to the examples below.

Example statements:

- *The use of "you" in this consent form refers to your child as the potential research participant. If you are the parent or legal guardian of the child providing permission, please remember that "you" refers to the study participant.*
- For studies involving children under the age of 7: *The use of "you" in this consent form refers to your child as the potential research participant. The researchers are asking you to allow your child to participate in this research study.*

IMPORTANT INFORMATION ABOUT THIS RESEARCH STUDY (Required section)

- ☐ Provide "a ***concise and focused presentation of the key information*** that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research."
- ☐ Organize and present this section in a way that facilitates comprehension.
- ☐ The essential elements of the key information include:
  - ■ The fact that consent is being sought for research and that ***participation is voluntary***;
  - ■ The ***purposes of the research***, ***expected duration*** of the prospective subject's participation, and ***procedures to be followed*** in the research;
  - ■ The reasonably foreseeable ***risks or discomforts*** to the prospective subject;
  - ■ The ***benefits*** to the prospective subject or others that may reasonably be expected from the research; and
  - ■ Appropriate ***alternative procedures*** or courses of treatment, if any, that might be advantageous to the prospective subject.
- ☐ There is no specific length requirement for this section. As an example, the Final Rule's expectation is that this section "would be no more than a few pages… for most complicated clinical trials involving cancer patients with long (e.g., 20- to 25-page) consent documents." Overall, the general "expectation is that this initial presentation of the key pieces of information will be relatively short."
- ☐ For studies with a relatively brief consent document (*e.g.*, research with limited risks and benefits), "the information included [in this section] need not be repeated later in the body of the informed consent."

WHY IS THIS STUDY BEING DONE? (Required section)

- ☐ Discuss the ***purpose of the study*** in lay terms and include a statement that explains why the study is research (*e.g.*, *this study will test how an experimental drug works and whether it is safe*).
- ☐ Include a statement that the ***study involves research***. This is particularly important for clinical studies because the relationship between patient-physician is different than that between participant-researcher.
- ☐ State clearly ***what the study is designed to investigate***. Do not overstate or exaggerate the importance of the research.
- ☐ If the study involves ***investigational test articles*** (*i.e.*, drugs or devices that are not FDA-approved), include this information in the consent. As appropriate, include a statement that a purpose of the study includes evaluation of the safety and efficacy of the test article.
  - Refer to the drug or device as "experimental" or "investigational" and explain why it is being used in the study. Do not use the term "new."
  - Avoid statements that indicate test articles are safe or statements that the safety has been established in other studies when the purpose of the study includes the determination of safety.
  - Studies that involve an evaluation of safety and efficacy should not make claims of effectiveness.
- ☐ Include ***definitions for specific research design features*** (e.g., double-blind, randomization, placebo-controlled, dose escalation) if these will help participants understand the study.

Suggested clinical trial purpose statements:

For Phase I drug studies:

- ✦ *The purpose of this research study is to test the safety and possible harms of drug XX when it is given to humans at different dose levels. The researchers want to find out what effects (good and bad) drug XX has on you and your condition.*

For Phase II drug studies:

- ✦ *The purpose of this research study is to see if drug XX has any benefits at dose levels thought to be acceptable in earlier studies. The researchers want to find out what effects (good and bad) drug XX has on you and your condition.*

For Phase III drug studies:

- ✦ *The purpose of this research study is to see if drug XX is safe and effective for the treatment of your condition. The researchers want to confirm the right dose levels of drug XX and find out what effects (good and bad) drug XX has on you and your condition.*

Suggested statements for unapproved drugs and devices, procedures:

- *XXX is an investigational drug that has not yet been approved by the Food and Drug Administration. The safety and usefulness of the drug is being tested in this study.*
- *XXX is being compared to a standard drug, XXX that has already been approved by the Food and Drug Administration (FDA). The researchers are interested in learning which drug is more helpful in treating your condition.*
- *Procedure XXX is being compared to the standard procedure XXX. The researchers are interested in learning which procedure is more useful in treating your condition.*

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY? (Required section)

Guidelines for All Consents:

