

Department of Veterans Affairs
Tuscaloosa VA Medical Center

Human Research Protections Program SOP #7

October 7, 2007

RESEARCH INFORMED CONSENT

1. POLICY

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is committed to the protection of veterans who volunteer to participate in research. As outlined in this Standard Operating Procedure (SOP), the policy of the TVAMC HRPP is to assure that provisions are made to obtain legally authorized informed consent prospectively from each research participant or permission from his or her authorized representative, unless a waiver of informed consent has been approved by the TVAMC Institutional Review Board (IRB).

Informed consent - an individual's *voluntary agreement*, based upon *adequate knowledge and understanding* of relevant information, to participate in a research project - is a critical element of ethical research with human subjects. Informed consent is an ongoing process that involves interactions and communications between the subject and personnel conducting the study. There are multiple components to the informed consent process, including the presentation, reading, discussion about and signing of the Informed Consent Form (ICF), recruitment materials, verbal contacts prior to and after enrollment, and provision of new information that becomes available during the study.

The Belmont Report describes three basic ethical principles relevant to the ethics of research involving human subjects - respect for persons, beneficence, and justice. While the informed consent process helps ensure that all three of these ethical principles are upheld in the exercise of research at TVAMC, it is an especially important expression of respect for persons. By adherence to a policy of informed consent for research, TVAMC investigators and the HRPP demonstrate treatment of potential research participants as autonomous agents and ensure protection of those potential research participants with diminished autonomy. In its review of research proposals, the TVAMC HRPP, through the IRB, considers the entire informed consent process in relation to the required elements and has authority to observe the consent process (i.e., in person, periodic audits, etc.).

2. RESPONSIBILITIES

The TVAMC Medical Center Director has ultimate responsibility for the TVAMC R&D program, including the informed consent process for research projects.

TVAMC HRPP and Research and Development (R&D) Committee must assure that provisions are made to obtain legally authorized informed consent prospectively from each research participant or permission from his or her authorized representative, unless a waiver of informed consent has been approved by the TVAMC IRB. The R&D Committee is also responsible for reviewing and evaluating all its subcommittees' decisions, including IRB approval or exemption and waiver of informed consent.

TVAMC Institutional Review Board is responsible for protecting the rights and welfare of subjects. The TVAMC IRB will not approve a protocol unless its informed consent plan (form and process), or a waiver of informed consent, is in full compliance with relevant TVAMC and VHA policies.

Every investigator or VHA employee engaged in research must receive annual training in Human Subjects Protection and Good Clinical Practices, which includes specific training about the informed consent process. All individuals engaged in research at TVAMC must comply with this SOP and with relevant TVAMC and VHA policies regarding informed consent.

Principal Investigators (PIs) are responsible for developing and submitting a plan to the IRB and R&D Committee for obtaining legally authorized informed consent prospectively from each research participant or permission from his or her authorized representative, unless a waiver of informed consent has been approved by the TVAMC IRB. If a waiver of informed consent is requested, the request must specify the specific criteria that justify consideration for such a waiver, as detailed below. PIs may delegate responsibility to conduct the informed consent process to appropriately credentialed and trained coinvestigators, study coordinator(s) or research assistant(s). Though the PI is ultimately responsible for the informed consent process for each of his or her research projects, study personnel with delegated responsibility for informed consent are required to uphold the same standards in the conduct of the informed consent process as PIs. Research Personnel must understand the concept of a legally effective informed consent, must appropriately document the informed consent, and must understand the difference between the informed consent process and the documentation of informed consent, as described in this SOP.

3. DEFINITIONS

- a. Informed Consent:** An individual's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.
- b. Assent:** An individual's affirmative agreement to participate in research obtained in conjunction with permission from the individual's authorized representative. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- c. Authorized Representative for Surrogate Consent:** A Legally Authorized Representative for Surrogate Consent (as defined below) or, in the absence of a Legally Authorized Representative, a next-of-kin willing to participate in surrogate informed consent, in the following order of priority: spouse, adult child (age 19 or

older), parent, adult sibling (age 19 or older), grandparent, or adult grandchild (age 19 or older).

