McLeod Health
The Choice for Medical Excellence

Institutional Review Board Policy Manual

INFORMED CONSENT

I. Purpose Statement

The purpose of this policy is to describe the reasons for and process of obtaining informed consent in human subject research, including the necessary elements of consent and the documentation thereof.

II. Policy

The McLeod Health Institutional Review Board (IRB) shall ensure that all the federal requirements for obtaining informed consent are met before initially approving, and throughout its ongoing review of, any research protocols involving human subjects. Principal investigators are responsible for ensuring that research subjects provide valid informed consent prior to participating in research, unless the requirement for informed consent is waived or altered by the IRB. When obtaining informed consent, investigators must follow the process described in this policy (unless altered by the IRB), including required and additional elements of consent disclosure. In its consideration of a proposed waiver or alteration of informed consent/documentation, the IRB shall reference the criteria described within this policy.

III. Procedure

Overview

1. Before involving a human subject in research, 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 LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
3. The information that is given to the subject or LAR shall be in language understandable to the subject or LAR.
4. The prospective subject or LAR 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. Except in cases of broad consent, informed consent must:
    a. Begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This must be organized and presented in a way that facilitates comprehension.
    b. Present information in sufficient detail relating to the research in a way that does not merely list isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate.
    c. NOT include exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or which releases or appears to release the investigator, sponsor, institution, or associated agents from liability for negligence.

Elements of Informed Consent

A. Required Elements – The information provided to the subject or LAR during the consent process is to be consistent with the federal requirements. Unless informed consent is waived or altered by the IRB (see "Waiver or Alteration of Informed Consent" below), the consent process must include the following basic elements:

- A statement that the study involves research, explanation of the purposes of the research, expected duration of participation, description of the procedures to be followed, and identification of any procedures that are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject [also a broad consent requirement (BC*)]
- A description of any benefits to the subject or to others that may reasonably be expected from the research (BC*)
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (BC*)
- Whom to contact for answers to pertinent questions about the research and the subject's rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled (BC*)
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

    a) 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 LAR, if this might be a possibility; or

b) 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.

- For research involving more than minimal risk, an explanation about 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 found

For research subject to FDA regulation, informed consent must also include:

- A statement that informs the subject of the possibility that FDA may inspect the records
- For applicable clinical trials, the following statement notifying the subject that trial information has been/will be submitted for inclusion in the clinical trial registry databank: "A description of this clinical trial 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."

B. Additional Elements – One or more of the following elements will also be provided to the prospective subject or their LAR during the consent process, when appropriate:

- 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 during the trial) that are currently unforeseeable
- Anticipated circumstances under which participation may be terminated by the investigator without regard to the subject's or LAR's consent
- Any additional costs to the subject that may result from participation in the research
- Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that the subject will be provided with any significant new findings developed during the course of the research that may relate to or influence the subject's willingness to continue participation
- Approximate number of subjects involved in the study
- 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 (BC* when appropriate)
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- 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 (BC* when appropriate)

Additional information beyond the basic and additional elements of consent listed above may also be required if the IRB determines that such information would meaningfully add to the protection of research participants.

C. Elements of Broad Consent* – For the storage, maintenance, and secondary research (i.e. not part of a planned or active, IRB-approved protocol) use of identifiable private information or identifiable biospecimens, broad consent is permitted as an alternative to the informed consent requirements. In such cases, the consent provided to the subject or the subject's LAR must contain the following:

- Certain basic and additional elements of consent, as noted in the sections above by (BC*) and (BC* when appropriate)
- 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
- 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
- A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which 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 could be indefinite)
- Unless the subject or LAR 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
- 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
- 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 research-related harm.

Waiver or Alteration of Consent

The IRB may waive the requirement to obtain informed consent (but not broad consent), provided the IRB satisfies the requirements for waiver and alteration noted below. 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 section C above, and refused such consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the subject's identifiable private information or identifiable biospecimens.

An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of consent set forth in sections A and B above, provided the IRB satisfies the requirements

below. Aside from waiving consent in its entirety, an IRB may not omit or alter any requirement described in the Overview of this policy. If broad consent is used, an IRB may not omit or alter any of the elements required in section C above.