- ☐ If ***screening procedures*** are involved, note these first and identify them as tests that will determine whether or not the person can continue in the study.
- ☐ Explain the ***study design*** to participants. Define complex design terms. Explain any procedures relating solely to research (e.g., randomization, placebo control) to the participants.
- ☐ Include a ***description of the procedures*** involved in the study and an explanation of which procedures are considered investigational and why.
  - Procedures do not necessarily need to include specific names of standard lab tests (e.g., CBC, CMP, lipid panel, UA). But participants should know the type of specimen required for testing and the general purpose of the testing (*e.g., A blood sample will be taken from your arm to perform standard lab testing to make sure you do not have a low red blood cell count.*).
  - Procedures do not necessarily need to include specific names of common psychological tests (e.g., BDI-II, MMSE, MCMI-III, MACI, QOLI). But participants should know the general purpose of the testing and how long the testing will take (*e.g., A standard test will be used to measure how you are feeling and your current level of depression. The test should take about 30 minutes to complete.*).
- ☐ Explain ***how participation in the study differs from standard treatment*** (if applicable).
- ☐ ***List each procedure*** in the order in which it will occur. Discuss each in a separate paragraph. Use subheadings as appropriate for complex studies, e.g., Screening, Visit 1, Visit 2, etc.
- ☐ As applicable, note the ***amount of time for each procedure*** and number of times each procedure will be performed.
- ☐ ***Summarize the subject's time commitment*** 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.

- ☐ ***Describe randomization to study groups*** as a study procedure. Explain the probability of assignment to a given group or condition. See suggested statement below.
- ☐ **Define terms** which might not be familiar to the average person the first time they are mentioned or replace them with a lay term. Consult the **PRISM Readability Tool Kit** for suggestions.
- ☐ Specify the ***amounts of blood or tissue*** to be taken for study purposes using lay equivalents (e.g., teaspoons, ounces) for metric terms.
- ☐ Include ***medical record review*** as a study procedure when protected health information is created, accessed or disclosed for the study.
- ☐ If the study involves a ***survey***, indicate that participants may skip any questions which they do not want to answer.
- ☐ ***Use a study chart***, diagram, calendar, schedule, etc. as a possible addition to the narrative explanation of study procedures.
- ☐ For device studies, you may wish to ***include simple diagrams*** or pictures in the consent.

Guidance for Studies that Involve Standard of Care Medical Procedures:

- ☐ Make clear in the consent form whether procedures are being done for clinical reasons or for study purposes, including whether the procedures are being done more often because of the study.
- ☐ Use the following guidelines to determine the extent to which standard procedures and their associated risks need to be described in consent forms:
- ☐ If the standard procedure is not explicitly required by the study protocol, the consent form need not describe that procedure or its risks.
- ☐ If the standard procedure is a main focus of the study (e.g., one or more arms of a randomized study is standard) or is explicitly required by the study protocol, the consent form must include a full description of the procedure and its risks.

Suggested simple screening or procedure statements:

- ✦ *A number of standard lab tests will be performed using your blood sample to make sure you can participate in this study.*
- ✦ *A number of standard psychological tests will be performed to measure how your brain processes information.*

Suggested statements for describing study designs:

Randomized Studies:

- ✦ *Randomization is a procedure used to assign research participants by chance to a study group in a clinical trial. It is used to make sure study results are not influenced by the selection of participants in one group as compared to another. In this study, you have a XX chance of being assigned to one group or another.*
- ✦ *Randomization means that you are assigned to a group by chance (like a flip of a coin). A computer program will place you in one of the groups. Neither you nor the*

researchers can choose the group you will be in. You will have an [equal/one in three/etc.] chance of being placed in any group. You will be randomized into one of the study groups described below.

- *If you are in Group 1* [Explain what will happen for this group with clear indication of which interventions depart from routine care.]
- *If you are in Group 2* [Explain what will happen for this group with clear indication of which interventions depart from routine care.]
- [For studies with more than two groups, an explanatory paragraph containing the same type of information should be included for each group.]

Blinded Studies:

- *Double-blind means that neither you nor the researcher(s) conducting the study will know which treatment you are receiving. However, in the case of an emergency, the research team can quickly find out to what study group you are assigned.*
- *Single-blind means that you will not know which treatment you are receiving.*

Placebo-controlled Studies:

- *Placebo-controlled means that the one group will get a placebo. A placebo looks like the investigational drug but it includes no active ingredients. If you are in the group that receives placebo, your condition will go without active treatment for XX weeks.*

Dose Escalation Studies:

- *Dose escalation means that participants enrolling early in the study will be given relatively low doses of the study drug. If the low doses appear to be safe, participants enrolling later will receive higher doses.* [If appropriate, inform participants where they are in the dosing scheme.]
- *The purpose of this research is to find the best way to give an experimental drug and how much of it can be given safely. In this study, an experimental drug is given to a small number of people. The study starts by giving a very low dose of XX, and then the dose is slowly increased as other people enter the trial.* [If appropriate, indicate whether dose escalation is by cohorts or if individuals will receive escalating doses.]

