

## VAMHCS HUMAN RESEARCH PROTECTION STANDARD OPERATING PROCEDURE

SOP: HRP 03.02

Approval Date: 11/8/07

### WRITING A VAMHCS INFORMED CONSENT DOCUMENT

#### OBJECTIVE:

- To ensure that the Informed Consent Form (ICF) submitted to the IRB and R&D Committee for approval meets all Veterans Health Administration (VHA) requirements.

#### BACKGROUND & SCOPE:

In order to enroll a person into a research study, research staff must obtain written informed consent from the person (unless a waiver of informed consent has been granted by the UMB IRB). Written informed consent is most often obtained by presenting and an “informed consent form” (ICF) to the potential participant and discussing it with them. If they decide to participate in the study, the ICF is signed by the participant and witnesses. Copies of the signed form are given to the participant and are recorded in the person’s medical record (CPRS); the original is retained by the investigator in the study files.

On this campus, ICFs must be approved by the UMB IRB, and the ICFs used for VAMHCS studies must be printed in Veterans Administration (VA) format. This format is known as VA form 10-1086 and is automatically produced from BRAAN if the VAMHCS is chosen as a study site.

This SOP often refers the reader to the Research Service “Informed Consent Guidebook” for most of the content regarding writing informed consent forms. The “Informed Consent Guidebook” is intended to be a comprehensive and easily understandable treatment of the topic of informed consent. It includes practical tips on how to fulfill campus requirements (VAMHCS, IRB, BRAAN, etc.). Both experienced and new investigators and staff should regard the Guidebook as a master reference for performing research at the VAMHCS.

The approved ICF must be viewed as a tool for informing potential subjects about a study and for documenting their consent. The overarching principle in the process of informed consent is to take all possible steps to inform and protect the rights and welfare of potential study participants. See the “Informed Consent Guidebook” and the Research Service SOP, “Obtaining and Documenting Informed Consent (Informed Consent Process)” for further details.

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### RESPONSIBILITIES:

- The PI is responsible for complying with all federal, VAMHCS and IRB requirements for an informed consent form (ICF).
- The PI is responsible for submitting the ICF to the UMB IRB and the VAMHCS R&D Committee for approval.
- The PI is responsible for notifying the IRB and the R&D Committee of protocol amendments that require amendments to the ICF.
- The PI is responsible for using current, valid ICFs.

### DEFINITIONS

**Basic elements of informed consent / Additional elements of informed consent:** In Section 50.25 of 12CFR, the FDA requires 8 “basic elements of informed consent” and 6 “additional elements of informed consent to be included when appropriate. ICH Guidelines (4.8.10) require essentially the same elements as do the VHA guidelines (VHA Handbook 1200.5, Appendix C), which encompass 38CFR16.116.

### ATTACHMENTS:

Appendix A	Sample 10-1086
Appendix B	“Elements of Informed Consent”

### SEE ALSO:

Research Service	Informed Consent Guidebook (HRP 03.01G)
Research Service	Flowchart Guidance on R&D Submissions (HRP 01.05G)
Research Service	Obtaining and Documenting Informed Consent (Informed Consent Process) (HRP 03.03)
VHA Handbook 1200.5	<u>Requirements for the Protection of Human Subjects in Research</u> (in particular, Appendix C)

### PROCEDURE:

1. Log in to BRAAN and begin the submission process of the research project.

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2. Select the VAMHCS as a study site in Section A6a. By doing this, BRAAN will later automatically put the completed consent form onto the VA template (VA Form 10-1086).
3. In Section Q of BRAAN (Informed Consent Form), enter text to complete the numerous sections prompted by BRAAN. The text should be readable (8<sup>th</sup> grade level) and grammatically correct. The sections cover all “**essential elements of informed consent**” and *some* “**additional elements of informed consent**”. Depending on your study, it may be appropriate to include more of the “additional elements of informed consent”. See Appendix B for detailed information on elements of informed consent.
4. ***There is extensive, specific, detailed information concerning the completion of BRAAN Section Q in the Informed Consent Guidebook (Parts II.F-G). It is HIGHLY RECOMMENDED that investigators and staff refer to the Guidebook when completing Section Q.***
5. Print out a hardcopy of the VA 10-1086 version of the BRAAN form. Read through this version carefully. Frequently, investigator text does not flow well with BRAAN boilerplate language (the “Benefits” and “Alternatives” sections are particularly prone to this). Also, the investigator will frequently discover unnecessary hard returns and other formatting issues that were not obvious on the “screen version” of the BRAAN composition.
6. Make corrections to Section Q if necessary.
7. Proceed with the remainder of the BRAAN submission and IRB approval.

