Subject: Procedure for Incorporating the Element of Informed Consent

Procedure:
This procedure outlines the responsibilities of the Institutional Review Board (IRB) and the Investigator in incorporating the required elements into the informed consent document as required by the federal regulations.

I. Investigator Responsibilities.
   A. Required Elements. The PI is responsible for incorporating the elements of informed consent as required by federal regulations into each informed consent document. The basic required elements of consent to be included in each informed consent document are:
      1. A clear statement that the study involves "research";
      2. An explanation of the purposes of the research;
      3. The expected duration of the subject's participation;
      4. A complete description of the procedures to be followed, and identification of procedures that are performed as standard of care and identification of procedures that are performed solely for the purposes of research;
      5. A description of the reasonably foreseeable risks and discomforts;
      6. A description of any benefits to the participant or others that may reasonably be expected from the research;
      7. A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the participant;
      8. A description of the extent to which confidentiality of records identifying the participant and privacy will be maintained (See HRPP website at http://www.mc.vanderbilt.edu/irb);
      9. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained (See HRPP Policy X.C);
      10. An explanation of whom to contact for answers to pertinent questions about the research and to voice comment or concerns (e.g., Investigator or the IRB) and research participants' rights (e.g., HRPP Office), and whom to contact in the event of a research-related injury to the participant with an alternate number in case no answer is received; and
      11. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
A. **Additional Elements.** The informed consent document should, where appropriate, include the following additional elements:

1. For women of child bearing potential, a statement that the particular treatment or procedure may involve risks to the participant (or the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject’s participation may be terminated by the Investigator without regard to the participant’s consent;
3. If there is the potential that costs of research procedures will not be paid by the sponsor or the participant’s insurance, a description of any additional costs to the participant that may result from participation in the research should be described in the consent document;
4. The consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. 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;
6. The approximate number of participants involved in the study;
7. Study treatment(s) and the probability of random assignment to placebo or to each treatment; and
8. The IRB may require that information, in addition to that required in federal regulations, be given to research participants when in its judgment the information would meaningfully add to the protection of the rights and welfare of participants.

B. **No Omission of Required Elements unless Waiver Granted.** Required elements of informed consent may not be omitted unless waiver by the IRB (See HRPP Policy IV.C). In addition, there may not be discrepancies within the informed consent documents, the IRB application, the Sponsor’s or Investigator’s Protocol, the Investigator’s Brochure, the grant and/or the contract regarding the purpose, risks, and benefits of the research. The IRB encourages Investigators to use the IRB template informed consent document when developing consent documents. Templates are available on the HRPP website at [http://www.mc.vanderbilt.edu/irb/](http://www.mc.vanderbilt.edu/irb/).

C. **Second Person.** The language of the consent documents should be in the second person style (i.e., “you, your”), which may help convey that there is a choice to be made by the participant rather than a presumption of the participant’s consent with use of the first person style (i.e., “I, me, my”).

D. **No Unproven Claims of Effectiveness.** No unproven claims of effectiveness or certainty of benefit, either implicit or explicit, may be included in the informed consent documents.

E. **No Complex Language.** The information provided in the informed consent documents must be in a language understandable to the participant (target population). The informed consent documents should not include complex language that would not be understandable to all participants. Technical and scientific terms should be adequately explained using common or lay terminology consistently. Generic names are preferable when describing pharmaceuticals unless the brand name is more commonly known and understood. Regardless of which name is preferred, it should be used consistently throughout the informed consent documents. Devices and procedures should also be described consistently throughout the documents and explained in simple language. It is generally recommended that the adult consent documents be written at a sixth to eighth-grade reading level.

F. **No Exculpatory Language.** The informed consent documents may not contain any exculpatory language through which the participant is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the investigator, the sponsor, the University, or its agents from liability for negligence.

1. **Examples of Acceptable Language:**
   a) Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
II. IRB Committee Responsibilities.

A. The IRB Committee, the Chairperson or his/her designee will review the informed consent documents to assure the documents contain all the required elements of consent as defined by the Federal Regulations and determine the additional elements that are appropriate and should be incorporated into the documents.

B. There are two circumstances under which the regulations give the IRB the authority to waive the required consent (See HRPP Policy IV.C).

C. The IRB Committee, the Chairperson or his/her designee will review the informed consent documents to assure:

1. There are no discrepancies within the informed consent documents, the IRB application, the Sponsor’s or Investigator’s Protocol, the Investigator’s Brochure, the grant and/or the contract regarding the purpose, risks, and benefits of the research;
2. The language of the consent document is in the second person style (i.e., “you”);
3. The documents do not contain unproven claims of effectiveness or certainty of benefit, either implicit or explicit;
4. The information provided in the informed consent documents are in a language understandable to the participant population and does not include complex language that would not be understandable to all participants;
5. Informed consent documents do not contain any exculpatory language through which the participant is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the investigator, the sponsor, the University, or its agents from liability for negligence;
6. For all research involving test articles regulated by the U.S. Food and Drug Administration (FDA), informed consent document(s) includes a statement that the purpose of the study includes evaluation of both the safety and the effectiveness of the test article;

b) By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.

2. Examples of Unacceptable Exculpatory Language:

   a) By agreeing to this use, you should understand that you would give up all claims to personal benefit from commercial or other use of these substances.
   b) I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
   c) By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
   d) I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

G. FDA Regulated Test Articles. For all research involving test articles regulated by the U.S. Food and Drug Administration (FDA), informed consent documents should include a statement that a purpose of the study includes an evaluation of the safety of the test article. Statements that test articles are safe or statements that the safety has been established in other studies are not appropriate when the purpose of the study includes determination of safety. In studies that also evaluate the effectiveness of the test article, informed consent documents should include that purpose, but should not contain claims of effectiveness.

   1. Phase I Studies. Phase I studies are typically designed to determine safety, but not effectiveness. Phase I consent documents will include the approved Phase I template language (See HRPP website at http://www.mc.vanderbilt.edu/irb/).
   2. Phase II and Phase III Studies. Potential participants should be told, and a statement included in the purpose of the informed consent document, that Phase II and III studies are designed to determine both safety and effectiveness.
7. For Phase I Studies, the consent documents will include the approved Phase I template language (See HRPP website at http://www.mc.vanderbilt.edu/irb/ and select "Template Language" from the left column); and
8. For Phase II and Phase III Studies, the informed consent document includes a statement that the purpose of the study is to determine both safety and effectiveness.

III. HRPP Regulatory Compliance Analyst Responsibilities.
A. The RCA will conduct a pre-review of the informed consent documents submitted with a new study to determine that the correct information has been submitted for the targeted population, assess the readability of the document, and that all required elements are present for adequate informed consent, including if any additional elements are appropriate.
B. If additional information regarding the informed consent process or documentation is needed, the RCA will contact the Investigator and request the additional information.