1. PURPOSE

This policy describes the general requirements for obtaining and documenting informed consent.

2. RESPONSIBILITY FOR EXECUTING THE POLICY

Investigators; IRB Medical Director; IRB Associate Directors; IRB Administrative Support; IRB Chair; IRB Vice-Chair; IRB Members and Subcommittees

3. POLICY STATEMENT

This policy pertains to all research submitted to the IRBs. Informed consent must be legally effective and prospectively obtained (45 CFR 46.116; 21 CFR 50.20). Except as delineated in SLUHN Policy IC 606, *Waiver of Informed Consent and HIPAA Authorization*, no investigator may enroll a human being as a research subject unless s/he has obtained legally effective informed consent from the subject or the subject's legally authorized representative (LAR). Consent shall be sought only under circumstances that provide the prospective subject or the LAR sufficient opportunity to consider whether or not to participate in the study, and that minimize the possibility of coercion or undue influence.

Subject authorization also must be obtained for prospective use or disclosure of protected health information (PHI) for research conducted within the University or the University Hospital. Except as described in SLUHN Policy IC 606 no investigator may prospectively collect PHI unless s/he has obtained legally effective authorization of the subject or the subject's legally authorized representative.

The IRB requires documentation of informed consent by use of a written consent form approved by the IRB and signed and dated by the subject or the subject's LAR. Authorization to collect PHI will also be obtained by the use of the IRB-approved consent form that contains a federally-compliant HIPAA Confidentiality Section or, as appropriate, a separate HIPAA Authorization document.

4. PROCEDURES

The consent form document may be either of the following:

- A written consent document that encompasses the elements of informed consent and the required elements of a HIPAA authorization. This form may be read to the subject or the subject's LAR. The investigator shall give the subject or the LAR adequate opportunity to read it before it is signed. The subject or LAR shall receive a copy of the signed and dated consent document.
- A "short form" written consent document stating that the elements of informed consent as required have been presented orally to the subject or the subject's LAR. When this method is used, there shall be an impartial witness to the oral presentation. The IRB must approve a written summary of what is to be said to the subject or representative. The subject or the LAR will sign the short form. The witness shall sign both the short form and a copy of the summary, and the person actually obtaining the informed consent shall sign the summary. A copy of the signed and dated summary and the signed and dated short form shall be given to the subject or the LAR.

4.1: Required Elements of Informed Consent

The following elements must be present in all IRB-approved informed consent documents:

- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental or investigational.

- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that the subject can pursue outside of the study.
- A statement describing the extent to which, if any, the confidentiality of records identifying the subject will be maintained and that states the possibility that the Food and Drug Administration (FDA) and representatives of the IRB may inspect the records.
- For research involving greater than minimal risk, or any study reviewed by the convened Board, an explanation as to whether any compensation is available and that medical treatments are available if injury occurs and where further information may be obtained
- The informed consent document must not waive or appear to waive the rights of the participant or release, or appear to release, those conducting the study from liability for negligence.
- 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.
- A statement that participation is voluntary and 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.
- Informed consent documents may not contain any exculpatory language through which the subject is made to waive or appear to waive legal rights or releases or appears to release the investigator, the sponsor, or the university from liability for negligence.

4.2: Additional Elements of Informed Consent

When appropriate, one or more of the following elements also may be required in the informed consent document:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant) which are currently unforeseeable.
- Anticipated circumstances in which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- Any additional costs to the subject that may result from participation in the research.
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
- The approximate number of subjects involved in the study at Jefferson and nationally if a multi-site study.

4.3: Elements of HIPAA Authorization

The following elements are required in a federally-compliant HIPAA Authorization. These elements should be part of the Confidentiality Statement in the SLUHN Informed Consent Document template:

- A description of the health information to be collected as part of the research.
- A description of the person or classes of persons authorized to use or disclose the protected health information.

- A description of the person or classes of persons who may receive the information, and the purpose(s) for each disclosure.
- An expiration date or the extent of the authorization for use or disclosure if any
- A statement of the subject's right to revoke authorization and person to contact to revoke
- Reference to the covered entities Notice of Privacy Practices
- Notice that disclosure of protected health information to non-HIPAA compliant entities may result in subsequent loss of protection of PHI.
- Limitations, if any, on a subject's access to their records during the study.

4.4: Documentation of Informed Consent

At some point in the consent process, an interview or session is held with the prospective subject and/or LAR so that all of the subject's/LAR's questions and concerns are answered before s/he makes the final decision on participation. This interview can be conducted by the PI, a Co-I, or any key personnel designated by the PI. When the subject or LAR signs the consent form, this is referred to as "obtaining informed consent."

The ultimate responsibility for ensuring that informed consent is obtained, and that the consent interview is conducted in such a way that all of the subject's/LAR's questions and concerns are answered rests with the PI. However, because consenting situations are so varied, the IRB will only make specific determinations as to who can and cannot obtain informed consent on a case-by-case basis.

Whomever is designated to conduct the consent interview must describe the research study to the potential subject/LAR, discuss appropriate alternatives, and answer any questions regarding the research, and obtain the subject's/LAR's consent to participate prior to initiating any research procedure.

If the consent interview is conducted by key personnel other than the PI (or Co-I if the PI is unavailable), the PI or Co-I must be reachable by phone if the subject should have questions that cannot be answered by the person conducting the interview. If the research poses greater than minimal risk, the PI or a Co-I should make every effort to be present at some time during the consent interview.

When the subject signs and dates the consent form, the person conducting the consent interview will also sign and date

The original consent form, signed and dated by the subject, or the subject's authorized representative, and the person obtaining consent, and a witness if necessary, must be kept in the subject's study file and a photocopy provided to the subject.

4.5: Other Requirements

Second Person: The consent document should use the second person (You/your) style so the consent form conveys a dialogue with information being provided and that there is a choice to be made by the subject rather than presumption of the subject's consent with the use of the first person style (I/mine).

***Simple Language*:** The information provided in the informed consent documents must be in language understandable to the subject. The informed consent document should not use complex language that would not be understandable to all subjects. Technical and scientific terms should be adequately explained using common or lay terminology (See SLUHN Guidance Document G 703).

***FDA-Regulated Test Articles*:** For research involving test articles regulated by the U .S. Food and Drug Administration (FDA), informed consent documents must include a statement that the purpose of

the study includes evaluation of the safety and/or efficacy of the test article. The consent form must also include a statement that the FDA has access to the subject's medical records.

4.6: IRB Review of Consent Process

The IRB will take the following into consideration when reviewing the protocol and consent document:

- Person(s) who will conduct the informed consent process.
- Matters of timing of obtaining informed consent and the waiting period between informing the subject and obtaining consent.
- Ensuring that the process provides ample time for the person conducting the consent interview and the prospective subject to exchange information and ask questions.

5. TOOLS

SLUHN Informed Consent Document Template
SLUHN Policies IC 601, Informed Consent and HIPAA, and IC 602, IC documentation
SLUHN Guidance G 703, Lay terminology

Approved by:

_____ **Date:** _____
Senior Vice President for
Medical and Academic Affairs

_____ **Date:** _____
Medical Director, IRB