Dose Titration Studies:

- *The purpose of this research is to find the best way to give an experimental drug and how much of it can be given safely. In this study, the experimental drug will be given at a very low dose, and then it will be slowly increased to determine an effective dose of XX. The dose can be increased by giving more at one time or by giving the same dose more often.*

WHAT SHOULD I KNOW ABOUT GENETIC RESEARCH? (Optional section; required for studies generating, using, or analyzing participant's genetic information)

☐ Describe how the prospective participant's genetic information will be generated, used and/or analyzed.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY AND HOW LONG WILL IT LAST? (Required section)

- ☐ State the ***accrual goal*** of the study and where appropriate discuss study cohorts.
- ☐ For multi-center studies, indicate ***accrual numbers for the entire study*** and for enrollment at LSUHSC-NO; be consistent with the protocol.
- ☐ Explain the ***duration of the study*** or how long the study will last. This will help participants decide if they have the time to participate.
- ☐ When appropriate, state that the study involves long-term follow-up by specifying the timeframes and requirements for long-term participation.

Additional suggested study duration statements:

Short-term, simple studies:

- ✦ *You will be in this study for XX days.*
- ✦ *Your participation in this study will last .*
- ✦ *Participation in this study will require about XX hours of your time.*
- ✦ *This study will require approximately XX hours of your time for each study visit. There will be a total of XX study visits over six months.*
- ✦ *You will be in the* [insert clinic/center name] *for a total of XX days.*

Long-term, complex studies:

- ✦ *If you agree to participate in this study you will* [describe the research intervention, e.g., you will take drug XX for XX months/weeks/until a certain event occurs]. *After you complete [drug XX, procedure YY] the researchers will ask you to visit the office for follow-up exams every XX months for XX years.*

WHAT ARE THE RISKS OF TAKING PART IN THIS STUDY? (Required section)

General Guidelines

- ☐ ***Provide 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 risks or discomforts that might occur to the subjects as a result of the study.
- ☐ ***Risks and discomforts include*** physical, psychological, social and economic harm.
- ☐ ***Explain the risks*** and/or possible side effects and discomforts of procedures relating solely to research.
- ☐ ***Explain the risks of the tests*** required in the study protocol, especially for tests that carry significant risk of morbidity/mortality themselves.

- ☐ ***Explain the risks associated with each drug separately***; however, for a given drug list the associated risks once and not multiple times by treatment arm. Explain any risks associated with combination drug regimens.
- ☐ ***Organize and describe risks according to their probability or severity*** of occurrence (e.g., likely, less likely, and rare but serious).
- ☐ ***List all known side-effects*** of drug(s) being tested. Point out that there is always the risk of previously unknown side-effects occurring.
- ☐ ***Provide the consequences of risks***; that is, whenever possible, describe how the risks and side effects will make the participant feel. For example, explain "anemia" as follows: "Loss of red blood cells, also called anemia, can cause tiredness, weakness and shortness of breath."
- ☐ ***Describe the precautions to prevent risks from occurring*** when appropriate. Also describe what will be done if they occur.

Guidelines for Explaining Certain Risks Associated with Procedures Performed for Research

- ☐ **Blood draw risks:** Standard wording notes temporary discomfort from the needle stick, bruising and, rarely, infection and fainting. If more than one unit of blood is to be drawn within an 8-week period, a medically appropriate precaution concerning subsequent blood donation is required.
- ☐ **Radiation risks:** The IRB recognizes that the risk from small amounts of radiation exposure is extremely difficult to describe in terms that are meaningful to the average layperson. While comparisons to chest x-rays are often used, most lay people have no way of estimating the risks of exposure from chest X-rays either, even though they are probably familiar with the procedure itself. Use a simple statement that alerts participants to the risk of the radiation exposure and advises him/her to speak with the researcher if there are further concerns about this exposure.
- ☐ **CT scan risks**: Describe radiation risks from CT scans in the same way as those from x-rays. As with MRI, note the possibility of claustrophobia or discomfort from being in the CT scanner. In addition, include risks and discomforts of contrast agents and sedation if appropriate.
- ☐ **MRI risks:** Warn subjects that because the MRI machine acts like a large magnet, they must not have any metal on or in their bodies. This precaution is needed to prevent any resulting injury. Also note that subjects will be in a tight confined space and may be bothered by feelings of claustrophobia. They may also be bothered by the loud clanging noise during the MRI scan. Since the risks to a fetus from MRI are unknown, state that pregnant women may not participate in studies involving MRI procedures.
- ☐ **Reproductive risks:** Include among the screening procedures any pregnancy testing done for study purposes. If men or women are advised to use birth control or avoid pregnancy before, during, or after the study, describe these precautions among the study

procedures. As appropriate, identify any required or acceptable methods of birth control and describe the risks to pregnant mothers, fetuses, and/or fertility of subjects.

