Procedure

Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: IV.A.1
Section: Informed Consent Process
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: February 9, 2004
Revision Dates: August 30, 2004; May 21, 2010; July 1, 2015

Subject: Procedure for Obtaining Legally Effective and Prospective Informed Consent

Procedure:
This procedure outlines the responsibilities of the Institutional Review Board (IRB) and the Investigator in obtaining legally effective and prospective informed consent from research participants.

I. Investigator Responsibilities.
A. The Investigator provides a detailed description of the intended method for obtaining informed consent in the initial “Application for Human Research”.
B. All informed consent documents (full written documents, oral scripts, short forms, assent and dissent forms, and genetic or healthcare surrogate riders) are submitted for review and approval by the IRB prior to use.
C. Any changes in the informed consent documents are submitted as an amendment to the IRB for review and approval prior to use.
D. Informed consent must:
   1. Be solicited in circumstances that minimize the possibility of coercion and undue influence;
   2. Utilize language understandable to the participant (may use SMOG readability tool available on the HRPP website at http://www.mc.vanderbilt.edu/irb/ or other mechanisms to validate readability);
   3. Not waive or appear to waive participants’ rights; and
   4. Include each of the required elements and applicable additional elements of informed consent describing the research and the nature of research participation as required by federal regulations (See HRPP Procedure IV.A.2); and
   5. Be sought by utilizing the most currently-approved informed consent document.
E. Unless specifically waived by the IRB, informed consent is documented in writing through the use of a current IRB-approved informed consent document signed and dated by the participant or by the participant’s legally authorized representative prior to enrollment or participation in any phase of the research study.
F. The Investigator assures the informed consent process in research is an ongoing exchange of information between the research team and the study participants throughout the course of a research study. Informed consent is a continuous process of communication and acknowledgement over time, not just a signed document.
II. IRB Committee Responsibilities.
   A. The IRB Committee, the Chairperson or his/her designee reviews the planned research activities to assure that the informed consent document is congruent with the IRB application, Investigator's brochure, Sponsor's or Investigator's protocol, grant and/or contract, and contains the necessary elements of informed consent as required by the federal regulations.
   B. When reviewing the informed consent document, the Reviewers may request necessary revisions to the content, language, punctuation, and/or grammar in order for the intended target population to clearly understand the proposed research activities and make an informed decision on whether to participate in the research.
   C. The IRB Committee, the Chairperson or his/her designee approves the informed consent process and method of documentation, indicating whether the proposed consent process is appropriate for the proposed research activities and the target population as a part of the overall IRB approval of the study.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
The RCA conducts a pre-review of the informed consent documents submitted with a new study application to determine that the correct forms have been utilized for the targeted population, assesses the readability of the document, and assures that all the necessary elements as required by the federal regulations are present for adequate informed consent. If additional information regarding the informed consent process or documentation is needed, the RCA contacts the Investigator and requests the additional information.