**Subject: Procedure for Documentation of Informed Consent for Human Subjects Research**

**Procedure:**
The purpose of this procedure is to provide guidance on documentation of prospective, legally effective informed consent from research participants or their legally authorized representative.

I. Investigator Responsibilities.
   A. All informed consent documents (full written documents, oral scripts, short forms, assent forms, and genetic or healthcare surrogate riders) will be submitted to the IRB with the new study submission.
      1. The templates for informed consent will be used to draft all written informed consent documents. Appropriate templates, template language, and instructions are located on the HRPP website at [http://www.mc.vanderbilt.edu/irb/](http://www.mc.vanderbilt.edu/irb/).
      2. Informed consent documents will be written in language that is at the appropriate reading and comprehension level for the targeted population. Generally, a sixth to eighth grade reading level is recommended for adult consent documents.
      3. The IRB recommends that the informed consent documents apply to the following division of target populations:
         a) Ages 18 or older utilizing the adult informed consent document
         b) Ages 13 to 17 utilizing an assent form, which may be in the same language as the adult informed consent document.
         c) Ages 7 to 12 utilizing an assent form written simply and at a comprehension level appropriate for a 7 year old; and
         d) On a case by case basis, less than 7 years of age may use an oral script in very simple language appropriate for children.

   B. Obtaining Informed Consent.
      1. The Investigator will provide a copy of the currently approved and IRB date-stamped informed consent documents to the participant or his or her legally authorized representative.
      2. A court-appointed guardian or conservator, or someone appointed as an agent for the participant under a durable power of attorney for health care may grant permission for the individual to participate in research. In such cases, the Investigator must obtain a copy of the court order or durable power of attorney as evidence of that person’s authority to grant permission on the individual’s behalf.
      3. The Investigator will provide the participants or his or her legally authorized representative adequate time to read the consent, ask questions, and consider the risks and/or benefits to participation in the research study prior to obtaining their signature.
4. Assent and dissent and documentation of such are to be obtained as directed by the determination of the IR Committee.

5. Participants or the participant’s legally authorized representative will provide a signature and the date of signature on all informed consent documents, unless a waiver of documentation has been requested by the Investigator and approved by the IRB.

C. Oral Presentation Using Short Form.

1. When consent is obtained orally, the Investigator will use a short form written informed consent document stating that the elements of consent have been presented orally to the participant or the participant’s legally authorized representative, as well as written summary of the information that is presented orally.

2. A witness to the oral presentation is required. The witness must sign and date both the short form written consent document and a copy of the written summary.

3. The participant or the legally authorized representative must sign and date the short form written consent document, but should be given a copy of both the IRB approved stamped short form and the written summary.

4. The person obtaining consent (e.g., the Principal Investigator or Study Coordinator) must sign and date a copy of the written summary of the information that is presented orally. The person obtaining consent may not be the witness to the consent.

D. Non-English Speaking Participants.

1. Translation of English Language ICD. Participants who do not speak English should be presented with an informed consent document written in a language understandable to them. The IRB strongly encourages the use of a full translation of the entire ICD.

   a) Translations for targeted populations that are non-English speaking must be submitted for review and approval. The Investigator may wish to delay translation until IRB approval is granted for the English version informed consent documents or the short form documents to avoid extra translation costs.

   b) The Investigator must provide the qualifications of the individual or the service that was used to translate the informed consent documents or short form documents. For example, include any credentials, certifications, education, native language fluency, etc. All non-English consent forms must be translated by someone not associated with the study.

   c) The VU Translator Declaration form, that can be located on the HRPP website at http://www.mc.vanderbilt.edu/irb/, should be submitted by the investigator along with the translation of the non-English consent documents when submitted for review.

   d) The IRB application should be updated to include specific information relative to how non-English speaking participants will be consented.