- d. Legally Authorized Representative for Surrogate Consent:** An individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective participant to the participants' participation in the procedure(s) involved in the research [38 CFR 16.102(c)].

4. PROCEDURES

- a. Basic IRB Requirements:** No investigator may involve a human as a subject in research covered by these regulations, or conduct any procedures required by the protocol, unless the investigator has obtained IRB-approved waiver or the legally effective IRB-approved VA Form 10-1086 informed consent of the subject or the subject's authorized representative. A subject's legally authorized representative (for a subject determined to be incapable of making an autonomous decision) is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research [38CFR16.102(c)]. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. Translated consent forms are used for studies involving non-English-speaking subjects. The IRB reviews the Consent Form to ensure that the information is in a language that is understandable. No Informed Consent, whether oral or written, may include any exculpatory language through which the subject or the 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. Informed Consent must be obtained prior to initiation of any clinical screening procedures that are performed solely for the purposes of determining eligibility for research.

The IRB reviews the informed consent form and plan/process at the time of expedited, initial, modifications/amendments, and/or continuing review and evaluates whether the consent process is legally effective, provides sufficient opportunity for the prospective participant/surrogate to consider whether to participate, minimizes the possibility of coercion or undue influence, is in language understandable to the participant/surrogate, and is free of exculpatory language. On the primary reviewer checklist, the primary reviewer documents his/her review and whether the required elements are thoroughly and clearly described.

The IRB requires that:

1. The consent document does not overstate benefits and understate risks.
2. Federally required basic elements of informed consent (listed below) are stated.

3. Information is presented in simple language at approximately the 6th grade level. Individual studies may deviate from the policy when appropriate for the populations being recruited for those studies (with IRB approval).
4. Documentation of Informed Consent is completed and a copy is placed in the medical record, unless a specific waiver is granted by the IRB or unless specific criteria for exception from Informed Consent are met.
5. New findings potentially impacting subjects' willingness to participate in studies to be conveyed to subjects. The IRB assists investigators in determining the urgency of the situation and the speed and manner in which information should be conveyed to subjects. Significant new information may require re-consenting of all affected subjects. Re-consenting is not required of subjects that have completed their active participation in a study, or of subjects who are still actively participating when the change will not affect their participation.

b. The 10-1086 (VA Research Consent Form) must be used (unless otherwise waived) and it must contain all of the required elements as described below. The IRB review process focuses on the Informed Consent document and validates inclusion of the basic and appropriate additional elements required elements set forth in VA and other Federal and state regulations.

VA Form 10-1086 provides a template to guide the PI in the requirements of informed consent and VA-specific information. Obtaining signatures on the consent form is not, in itself, the goal of the informed consent process, but the form both documents the elements of a thorough informed consent discussion and prompts research staff, potential study participants, and authorized representatives to discuss each of these elements.

The required elements of informed consent are (also see Research Informed Consent Template):

1. Names of all investigators.
2. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
3. The approximate number of subjects involved in the study.
4. A description of any reasonably foreseeable risks or discomforts to the subject (including physical, psychological, social and/or economic).
5. A description of any benefits to the subjects or to others, which may reasonably be expected from the research.
6. A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject.
7. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and notes (if applicable) the possibility that the VA, FDA or other federal oversight agencies may inspect the records.
8. Indication of a willingness to answer questions by the investigator

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 about research subjects' rights.
10. An explanation of whom to contact for answers to pertinent questions about the research, research subjects' rights, any concerns about the research, complaints about research, and who to contact in the event of a research-related injury to the subject. The IRB shall ensure that the Informed Consent has accurate information to the subjects about the availability of compensation and/or treatment for injury occurring in the research study. However, this requirement does not apply to treatment for injuries due to non-compliance by the subject with study procedures. In the event of research related questions, concerns or complaints, the policy and procedures can be found in TVAMC SOP #14.
11. A statement that 1) participation is voluntary, 2) refusal to participate will involve no penalty or loss of benefits or eligibility for continuing care to which the subject is otherwise entitled, and 3) the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
12. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject.
13. When appropriate a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.
14. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
15. Any additional costs to the subject that may result from participation in the research (if applicable and consistent with Federal laws concerning veterans' eligibility for medical care and treatment).
16. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject (if applicable).
17. Information concerning compensation to the subjects for participation in the study, including amounts and schedule of payments.
18. HIPAA authorization form that includes provisions for confidentiality and the protection of a subject's privacy. These provisions include a description of the use of personally identifiable records, the methods to protect the confidentiality of research data, and whether or not there is a Federal Certificate of Confidentiality in place.

