Research cannot be conducted under the auspices of WVU involving a human being as a participant in non-exempt research without obtaining the legally effective informed consent of the participant or the participant’s legally authorized representative unless a waiver of consent has been approved by the WVU IRB following SOP Section 5. Except as provided in Section SOP Section 5, informed consent must be documented using a consent form and process approved by the IRB (See SOP Section 5).

The IRB will evaluate both the consent process and the procedures for documenting informed consent to ensure that adequate informed consent is obtained from participants.

The following procedures describe the requirements for obtaining consent from participants in research conducted under the auspices of WVU.

9.1 Basic Requirements

The requirement to obtain the legally effective informed consent of individuals before involving them in Research is one of the central protections provided for by the Federal regulations and the WVU HRPP. PIs are required to obtain legally effective informed consent from a participant or the participant’s Legally Authorized Representative.

When informed consent is required, it must be sought prospectively and adequately documented. The informed consent process involves three key features:

1. Disclosing to the prospective human participant information needed to make an informed decision;
2. Facilitating the understanding of what has been disclosed; and
3. Promoting the voluntariness of the decision about whether or not to participate in the research.

Informed consent is more than just a signature on a form. It is a process of information exchange to include reading and signing the informed consent document. The informed consent process is the critical communication link between the prospective Human Participant and an PI, beginning with the initial approach of an PI and continuing through the completion of the research project. PIs must have received the appropriate training and be knowledgeable about the project Protocol so that they may answer questions to help provide understanding to the project participant or potential project participant.

The exchange of information between the PI and project participant can occur via one or more of the following modes of communication, among others: face to face contact, mail, telephone, or fax; however, obtaining informed consent must be obtained face to face between the PI and the potential project participant unless the IRB allows a modified process.

PIs must obtain consent before entering a participant into a project and/or conducting any procedures required by the protocol unless consent is waived by the IRB.

If someone other than the PI conducts the interview and obtains consent from a patient or participant, the PI needs to delegate this responsibility formally, and the person so delegated must have received appropriate training to perform this activity. The person so delegated must be knowledgeable about the research to be conducted and the consenting process and must be able to answer questions about the project.
A Sponsor or cooperative project group may develop sample or draft consent documents. However, the IRB-of-record is the final authority on the content of the consent documents that are presented to the prospective project participants.

**The informed consent requirements are not intended to preempt applicable federal, state, or local laws that require additional information to be disclosed for informed consent to be legally effective.**

### 9.2 Informed Consent Process

Informed consent must be obtained under the following circumstances:

1. Informed consent may only be obtained from participants who have the legal and mental capacity to give consent. For participants without that capacity, consent must be obtained from a legal guardian or a legally authorized representative.

2. The informed consent process shall be sought under circumstances that provide the participant (or legally authorized representative) with sufficient opportunity to consider whether or not to participate.

3. The informed consent process shall be sought under circumstances that minimize the possibility of coercion or undue influence.

4. The informed consent information must be presented in language that is comprehensible to the participant (or legally authorized representative). To the extent possible, the language should be understandable by a person who is educated at the 8th-grade level. Layman’s terms shall be used in the description of the research.

5. For participants not fluent in English, informed consent must be obtained in a language that is understandable to the participant (or the participant’s legally authorized representative). Following this policy, the IRB requires that informed consent conferences include a reliable translator when the prospective participant does not understand the language of the person who is obtaining consent.

6. The informed consent process may not include any exculpatory language through which the participant is made to waive, or appear to waive, any of the participant’s legal rights or through which the PI, the sponsor, WVU employees or agents are released from liability for negligence, or appear to be so released.

7. The PI is responsible for ensuring that each prospective participant is adequately informed about all aspects of the research and understands the information provided.
9.3 Basic Elements of Informed Consent

9.3.1 Additional Elements of Informed Consent

These additional elements to the informed consent process must be applied, as appropriate:

1. Risks should be categorized by frequency and severity pertaining to “More than Minimal Risk” protocols to the extent data is available. Frequency should be described as being common, uncommon, and rare (or similar terms); if the percentage is known, that should be included. A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable. (For example: Include when the research involves investigational test articles or other procedures in which the risk to participants is not well known.)

2. A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. (For example: Include when the research involves pregnant women or women of childbearing potential and the risk to fetuses of the drugs, devices, or other procedures involved in the research is not well known.)

3. If there are any anticipated circumstances under which the participant’s participation may be terminated by the PI without regard to the participant’s consent.

4. Any additional costs to the participant that may result from participation in the project.

5. The consequences of a participant’s decision to withdraw from the research. (For example: Include when withdrawal from the research is associated with adverse consequences.)

6. Procedures for orderly termination of participation by the participant. (For example: Include when the protocol describes such procedures.)

7. A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant. (For example: Include when the research is long term and interim information is likely to be developed during the conduct of the research.)

8. The approximate number of participants the PI intends to enroll involved in the project. Sample size should include the number to be enrolled by the local PI and worldwide for multi-center studies.

