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## Research: Informed Consent, Assent, Re-Consenting, Parental Permission, Remote Consent and Remote Assent Process- CL.0218

### PURPOSE

The purpose of this policy is to provide guidelines to obtain informed consent, assent, parental permission, re-consent, remote consent, and remote assent for participation in research and clinical trials consistent with the 2018 Common Rule and Food and Drug Administration regulations. It is intended that this informed consent policy be consistent with Food and Drug Administration federal regulations and good clinical practice, each as amended from time to time. Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

### APPLICABILITY

This policy applies to Lakeland Regional Health's **Workforce** and personnel engaged in research for which the LRH **IRB** is the IRB of Record.

### POLICY

#### I. INFORMED CONSENT

##### A. General

1. Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR).
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity

to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

3. The **IRB** will review details of the consent process as well as the qualifications of the individual(s) who will be obtaining consent (e.g., the investigator, sub-investigator, or qualified designee). When the potential subject's understanding of the research may be impaired, the IRB may require an alternative process. (For example, the IRB may require that only the investigator or sub-investigator obtain consent or that consent be obtained prior to entry into the cardiac catheterization waiting area.) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
4. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
5. The IRB asks the investigator to strive for an eighth-grade reading level in all consent forms. The IRB may use consultants to verify that consent documents and information sheets have been accurately translated.
6. Except for broad consent obtained in accordance with I.D.1 of this section:
  - a. Informed consent must begin with 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. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
  - b. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
7. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, LRH or its agents from liability for negligence.

**B. Basic elements of informed consent:**

1. Except as provided in paragraph 4, 5, or 6 of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:
  - a. 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 that are experimental;

- b. A description of any reasonably foreseeable risks or discomfort to the subject;
- c. A description of any benefits to the subject or to others that may reasonably be expected from the research;
- d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. For FDA regulated research, the informed consent must state that the FDA may inspect all records.
- f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- g. 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;
- h. 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; and
- i. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
  - i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
  - ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

C. Additional elements of informed consent:

1. Except as provided in paragraphs D, E, and/or F of this section, one (1) or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:
  - a. 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) that are currently unforeseeable;
  - b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally

- authorized representative's consent;
  - c. Any additional costs to the subject that may result from participation in the research;
  - d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
  - e. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
  - f. The approximate number of subjects involved in the study;
  - g. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
  - h. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
  - i. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
- D. Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens:
- 1. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to the informed consent requirements in paragraphs 2 and 3 of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:
    - a. The information required in paragraphs B.1.ii, B.1.iii, B.1.v, and B.1.viii and, when appropriate, C.1.vii and C.1.ix;
    - b. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
    - c. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
    - d. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period

of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

- e. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
- f. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
- g. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

E. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials:

1. *Waiver.* The IRB may waive the requirement to obtain informed consent for research under paragraphs A through C of this section, provided the IRB satisfies the requirements of paragraph E.3 of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements under paragraph C of this section, and refused to consent, the IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.
2. *Alteration.* The IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs B and C of this section provided the IRB satisfies the requirements of paragraph E.3 of this section. The IRB may not omit or alter any of the requirements described in paragraph A of this section. If a broad consent procedure is used, the IRB may not omit or alter any of the elements required under paragraph D of this section.
3. *Requirements for waiver and alteration.* In order for the IRB to waive or alter consent as described in this subsection, the IRB must find and document that:
  - a. 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
- b. The research could not practicably be carried out without the waiver or alteration.

