

VAMHCS RESEARCH SERVICE
STANDARD OPERATING PROCEDURE

SOP: HRP 03.03

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OBTAINING AND DOCUMENTING INFORMED CONSENT

OBJECTIVE:

- To ensure that adequate and legal informed consent for participation in a clinical study has been obtained from a competent, non-coerced person;
- To comply with VAMHCS policies and procedures;
- To comply with UMB IRB policies and procedures;
- To meet federal regulations and Good Clinical Practices regarding informed consent for clinical studies.

SCOPE:

This SOP assumes that documentation of informed consent has not been waived by the IRB and that there is already an ICF in the VA format (form 10-1086 or its equivalent) containing all the required elements of an informed consent document and which has been approved by the UMB IRB and the VAMHCS R&D Committee¹.

The consent form must be viewed as a tool for informing potential subjects about a study and for documenting their consent. *It should be used in conjunction with* such documents as an “Informed Consent Checklist”, tests for mental capacity (“Mini-Mental” or other tests), and tests for understanding (ICF post-tests, etc.).

¹ For help with writing an informed consent document, the following Research Service and HRPO references are useful: “Writing a VAMHCS ICF” (HRP 03.02), Informed Consent Guidebook (HRP 03.01G) both available at <http://www.maryland.research.va.gov/>; HRPO ICF checklist available at www.medschool.umaryland.edu/orags/hrpo/checklist9.pdf.

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Most importantly, “informed consent” should be a process of discussion, questions & answers, deliberation, and other personal interchanges between the potential participant and the study staff, including the Principal Investigator.

The overarching principle in the process of informed consent is to take all possible steps to protect the rights and welfare of potential and enrolled study subjects.

RESPONSIBILITIES:

- The Principal Investigator (PI), co-investigators, and appropriate members of the PI’s staff may administer informed consent procedures with a potential study subject and are responsible for presenting complete information on all aspects of the study.
- The PI is responsible for the quality of the informed consent process and documentation.
- The PI/staff is responsible for using current, IRB-approved informed consent forms.
- The PI is responsible for ensuring that the designated staff are qualified to obtain consent.

DEFINITIONS

Informed Consent, Process of: The knowing consent of an individual, so situated as to be able to exercise free power of choice without undue inducement by any element of force, fraud, deceit, duress, or other forms of constraint or coercion. Informed consent is not merely an executed form, it is a process that involves giving a subject adequate information concerning the study, providing adequate opportunity for the subject to consider all available options, responding to the subject’s questions, ensuring that the subject has comprehended this information, and finally, obtaining the subject’s voluntary consent to participate.

The process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form. (E6 Good Clinical Practice: Consolidated Guidance, 1.28)

Private information: “includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and [includes] information which has been provided for specific purposes by an individual and which the individual ‘can reasonably

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expect will not be made public (for example, a medical record)". Private information must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. (Guidance on Research Involving Coded Private Information or Biologic Specimens [OHRP]). "

Sensitive Information: data which, if divulged, could result in legal or socioeconomic hardship.[For example]: information relating to sexual attitudes, references, or practices; information relating to the use of alcohol, drugs or other addictive products; information pertaining to illegal conduct; information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community; information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; information in other categories not listed here which might be considered sensitive because of specific cultural and other factors.

Legally Authorized Representative (LAR): means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant for that person's participation in the procedure(s) involved in the research. Under appropriate conditions (see "Impaired Decision Making Capacity" in the VHA Handbook [1200.5] or the VAMHCS "Informed Consent Guidebook" [HRP 03.01G]), investigators may obtain consent from the legally authorized representative of a subject (surrogate consent). For VAMHCS studies, such consent may be obtained from (in order of hierarchy)²:

