TITL E: Informed Consent Process Requirements

1.0 PURPOSE

This Standard Operating Procedure (SOP) sets forth the policies and procedures required by the VA Central IRB as part of the informed consent process. This includes the required elements of informed consent, the process of obtaining informed consent, documentation of informed consent, and requirements for requesting a waiver or alteration of the informed consent process and/or a waiver of documentation of informed consent.

2.0 REVISION HISTORY

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3.0 SCOPE

This SOP applies to all VA investigators and members of their project teams who submit projects involving the use of human participants to the VA Central IRB for review. It also pertains to VA Central IRB members and the VA Central IRB administrative staff.

4.0 POLICY

4.1 It is the policy of the VA Central IRB that an investigator may not involve a human being as a participant or subject in non-exempt research the VA Central IRB oversees unless the investigator or the investigator’s designee obtains the informed consent of the person or the person’s legally authorized representative, unless the requirement for obtaining such consent is waived by the VA Central IRB.

4.1.1 If someone other than the investigator conducts the interview and obtains consent from a participant or the participant’s legally authorized representative, the investigator needs to formally delegate this responsibility in writing, and the person so delegated must have appropriate qualifications and have received appropriate training to perform this activity. The PI/SC or LSI does not have to designate the individuals by name but can designate the position title in the protocol and VA Central IRB Forms 108 and 104, unless the VA Central IRB requires the individual’s be designated by name.
4.1.2 All project personnel involved in the informed consent process must be knowledgeable about the research to be conducted and the process for obtaining informed consent. They must be able to answer questions about the project.

4.2 An investigator can seek consent only under circumstances that provide the prospective participant, or the participant’s legally authorized representative, sufficient opportunity to read the informed consent document and consider whether or not to participate. The investigator must also minimize the possibility of undue influence or coercion. If a participant’s legally authorized representative provides surrogate consent, assent must be sought from the participant whenever possible.

4.3 The information given to the participant or the participant’s representative must be in language understandable to the participant or the participant’s representative.

4.4 No informed consent, whether oral or written, may include any exculpatory language through which the participant, or the participant’s legally authorized representative, 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 institution, or its agents from liability for negligence.

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

6.0 RESPONSIBILITIES

6.1 It is the expectation of the VA Central IRB that, when appropriate, investigators are responsible for:

6.1.1 Ensuring that informed consent is obtained from a participant or a participant’s legally authorized representative prior to conducting any research activities with the subject in accordance with the requirements of this standard operating procedure, as well as VA and other federal requirements. The only exceptions are if the VA Central IRB determines the research is exempt or if a waiver of informed consent is approved by the VA Central IRB for the project or a portion of the project.

6.1.2 Creating an informed consent document containing all required basic elements, as well as any additional elements as applicable, for the participant populations that will be enrolled and describing the type of research that will be conducted. The investigator will obtain approval of this document by the VA Central IRB prior to initiating any research activities or enrolling any participants.

6.1.3 Ensuring that such informed consent is appropriately documented using the most current version of the VA Central IRB-approved consent form unless a waiver of documentation of informed consent has been approved by the VA Central IRB.
6.1.4 Ensuring that all members of the investigator's project team who seek informed consent are appropriately qualified and trained to perform this function. The investigator must indicate on the VA Central IRB Application a plan for training study team members who will be obtaining the informed consent and designate in writing those members of the study team who are authorized and qualified to obtain informed consent.

6.1.5 Maintaining documentation of informed consent in accordance with VA requirements, to include keeping a copy of the signed informed consent document in the research study file, as well as forwarding a copy for file in the subject's medical record if applicable.

6.1.6 Appropriately requesting a waiver or alteration of the informed consent process when needed or required by the study design.

6.1.7 Appropriately requesting a waiver of documentation of informed consent, when needed or required by the study design.

