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VA Informed Consent Document Requirements

Any informed consent form (ICF) accompanying new applications, generated due to protocol changes, or submitted as part of a continuing review, must meet the following criteria.

1. Informed consent must be obtained from every subject participating in human research conducted under the auspices of the VA.
2. Only VA research consent documents (form 10-1086) that have been approved by both the VA R&D Committee and the UW HS-IRB may be used for consenting VA research subjects.
3. All basic elements of informed consent must be included in all ICFs unless both the R&D Committee and the HS-IRB specifically allow their exclusion.
Note: The wording for basic element #11 (subject injury compensation) differs from that required by the University.
4. The additional elements of informed consent should be included in all ICFs in studies where they are applicable.
5. If tissue banking is involved, VA-specific language addressing tissue banking must be included in the ICF.
6. For VA ICFs:
 - a. each page must be stamped and dated by the HS-IRB.
 - b. subjects must initial each page.
 - c. subjects must sign and date the final page.
 - d. the person obtaining consent, and a witness to the subject's signature, must sign and date the final page. [If the same person is to serve both capacities then a note to that effect must be placed under the witness's signature line]

Basic Elements for Informed Consent under the VA Regulations

1. Name of study
2. The name of the Principal Investigator (or VA responsible investigator, if different)
3. A statement that the study involves research
4. An explanation of the purposes of the research and the expected duration of the subject's participation
5. A description of the procedures to be followed
6. Identification of all procedures that are experimental and of those that are considered standard of care
7. A description of any reasonably foreseeable risks or discomforts to the subject including, for example, privacy risks (legal, academic, employment and/or social)
8. A description of any benefits to the subject or to others that may reasonably be expected from the research.
9. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.
10. A statement describing the extent to which confidentiality of records identifying the subject will be maintained [If appropriate, a statement that Federal agencies such as FDA, OHRP, and GAO may have access to the records].
11. For research involving more than minimal risk, an explanation as to whether any compensation is available 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. The following text should be used unless otherwise specified by the R&D Committee: *"In the event you sustain physical injury as a result of participation in this investigation, if you are eligible for medical care as a veteran, all necessary and appropriate care will be provided. If you are not eligible for*

medical care as a veteran, humanitarian emergency care will be provided, and further treatment will be made available on a case-by-case basis. You realize you have not released this institution from liability for negligence. Compensation may or may not be payable, in the event of physical injury arising from such research, under applicable federal laws"

12. The following information must be included:
 - a. Who to contact for answers to questions about the research
 - b. Who to contact for inquiries as to research subjects' rights
 - c. Who to contact in the event of a research-related injury to the subject.[at least one contact's name and phone number must be other than that of the investigator or study personnel, for example the VA Patient Representative or the UW Hospital patient relations representative].
13. A statement that participation is voluntary, and that the subject may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
14. The VA requires a statement that a veteran-subject will not be required to pay for care received as a subject in a VA research project (with exceptions for category 7 veterans).

Additional Elements of Informed Consent

One or more of the following elements shall also be provided to each subject when appropriate to a specific study:

1. A statement that the particular treatment or procedure may involve currently unforeseeable risks to the subject, or to embryo or fetus if the subject is or becomes pregnant.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject'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 affect the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.
7. If the human biological specimens obtained could be part of or lead to the development of a commercially valuable product or if the specimens will be retained after the end of the study, guidance and regulations found in VHA Handbook on Banking of Human Biological Specimens shall be followed*.
8. As appropriate, a statement regarding any payment the subject is to receive and how payment will be made.

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*Note on tissue banking

For a study that includes tissue banking, the consent form must clearly address the following points:

1. Will the collected specimen be used for future research (i.e., beyond the scope of the current project) and if so, what kind of research (research specified in the consent form; research conducted by the PI only; research conducted by other investigators; research related to specific diseases; etc.)?
2. Will the specimen be used to generate a cell line or for genetic testing?
3. Will the specimen be stored without any identifiers ("deidentified")?
4. Will the research results be conveyed to the subject and/or health care provider?
5. What is the disposition of the specimen after completion of the study or at the end of the banking period?
6. Will the specimens and all links to clinical data be destroyed or removed from the bank upon the subject's request?
7. Are there any potential conflicts of interest or financial gains for the investigator or the participating institution?