☐ **Unknown risks:** For studies involving investigational agents, or experimental doses or combinations of drugs and/or treatments, tell subjects that there may be risks associated with the drug/treatment that are as yet unknown , but that the researcher will advise them if any new information becomes available that might affect their desire to participate in the study.

Suggested statements for routine risks/discomforts:

- **Statement about treating side effects:** *The researchers will observe you carefully for any harmful side effects. Although the experimental drug/device has been well-tested in laboratory and animal studies, the side effects in people are not completely known at this time. You will be followed closely by the study doctor for the entire time you are a part of this study. If you experience any side effects from the study, the researchers will provide you with the treatment that has the best chance of taking care of the side effects. If you experience any side effects related to the study drug/device that continue at the end of study, we will continue to follow-up with you until these effects stabilize or resolve.*
- **Risks associated with randomization:** *You will be assigned to a study group at random (by chance). Your assignment is based on chance (like a coin flip) rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. It might also prove to be less effective or have more side effects than the other study groups(s), or standard treatments available for your condition.*
- **Risks associated with withdrawing from current medication (washout period):** *During this study the medication you normally use for your condition will/may be stopped for up to* [XX days/weeks/months]*. You will/may receive no medication, or medication at a dose which may not help your condition. As a result, you will/may have an increase in symptoms including* XX*.*
- **Placebo risks:** *During this study there is a* XX *chance that you will receive a placebo. This could lengthen the amount of time before you receive a treatment that may be effective. During this time you may experience worsening of your condition, including increased symptoms such as* XX*. The researchers will carefully monitor your condition. If your symptoms worsen and make you uncomfortable, you can withdraw from the study.*
- **HIV testing risks:** *Being tested for HIV can make you feel nervous or anxious about the test results. A positive test indicates that you are infected with the HIV virus, but no one knows for certain when, if ever, you will get AIDS or a related condition. Receiving positive results may make you very upset. If other people learn about your positive test results, there might be a risk that you could be treated unfairly or badly, and even have trouble obtaining insurance or employment. To the extent permitted*

by law, the researchers will keep your test results confidential and will not release them to anyone without your written permission.

- **Blood draw risks:** *Drawing blood may cause temporary pain from the needle stick, bruising or swelling at the site, and rarely, infection or fainting.*
- **Exercise testing risks:** *The exercise test(s) may cause muscle soreness, dizziness, or shortness of breath. In rare instances, exercise tests may cause chest pain, tightness, or a change in vital signs.*
- **Psychological risks:** *Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.* [If appropriate, indicate that counseling or a referral for counseling will be provided should a subject experience emotional distress.]
- **Standard of Care (SOC) Radiation Exposure Risks**: *Since the radiation procedures used in this study are all standard of care, the amount of radiation you will receive is the same as that for similar patients who are not participating in this study. Therefore, you will not be exposed to any additional radiation for participation in this study.*
- **Non-SOC Radiation Exposure Risks:** *You are exposed to radiation on a daily basis, both from natural (sun and earth) and manmade sources. The estimated radiation dose that you will receive as a participant for this type of research has been compared to the limits allowed for a radiation worker. This limit is low and is not expected to be harmful. The person obtaining your consent can answer any questions you have, and provide detailed written information about the amount of radiation resulting from this study.*
- **CT scan risks:** *CT scans involve the risks of radiation (see above). In addition, if contrast material (iodine dye) is used, there is a slight risk of developing an allergic reaction, which may cause symptoms ranging from mild itching or a rash to severe difficulty breathing, shock, or rarely, death. The contrast material may also cause kidney problems, especially if you are dehydrated or have poor kidney function. The study doctors will ask you about any allergies or related conditions before the procedure. If you have any of these problems, you may not be allowed to have a CT scan* [or continue in the study].

  Having a CT scan may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia when placed inside the CT scanner, or by lying in one position for a long time. If contrast material is used, you may feel discomfort when it is injected [given by XXX]. *You may feel warm and flushed and get a metallic taste in your mouth. Rarely, the contrast material may cause nausea, vomiting or a headache.* [List other risks as appropriate to the method by which contrast agent is administered]. [If sedation may be used, discuss risks of sedation here].