- a) a health care agent appointed by the person in a Durable Power of Attorney for Health Care (DPAHC) or similar document;
- b) court-appointed guardians of the person;
- c) next-of-kin in the following order of priority:
 1. spouse
 2. adult child (18 years or older)
 3. parent of the patient
 4. adult sibling (18 years or older)
 5. an adult grandparent or an adult grandchild (in that order of preference) of the patient (but no other relative or friend, even though other relatives or friends may be surrogates under the Health Care Decisions Act [HCDA]) who has qualified as a surrogate under the HCDA by proving that
 - he/she is a competent individual and

² VHA Handbook 1200.05

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- presenting an affidavit to the attending physician stating that the patient is a grandchild or grandparent, and
- stating specific facts and circumstances demonstrating that the person has maintained regular contact with the patient sufficient to be familiar with the patient's activities, health and personal beliefs.

At hierarchy level c.5, the HRPO policy differs from 1200.5 above:

c) 5. any other adult relative or friend of the patient who has qualified as a surrogate under the HCDA by proving that he/she is a competent individual and by presenting an affidavit to the attending physician stating that the patient is a relative or close friend and stating specific facts and circumstances demonstrating that the person has maintained regular contact with the patient sufficient to be familiar with the patient's activities, health and personal beliefs³.

These are the only surrogate entities who are allowed to provide consent for research purposes in the VAMHCS.

RELATED POLICIES:

VHA Handbook (1200.05)	Requirements for the Protection of Human Subjects in Research
Research Service Guideline	"Informed Consent Guidebook" (HRP 03.01G)
Research Service SOP	"Writing a VAMHCS Informed Consent Document"(HRP 03.02)
Research Service SOP	"Research Personnel Education & Training" (HRP 04.02)
Research Service SOP	"Enrollment Notes for Research Participants" (HRP07.01)
Research Service SOP	"Guidelines for Setting Up a Study Binder and Regulatory Documents Binder" (HRP 07.02G)
IRB Policy & Procedures	

PROCEDURES:

1.0 QUALIFICATIONS FOR STAFF TO CONDUCT THE INFORMED CONSENT PROCESS

- 1.1 If the PI does not personally obtain informed consent, the investigator must formally and prospectively designate to another research team member in CICERO the responsibility for obtaining

³ As stated in HRPO Policy/Procedure

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informed consent, whether or not a waiver of documentation of informed consent has been approved by the IRB.

1.1.1 This designee must be a member of the research team.

1.1.2 must receive appropriate training and be knowledgeable enough about the protocol to answer the questions of prospective subjects (See 1.2 below).

1.1.3 The PI does not have to designate the individual by name, but can designate the position(s) title in the protocol or in CICERO.

1.2 Refer to VAMHCS SOP, "Research Personnel Education & Training" (HRP 04.02) for specific requirements and details.

1.2.1 In summary, the requirements are:

- S/he must maintain employment status at the VA, either as a VA employee or a "without compensation" (WOC) appointment, provide documentation of degrees earned, provide current license(s);
- S/he must have a Scope of Practice on file in the Research Service office;
- S/he must be current on all mandatory research protections trainings. Information on mandatory trainings is found on the Research Service "Training/Education" webpage, <http://www.maryland.research.va.gov/training.asp>

1.3 Anyone who discusses the research study with a potential subject must be knowledgeable about the study and the medical condition or research question for which the study is being performed. They must also be able to contact the Principal Investigator or other senior study staff in order to obtain further information for the subject or family.

2.0 THE INFORMED CONSENT PROCESS

2.1 Potential study participants are identified through several mechanisms such as queries to advertisements (approved by the IRB), referrals by primary physicians and other methods approved by the IRB and which are compliant with VA and HIPAA rules or waivers.

2.2 Potential participants are contacted, informed that they might be qualified for the study, told a brief summary of the study and asked whether they think they would like to be screened for the study.

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The potential participant is free to ask further questions and have them answered. The recruiter may ask some superficial “pre-screening” questions if appropriate. (For example, age, veteran status, general elements of medical history or demographics, etc.). Pre-screening questions should be approved by the IRB as part of the CICERO submission. NO INFORMATION (see “Definitions” section) MAY BE OBTAINED FOR RESEARCH PURPOSES UNTIL INFORMED CONSENT HAS BEEN OBTAINED (see #2.6 below).