F. General waiver or alteration of consent:

1. *Waiver.* The IRB may waive the requirement to obtain informed consent for research under paragraphs A through C of this section, provided the IRB satisfies the requirements of paragraph F.3 of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph D of this section, and refused to consent, the IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.
2. *Alteration.* The IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs B and C of this section provided the IRB satisfies the requirements of paragraph F.3 of this section. The IRB may not omit or alter any of the requirements described in paragraph A of this section. If a broad consent procedure is used, the IRB may not omit or alter any of the elements required under paragraph D of this section.
3. *Requirements for waiver and alteration.* In order for the IRB to waive or alter consent as described in this subsection, the IRB must find and document that:
  - a. The research involves no more than minimal risk to the subjects;
  - b. The research could not practicably be carried out without the requested waiver or alteration;
  - c. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
  - d. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
  - e. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

G. Screening, recruiting, or determining eligibility:

1. The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:
  - a. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative; or

- b. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

#### H. Documentation of Informed Consent:

1. Except as provided in section 3, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form. 45 CFR § Part 46, addresses the requirements of HHS, while 21 CFR § Part 50 addresses the requirements of the FDA.
2. Except as provided in section 3 of this section, the informed consent form may be either of the following:
  - a. A written informed consent form that meets the general requirements of 45 CFR § 46.116 or 21 CFR § 50.20, as applicable. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.
  - b. A short form written informed consent form stating that the elements of informed consent required by 45 CFR § 46.116(b) and (c); or 21 CFR § 50.25, as applicable, have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by 45 CFR § 46.116(a)(5)(i) or 21 CFR § 50.25, as applicable, was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized 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 subject's legally authorized representative, in addition to a copy of the short form.
3. The IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:
  - a. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
  - b. 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; or

- c. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
4. PIs may request a waiver of written documentation of the consent process during the IRB protocol review process. If the IRB approves such a waiver, the researcher may still be required to obtain verbal approval to participate from potential subjects.
5. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

#### **I. Informed Consent Form Requirements**

1. The LRH IRB requires that investigators include the following information in consent forms for clinical trials:
  - a. LRH Research Subject's Bill of Rights;
  - b. Financial Statement (when applicable);
  - c. Injury Statement (when applicable);
  - d. Conflict of Interest Statement (when applicable, see [Research: Conflict of Interest- AD.0157](#));
  - e. Billing Error Statement (when applicable); and
  - f. IRB Contact Information.
2. Unless the IRB has approved a waiver of documentation of informed consent, all subjects or their legally authorized representatives must sign and date a current, LRH IRB-approved consent document. Current IRB approval will be documented by a stamp on the signature page of the consent form and/or assent form that indicates the date of approval. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator must give either the subject or the representative adequate time to read the consent document and ask questions before signing.
3. A copy of the consent form must be given to the person signing the form.
4. Researchers must document consent for research in the subjects' medical records when protocol-directed interventions take place.
5. A copy of the signed consent form must be available on short notice for audit or regulatory review.
6. There must not be discrepancies between the consent document(s) and the IRB forms, protocol, or investigator's brochure.

#### **J. Informed Consent Key Information**

1. The following questions may help authors of consent materials and IRBs identify the key information a prospective subject needs in order to make a well-informed choice about whether to participate:

- a. What are the main reasons a subject will want to join this study?
- b. What are the main reasons a subject will not want to join this study?
- c. What is the research question the study is trying to answer? Why is it relevant to the subject?
- d. What aspects of research participation or this particular study are likely to be unfamiliar to a prospective subject, diverge from a subject's expectations, or require special attention?
- e. What information about the subject is being collected as part of this research?
- f. What are the types of activities that subjects will do in the research?
- g. What impact will participating in this research have on the subject outside of the research? For example, will it reduce options for standard treatments?
- h. How will the subjects' experience in this study differ from treatment outside of the study?
- i. In what ways is this research novel?

#### K. Compensation of Subjects Guidance

1. Subjects may be compensated in a variety of ways for participating in research activities. These include financial remuneration, merchandise (gifts, toys, or vouchers) of nominal value, and provision of services (parking fees, free meals, hotel stays, and/or medical treatment). The terms of all types of compensation must be described in the consent form.
2. Compensation is intended to reimburse subjects for time and inconvenience, not for risk. The amount of compensation should not be so high that it would be the sole motivation for a subject to participate in the research. Payment to subjects for participation in research is not considered a benefit; instead, it is a recruitment incentive or reimbursement for the subject's time and inconvenience.
3. Compensation should be appropriate to the subject population. Adults may be offered, for example, a higher rate of compensation than children. The IRB will consider the compensation offered in the context of the subject population of the proposed study.
4. In most cases, compensation should be prorated for subjects who are not able to complete the study. The schedule of payments should be outlined in the consent form, but the specific amount of compensation should not be included in recruitment materials.