6.1.8 Ensuring the informed consent process clearly defines for the research participant which potential risks are related to the research and must be thoroughly discussed as part of the consent process versus those solely related to the usual care provided by the participant's health care provider. The investigator must ensure that the informed consent process contains language advising participants to review the risks of usual care with the participant's health care provider.

6.1.9 Ensuring that appropriate HIPAA authorization has been obtained if applicable by only those personnel designated in writing on the VA Central IRB application to obtain informed consent. The investigator must ensure that the HIPAA authorization is consistent with the informed consent form, the protocol, and the VA Central IRB Application.

6.2 The VA Central IRB is responsible for evaluating investigator compliance with the policies and procedures on seeking informed consent or assent from participants.

6.2.1 The VA Central IRB will review the entire informed consent process, including the informed consent document, the processes by which informed consent is obtained from each participant, and how participants are recruited. The VA Central IRB will review the process with a focus on improving the participant's understanding and voluntary decision making. This will be done through a combination of review of Local Site Investigator Applications, local site Research Compliance Officer audit reports, other outside audit reports, and on-site visits by VA Central IRB personnel.

6.2.2 The VA Central IRB will also review requests from investigators to waive or alter the informed consent process and requests for waiver of documentation of the informed consent process.
6.3 The VA Central IRB Coordinators and the Administrator are responsible for ensuring that investigators are adequately informed of the VA Central IRB's requirements for submitting a project involving the use of human subjects to the VA Central IRB for review. This includes making available the applicable forms and checklists to aid investigators in ensuring their applications are complete and contain all necessary documentation required for the VA Central IRB to adequately review the investigator's proposed informed consent process, requests for waiver or alteration of this process, or requests for waiver of documentation of the informed consent process.

7.0 PROCEDURES

7.1 Informed Consent Required Elements. All investigators submitting projects to the VA Central IRB who plan to seek informed consent from participants or the participants' legally authorized representatives will submit a proposed informed consent document using the VA Central IRB template of the VA Form 10-1086, Research Consent Form (Attachment 1.) The following are the required elements that must be in all informed consent forms submitted to the VA Central IRB:

- The name of the project, the name of the sponsoring organization, and the name of the Principal Investigator (PI). For multisite studies that involve submission of Local Site Investigator Applications, both the name of the PI and the LSI must be provided on the informed consent documents for a particular site.
- A statement that the project involves research and an explanation of the purposes of the research.
- The expected duration of a participant's active participation, to include long-term follow-up, and the approximate number of participants to be involved in the project if known.
- A description of the procedures to be followed, identifying any procedures which are going to be performed solely for research purposes and/or any procedures that are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant to include but not limited to physical, social, legal, economic, psychological, and any privacy risks that may result from the research. Risks of usual care are not to be included and the participant must be advised to discuss these with the participant's health care provider.
- A description of the potential benefits to the participant or to others that may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. If the only alternative is not to participate, this element does not need to be included in the consent form.
- A statement describing the extent to which confidentiality of any records identifying the participant will be maintained. If appropriate, a statement that other federal agencies including but not limited to the VHA Office of Research Oversight (ORO), the Office for Human Research Protections (OHRP), and the Government Accountability Office (GAO) may have access to the records. If an FDA-regulated test article is involved, there must be an additional statement.
indicating the FDA may choose to inspect research records that include the participant’s medical records.

- For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available from the VA if injury occurs; what those treatments consist of; what the VA’s authority is to provide such treatment; and where further information can be obtained.

- An explanation of whom to contact with questions about the following: the research process; concerns, or complaints about the research; the research participant’s rights in the event of a research-related injury; and to verify that the project in question is a valid VA project. The contact's name and phone number for questions about the participant's rights and whom to contact to verify that the project is a valid VA project, must be someone knowledgeable but not affiliated with the specific research project. The VA Central IRB toll free number (877-254-3130) will be included.

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

- A statement that a Veteran participant will not be required to pay for care received that is part of a VA research project. They will, however, be required to pay any co-payments they would ordinarily be required to pay for any nonresearch related VA medical care and/or services.