## REFERENCES

Research Service SOP	Informed Consent Guidebook (HRP 03.01)
HRPO SOP	“BRAAN Human Subject Investigator Guide” <a href="http://medschool.umaryland.edu/orags/hrpo/PI_GUIDE.pdf">http://medschool.umaryland.edu/orags/hrpo/PI_GUIDE.pdf</a>
VHA Handbook (1200.5)	Requirements for the Protection of Human Subjects in Research [Par 7a(5), 7c(2), 10c, 10e]
FDA Regulations (21 CFR 50)	“Protection of Human Subjects” [50.25, 50.27]
FDA Information Sheets	“A Guide to Informed Consent Documents”
DHHS Regulation (45 CFR 46)	“Protection of Human Subjects” [46.116, 46.117]
DHHS/FDA	“International Conference on Harmonization; Good Clinical

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Practice; Consolidated Guideline" (ICH GCP's)

APPROVAL

This Standard entitled "Writing Informed Consent" has been approved by the R&D Committee, effective 11/8/07.

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APPENDIX A: Copy of VAMHCS form 10-1086

See hard copy in the Research Service Office or at the following  
website(s):

[www1.va.gov/resdev/funding/process/forms/10-1086.doc](http://www1.va.gov/resdev/funding/process/forms/10-1086.doc)

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## APPENDIX B: VHA Handbook 1200.5, Appendix C

### THE INFORMED CONSENT

1. **General Requirements for Informed Consent.** An investigator may not involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the person or the person's legally authorized representative. If someone other than the investigator conducts the interview and obtains consent from a patient, the investigator needs to formally delegate this responsibility, and the person so delegated must have received appropriate training to perform this activity. The person so delegated must be knowledgeable about the research to be conducted and the consenting process, and must be able to answer questions about the study.

*NOTE: This policy does not apply to research ruled exempt from Institutional Review Board (IRB) review. See Appendix A.*

- a. An investigator must seek such consent only under circumstances that:
  - (1) Provide the prospective subject or the subject's legally-authorized representative sufficient opportunity to consider whether or not to participate, and
  - (2) Minimize the possibility of coercion or undue influence.
- b. The information that is given to the subject or the subject's representative must be in language understandable to the subject or the subject's representative.
- c. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the subject's representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
- d. Department of Veterans Affairs (VA) Form 10-1086, Research Consent Form, or an electronic version of VA Form 10-1086, must be used as the consent form, and all required elements must be completed.

### 2. **Basic Elements for Informed Consent**

- a. In seeking informed consent, the following information must be provided to each subject:
  - (1) Name of the study.
  - (2) The name of the Principal Investigator (PI).
  - (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.

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(5) A description of the procedures to be followed and identification of those being done for research purposes.

(6) Identification of any procedures that are experimental.

(7) A description of any reasonably foreseeable risks or discomforts to the subject including for example, privacy risks (legal, employment, and social).

(8) A description of any benefits to the subject, or to others, which may reasonably be expected from the research.

(9) A disclosure of appropriate alternative procedures or courses of treatment, if any, that 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 the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP) and the Government Accounting Office (GAO) may have access to the records. If an FDA-regulated test article is involved, the FDA requires a statement that the FDA may choose to inspect research records that include the subject's individual medical 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.

(a) According to Title 38 Code of Federal Regulations (CFR) 17.85 "Treatment of Research-Related Injuries to Human Subjects," VA must provide necessary medical treatment to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, the necessary care must be provided in VA medical facilities. Exceptions include: situations where VA facilities are not capable of furnishing economical care; situations where VA facilities are not capable of furnishing the care or services required; and situations involving a non-veteran research subject. Under these circumstances, Directors may contract for such care. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. The informed consent form needs to include language explaining VA's authority to provide medical treatment to research subjects injured by participation in a VA research project. **NOTE:** *VA regulations on research related injuries (see 38 CFR 17.85 apply to minimal-risk research.*

(b) The regulation at 38 CFR 17.85 does not apply to research conducted for VA under a contract with an individual or a non-VA institution (although veterans injured as a result of participation in such research may nevertheless be eligible for care from VA under other statutory and regulatory provisions). Information on the responsibility for research-related injury under such circumstances must be included in the consent form. **NOTE:** *It is strongly suggested that the investigator make provisions for coverage of such cost in research awards and contracts.*

(12) An explanation of whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of research-related injury

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to the subject. At least one contact's name and phone number must be other than the investigator's or study personnel.

(13) A statement that participation is voluntary, and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(14) A statement that a veteran-subject will not be required to pay for care received as a subject in a VA research project except as follows:

(a) In accordance with Title 38 United States Code (U.S.C.) 1710(f) and 1710(g) certain veterans are required to pay co-payments for medical care and services provided by VA. Veterans receiving medical care and services from VA that are not rendered as part of the VA-approved research study, must pay any applicable co-payment for such care and services.

(b) Suggested wording for the consent form needs to note this requirement. For example: "Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payments requirements will continue to apply medical care and services provided by VA that are not part of this study."

(c) Investigators need to note, pursuant to 38 CFR 17.102, charges will not be made for medical services, including transportation furnished as part of a VA-approved research study. Section 17.102 requires that if services are furnished to a person who is not eligible for the services as a veteran, the medical care appropriation will be reimbursed from the research appropriation.

b. **Additional Elements of Informed Consent.** One or more of the following elements of information must also be provided to each subject when appropriate:

(1) A statement that the particular treatment or procedure may involve currently unforeseeable risks to the subject, or to the 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 the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research, consistent with the Federal laws concerning veterans' eligibility for medical care and treatment.