## II. ASSENT

### A. General:

1. In pediatric studies, the investigator must obtain, in addition to written permission from the child subject's parent(s) or legal guardian, the child's affirmative agreement or "assent" before the child may participate in the study. (A child's mere failure to

object is not assent.)

2. Assent must be obtained from children who are capable of understanding the concepts involved in the research and should usually be obtained from any child with an intellectual age of seven (7) years or more. Thus, in addition to explaining the study to the parents, the investigator must explain the purpose, risks, and benefits to the child at a level appropriate to the child's intellectual age, and the child must affirmatively agree to participate.
3. Assent from participants younger than seven (7) is not permitted.
4. Assent from participants seven (7) and older is required.
5. Assent from participants fourteen (14) and older is required and the consent form should be provided in the same form as provided to an adult participant.

a. Table II.A.5

b. Participant age and Assent/Consent Requirements:

c.

Participant Age	Assent/Consent
7 to <14 years old	Separate assent form
14 years old and older	Assent line in main ICF

6. Under the FDA regulations, the IRB must determine that adequate provisions are made for soliciting the assent of the children when, in the judgment of the IRB, the children are capable of providing assent.
7. In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent.
  - a. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.
  - b. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.
  - c. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accordance with the Code of Federal Regulations.
8. The IRB will review proposals that vary from these general guidelines on a case-by-case basis.

B. Parental Permission and Consent Requirements:

1. The regulations define whether one (1) or two (2) parents must sign the ICF for research involving minors. In general, permission should be obtained from both parents before a child is enrolled in research. However, the Institutional Review Board (IRB) may find that the permission of one (1) parent is sufficient for research to be conducted under 45 CFR § 46.404 or 45 CFR § 46.405. When research is to be conducted under 45 CFR § 46.406 and 45 CFR § 46.407 permission must be obtained from both parents. See LRH Policy: Research in Children for additional details. For FDA research, see 21 CFR § 50.55 - Requirements for permission by parents or guardians and for assent by children.
2. Table IRB Criteria for determining how many parents must consent:

<b>One (1) Parent may be Sufficient to Provide Consent</b>	<b>Two (2) Parents must Provide Consent*</b>
<p>Proposed research</p> <ul style="list-style-type: none"> <li>• Is not greater than minimal risk</li> </ul>	<p>Proposed research</p> <ul style="list-style-type: none"> <li>• Is greater than minimal risk</li> <li>• Presents no prospect of direct benefit to individual subjects</li> <li>• Is likely to yield generalizable knowledge about subject's disorder/condition</li> <li>• Intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations</li> </ul>
<p>Proposed research</p> <ul style="list-style-type: none"> <li>• Is greater than minimal risk</li> <li>• Presents prospect of direct benefit to individual subjects</li> <li>• Relation of anticipated benefit to risk is at least as favorable to subjects as that presented by available alternative approaches</li> </ul>	<p>Proposed research</p> <ul style="list-style-type: none"> <li>• Is not otherwise approvable</li> <li>• Presents opportunity to understand, prevent or alleviate a serious problem affecting health/welfare of children</li> <li>• Separate approval from the FDA/OHRP is required</li> </ul>
<p>*For research involving placebo, note that placebo presents no direct benefit, so the IRB may require two (2)-parent signatures for these studies. If any</p>	

component of the study meets the two (2)-parent criteria, the IRB will require two (2) parent signatures for the entire study.

3. The regulations include possible exceptions to the two (2)-parent consent requirement, including situations where:
  - a. One (1) parent is deceased, unknown, incompetent, or not reasonably available.
  - b. Only one (1) parent has legal responsibility for the care and custody of the child, if consistent with state law.
4. The investigator will document the situation allowing for an exception to the two (2)-parent consent requirement on the ICF. This documentation will include the source/verification method for the exception.