9.4 Documentation of Informed Consent

Except as provided in SOP Section 5, informed consent must be obtained using a WVU IRB approved form and process.

1. Informed consent is documented by the use of a written consent form approved by the IRB and both signed and dated by the participant or the participant’s legally authorized representative at the time of consent. The participant needs to initial and date each page of the consent.
2. A copy of the signed and dated consent form must be given to the person signing the form.

3. The consent form may be either of the following:
   a. A written consent document that embodies the basic and required additional elements of informed consent. The consent form may be read to the participant or the participants legally authorized representative. Still, the participant or representative must be given adequate opportunity to read it before it is signed.
   b. A short-form written consent document stating that the elements of informed consent have been presented orally to the participant or the participant's legally authorized representative.

When this method is used:

- The oral presentation and the short form written document (see sample on OHRP website) should be in a language understandable to the participant; and
- There must be a witness to the oral presentation; and
- The IRB must approve a written summary of what is to be said to the participant; and
- The participant signs the short-form document;
- The witness must sign both the short form and a copy of the summary; and
- The person obtaining consent must sign a copy of the summary; and
- A copy of the summary must be given to the participant or representative, in addition to a copy of the short form.

NOTE: When this procedure is used with participants who do not speak English, (i) the oral presentation and the short-form written document should be in a language understandable to the participant; (ii) the IRB-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the participant. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

The IRB must receive all foreign language versions of the short-form document as a condition of approval. Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short-form document have already been approved by the convened IRB.
9.6 Special Consent Circumstances

9.6.1 Non-English-Speaking Participants

9.6.1.1 Expected Enrollment of Non-English-Speaking Participants

In some protocols, the PI expects non-English speaking participants to enroll because, for example, the protocol is projecting a disease or condition that is likely to attract them, or the PI is actively recruiting them. When the project participant population includes non-English speaking people or the PI and/or the IRB anticipates that consent discussions will be conducted in a language other than English, the IRB shall require a translated consent document to be prepared. To assure itself that the translation is accurate, the IRB requires a certified translation and may choose to have an independent back translation or to have a review of the consent document by an IRB member or other person who is fluent in that language.

Where non-English speaking participants enroll, the participant and the witness sign the translated document. The participants are given a copy of the signed, translated consent document.

9.6.1.2 Unexpected Enrollment of Non-English-Speaking Participants

If a non-English speaking participant is unexpectedly eligible for protocol enrollment, there may not be an extant IRB-approved written translation of the consent document. PIs should carefully consider the ethical and legal ramifications of enrolling participants when a language barrier exists. If the participant does not clearly understand the information presented at the signing of the consent document or in subsequent discussions, his/her consent may not be informed, and therefore, not effective.

If a PI decides to enroll a participant into a protocol for which there is not an extant IRB-approved informed consent document in the prospective participant's language, the PI must receive IRB approval to follow the procedures for a “short form” written consent in as described in Section 5.5 (3b).

9.6.1.3 Use of Interpreters in the Consent Process

Unless the person obtaining consent is fluent in the prospective participant’s language, an interpreter will be necessary to deliver information in the IRB-approved script and to facilitate the consent conversation. Preferably someone independent of the participant (i.e., not a family member) should assist in presenting information and obtaining consent. Whenever possible, interpreters should be provided copies of the short form and the IRB-approved consent script well before (24 to 48 hours if possible) the consent conversation with the participant.

If the interpreter also serves as the witness, she/he may sign the short form consent document and script as the witness and should note “Interpreter” under the signature line. The person obtaining consent must document that the “short form” process was used in the progress notes of the participant's medical record, including the name of the interpreter.

9.6.2 Braille Consent

For blind participants who read Braille, the IRB may approve a consent document prepared in Braille. To assure itself that a Braille consent document is accurate, the IRB may require transcription into print text or review of the document by an IRB member, or another person, who reads Braille. If possible, the
participant will sign the Braille consent’ otherwise; verbal consent will be obtained, witnessed, and documented as described below in Section 5.6.3.

9.6.4 Oral Consent

When participants are unable to read a written consent form (such as blind or illiterate participants), the IRB may approve an oral consent process, provided the participants:

1. Retains the ability to understand the concepts of the project and evaluate the risk and benefit of being in the project when it is explained.

2. Can indicate approval or disapproval to project entry.

For research that is no more than minimal risk, documentation of consent may be waived according to the criteria in Section 5.10.

For more than minimal risk research, the consent form must be read to the participants, and the participants must be provided an opportunity to ask questions. Digital recordings, approved by the IRB, may be used. If capable of doing so, the participants signs or marks an ‘X’ to signify consent. If that is not possible, the participant will provide verbal consent. The person obtaining consent and a witness will sign the written project consent form with a statement that documents that an oral process was used and, if necessary, that the participant gave verbal consent. The consent process will also be documented in the medical record or accord with WVU procedures. Signed copies of the consent form are given to the participant and, whenever possible, these documents and recordings should be provided to the participant.