- **PET Scan - General Risk Statement:** *PET scans involve the risks of radiation (see above). If you have had a PET scan or have been exposed to radiation while participating in other research during the past year, you should inform the researcher(s). This will enable the researcher(s) to determine your total radiation exposure and make sure it does not exceed accepted safety guidelines. If you participate in future studies that involve the use of X-rays or radioisotopes, you should discuss the safety guidelines for radiation exposure with the researcher who is performing the study.*
- **Clinical MRI risks:** *The MRI procedure uses a powerful magnetic field to generate detailed images of the body. The magnet could move objects within your body that contain metal, such as implants, clips and pacemakers. Tell the doctor if you have any metal items within your body. MRI scanning is painless but you might experience discomfort in the machine. In particular, loud beeping and hammering noises occur during the study when the scanner is collecting measurements. You also may be bothered by feelings of claustrophobia when placed inside the MRI, or by lying in one position for a long time. You might also experience stimulation of the nerves in your body, which feels like a gentle tap or sensation of mild electric shock.* [If appropriate, also discuss the risks of sedation here]. *Because the risks to a fetus from MRI are unknown, you cannot participate in this study if you are pregnant.*
- **Injection of Gadolinium during Clinical MRI:** *Gadolinium, a substance given during the MRI examination, will be given by injection into a vein in your arm. This may cause some minor pain, and may cause some bruising near the area of injection. Gadolinium may also cause headache, nausea, and vomiting. Rarely, it may cause dizziness, rash, itching, or a numb or tingling feeling in the hands or feet, or an allergic reaction. Medical personnel will be available to treat any of these problems if they should occur.*
- **Known reproductive risks:** *You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. Therefore, you need to use effective birth control while on this study.* [As appropriate, specify what methods of birth control are required or acceptable and discuss how long to use them.]
- **Unknown Risks to Women of Child Bearing Potential and Pregnant Women:** *The effects of* XXX *on fertility or a fetus are not known. For this reason, if you believe that you are pregnant or have a chance of becoming pregnant you should not participate in this study. A [blood / urine] pregnancy test will be performed before the start of study procedures. If you are pregnant, you will not be allowed to participate in the study. If you do participate in this study, you must use a medically effective form of birth control before entering the study, while participating in the study, and for at least* XXX *after stopping the study. If you become pregnant during the study, tell the researchers right away.*
- **Unknown risks to infants:** *The side effects of* XXX *on infants are also not known, therefore if you are currently breastfeeding you cannot participate in this study.*

- **Loss of confidentiality:** *As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening (see "How will my private information be kept confidential?" section below).*
- **Unknown Risks:** *The experimental drug may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.*

ARE THERE ANY BENEFITS TO PARTICIPATING IN THIS STUDY? (Required section)

- ☐ Clearly ***describe all expected benefits***. Do not overstate the benefits. **Note:** Federal regulation does not allow the provision of free drugs or medical procedures (including increased monitoring) to be described as a benefit.
- ☐ **If there is no anticipated direct benefit** to the participant from the study, state this at the beginning of the section.
- ☐ Describe any potential direct benefits to the participant first, followed by **potential general benefits** (e.g., to the group of patients to which the individual belongs, or to medical knowledge).

Additional suggested statements:

- *You will not directly benefit from participation in this study.* (Note: This statement cannot be used if participants will be billed for research-related procedures.)
- *There will be no direct benefit to you from participating in this study. However, this study will help the researchers learn more about [procedure/drug/ intervention/ device]. Hopefully this information will help in the treatment of future patients with [disease /condition] like yours.* (Note: Do not use this statement if participants will be billed for research-related procedures.)
- *You may benefit from this study if you are assigned to the study group that receives [XXX] and [XXX] proves to be beneficial.*
- *The study will test whether [XXX] improves your condition. However, you personally may not benefit from taking part in this study.*
- *Taking part in this study may or may not improve your health. While doctors hope [procedure/ drug/ intervention/ device] will be [more effective/have fewer side effects] than standard (usual) treatments, there is no proof of this yet.*

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY? (Required section)

- ☐ Describe the ***alternatives to participation*** in the study.

- ☐ Inform participants of the range of options available to them, especially for ***studies that involve medical interventions***. If a drug or device is available for use outside the proposed protocol, provide this information.
- ☐ For ***studies that do not involve medical interventions***, state if there are other alternative actions such as private weight loss clinics, private counseling, special courses, etc. It is acceptable to say that the alternative is not to participate in the study.
- ☐ Include applicable information on ***alternative procedures or courses of treatment*** that may be advantageous to the participant if he/she refuses to participate or withdraws from the study (e.g., treatment without being in a research study; participating in another study; getting no treatment). If no alternative treatment is available, include a statement to this effect.