### III. REMOTE CONSENT & ASSENT

#### A. General

1. Remote consent and assent will be provided in a way that is similar to what would be conducted in-person under normal circumstances. The appropriate option for obtaining a patient's consent/assent will depend on the individual circumstances for the patient and require study teams to follow informed consent/assent procedures as approved by the IRB.
2. Since the participant needs to reference the informed consent document during the conversation, the informed consent must be sent to the participant prior to engaging in the informed consent conversation.
3. The remote consent or assent procedure must include a witness.
4. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.
5. If e-consent is utilized, the number of electronic pages should not be excessive for participants with poor vision.
6. Multiple contingency plans should be made for obtaining remote consent or assent.
7. Consider smart phone options over options that require WiFi service.

## PROCEDURE

### I. INFORMED CONSENT

- A. The patient is asked by the investigator to consider a clinical trial as a treatment option. The investigator/research nurse discusses with the patient the risks and benefits to participating in the clinical trial. The patient is encouraged to ask questions.
- B. The Investigator/Research Nurse will encourage the patient to take home the consent form to read away from the clinic setting to consider participating in the study.
- C. The patient is encouraged to discuss the treatment plan and expected risks and benefits of the clinical trial with the referring physician and family members prior to committing to the study.

1. Note: Explanation of studies may take place in person, or via telephone. The patient will be encouraged to ask questions concerning any explanation which was unclear prior to and at the time of signing the consent; clarification will be given by the person obtaining consent.
- D. If the patient agrees to participate in the clinical trial, the patient must sign and date the consent form prior to enrollment in the study. If the patient is not able to sign the informed consent, a representative appointed by the patient may sign the consent form. The person obtaining the informed consent must also sign and date the form.
- E. A copy of the signed consent form is given to the patient. The original signed consent is placed in the patient's research chart.
- F. The above process is repeated for the Permission to Disclose Identifiable Health Information for Research consent. For FDA regulated research, the consent must state that the FDA may inspect all records.
- G. Patient will be re-consented as required by the study sponsor (e.g., changes to the protocol that may alter patient care or change risk factors).

## II. RE-CONSENT

- A. When a sponsor has made changes to the protocol that require additions or corrections to the consent form, the regulatory coordinator is responsible for making those changes and submitting the updated consent form documents to the IRB.
- B. Once the new consent form has been approved by the IRB, the regulatory coordinator places copies of the approved consent form in the research office regulatory hanging files. An email is forwarded to the research staff alerting them that the new version of the consent is now available. This process can take several days to complete. The date of IRB approval is not the date that the document is available for use by the staff.
- C. The research staff place a copy of the newly approved consent into the research chart of all patients that will need to be re-consented for the study.
- D. Explanation of any change(s) may take place in person, or via telephone.
  1. Face to Face Consent: At the next patient visit, the new consent is reviewed with the patient and is advised of any changes that have occurred in the consent form since the original version was signed. The patient is encouraged to ask questions.
    - a. If the patient chooses to continue in the study after reviewing the consent changes, the consent is reviewed, signed, and dated by the patient.
    - b. The individual obtaining the consent witnesses the signature, signs, and dates as the individual obtaining consent.
    - c. A copy of the newly signed consent is given to the patient. The original is stored in the research chart.
  2. Telephone Consent: The authorized personnel may obtain consent by telephone, as approved by the IRB. In such instances, the authorized personnel shall provide informed consent to the human subject and his/her legally authorized representative, if applicable, over the telephone.

- a. The authorized personnel shall document in the research record the informed consent process.
- b. The written informed consent document shall be sent by mail or facsimile or electronic version via email to the human subject or his/her legally authorized representative for signature and returned. A facsimile or electronic version of the signed informed consent document is as valid as the original.
- c. If the patient chooses to continue in the study after reviewing the consent changes, the consent is reviewed, signed and dated by the patient.
- d. The subject and/or legally authorized representative shall be given a copy of all the consent documents.
- e. When the authorized personnel receives the signed consent, the authorized personnel should call the subject to ensure that the subject understands the study and that all questions have been answered; at this time, the authorized personnel should sign and date the document.