If compensation is to be provided for participation in a TVAMC research study, a statement about any compensation the subject is to receive for participation, the required conditions for compensation, and the compensation schedule should be included in the VA Research Consent Form for that study. There should be a description of how compensation will be prorated and calculated for subjects who withdraw early (completion of the research may not be made a condition of compensation).

The informed consent process, as documented in the VA Research Consent Form and as presented to potential participants or their authorized representatives, must not overstate benefits and understate risks of participation in the study. Information is to be presented in simple language at approximately the 6th grade level.

- c. **The Informed Consent Process:** It is important that informed consent be viewed as a process rather than an event. Though the signing of the informed consent document is the most visible feature of this process, the process of informed consent begins with recruitment and continues throughout the course of the study. During recruitment and before the ICD is signed, this process includes:
- The potential participant is given all the information needed to decide about participating in a study;
 - The potential participant has opportunity to ask questions and to exchange information freely with investigator;
 - The potential participant has an opportunity to consider participation in the study; and
 - The investigator ensures that the potential participant understands the information.

Persons authorized to conduct the informed consent are the PIs and Co-investigators listed on the IRB-approved Informed Consent. Participants' questions regarding medical illnesses, procedures, treatments, or investigational drugs must be directed to an investigator with relevant clinical training and competency. If someone other than the investigator conducts the informed consent, the protocol must define the formal delegation of this responsibility and the training or credentials of the person delegated to perform this activity. **Using the IRB-approved stamped consent form**, investigators must obtain consent (signature and date) *prior to* entering a subject into a study and/or conducting any procedures required by the protocol, unless consent is waived by the IRB. In addition, informed consent must be obtained *prior to* initiating any screening tests or procedures that are performed solely for the purposes of determining eligibility for research. **A signature and date of a witness** is required on all VA Research Consent Forms, unless waiver of this requirement is specifically requested from and granted by the IRB. The witness' signature is intended to certify that the participating veteran or his or her authorized representative actually, personally, and voluntarily signed the VA Research Consent Form. By signing the VA Research Consent Form, the witness is *not* acting as a "co-consenter" or otherwise participating in the process of granting informed consent for participation in the study. If the sponsor or IRB requires a witness to the consenting process in addition to the witness to the participant's signature and if the same person needed to serve both capacities, a note to that effect was placed under the witness's signature line. When informed consent is obtained using a VA Research Consent Form, copies of the signed form are:

- Sent to medical records to be scanned into the veteran's medical record;
- Given to the participant or to the authorized representative granting consent;
- Delivered to the pharmacy to file in the study binder (for drug studies); and
- Kept (original) by the study research team in the patient's research record.

A progress note documenting the informed consent process and a clinical warning (if applicable) must be placed in the subject's medical record. Templates for this note are available in the TVAMC electronic medical records under the name of "Informed Consent Template" or Research Consent Form (T)." This information should include:

1. The name of the study or reason for consent;
2. Persons present at the discussion;
3. Patient's mental status
4. How decision-making capacity was demonstrated
5. A statement that the treatment and/or procedure was explained to the subject and/or surrogate;
6. A statement that the indications, risks, benefits and alternative treatments options were explained
7. A statement that the subject and/or surrogate was offered an opportunity to ask questions; and
8. A statement that consent was obtained prior to any study procedures.

When the subject is no longer active in a research study: a progress note documenting the completion of participation will be entered and the clinical warning posted in the subject's electronic chart will be removed.