- 2.3 One goal of the “Pre-screening” process is to establish a comfortable working relationship with the potential participant and/or their family. The participant should feel un-coerced and able to ask questions.
- 2.4 The process which began during Pre-screening (2.1-2.2 above) continues during the Informed Consent process. The PI/staff carefully go through the study events, risks, benefits, and other aspects of the study in detail. The informed consent form itself and other IRB-approved materials such as information sheets and video presentations may be used to aid the process. Questions asked by the potential participant also supplement the process. The investigator/staff must be sure to explain to potential participants that this is a RESEARCH study.
- 2.5 Effort must be made to assess the subject’s capacity to understand the facts of the study and to give consent.

Patients with impaired decision-making capacity (IDMC) are prohibited from being recruited to VA research studies unless the IRB has specifically approved the study for VA IDMC populations. See the Research Service SOP: “Informed Consent Guidebook” (HRP 03.01G, Section II.B.7).

For decisionally impaired participants, there must be documentation in CPRS by independent medical staff. This is discussed in detail in HRP 03.01G (Section II.C). Contact the VAMHCS Research Compliance Officer for questions.

If use of proxy consent by a legally authorized representative is authorized, see the definition of LAR above (“Definitions”) for the hierarchy of proxies and Section II.D of the Informed Consent Guidebook.

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If it is necessary to use a LAR for consent to participate in a research study, the IRB requires that staff complete a “Legally Authorized Representative Identification Documentation Form” (Appendix A). The completed form must be filed in the study files and a copy must be sent to the Research Service Office to be scanned into CPRS with the ICF.

- 2.6 The PI/staff give the potential participant as much time as needed for him/her to think about the study, ask questions of the staff or ask advice from his/her private physician or others.
- 2.7 If the subject/LAR decides to participate in the study, he/she signs and dates the ICF. The person who performed the informed consent process (PI or qualified staff person) must also sign and date the ICF. Other signatures may be required by sponsors or circumstances (for example, a witness signature if a LAR is necessary). The ICF itself will provide space for additional signatures if any are required. (See Section II.J of the “Informed Consent Guidebook” (HRP 03.01G) for details.
- 2.7.1 If use of facsimile is approved by IRB, the subject may submit the signed and dated informed consent form to the investigator or designee by facsimile
- 2.8 The original signed ICF is retained by the PI/staff in a source documents file (SOP# HRP 07.02G, “Guidelines for Setting Up a Study Binder and Regulatory Documents Binder”).
- 2.8.1 Signed consent forms must be readily retrievable and secure.
- 2.8.2 A copy of the signed ICF is given to the participant/LAR
- 2.8.3 A copy is also sent to the Research Service to be scanned into CPRS for placement into the subject’s permanent medical record.
- 2.9 The person obtaining consent writes a progress note in CPRS documenting the following: the name and IRB number of the study, the date and time that consent was obtained, the name of the person obtaining consent, a statement that the study was explained to the subject, a statement that the subject/legal representative was capable of understanding the consent process and how this was determined, a statement that the subject had been given ample time to ask questions and consider the study, a statement that a copy of the ICF was given to the participant, and, if applicable, a

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description of the circumstances for which an LAR was used. When the Research Service subsequently scans the ICF into CPRS, it will “attach” it to this note (see 2.7 above). A copy of this note should be placed in the participant’s research source documents file. See Appendix B for a sample enrollment note.