E. Patient will be re-consented as often as required by the study sponsor.

1. In certain situations, such as when patients are in long-term follow up, re-consenting may not be necessary unless the IRB and/or Sponsor requires the re-consent.

### **III. REMOTE CONSENT**

A. The following are to be specified in the study protocol/materials:

1. Include a statement that the research will not begin until the LRH IRB approved signed consent/assent form is received by the study team.
2. Create a standard process to verify the identity of the individual who signs the documents. Acceptable examples include state-issued ID, biometric methods, visual methods, or personal questions. Document both the verification of identity and the consent/assent process.
3. Document that the informed consent conversation occurred, the method by which it occurred (e.g. telephone call, telehealth encounter), and the subject's understanding of the information presented to them.
4. Have a second person listen to the whole discussion and sign the witness attestation form.

B. When a copy of the fully executed ICF has been returned to the study team, informed consent may be obtained by telephone. When obtaining consent by telephone, researchers must:

1. Document how the ICF was transmitted to the participant (e.g., email, fax, mail, etc.).
2. Document how the participant's signature was obtained (e.g. scanned and emailed, faxed, or mailed back or photograph of signature/signature page sent back to the study team). In cases where subjects are faxing a consent form to the research team, the subject need not provide the investigator with the original signed consent document.

- C. For all research requiring a signed ICF, the participant must also date the ICF.
- D. When individuals cannot print and sign a paper copy of the ICF provided by the investigator/designee and providing a paper copy of the ICF via mail/courier is not feasible within the timeframe for enrollment into the clinical trial, the investigator may consider using the following alternative process to satisfy FDA requirements for obtaining and documenting informed consent:
1. The investigator/designee provides the prospective participant (or LAR) with an electronic version of the ICF.
  2. The investigator/designee arranges a telephone call or video conference call with the prospective participant (or LAR), the investigator/designee, an impartial witness who is not otherwise connected with the clinical investigation, and, if desired and feasible, additional participants requested by the prospective participant (e.g., next of kin).
  3. To ensure the prospective participant (or LAR) is approached in a consistent fashion, a standard process should be used that will accomplish the following:
    - a. Identification of who is on the call;
    - b. Review of the ICF with the prospective participant (or LAR) by the investigator/designee and response to any questions the prospective participant (or LAR) may have;
    - c. Verbal confirmation by the prospective participant (or LAR) that their questions have been answered and that they would like to participate in the trial;
    - d. Documentation of these steps in the research record;
    - e. Verbal confirmation by the participant (or LAR) that they signed and dated a blank piece of paper with a written statement that they voluntarily agree to participate in the protocol, noting both the protocol number and brief protocol title;
    - f. After signing and dating the newly created document, the trial participant (or LAR) sends a photograph of the signed and dated statement by fax, text message, or email to the investigator/designee OR returns the document to the investigator by mail at a later date or at a future study visit that might occur in person; and
    - g. After the signed and dated document is received by trial staff, it should be appended to a copy of the ICF that was reviewed with the trial participant (or LAR) and retained in the trial records as would normally be done for a signed ICF. Additionally:
      - i. A note in the trial records should be made explaining the circumstances of why informed consent was obtained through an alternative method.
      - ii. The case history for each trial participant must document that informed consent was obtained prior to participation in the trial.
      - iii. Questions and/or check boxes embedded throughout the

document for the subject to complete are included.

## DEFINITIONS

**Assent:** A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

**Children:** Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted ([45 CFR § 46.402\(a\)](#)).

**FDA:** Food and Drug Administration.

**Guardian:** An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

**ICF:** Informed Consent Form.

**IRB:** Institutional Review Board.

**LAR:** Legally Authorized Representative.

**Legally Authorized Representative:** An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

**Parent:** A child's biological or adoptive parent.

**Permission:** The agreement of parent(s) or guardian to the participation of their child or ward in research.

**Workforce:** All LRH employees, volunteers, trainees/students, contractors, and medical staff.

## REFERENCES

Advara Remote Consenting Guidance April 10, 2020 <https://www.advarra.com/coronavirus-guidance/#remote-consent>.