- d. Protection of Vulnerable Patients and Patient Populations:** An essential part of ensuring that the three basic ethical principles relevant to the ethics of research involving human subjects - respect for persons, beneficence, and justice – are respected in the exercise of clinical research at TVAMC is ensuring that potentially vulnerable patients and patient populations are given special consideration and protection. Potential research participants may be vulnerable in the informed consent process for a variety of reasons that may affect their abilities to understand, evaluate, and consider information presented or the "voluntariness" of their consent. The TVAMC HRPP assesses potential vulnerability in terms of the *potential for limitations on autonomy* in considerations of whether research projects contain sufficient safeguards to protect the rights and welfare of these subjects.

Examples of potentially vulnerable patients and patient populations relevant to research performed at TVAMC include:

- Patients with serious mental illness that might interfere with decision-making capacity or who are otherwise cognitively impaired (capacity-related cognitive vulnerability);
- Veterans, military personnel, employees, and students (deferential vulnerability);
- Seriously or chronically ill patients who may view research treatments with unrealistic hope for cure or recovery (medical vulnerability);
- Economically disadvantaged persons who might enroll in a research study due to a financial incentive when they would otherwise not do so;

Since research at TVAMC focuses on veterans, and veterans are accustomed to obeying orders and making sacrifices, particular attention is paid to potential

vulnerabilities related to veteran status in the review of proposed research at TVAMC.

Other potentially vulnerable patients and patient populations include pregnant women, young children, prisoners, and research involving human fetal tissue, but research with these patient populations is not conducted at TVAMC.

As part the IRB initial review and continuing review application process, investigators are required to identify any potentially vulnerable populations and to describe precautions taken to protect autonomy and prevent coercion. The IRB may require special precautions or safeguards to be taken by the investigator to protect the rights and welfare of potentially vulnerable populations (e.g., the IRB may require a patient advocate or authorized person to witness consent, a waiting period between initial contact and enrollment, or oversight of the informed consent process).

Certain types of studies may raise issues of vulnerability due to study design (as opposed to population) and the potential for limitations on autonomy will receive special consideration during IRB review. Examples of such types of studies include:

1. Studies of the withdrawal of therapy, whether or not the withdrawn therapy is replaced by experimental treatment, when there is significant risk of morbidity or mortality;
2. Significant risk of serious impairment; and
3. Risks when there is no potential clinical benefit to the subject (e.g. Phase I studies).

- e. Informed Consent for Potential Research Participants Who Lack Decision-Making Capacity:** Informed Consent requires that research participants be: 1) capable of deciding whether to participate; 2) adequately informed about the risks and benefits of participation; 3) able to understand the information; and 4) free to make a voluntary decision to participate. Investigators must determine the decision-making capacity of all potential research participants approached for informed consent and document this process in a progress note in the subjects' medical record (note entitled "Informed Consent Template" or "Research Consent Form (T)"). Determination of capacity to make a decision is made on an individual basis. As documented in the consent note, decision-making capacity can be assessed by one or more of the following exams: 1) clinical interview, 2) mental status exam, 3) mini-mental state exam, 4) neuropsychiatric testing, 5) psychosocial history, or 6) other appropriate test. If the potential research participant does not have the capacity to make a decision or if the research project involves cognitively impaired individuals, surrogate informed consent is required by the IRB.
- f. Surrogate Informed Consent:** Some TVAMC research studies focus on populations with impaired decision-making capacity (e.g., patients with dementia). For such studies, surrogate informed consent is required as a matter of course and protocols submitted to the IRB for consideration must demonstrate:

- A compelling reason to focus the study on populations with impaired decision-making capacity, and, specifically, why populations with intact decision-making capacity are not suitable for the proposed research;
- A favorable risk/benefit ratio;
- Provision and plan to obtain surrogate informed consent from the subject’s authorized representative.

VHA Handbook 1200.5 describes the conditions under which consent from authorized representatives (i.e. surrogate consent) can be obtained in lieu of consent from the patient. Similarly, a procedure for informed consent for patients who lack decision-making capacity is spelled out in TVAMC Center Memorandum No. 11-56 (“Informed Consent”). ***These policies govern TVAMC R&D program policy and practice regarding surrogate consent.*** Consistent with these policies, the TVAMC HRPP recognizes the following, in descending order of priority, as authorized representatives for research informed consent when potential research participants lack decision-making capacity:

1. Persons appointed as health care agents under a Durable Powers of Attorney for Health Care or a similar document (Legally Authorized Representative for Surrogate Consent);
2. Court-appointed guardian (Legally Authorized Representative for Surrogate Consent);
3. Next-of-kin willing to participate in surrogate informed consent, in the following order of priority (unless otherwise specified in the TVAMC medical record for designated next of kin): spouse, adult child (age 19 or older), parent, adult sibling (age 19 or older), grandparent, or adult grandchild (age 19 or older).