(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 relate to this 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 investigators believe that the human biologic specimens obtained could be part of, or lead to the development of a commercially valuable product, or if the specimens are to be retained after the end of the study, current VA policy and Veterans Health Administration (VHA) regulations must be followed. **NOTE:** *If genetic testing is to be done, VA requirements pertaining to genetic testing must also be met.*

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(8) As appropriate, a statement regarding any payment the subject is to receive and how payment will be made.

c. As defined in 38 CFR 16.116(c) an IRB may:

(1) Approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent; or

(2) Waive the requirements to obtain informed consent, provided the IRB finds and documents that:

(a) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

1. Public benefit or service programs;

2. Procedures for obtaining benefits or services under those programs;

3. Possible changes in or alternatives to those programs or procedures; or

4. Possible changes in methods or levels of payment for benefits or services under those programs.

(b) The research could not practicably be carried out without the waiver or alteration.

d. As defined in 38 CFR 16.116(d), an IRB may:

(1) Approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in this appendix; or

(2) Waive the requirements to obtain informed consent, provided the IRB finds and documents that :

(a) The research involves no more than minimal tangible or intangible risk to the subjects;

(b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(c) The research could not practicably be carried out without the waiver or alteration; and

(d) Whenever appropriate, the subjects must be provided with additional pertinent information after participation.

e. The informed consent requirements stated are not intended to pre-empt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

***NOTE:*** *Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.*

### **3. Documentation of the Informed Consent**

a. Except as provided in subparagraph 3d of this appendix, informed consent must be documented by the use of a written consent form approved by the IRB and signed and dated by:

(1) The subject or the subject's legally-authorized representative,

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(2) A witness whose role is to witness the subject's or the subject's legally-authorized representative's signature, and

(3) The person obtaining the informed consent.

b. VA Form 10-1086, or an electronic version of VA Form 10-1086, must be used as the consent form. If the sponsor or IRB requires a witness to the consenting process in addition to the witness to the subject's signature; if the same person needs to serve both capacities then a note to that effect must be placed under the witness's signature line.

(1) The consent form must be the most recent IRB-approved consent form. The approval must be documented by the use of a stamp or preprinted box on each page of the consent form that indicates the date of the most recent IRB approval of the form. The IRB must maintain a copy of the approved form in its records.

(2) The original signed consent form must be filed in the subject's case history.

(3) A copy of the signed informed consent must be provided to the subject or the subject's legal representative.

c. **Flagging a Medical Record.** The IRB needs to determine if the patient's medical record (electronic or paper) must be flagged to protect the subject's safety by indicating the subject's participation in the study, and the source of more information on the study. The IRB may not want to require the medical record to be flagged if:

(1) The subject's participation in the study involves:

(a) Only one encounter,

(b) Only the use of a questionnaire, or

(c) The use of previously collected biological specimens.

(2) The identification of the patient as a subject in a particular study (if the study is not greater than minimal risk) would place the subject at greater than minimal risk.

d. **Consent Form.** Except as provided in subparagraph 3f herein, the consent form may be either of the following:

(1) **Written Consent Document.** VA Form 10-1086 (either paper or electronic version),” must be used as the consent form and must embody the elements required by this appendix and 38 CFR 16.116. In addition, it must contain any additional elements as required by the IRB. The consent form may be read to the subject or the subject's legally-authorized representative. The investigator must ensure that the subject (or representative) is given adequate opportunity to read the form and ask questions before signing it.

(2) **Written Consent Document (Short Form).** A shortened written consent document stating that the elements of informed consent required by this appendix and 38 CFR 16.116 have been presented orally to the subject or the subject's legally-authorized representative. When this method is used, there must be a witness to the oral presentation. This process includes the following:

(a) The IRB must approve a written summary of what is to be said to the subject or the subject's legally-authorized representative.

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(b) Only the short form is to be signed by the subject or the subject's legally-authorized representative.

(c) The witness must sign both the short form and a copy of the summary. The person actually obtaining the consent must sign a copy of the summary. The original short form and summary must be filed, as required.

(d) A copy of the summary must be given to the subject or the subject's legally-authorized representative, in addition to a copy of the signed short form.

e. Progress Note. A progress note documenting the informed consent process must be placed in the subject's medical record.

(1) At a minimum, the progress note must include:

(a) The name of the study,

(b) The person obtaining the subject's consent,

(c) A statement that the subject or the subject's legally-authorized representative was capable of understanding the consent process,

(d) A statement that the study was explained to the subject, and

(e) A statement that the subject was given the opportunity to ask questions.

(2) An entry must also be placed in the progress note when the human subject is actually entered into the study and when the human subject's participation is terminated.

*NOTE: Consent and entry notes can be combined when both occur at the same visit.*

f. **Waiver of Requirement for a Signed Informed Consent**

(1) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

(a) That the only record linking the subject and the research would be the consent document and the principal risk to the subject would be potential harm resulting from a breach of confidentiality. Each subject must be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(b) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

(2) In cases in which the documentation requirement is waived, the IRB must document the reason for the waiver and may require the investigator to provide subjects with a written statement regarding the research.