Additional suggested statement for alternative treatments or procedures:

- **Example #1:** *You may wish to talk with your treating physician about your choices before deciding if you will take part in this study. If you decide not to participate in this study, your other choices may include:*
  - *Receiving no treatment at this time.*
  - *Receiving the same drug being used in this study but not being in this study [only if available and easily prescribed].*
  - *Receiving standard treatment for your condition without being in a study.*
  - *Taking part in another study.*
- **Example #2:** [For studies involving end-stage diseases, add the following paragraph as an additional bullet.]
  - *Receiving comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by your disease. It does not treat the disease directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.*
- **Example #3:** *There are no alternative treatments or procedures available. The only alternative is not to participate in this study.*

HOW WILL INFORMATION ABOUT ME BE KEPT CONFIDENTIAL? (Required section)

- ☐ Inform participants of the ***extent to which the researchers intend to maintain confidentiality*** of records that identify them. Specifically:
  - How data, records, specimens containing private or personal information will be collected and used for the study.
  - What methods are in place to code or de-identify information.
  - How data, records, specimens will be stored, and who will have access to them (including how they will be shared for future research; see next section).

- ☐ Indicate ***what regulatory or other agencies might have access*** to the research records (e.g., the FDA, sponsoring company, authorized LSUHSC-NO representatives).
- ☐ Suggested consent statements below can be combined into paragraphs and all options provided should be considered.

Guidance

- ☐ **Do not guarantee complete confidentiality:** An inherent risk of participating in research is a loss of privacy and the potential for a breach in confidentiality. There is no legal privilege between the researcher and participant as there is between physician and patient or counselor and client. Thus, a guarantee of "complete" or "strictest" confidentiality should not be given or implied.
- ☐ **A separate LSUHSC HIPAA research authorization form is required:** A separate LSUHSC HIPAA Research Authorization form is used to comply with all applicable laws concerning access, use and disclosure of medical health information for research.

  Note: Do not add additional information about the use of protected health information in the consent form. The LSUHSC HIPAA research authorization form cannot be altered.
- ☐ **Protection from forced disclosure of research data and records:** Researchers may wish to obtain a Certificate of Confidentiality (COC) for studies that involve illegal activities or collect sensitive information, that if disclosed, could have adverse consequences for participants or damage their financial standing, employability, insurability, or reputation. COCs allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. For studies where a COC will not be obtained, participants should be informed about a loss of privacy if records are subpoenaed.
- ☐ **Use, storage, access and sharing of data and specimens:** Data statements below may also include information about specimens, as appropriate. In all cases, participants need to be informed about the confidentiality provisions in place for collection, storage, use and sharing of data and specimens.

Suggested Confidentiality Statements for All Consents:

- ✦ *The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. We will make every effort to maintain your privacy, but absolute confidentiality cannot be guaranteed. We will keep records private to the extent allowed by law.*
- ✦ *The researchers will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known. This signed consent form will be stored in a locked file that will be accessible only to a very small number of authorized people involved in this project. The research team will carefully follow the coding, storage, and data sharing plan explained below. We will make every effort to*

maintain your privacy, but absolute confidentiality cannot be guaranteed. We will keep records private to the extent allowed by law.

Combine one of the above suggested statements with the relevant suggested statements below to create simple paragraphs to describe data use, storage, access and sharing:

- **Describing identifiers linked to data and records:**
  - *No identifiable information about you will be kept with the research data.*
  - *All/some identifiable information about you will be replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.*
  - *All/some identifiable information about you will be kept with the research data.*
- **Describing storage of data and records:**
  - *All/some research data and records will be maintained in a secure location at* [site]*. Only authorized individuals will have access to it.*
  - *All/some research data and records will be stored on a laptop computer that is* [describe protection and/or has encryption software.]
  - *All/some research data and records will be stored electronically on a secure* [computer or network] *with* [encryption and/or password] *protection*.
- **Describing routine access to study data and records (suggested for all consents):**
  - *Individuals or 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, the FDA* [only required for FDA regulated studies]*, and the research study team staff. Research records provided to authorized, non-LSUHSC personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.*
- **Describing retention of data and records:**
  - *The researchers intend to keep the research data and records until the research is published and/or presented.*
  - *The researchers intend to keep the research data and records for approximately* XX *years.*
  - *The researchers intend to keep the research data and records indefinitely for future research.*
  - *The researchers intend to keep the research data and records in a repository indefinitely. Other researchers will have access to the data for future research.*
  - *The researchers intend to keep the research data and records until analysis of the information is completed.*

Certificate of Confidentiality statements:

- **Example #1 (NIH example):** *To help the researchers protect your privacy, they have obtained a Certificate of Confidentiality from the National Institutes of Health/Food and Drug Administration. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.*

  The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the Food and Drug Administration (FDA).

  A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold the information.