CIRB Remote Consent Procedures: Revised FAQs due to COVID-19 4/22/2020. <https://www.ncicirb.org/announcements/remote-consent-procedures-revised-faqs-due-covid-19>.

HHS SACHRP Committee Recommendations 11.13.2018.

UC Davis Consent Process. Remote Consent <https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/project-guidance/consent-process/>.

Use of Electronic Informed Consent Questions and Answers. Guidance for Institutional Review Boards, Investigators, and Sponsors. U.S. Department of Health and Human Services Office for Human Research Protections (OHRP) Food and Drug Administration Center for Drug Evaluation and Research (CDER) Office of Good Clinical Practice (OGCP) Center for Biologics Evaluation and Research (CBER) Center for Devices and Radiological Health (CDRH); December 2016 Procedural; <https://www.fda.gov/media/>

## APPENDIX

# Information for People Who Take Part in Research Studies

*The following information is being presented to help you decide whether you want to be a part of a research study. Please read carefully. If there is anything you do not understand, ask the study doctor or a member of the study staff.*

**Title of Study:**

**Primary/Principle Investigator:**

**Study Location:**

**Sponsor:**

*Introduction/Summary of Study.*

*How many people will take part in the research study?*

*What will happen if I take part in this research study?*

*How long will I be in the research study?*

*How many people will take part in the research study?*

*How do I stop being in the research study?*

*What side effects or risks can I expect from being in the research study?*

**Purpose of the Study/Why is study being done?**

**Procedures for the research study**

**Collection of Biospecimens**

There are **no experimental treatments or procedures** involved in contributing a blood sample, tissue sample or any other sample to the sponsor.

If you decide to contribute blood to the study, a staff member of your study doctor's office will obtain the blood sample (approximately 6 tablespoons). Once your blood is drawn, the study doctor's office staff will package and ship the sample according to the sponsor's procedures.

If you are having surgery or a procedure, it may be necessary for your doctor to remove some diseased tissue and healthy tissue to diagnose or treat your condition. Many times the doctor will not need all of the tissue he/she removed to diagnose or treat you. This extra tissue would normally be discarded because it is not needed for your medical care. Instead of having this extra tissue or other sample thrown away, you may choose to contribute this to the sponsor for medical and health research. If you agree to contribute a sample to the sponsor, **only left over (extra) tissue/samples** from a procedure or surgery will be included repository.

When the sponsor receives your sample, a small part of the sample may be used to evaluate sample quality and ensure the specimen is usable for research. Specimens that are usable may then be divided into smaller pieces for storage. Some samples may be used immediately for laboratory research as described below, while others may remain in storage until requested for research purposes.

### ***Contributing Samples That Have Already Been Collected and how they will be handled***

You may have already had surgery, and left over tissue sample(s) are in storage. If your stored sample is identified as useful for this research, you may choose to contribute the left over sample(s) to the sponsor repository. You may also be asked to contribute a blood specimen (approximately 6 tablespoons).

### ***Collection of Medical Information and how it will be protected***

If you decide to participate in this study, you will be assigned a randomly generated barcode number that will not identify you. Your health information will be linked to your sample with this barcode number. Your health information will be kept confidential and will not be shared with anyone outside the study unless required by law; however, the U.S. Food and Drug Administration (FDA), other government agencies and Sponsors, or Sponsor representative may review the study data and patient identifying information to make sure that the study data is correct and proper laws and procedures were followed.

Some of the information to be collected may include your year of birth, diagnosis, medications, medical treatments, and dates of service. This information will be recorded in a secure electronic database that will be connected to your sample(s).

If your health information and sample are useful for research, your health information may be collected once a year for up to five (5) years. The researchers will either call you or contact your physician's office to gather additional information about your health status, treatment and outcomes to enter updated information in the Sponsors database.

