**CREATING THE INFORMED CONSENT DOCUMENT**

**PURPOSE AND SCOPE**

This SOP describes the procedures that are involved in the creation of an informed consent form and the process for obtaining IRB approval of that informed consent form.

**PERSONS RESPONSIBLE**

*Principal Investigator* is responsible and accountable for ensuring that the informed consent document conforms to UC policies and is submitted to the IRB for review and approval. The PI may delegate this responsibility to Clinical Research Coordinators, Clinical Research Nurses, Research Assistants, and Regulatory Affairs Assistants, but may not delegate accountability.

**TRAINING**

The PI and all research personnel who are involved in creating the informed consent form must be able to demonstrate competency in understanding the ethical obligations of informed consent. Competency is demonstrated by satisfactorily completing UC’s online testing for informed consent. The PI and individual(s) to whom the creation of the informed consent form is delegated shall have the ability to define technical language in lay terms.

**Notes:**

1. The IRB provides a template for informed consent that contains all the elements required by federal regulations and university policy. This template will be used to develop the informed consent document or to adapt the sponsor’s informed consent document to meet the requirements of the IRB.

2. The informed consent document must be written in language understandable on an 8th grade reading level and all medical and scientific terms not in the lay person’s vocabulary must be explained.

3. If the research participant does not speak English, the informed consent must be in the participant’s language and the form must be approved by the IRB.

4. Generally the informed consent document is submitted to the IRB with the protocol.

5. Only the most recently IRB approved, stamped and dated version of the informed consent document may be used to consent potential participants.

**PROCEDURE FOR WRITING AN INFORMED CONSENT AND OBTAINING IRB APPROVAL**

1. Review the Guidelines for Writing Informed Consent and the Informed Consent Form Template on the University of Cincinnati IRB Website (http://researchcompliance.uc.edu/irb/IRBFormsMedical.html).

2. Create the Informed Consent Form by inserting information from the study protocol and sponsor-provided informed consent form (if provided) according to the IRB format.

3. Review the completed document to make sure it is correct, has all the appropriate information, all typographical errors are corrected, all medical jargon is explained, and all the required elements of the consent document are included.

4. After this informed consent form is approved by the sponsor, it can be submitted to the IRB for review.

5. The IRB may require changes to the consent document before it can be approved. Changes must be approved by the sponsor. The revised consent form will have additions in bold and deletions in strikethrough format. Both a bolded and a clean copy will be submitted, first to the sponsor for approval, then to the IRB.

6. Approval of the informed consent document is indicated by a stamp on the bottom of the signature page.

**REVISING AN INFORMED CONSENT FORM**

1. If during the course of the trial, the protocol is modified, new risks to subjects are identified, or regulations or policy affecting informed consent changes, the informed consent document may have to be revised. Revisions of the informed consent document must be submitted to the sponsor and IRB for approval in the same way as the original. The revised consent form may not be used until it is approved by the IRB.

1. The bolded, revised document is to be used to re-consent participants already enrolled in the study, and the clean copy is to be used to consent new participants prior to enrollment in the study.