Requirements for waiver and alteration: In order for an IRB to waive or alter informed consent as described above, the IRB must find and document that:

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

Informed Consent Exception for FDA-Regulated Emergency Research

Certain emergency research (i.e. research involving human subjects who are in life-threatening situations) may be approved by the IRB without requirements to obtain informed consent from the subjects. Any such approval may only take place if there is concurrence from an unbiased, licensed physician who is a member or consultant of the IRB, and if the IRB finds and documents the FDA requirements for research found at 21 CFR 50.24. In its review of such research, the IRB will ensure that the prospective subjects are treated as a vulnerable population entitled to additional protection (due to their susceptibility to coercion and their reduced capacity for being fully informed). Moreover, in accordance with the Declaration of Helsinki, the IRB will ensure that the rights and welfare of these subjects take precedence over all other interests.

Documentation of Informed Consent

Except as noted in the paragraph below, 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 LAR. A written copy shall be given to the person signing the informed consent form. A written informed consent or a short form** written informed consent may be used as long as the requirements included in 45 CFR 46.116 are met. The subject or the subject's LAR shall be given adequate opportunity to read the informed consent form before it is signed; alternatively, these forms may be read to the subject or the subject's LAR. (**See 45 CFR 46.117 for the procedures that must be followed for short form documentation.)

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all research participants if it finds any of the following:

(i) 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 LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) 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

(iii) If the subjects or LARs 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.

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

Additional Considerations for Informed Consent

Consent by Telephone/Teleconference

The IRB may approve research in which informed consent will be obtained via telephone or teleconference systems provided that all appropriate elements of consent, as noted in this policy, are met and:

- The signature requirement is waived by the IRB in accordance with the previous section; or
- The prospective participant or their LAR receives a copy of the consent form in advance of the telephone/teleconference discussion, signs the form following that discussion, and returns the form (e.g. via fax or mail/email) to the investigator for final signature before any research procedures take place.

This type of consent is only appropriate when patients are unable to be consented in person by the investigator (due to distance, lack of transport, physical/health limitations, etc.). When verbal consent is obtained via telephone/teleconference systems, this must be documented by the investigator and at least 2 witnesses. The investigator is required to provide subjects or LARs with a written copy of the consent agreement.

Uploading Consent Documents for Federally Funded Research

In order to promote transparency of federal research, one IRB-approved informed consent form (which has been used to enroll subjects) must be posted to either ClinicalTrials.gov or a specific docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021). The consent form must be posted after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol. **Note: this requirement applies only to research that is federally funded or conducted.** The federal department or agency supporting or conducting the clinical trial may permit or require redactions to the information posted (e.g. confidential commercial information).

IV. Equipment Needed

Not Applicable

V. Addendums

This policy is effective as of January 21, 2019, to coincide with the compliance date of the Final Rule (45 CFR 46, subpart A). Research approved or exempted from review by the IRB prior to this date may not be subject to the entirety of this policy. Such research must adhere to the requirements for informed consent contained in the pre-2018 Common Rule, unless the IRB determines and documents otherwise.

VI. Attachments

Not Applicable

VII. Related Links

Applicable regulations and guidelines include: 45 CFR 46.116-117, 21 CFR 50.24

Reference Information

Policy Number: 18039.IRB.I-15
Initial Date: 11/15/17
Effective Date: 1/21/19
Revision Date: 11/15/18
Revision History:
Review History:
Supersedes: N/A

This Policy Has Been Reviewed and Approved For:

McLeod Health Sites	Without Exceptions	Exceptions	N/A
McLeod Regional Medical Center of the Pee Dee, Inc.	X		
McLeod Medical Center Dillon	X		
McLeod Medical Center Darlington	X		
McLeod Physician Associates	X		
McLeod Regional Medical Center of the Pee Dee, Inc. d/b/a McLeod Home Health	X		
McLeod Regional Medical Center of the Pee Dee, Inc. d/b/a Hospice of the Pee Dee	X		
McLeod Loris Seacoast Hospital McLeod Seacoast (practice location)	X		
McLeod Loris Seacoast Hospital McLeod Loris (practice location)	X		
McLeod Regional Medical Center of the Pee Dee, Inc. d/b/a McLeod Ambulatory Surgery Center	X		
McLeod Family Medicine Center	X		
McLeod Cheraw	X		

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