A description of this study will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

In the future, a researcher may wish to conduct research that requires biospecimens with medical data such as yours. That researcher would contact the sponsor, Inc. for a sample and your sample might be provided for the research. The sample(s) may be used by other researchers at universities, government agencies (such as the National Institutes of Health), and/or private companies.

Your sample(s) and information from your medical record will be maintained by Sponsors, for such research purposes, as long as allowed by the law or until the Sponsor decides to withdrawal your sample(s) or discontinue the repository.

### ***Risks and Discomforts Utilize percentages if not available state so***

#### ***Physical Risks***

There are no risks associated with collecting biospecimens for the repository. There are no additional risks for donating biospecimens if you are a pregnant woman or nursing a child.

Every effort will be made to collect repository blood samples at the same time blood is collected for your usual care. If a blood sample must be obtained solely for the Sponsor, risks associated with collecting blood samples include:

**Most Common (percentages of occurrence not available):**

- Mild pain, bruising or tenderness at the puncture site

**Less Common (percentages of occurrence not available):**

- Excessive bleeding at the puncture site

**Rare (percentages of occurrence not available):**

- Fainting or light-headedness and/or infection at the puncture site

***Psychological or Social Risks Associated With Loss of Privacy***

Your privacy is very important to us and many safety measures are in place to prevent any unauthorized disclosure of personally identifiable information. However, in spite of all of the safety measures, there is no guarantee your identity will never become known. If there is an inadvertent or accidental disclosure of clinical data or data obtained from your sample or this research, it could have adverse (bad or harmful) effects on your insurability, employment, or social standing.

Only designated Sponsor employees will have access to identifiable samples, testing results, and medical information about you. Every effort will be made to keep records and testing private but no guarantee can be made.

Your sample contains DNA and RNA and, as a result, the Sponsor will have and store your genetic information. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other relatives. A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

In the unlikely event that there is an accidental disclosure of identifying information about you, this could have an effect on your insurability, family relationships, or other legal issues. For example, companies that sell disability, life or long-term care insurance may refuse to sell insurance to people with a certain illness or genetic makeup. In addition, the result of genetic research may not apply only to you, but also to your family members. However, the Genetic Information Nondiscrimination Act (GINA) and other laws and regulations prohibit health insurance companies and employers with more than fourteen (14) employees from discriminating against Americans based on their genetic information. More information about GINA is available at [www.geneticfairness.org/ginaresource.html](http://www.geneticfairness.org/ginaresource.html).

If research results are published in scientific journals, on-line databases and other places useful to improve care and treatment, your identity will not be disclosed in any published materials.

**New Information**

You will be kept informed about any changes to the study that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

## **Benefits**

Neither you nor your doctor will receive the results of research done with your sample(s). There is no direct benefit to you to participate in the study. The discoveries from the research of your sample(s) and medical information may help other people in the future.

## **Costs**

What the costs will be? If any.

## **Payment for Participation/Use in Commercial Development of Products**

You will not be paid for your participation in the study. Your biospecimen(s) and results of tests done on these samples are intended to be the property of the sponsor and may be used in grant applications, fundraising presentations, and as part of commercial agreements with private companies. As part of such activity, the sponsor may obtain alone or in partnership with private companies, patents or other legal licenses relating to potential diagnostic or treatment methods. Through such means, the sponsor, its scientists and physicians, and its collaborators or commercial partners may obtain financial benefit. The sponsor has no plan to share this financial benefit with you or any member of your family. You do not waive any legal rights by signing this consent form.

## **Alternative Treatment**

This is not a treatment study. Your alternative is to decline to contribute a sample(s) and data to the study. **What is available if applicable?**

## **May I Review your Information?**

You will not receive the results of any laboratory or genetic testing performed on your sample(s) that are not used for your routine medical care. Due to the likelihood that data related to your specimen and health information is not linked to you, you will not be informed of the specific research results.

