**Purpose**: Obtaining informed consent from a participant is essential in the conduct of human subjects’ research. It is the underpinning of the ethical principal – **respect for persons**. Informed consent is not just a signed document, it is a continual process that begins from the time prior to the participants’ enrollment into the research through the completion of the investigation. Informed consent reflects the persons’ understanding of the research to be conducted and their willingness to participate as well as their continued participation. This standard operating procedure (SOP) describes the process for obtaining informed consent from research participants and the documentation of such at this investigative site.

**Scope:** This SOP applies to Investigators and clinical research team members conducting human subject research at UNC.

**Definitions:**

Health Insurance Portability and Accountability Act (HIPAA): United States legislation that provides data privacy and security provisions for safeguarding medial information.

Legally Authorized Representative (LAR): an individual or body authorized under applicable law to provide permission on behalf of a prospective subject to the subject’s participation in the procedures(s) involved in the research.

Legal Guardian: a person appointed by a court of appropriate jurisdiction.

Principal Investigator (PI): the person responsible for the conduct of the investigation at this site.

**Procedures (Revise as necessary for pediatric populations involving the use of an assent and parental permission forms):**

**Obtaining Informed Consent**

1. Adherence to the Office of Human Research Ethics Standard Operating Procedures for obtaining informed consent is implicit in this SOP.
2. The PI will delegate those research team members who may obtain informed consent and will be listed on the Delegation of Authority form.
3. The person obtaining informed consent will review the entire consent document with the potential participant and/or their LAR.
4. The PI or the delegate will be available and able to answer questions the participant may have.
5. The participant or LAR will sign and date the informed consent document.
6. If a HIPAA authorization form is required, the participant or LAR will also sign and date this form.
7. The research team member obtaining consent will also sign and date the document.
8. A copy of the signed and dated documents (informed consent and HIPAA if applicable) will be given to the participant or their LAR.
9. The original documents will be placed in the participant’s research record.

**Documenting the Process of Obtaining Informed Consent**

1. The process of obtaining informed consent will be documented by completing the Informed Consent Process Documentation form (example attached to this SOP).

(If the trial involves pediatric participant’s, revise the Informed Consent Process Documentation form to reflect parental permission as well as assents.)

1. The Informed Process Documentation form will be placed in the participant’s research record.

**Applicable Policies and Guidelines:**

* UNC Office of Human Research Ethics Standard Operating Procedures
* 21 CFR 50 – Protection of Human Subjects
* 21 CFR 56 – Institutional Review Boards
* 45 CRF 46 – HHS Policy for Protection of Human Research Subjects
* ICH Good Clinical Practices E6 (R2)

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| --- | --- |
| **Revision History** | |
| Date of Revision: | Revision Description: |
|  |  |

IRB#: \_\_\_\_\_\_\_\_\_\_ Protocol #: \_\_\_\_\_\_\_ Participant Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Birth: Medical Record #:

Please **INITIAL** next to **“Yes” or “No”** by each line as appropriate **(if “No,” an explanation MUST be provided in the notes**

**section below).**

|  |  |  |
| --- | --- | --- |
| Yes | No | Participant and/or the participant’s legally authorized representative (LAR) was given a copy of the consent document to read. |
| Yes | No | Ample time was provided for reading the consent document, and the participant (or participant’s LAR) was encouraged to ask questions. |
| Yes | No | All questions and concerns were addressed to the satisfaction of the participant (or participant’s LAR) prior to signing the consent document. |
| Yes | No | The PI or Sub-I was available for questions prior to the subject signing the consent. |
| Yes | No | The subject (or subject’s LAR) agreed to participate in the study and signed/dated the consent document. |
| Yes | No | A copy of the signed consent document was provided to the participant (or participant’s LAR).  ❑ Verbal consent was obtained (per IRB approved consent process). Documentation of the process and the individual(s) witnessing the process is described below. |
| Yes | No | No procedures specifically related to the study were performed prior to the participant signing the consent document. |
| Yes | No | A copy of the signed consent document was placed in the participant’s medical record. |

The details of this research study were discussed with the participant (or participant’s LAR), including an explanation of all the elements of the consent document. The IRB-approved consent document was signed and dated by the participant (or participant’s LAR). No activities specifically related to the research were initiated until after the execution of the consent document. The principal investigator was notified of the participant’s consent to be enrolled in the study.

Consent Form:

The participant (or participant’s LAR) signed consent document version on

*(date)* at *(time)*.

HIPAA Authorization:

The participant (or participant’s LAR) signed HIPAA Authorization version \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(date)* at \_\_\_\_\_\_\_\_\_\_\_\_\_ *(time).*

Notes­­­­­­:

\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date Time