- **Example #2:** *To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health/Food and Drug Administration. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.*
  Exceptions:
  - *The researchers are required by law to disclose information about incidents such as child abuse or the intent to hurt yourself or others.*
  - *The Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.*
  - *A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you without your consent.*

WILL MY INFORMATION OR SPECIMENS BE USED FOR FUTURE RESEARCH? (Required section)

- ☐ Inform participants if their ***information or specimens*** collected as part of the study will be ***used or shared with others for future research***.
- ☐ If ***information or specimens will not be used for future research***, state this in the consent form.
- ☐ If intending to use or share for future research, provide a ***general description of the potential future research***.
- ☐ ***Participant must agree*** to the use of information/specimens for future research.

WILL THERE BE ANY COSTS TO ME FOR TAKING PART IN THIS STUDY? (Optional section; required if participants will incur costs)

- ☐ Inform participants about any ***additional costs*** that may result from participation in the study.
  - ■ **Note:** Do not provide an actual dollar amount for the costs.
  - ■ Do identify which drugs, visits, study procedures, etc. will result in additional costs.
- ☐ If there are ***no additional costs*** for participation, state this in the consent form.
- ☐ As appropriate, inform the participants of any additional costs they will incur such as parking fees or transportation that ***will not be reimbursed***.
- ☐ ***Do not discuss research related injury costs*** in this section. Discuss this in the section below entitled "What should I do if I get sick or hurt during the study?"
- ☐ **Sponsor covered items and services:** The costs section may be specific about items and services that will be covered by a Sponsor, e.g., study medication.
- ☐ **Insurance coverage and participation in research studies:** Include a statement informing subjects that because they are participating in a research study, insurance providers may not cover all costs.
- ☐ **For NCI-funded studies:** Provide participants with the website address and phone number of the National Cancer Institute (NCI) that offers more information on clinical trials and insurance coverage. See http://www.cancer.gov/clinicaltrials/education/insurance-coverage for details.

Additional suggested statements:

- ✦ **NCI clinical trial information about insurance coverage:** *For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.*

WILL I BE PAID OR FOR TAKING PART IN THIS STUDY? (Optional section; required if participants will be paid or reimbursed)

- ☐ If participants will be paid for participation or reimbursed for costs (e.g., parking), describe in detail the type of payment, amount, and terms of payment or reimbursement.
- ☐ Payment for participation and cost reimbursement should be commensurate to the participants' time and the inconvenience of being a research subject. Payment must not constitute an undue inducement to participate.
- ☐ The payment section of the consent form should indicate:

- The total dollar amount that participants will be paid and any relevant information such as pro-rating if a person does not complete the study, or bonus payments at the end of the study.
  - **Note:** Participants should not be required to complete the entire study in order to be paid, and any bonuses for study completion should be modest.
- How payment will be made (e.g., gift card, ClinCard, by check).
  - **Note:** If payments are made by check, participants will need to provide the researcher with an address and social security number.
- When participants will be paid.
  - **Note:** Payments must be made in equal amounts at each visit throughout the course of the study. Include a payment schedule, if appropriate.
- Whether participants need to submit receipts in order to be reimbursed.
- Whether participants need to provide their home address and social security number to receive payment, if applicable.
- Payments for research participation are considered taxable income. If subjects are paid more than $600 total in a calendar year for participation in research studies, the University will report this as income to the IRS.

Additional suggested payment statements:

- **No payment or reimbursement:**
  - *You will not be paid for your participation in this research study. You will not be reimbursed for any out-of-pocket expenses, such as parking or transportation fees.*
- **Reimbursement for out-of-pocket expenses:**
  - *You will be reimbursed for the following expenses [complete this sentence, e.g., parking.] In order to be reimbursed, please be sure and save your receipts so that you can provide these to the research staff.*
- **Identity of participant required for payment:**
  - *Personal information about you, including your name, address, and social security number, will be released to the UCLA Accounting Office for the purpose of payment.*
  - For payments of $600 or more - use the statement above and add, *"...and for tax reporting to the Internal Revenue Service (IRS)."*

WHO CAN PROFIT FROM STUDY RESULTS? (Optional section; required section if specimens are collected or there are researcher financial interests)

☐ **Researcher Financial Interests in this Study**

- If a member of the study team has a personal financial interest in the outside entity funding the study or other personal financial interests in entities that might reasonably be affected by the research, include a financial interest statement.

- The LSUHSC COI Committee will provide the conflict of interest statement once it has completed its review.

☐ **Use of Specimens**

- Inform the participant if his/her specimens will be kept for future research or discarded after the study.
- Inform the participant if the research being conducted with his/her specimens has the potential for commercialization.
- Describe who will share in any potential profits.