## **Voluntary Participation and Withdrawal**

Your participation in the study is voluntary. You may decide not to participate or you may leave the study at any time. When you withdraw your permission, no new health information identifying you will be gathered after that date. Your sample(s) and medical information will be taken out of the repository and destroyed. However, once your sample(s) and medical information have been distributed to a researcher outside of the sponsor, it may not be possible for us to get your sample(s) or medical information back.

If you wish to withdraw from the study, contact your research team at. Your decision will not result in any penalty or loss of benefits to which you are entitled. No matter what you decide to do, your decision will not affect your medical care.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- If it is in your best interest
- You do not consent to continue in the study after being told of changes in the research that may affect you

- For any other reason

## Source of Funding for the Study

## Questions

Contact the study doctor, for any of the following reasons:

- You have any questions about this study or your part in it
- You feel you have had a research-related injury
- You have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact the Chairman of the Lakeland Regional Medical Center Institutional Review Board (LRMC IRB) at (863) 687-1053. The LRMC IRB is a group of people who independently reviewed this research study to make sure your rights and welfare as a study participant are being protected.

**NOTE:** The LRHMC IRB will not be able to answer some types of questions, such as questions about appointment times.

Do not sign this consent form unless you have had a chance to ask questions and have obtained satisfactory answers.

## Injury Statement

In the event that you sustain an injury or illness as a result of participating in this research study, please be aware that medical treatment for a specific injury or illness may not be available. If you become ill or sustain an injury which you believe is related to participation in this research study, **immediately** contact the study doctor and if emergency care is needed seek emergency attention from your nearest local hospital. *List contact information.*

*What are my rights if I take part in this research?*

*Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.*

*We will tell you about new information or changes in the study, you do not lose any of your legal rights to seek payment by signing this form.*

*Who can answer my questions about the research study?*

*You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor. (Contact information)*

*For questions about your rights while taking part in this study, call the Chairman of the Lakeland Regional Medical Center Institutional Review Board (an ethics committee who reviews the research to protect your rights) at (863) 687-1100, ext. 7214.*

**Your Consent- By signing this form I agree that:**

- I have fully read or have had read and explained to me in language that I understand this informed consent form describing a research project.
- I have had the opportunity to question one of the persons in charge of this research and have received satisfactory answers.
- I understand that I am being asked to participate in research. I understand the risks and benefits, and I freely give my consent to participate in the research project outlined in this form, under the conditions indicated in it.
- I have been given a signed copy of this informed consent form, which is mine to keep.
- I understand that I may refuse to participate in this study or may withdraw at any time without penalty.
- By signing this form, I am not giving up any of my rights or releasing the sponsor, the investigator, the research site or its agents from any liability for negligence.
- I understand that all my medical records will be made available for collection of data related to this clinical research protocol, and I hereby give my permission to release those records to personnel associated with this study. I understand that my confidentiality will be maintained to the full extent of the law.

Signature of Participant	Printed Name of Participant	Date	Time
Signature of Witness (if applicable)	Printed Name of Witness (if applicable)	Date	Time
Signature of Person Obtaining Informed Consent	Printed Name of Person Obtaining Informed Consent	Date	Time

**Institutional Approval of Study and Informed Consent Form**

This research project/study and informed consent form were reviewed and approved by the Lakeland Regional Health Medical Center Institutional Review Board for the protection of human subjects. This approval is valid until the date provided below. The board may be contacted at 863-687-1100 x7214.

**Approved Consent Form Expiration Date:**

## Approval Signatures

**Step Description**

**Approver**

**Date**

Danielle Drummond: 0001 President & Chief Executive Officer - LRHS	03/2024
Jonn Hoppe: 1011 Executive VP, Chief Legal Officer-General Cou	03/2024
Timothy Regan: 0009 President - LRMC/Chief Medical Officer	03/2024
Renee Reed: 4064 Senior Attorney	03/2024
Deana Nelson: 4080 SVP - Administration and Corporate Initiative	03/2024
Georgia Ann Keriazes: 0729 QI/ Due Pharmacist	03/2024
Andrew Bugajski: 4387 AVP - Research and Sponsored Studies	12/2023

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