**PURPOSE:** The ethical conduct of clinical investigations is based upon a process by which a participant voluntarily confirms her willingness to participate in a particular trial. After the participant has been informed regarding all aspects of the trial that are relevant to her decision to participate, informed consent is documented by a written signed and dated informed consent. In order for informed consent to be legally effective, it must be documented by the use of a valid written consent form approved by the IRB and signed and dated by the participant or the participant’s legally authorized representative prior to the initiation of any research procedures, including study-specific screening procedures.

**SCOPE:** This applies to all clinical research staff engaged in obtaining informed consent from research participants who participate in all clinical studies during all study phases.

**PERSONNEL RESPONSIBLE:**  Principal Investigator and when delegated by the Principal Investigator---- Sub-Investigators, Study Coordinator and/or other pertinent staff.

**PROCEDURES:**

Informed consent of the participant shall be documented by the use of a written IRB approved consent form that is signed and dated by the participant and the Principal Investigator or designee. The consent process should be an on-going discussion between the research team and the participant for the duration of their participation. The discussion must include the *Eight* Elements of Consent which are also detailed in the IRB/IRB approved consent form.

A note must be included in the participant’s research record documenting the discussions regarding their willingness to continue participation.

The note may include the following if applicable:

* + no study related procedures, including screening procedures, occurred prior to consent
  + participant read the consent, was given ample time to review the consent and given time to ask questions
  + the version of the consent form that the participant signed
  + date consent signed and time of consent if applicable
  + a copy of the consent form was given to the participant
  + if applicable, the participant’s legally authorized representative signed and dated the informed consent
  + date and signature of person writing the note

If an amendment/revision is made to a protocol and approved which may affect the participant’s participation, a note must be included in the participant’s research record documenting that the participant was informed of the change, given ample opportunity to review the amendment/revision and sign and date the approved amended consent form.

In the event that their is a Non-English Speaking participant, please follow IRB policy at:[https://IRB.wustl.edu/IRB/Doc/0/T4FE20A62PCKLFVJR77N2NV742/IRB%20P%26Ps%207-2007.doc](https://hrpo.wustl.edu/HRPO/Doc/0/T4FE20A62PCKLFVJR77N2NV742/HRPO%20P%26Ps%207-2007.doc); VII. Informed Consent A. #4.

**RESOURCES:**

21 CFR Part 50

21 CFR Part 50.20