WHAT SHOULD I DO IF I GET SICK OR INJURED DURING THE STUDY? (Required section)

☐ **MMSEA 111 Language:** Section 111 of the Medicare, Medicaid and S-CHIP Extension Act, referred to as "MMSEA 111", requires liability insurers to report on certain payments made to or on behalf of Medicare beneficiaries in order to facilitate enforcement of the Medicare Secondary Payer rules. Such reports are required by law, may be a prerequisite to securing payment from sponsors for diagnosis or treatment of complications or injuries caused by a patient's participation in research, and qualify as coordination of benefits activities. Occasionally, sponsors request that information about this requirement be added to the consent form.

Additional suggested statement (with MMSEA 111 Language):

If you are injured as a result of being in this study, LSUHSC-NO will arrange for necessary medical treatment. The costs of the treatment may be covered by LSUHSC-NO or the study sponsor [sponsor name], or billed to you or your insurer just like other medical costs, depending on a number of factors. [MMSEA 111 language: If the study sponsor covers these costs they will need to know some information about you like your name, date of birth, and Medicare Health Insurance Claim Number, or, if you do not have one, your Social Security Number. This information will be used to check to see if you receive Medicare, and, if you do, report the payment they make to Medicare. The study sponsor will not use this information for any other purpose.] LSUHSC-NO and the study sponsor do not normally provide any other form of compensation for injury.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY? (Required section)

☐ Provide the name, address and telephone number of the Principal Investigator and one Co-Investigator if participants want to contact the study team:

- for answers to questions about the research itself
- to be able to express concerns

Note: Do not provide a long list of numbers for the participant to call.

☐ For greater than minimal risk studies, provide a 24-hour contact number and an emergency number for research injury in this section.

- ☐ Provide information about how to contact the LSUHSC's Office of the Chancellor if participants:
  - have questions about their rights,
  - have any concerns about the study, or
  - want to talk to someone other than a study team member.
- ☐ If the consent form is for a study that meets the definition of a **"clinical trial"** (as per NIH) or an **"applicable clinical trial"** (as per the Food and Drug Administration Amendments Act of 2007), provide information about *ClinicalTrials.gov* and the National Clinical Trials number for the study.

  Note: FDA asserts that the reference to the clinicaltrials.gov website allows participants to ascertain the nature, scope, and progress of a registered applicable clinical trial, thus reassuring the participant that participation in a trial contributes to the advancement of medical knowledge.

WHAT WILL HAPPEN IF I CANNOT COMPLETE THE STUDY? (Optional section; include if applicable to the study)

- ☐ Inform participants of ***circumstances under which their participation may be terminated*** by the investigator without their consent, if applicable.
- ☐ Inform participants of any ***procedures for safe and orderly withdrawal*** from the study if they withdraw or are removed from the study.

  Note: 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.
- ☐ Inform participants that the study might also be ***ended by the researchers or the study sponsor***.
- ☐ **Withdrawal from FDA-regulated clinical trials:** Inform participants if they withdraw from an FDA-regulated clinical trial, the data collected about them up to the point of withdrawal will remain part of the study database and may not be removed. See FDA Guidance for more details. Such a statement may be used for all studies.

YOUR PARTICIPATION IN THIS STUDY IS VOLUNTARY(Required section)

- ☐ Inform the potential participant that:
  - taking part in this study is completely voluntary.
  - regardless of the decision, he/she will not be subject to any penalties.
  - regardless of the decision, he/she will not lose any benefits to which he/she is entitled.

Alternate suggested statement for voluntary participation:
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 from the study at any time without jeopardizing, in any way, your medical treatment at this institution in the present or future.

YOUR CONSENT (Required section)

- ☐ ***Do not alter the language*** in this section of the consent form template.
- ☐ Delete signature blocks from the template that are not applicable to the study.
- ☐ The ***participant must sign and date*** the consent form. Rare exceptions include blind or illiterate subjects and subjects unable to consent for themselves.
- ☐ The signature of the ***person obtaining consent*** indicates he/she has explained the research to the participant (or the legally-authorized representative when IRB approved,) answered any questions and the participant understands the information described in the document and freely consents to participate.
- ☐ A ***legal guardian*** must give informed consent for minors.
- ☐ Adhere to the following rules for obtaining ***assent from children***:
  - The investigator is required to obtain assent from children 12 years of age or older
  - The investigator must make every attempt to obtain assent of children 7 years to 12 years of age
  - The investigator is not required to obtain assent of children below 7 years of age, however, it is recommended as good practice whenever possible
  - 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
  - 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
- ☐ ***Participant should receive*** as part of the consenting process:
  - A copy of the signed consent form, and
  - A separate HIPAA Research Authorization form for studies that involve Protected Health Information (PHI) (required per LSUHSC policy).