NOTE: Potential research participants who lack decision-making capacity and have no identifiable next-of-kin or whose available next-of-kin is limited to a “close friend” (see TVAMC Center Memorandum No. 11-56, “Informed Consent”) are NOT eligible to participate in research at TVAMC through surrogate consent. A “close friend” is not eligible to serve as a “legally authorized representative” or “surrogate consent” for research studies.

If needed, the PI may consult with the TVAMC Privacy Officer, IRB, or TVAMC Integrated Ethics Council, VA Regional Counsel if there are uncertainties about who should serve as a surrogate for an individual patient. When needed, the PI, Privacy Officer, IRB, or other staff on behalf of the TVAMC HRPP can consult with VA Regional Council for assistance in applying laws involving authorized representative surrogate consent.

Surrogate consent is allowed when a subject is deemed to lack decision-making capacity and the surrogate is provided the same information that would be given the potential subject if competent. Whenever possible, surrogates should make decisions based on “substituted judgment”, using views the individual expressed while fully capable; if the values of the subject are not known, “best interest” standards may be

used. The surrogate signs the informed consent on the appropriate signature line and the process of the surrogate consent is documented in the individual patient's medical record.

Under all circumstances, the subject's autonomy should be respected; their assent to participate should be obtained whenever possible, and their decision to withdraw at any time (whether expressed verbally or by resistance to participation) must be honored. Under no circumstances may a subject be forced or coerced to participate in a research study.

- g. Telephone Surrogate Consent; Consent of Illiterate Persons; Consent of Non-English Speaking Participant:** It is acceptable to send the informed consent document to the authorized representative/surrogate and conduct the consent interview by telephone when the surrogate can read the consent as it is discussed. A witness to the consent process needs to also be on the telephone during the call. If the surrogate agrees, he/she can sign the consent and return the signed document to the PI by facsimile or mail. Illiterate persons who understand English may have the consent read to them and "make their mark" with a witness to the entire consent process. Informed Consent should be obtained in language that is understandable to the subject (or the subject's authorized representative). When the prospective subject does not understand the language of the person who is obtaining consent, a reliable translator is required. If recruitment of non-English speaking subjects is anticipated, an IRB approved Consent Form written in the language understandable to the subject must be made available (and approved by the IRB). Translation of the document is not generally necessary for the TVAMC study population however, if translation is required, translation services will be necessary and will be arranged by the PI. If ever planned, the recruitment of non-English speaking persons should be stated in the protocol.
- h. HIPAA Authorization Form and Waiver of HIPAA:** Regardless of expedited or convened procedures, at the time of initial review, the investigator submits a Health Insurance Portability and Accountability Act (HIPAA) Authorization Form, HIPAA Revocation Form, or Request for Waiver of HIPAA, following or using the suggested IRB templates. Unless waiver is approved, the HIPAA Authorization Form is signed at the time of the informed consent by the participant or surrogate and filed with all copies of the informed consent. If the investigator is requesting a Waiver of HIPAA Authorization, she/he must submit a memo with the explanation of how it meets the below criteria, a brief description of the Protected Health Information (PHI) for which the investigator plan to use in the research. Waiver of HIPAA Authorization is based on the IRB review (expedited or convened) and approval, provided that the request meets the following:
1. The use or disclosure of the requested information involves no more than a minimal risk to the privacy of individuals based on at least, the presence of the following elements:
 - i. An adequate plan to protect the identifiers from improper use and disclosure