7.2 Additional Informed Consent Elements. One or more of the following additional elements of informed consent must also be included in the informed consent form if appropriate or applicable:

- A statement that the particular treatment or procedure may involve currently unforeseeable risks to the participant or to an embryo or fetus if the subject becomes pregnant.

- Any anticipated circumstances under which the participant’s participation in the research may be terminated by the investigator without the subject’s consent, such as noncompliance with the project procedures, if the investigator determines that termination is in the interest of the participant’s safety or well-being, or if a data safety monitoring board determines the research must stop.

- Any additional costs to the participant that may result from participation in the research consistent with federal laws concerning the Veteran’s eligibility for medical care and treatment, such as transportation and lost time from work. If there are additional costs, the informed consent form must contain a statement that the Veteran or non-Veteran subject will not be required to pay for medical services received as a subject in an approved VA research study.

- An explanation of the consequences of a participant’s decision to withdraw from the research and the procedures for the orderly termination of participation by the participant.

- 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 to include the procedures for
contacting the participants and for confirming their continued participation if applicable.

- If investigators believe that the human biologic specimens being collected in conjunction with the research could be part of or lead to the development of a commercially valuable product, a statement that participants will not be able to profit from any product or test developed as a result of using their sample.
- As appropriate, a statement regarding any payment the participant is to receive and how it will be made, to include a description of how payment will be prorated and calculated for participants who withdraw early.
- A clear statement concerning any conflict of interest by investigators involved with the project or the institution at which the research will be performed that has not been resolved or eliminated.
- If photographs or voice recordings are to be made and kept in the participant's medical record, a statement that an additional consent form (VA Form 10-3203, Consent for Use of Picture and/or Voice) must also be completed.
- If part of the study process approved by the IRB, a statement that participants will receive a report of the aggregate results or any results specific to the subject.
- If data is to be retained for future use after the study, a statement must be included indicating where the data will be stored and who will have access to it.
- If the participant will be contacted for future research, whether inside or outside the VA, this must be stated.

7.3 Required Elements if Collecting Biological Specimens to be Banked.

7.3.1 For projects involving the collection of biological specimens that will be banked, the informed consent under which the specimens are collected will contain all of the above required elements, any of the additional elements as applicable, and it will also clearly state the following:

- The types of specimens that will be stored and the name and location of the biorepository/tissue bank where they will be stored, and who will have access to the specimens.
- Whether the specimen will be used for future research to include provisions for allowing the participant the choice of how the specimen will be used if applicable.
- The length of time the specimen will be stored.
- When and under what conditions research results will be conveyed to the participant, the participant's family, or the participant's physician.
- Whether the participant will be re-contacted after the original project is completed.
- If the participant requests, the specimen will be destroyed and the data no longer made available for future research. The participant will be advised that data that has already been used in a project cannot be withdrawn.

7.3.2 All studies involving genetic analysis will contain the language, as suggested by OHRP, pertaining to the Genetic Information Non-Discrimination Act (GINA). Substantial sub-studies involving genetic research and analyses will require a
separate consent form from the rest of the main study. If there is to be a separate
genetic substudy related to the main study, this should be stated in the main study
informed consent document and reference made to the additional form and consent
process for the study.

7.3.3 If tissue is going to be collected as part of Cooperative Studies
Program (CSP) projects solely for banking in the CSP Tissue Biorepository a separate
VA Central IRB-approved informed consent document as required by the VA Genomic
Medicine Program must be completed by the participant.

7.4 Language and Readability. The language used in the informed consent form
will be simple and understandable to all potential subjects. Any scientific or technical
terms used must be adequately explained using common or lay terminology.

7.4.1 If a potential subject population reads or speaks a language other than
English, the VA Central IRB will determine if a translated copy of the consent form in the
subjects' language must be developed and submitted for review or if any other
accommodations should be made, such as having a translator present during the
consent process.