- 2.10 A “Research Subject Clinical Warning” (RSCW) must also be put into CPRS, “flagged”, if the participant’s involvement in the study involves :
- Any invasive research procedure (e.g., muscle biopsy or bronchoscopy);
 - Interventions that will be used in the medical care of the subject, or that could interfere with other care the subject is receiving or may receive (e.g., administration of a medication, treatment, or use of an investigational device);
 - Clinical services that will be used in the medical care of the subject (e.g., orders for laboratory tests or x-rays ordered as a part of the study), or that could interfere with other care the subject is receiving or may receive; or
 - The use of a survey or questionnaire that may provoke undue stress or anxiety unless the IRB determines that mandatory flagging is not in the best interests of the subject (e.g., an interview study of victims of sexual assault)..
 - In other situations, the IRB determines if flagging is necessary. See “Enrollment Notes for Research Participants” HRP 07.01 for further details.
- 2.11 Both the ORC and the IRB have the authority to observe the consent process between an investigator/research staff and a prospective subject and to make judgments as to its effectiveness and compliance with institutional standards.
- 3.0 PROCEDURE FOR ALTERNATIVE INFORMED CONSENT
- 3.1 In certain circumstances, informed consent may be obtained in an alternative manner. The Investigator, with the approval of the IRB and the R&D Committee must determine these occasions.
- 3.2 Oral informed consent / Short Form [21 CFR 50.27(b)(2), 45 CFR 46.117(b)(2), 38 CFR 16.117(a)(2), VHA Handbook 1200.05]
If the standard written informed consent cannot be obtained (for example, if the subject or legal representative cannot read), a written summary document that embodies the elements of informed

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consent can be read to the study subject or the study subject's legally authorized representative. The oral presentation must be witnessed by an impartial party and the IRB must approve the written summary or the oral presentation. A "short form", stating that the elements of the informed consent have been presented orally to the subject, must be signed by the study subject or the study subject's legally authorized representative. The witness and the investigator (or presenter) must sign the short form *and* the summary. The study subject must be given a copy of the summary and the short form. [There should be clear documentation that the witness was present for the entire oral presentation and that it adequately reflected the material in the IRB-approved short form and summary.] See also, Research Service SOP "Informed Consent Guidebook" (HRP 03.03G) Section I.G.2.

3.3 IRB waiver of need for documentation of informed consent (waiver of need for a signed informed consent form) [21 CFR 56.109(c)(1), 45 CFR 46.117(c), 38 CFR 16.116(c),(d), 38 CFR 16.117(c), VHA 1200.05]

An IRB may, for some or all study subjects, waive the requirement that the study subject sign a written informed consent form if it finds that the research presents no more than minimal risk of harm to study subjects and involves no procedures for which written informed consent is normally required outside the research context. When this waiver is in effect, the IRB may require the investigator to provide the study subjects with a written statement regarding the research. See also, Research Service SOP "Informed Consent Guidebook" (HRP 03.03G) Section I.G.3a.

3.4 Exempt from the informed consent process [45 CFR 46.116(c),(d), 38 CFR 16.116(c),(d) VHA 1200.05]

An IRB may approve a consent procedure which does not include or which alters some or all of the 'general requirements of informed consent'⁴ provided the IRB finds that the research involves no more than minimal risk to the subjects, that the waiver or alteration will not adversely affect the rights and welfare of the subjects, that the research could not practicably be carried out without the waiver or alteration, and that whenever appropriate, the subjects will be provided with additional pertinent information after participation. See also, Research Service SOP "Informed Consent Guidebook" (HRP 03.03G) Section I.G.3b.

⁴ General Requirements of Informed Consent are listed in 45 CFR 46.116 and 21 CFR 20.23

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3.5 Exception from general requirements("Emergency Consent")[21 CFR 50.23, VHA 1200.05]

The obtaining of informed consent shall be deemed feasible unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

- 3.5.1 The human study subject is in a life-threatening situation necessitating the use of the test article.
- 3.5.2 Informed consent cannot be obtained from the study subject because of an inability to communicate with or obtain legally effective informed consent from the study subject.
- 3.5.3 Time is not sufficient to obtain informed consent from the subject's legal representative.
- 3.5.4 There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the study subject.

If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the study subject and time is not sufficient to obtain the independent determination required above in advance, the determinations of the investigator shall be made and within 5 working days, be reviewed and evaluated in writing by a physician who is not participating in the investigation.