- ii. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law
 - iii. Adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule.
 - 2. The research could not be practicably conducted without the waiver or alteration
 - 3. The research could not practicably be conducted without access to and use of the requested information.
- i. IRB Approval Stamp:** After all contingencies are satisfied and IRB-approval has been obtained, the approved VA 10-1086 consent form is stamped on each page with an IRB approval stamp using date of the most recent IRB approval date. If the consent form is amended during the protocol approval period, the form must bear the approval date of the amendment rather than the date of the approved protocol. The most recently IRB approved and stamped consent form must be used thereafter. If substantial or significant changes to the consent form have been made, participants who are currently active should sign a new consent form at their next study visit.
- j. IRB Procedures for Evaluation and Observation of the Informed Consent Process:** The TVAMC IRB has authority to designate a member of the IRB or the HRPP to observe or have a third party observe the investigators or research assistants conducting an informed consent. Role-play or situations with actual patients can be used to demonstrate the informed consent process. Some situations where observation may be used include: to reduce the possibility of coercion and undue influence, if the study poses significant risk to the participant, if subjects may have trouble understanding the information, and when IRB has identified problems associated with an investigator or research project.
- k. Exceptions to the Informed Consent for Emergency Use Procedures:** The TVAMC HRPP does not allow Emergency Use Research at this time. If such research is needed in the future, the TVAMC HRPP will prepare written policies and procedures for exceptions to informed consent requirements in protocols for emergency situations.
- l. Waiver of the Requirement to Obtain Informed Consent for Participation in a TVAMC Research Project:** The IRB may determine if a project meets the federal criteria for waiver of informed consent requirements, alternate consent procedures, or waiver of documentation of Informed Consent. This determination is documented in the IRB minutes. However, no use of “short-form” consent is allowed. **If an FDA regulated test article is being used, then waiver of documentation of Informed Consent is not allowed.** An IRB may approve a consent procedure, which does not

include, or which alters, some or all of the elements of Informed Consent or waives the requirements to obtain documentation of Informed Consent, provided the IRB finds and documents one of the following reasons.

There are two exceptions to the requirement for informed consent and/or authorization in research conducted at TVAMC:

1. When an IRB has approved a waiver of consent based on the following criteria:
 - i. The research involves no more than minimal risk to the subjects;
 - ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - iii. The research could not practicably be carried out without the waiver or alteration; and
 - iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

NOTE: The IRB must also have approved a waiver of authorization based on additional criteria for waiver of authorization if the records are held by an institution that maintains or transmits medical data (or “protected health information”).
2. An institution or IRB has certified, in accordance with its policies, that the records-based research is exempt from federal regulations (45 CFR 46) because:
 - i. The sources of the records are publicly available; or
 - ii. The information collected by the investigator is recorded in such a manner that subjects of the research cannot be identified, directly or through identifiers linked to the subject.

All determinations of the appropriateness of a request for waiver of consent are made by the IRB - an investigator himself/herself is never allowed to make such a determination.

If an FDA regulated test article is being used, then waiver of documentation or process of Informed Consent is not allowed. Investigators may request *waiver of the requirement for written documentation of informed consent* when all of the following are true:

1. The research presents no more than minimal tangible or intangible risk of harm to participants;
 2. The research involves no procedures for which written consent is normally required outside of the research context;
- OR
3. The only record linking the participant and the research would be the consent document;
 4. The principal risk would be potential harm resulting from a breach of confidentiality;

5. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; and
6. The research is not subject to FDA regulations.

In cases in which the documentation requirement is waived, the IRB may require the principal investigator to provide subjects with a written statement regarding the research. IRB minutes shall clearly reflect this waiver provision and the justification for its use. The IRB must review the written description of the information that would be provided to the participants.

5. REFERENCES

- VHA Handbook, 1200.5 – Requirements for the Protection of Human Subjects
- TVAMC Center Memorandum No. 11-09, Research and Development Committee
- TVAMC Center Memorandum No. 11-56, Informed Consent

6. ATTACHMENTS

- VA Form 10-1086 (VA Research Consent Form)
- TVAMC “Progress Note for Informed Consent Discussion” template

7. RESCISSIONS

TVAMC HRPP SOP#7 Research Informed Consent dated May 7, 2007.

8. REVIEW DATE

January 1, 2012

Signature on File in R&D Office

Lori L. Davis, MD

Coordinator of Research and Development