2. Use of Short Form Consent Document.

   a) When informed consent is documented using the short form consent procedure for non-English speaking participants, the following is applicable:

      (1) The oral presentation and the short form consent documents will be provided in a
language understandable to the participant; 

(2) The IRB-approved English language informed consent document may serve as the summary; and 

(3) A witness who is fluent in both English and the language of the participant should be present.

b) Required signatures for short form consent procedures include: 

(1) The short form document should be signed and dated by the participant or the participant’s legally authorized representative; 

(2) The summary (i.e., the English language informed consent document) should be signed and dated by the person obtaining consent as authorized under the protocol and 

(3) The short form document and the summary should be signed and dated by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

c) It is important to note that the FDA discourages the use of the short form consent document in research.

E. Waiver of Documentation of Informed Consent 

1. The Investigator will assess the proposed research to determine if it meets regulatory requirements for a waiver of documentation of informed consent. 

2. The Investigator will complete and submit for review a request for waiver or alteration of consent or authorization. 

3. When the IRB waives the requirement for documentation of informed consent, each participant must be asked whether he or she wants documentation linking him or her with the research, and the participant’s wishes will govern.

F. The person obtaining consent should document the consent process in the participant’s medical record or the participant’s research record. This may include:

1. How consent was obtained; 

2. The participant’s level of comprehension (did they appear to understand, did they ask questions, were they able to reiterate the main purpose of the study, procedures, risks, etc.); 

3. The participant’s decision-making capacity at the time of consent (were they alert and oriented); 

4. The time given for the participant to consider the research and whether others were involved in the decision-making; and 

5. Identify who was present during the consenting process. 

G. Any revisions to the informed consent process or documents will be submitted to the IRB for review and approval as presented in the amendment policy and procedure (See HRPP Policy III.J and Procedure III.J.1).

II. IRB Committee Responsibilities. 

A. The Investigator’s plan to obtain informed consent should be assessed by the IRB Committee the Chairperson, or his or her designee to assure the appropriate conditions are met

1. The IRB should consider the nature of the proposed subject population, the type of information to be conveyed, and the circumstances under which the consent process will take place(e.g., manner, timing, place, personnel involved); 

2. All elements of consent as required by the federal regulating, as well as any appropriate additional elements are incorporated into the documents; 

3. Provisions have been made if the study is to include non-English speaking participants and the translated documents
have been verified to be in a language understandable to the participant.

4. The IRB Reviewers must assure that provisions for genetic riders or health care surrogates are reviewed for appropriateness, when applicable.

5. The reviewers are to verify that the informed consent documents are congruent with the study protocol and IRB application. If not, the Reviewer or Committee will request revisions prior to granting final approval.

6. The Reviewers will assure that the written language is in lay terms with correct grammar, spelling, and punctuation for readability and understanding.

B. The IRB must review all amendments to the informed consent process or documentation. If the requested amendments change the risk/benefit ratio, the review must be conducted by the IRB Committee and a determination of the necessity of re-consenting participants must also be rendered.

C. When the research includes minors (children less than 18 years of age), the IRB must determine whether assent and dissent is required, for what ages assent and dissent is required, and how assent and dissent is to be documented.

D. Decisions to waive documentation of informed consent must be clearly documented in the Reviewer’s Comment Form and IRB minutes.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.

A. The RCA will conduct a pre-review of all informed consent documents submitted for IRB review and approval utilizing the pre-review checklist.

B. If pre-review changes are needed to the informed consent documents, the RCA sends the requested changes to the Investigator.

C. Once the pre-review revisions are received from the Investigator, the RCA will place the new study on the next available IRB Committee agenda assign Reviewers and assure appropriate materials are available. Reviewers are electronically notified once assigned.

D. Once final approval is granted by the IRB, the informed consent documents will be stamped with current “Date of IRB Approval” and the “Date of IRB Expiration” (See HRPP Policy IV.D).

E. Changes to the informed consent process and/or documents are to be completed according to the HRPP amendment policy and procedure.

F. Appropriate data base entries are to be completed.

References

HRPP IV.B - Documentation of Informed Consent for Human Subjects Research