The documentation required above shall be submitted to the IRB or ethics committee within 5 working days after the use of the investigational drug/device. A copy must be placed in the study's regulatory binder. The Sponsor should also be notified.

See also, Research Service SOP "Informed Consent Guidebook" (HRP 03.03G) Section I.G.4a.

3.6 Emergency use of a test article (prior to IRB approval) [21 CFR 56.104(c), 21 CFR 56.102(d), VHA 1200.05]

FDA regulations permit the emergency use of an investigational drug, biologic or device for a strictly limited class of research where the patient must be in an immediate life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102.(d)]. The UMAB IRB recognizes this as well and requires a written report within 5 working days of the use of the test article.

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Additionally, both the FDA and the IRB still require consent as described in the item(s) above. A standard Consent Form can usually be obtained from the FDA, the sponsor, or the manufacturer of the test agent.

See also HRP 03.03G, Section I.G.5.

ATTACHMENTS

Appendix A

Legally Authorized Representative Identification Form

Appendix B

Enrollment Note Template

REFERENCES

Research Service SOP	Informed Consent Guidebook (HRP 03.01G) Writing a VAMHCS Informed Consent Form (HRP 03.02)
IRB Policies and Procedures	Investigator Manual
VHA Handbook (1200.05)	Requirements for the Protection of Human Subjects in Research
VA Regulations (38 CFR 16)	Protection of Human Subjects” [16.101(b), 16.116 (c) and (d), 16.117(a)(2), 16.117(c)]
FDA Regulations (21 CFR 50, 21 CFR 56)	“Protection of Human Subjects” [50.23, 50.27(b)(2),56.102(d), 56.104(c), 56.104(d), 56.109(c)(1)]
FDA Information Sheets	“Frequently Asked Questions” “Screening Tests Prior to Study Enrollment” “A Guide to Informed Consent Documents” “Emergency Use of an Investigational Drug or Biologic” “Waiver of IRB requirements”
DHHS Regulation (45 CFR 46)	“Protection of Human Subjects” [46.117(b)(2), 46.117(c), and (d)]
DHHS/FDA	“International Conference on Harmonization; Good Clinical Practice; Consolidated Guideline” (ICH GCP’s)

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COMPLIANCE

The VAMHCS Office of Research Compliance regularly conducts routine and for-cause audits of research protocols. Informed consent forms, enrollment notes, tests of understanding / mental capacity, and other documentation of the informed consent process are all subject to the audits. The ORC or HRPO are authorized to observe the informed consent process.

Investigators and staff are subject to suspension or termination of their protocol(s) if significant noncompliance is uncovered.

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APPENDIX A

UMB form for legally authorized representatives (LAR)

**Check the HRPO website for the most recent
version of this form.**

http://www.hrpo.umaryland.edu/toolkit_additional_docs.asp

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APPENDIX B: Suggested template for enrollment notes. Adapt it to the particulars of a study. All of the information below should be included. This template is subject to change. See the Research Service website for the most current version: www.maryland.research.va.gov

ENROLLMENT NOTE FORM

Protocol Title:

Principal Investigator:

IRB #:

IRB Validation Dates:

Date the Informed Consent form was signed:

Time the Informed Consent form was signed:

Person Obtaining Consent:

Participant was enrolled in above-mentioned protocol. Participant/legal guardian has been fully informed about the study including procedures, risks and benefits. Participant/legal guardian has read the consent form or had it read to them and was given the opportunity to have questions answered prior to signing the informed consent document. Participant/legal guardian was [*description of participant's/guardian's mental capacity and the type(s) of assessments used*]. Participant/legal guardian agreed to comply with all follow-up procedures including the length of participation. The participant/legal guardian was given a copy of the informed consent document and study contact information.

STUDY-SPECIFIC COMMENTS (If applicable):

- Specific aspects of the study's consent process
- Combine with an "entry note" if applicable
- Circumstances that necessitated an LAR
- Forms of alternative consent