7.4.2 The readability of the informed consent form must be measured using
a software program, such as the Flesch-Kincaid Grade Level Scoring System that is
available in Microsoft Word, or any other system available. The score should be in the
range of an 8th grade reading level. Higher reading grade levels will be considered
based on the participant population being targeted. This score will be provided to the
VA Central IRB on the VA Form 108, Principal Investigator/Study Chair New Project
Application. If the Flesch-Kincaid system is not used, the investigator will indicate what
system was used and provide an explanation of the scoring system, along with the
score. If the investigator does not have a means of providing readability score, the VA
Central IRB administrative staff will perform the readability testing using the Flesch-
Kincaid system.

7.5 Informed Consent Template. The written informed consent will be
documented using the VA Form 10-1086. The VA Central IRB does not allow use of a
short form. The most recent VA Central IRB template version of the VA Form 10-1086
must be used by the investigator as a guideline for preparing an informed consent form
for submission to the VA Central IRB for approval. Once approved, the date of approval
will be documented by the VA Central IRB Coordinator by placing a date stamp on each
page of the consent form. The VA Central IRB will keep a copy of each approved
version of the consent form in the project file. An approved VA Central IRB consent
form will have the following three dates: 1) date of the VA Central IRB template version
used, 2) a version date for the actual form prepared by the investigator, and 3) the VA
Central IRB-approval date. These dates will be on all pages of the consent form.

7.6 Documenting the Informed Consent Process.
7.6.1 Upon completion of the interview, the informed consent form will be signed and dated by all of the following individuals unless one or more of these requirements is waived by the VA Central IRB:

- The participant or the participant’s legally authorized representative
- The person obtaining the informed consent.

7.6.1.1 The use of a witness signature is optional. The VA Central IRB may still require the signature of a witness based upon the study design and/or the population being targeted for the research. The sole role of a witness is usually to witness the participant’s or the participant’s legally authorized representative’s signature on the consent form. The witness can be a member of the study team but cannot be the member that obtained the informed consent.

7.6.1.2 If required by the VA Central IRB or a sponsor, the witness will witness the entire informed consent process. When witnessing the entire consent process, the witness is attesting that the information in the document was accurately relayed to the participant, the participant had the opportunity to ask questions and have them answered, and that informed consent was given freely by the participant or LAR as applicable. The witness can be a study team member but cannot be the member that obtained the informed consent.

7.6.1.3 If the use of facsimile is approved by the VA Central IRB, the participant may submit the signed and dated informed consent document to the investigator or designee by facsimile.

7.6.2 The original signed consent form will be kept in the participant’s project case history and a copy provided to the participant or the participant’s legally authorized representative.

7.6.3 If the participant is a VA patient with a medical record and the research intervention is taking place at a VA facility as part of a documented encounter in the VA patient’s medical record, a copy of the signed informed consent document is to be filed in the record and the investigator and study team are responsible for following all VA and local VA medical facility requirements for documenting the subject’s participation in the project, if applicable.

7.6.4 If informed consent is being obtained from the participant’s legally authorized representative (LAR), the LAR must be informed of their role and obligation to protect the participant and to act in what the LAR determines to be the participant’s best interest. All information that would have ordinarily been provided to the subject must be provided to the LAR in order for the LAR to make a fully informed decision.

7.6.5 The VA Central IRB ensures the following information regarding data retention is part of the informed consent process when subjects withdraw from a clinical trial:
7.6.5.1 When a subject withdraws from a study, the data collected on the subject to the point of withdrawal remain part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.

7.6.5.2 An investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through noninvasive chart review, and address the maintenance of privacy and confidentiality of the participant’s information.

7.6.5.3 If a subject withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in paragraph 7.6.5.2, the investigator must obtain the subject’s informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). VA Central IRB approval of informed consent documents would be required.

7.6.5.4 If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.

7.7 Requesting a Waiver or Alteration of the Informed Consent Process.

7.7.1 If the research does not utilize an FDA-regulated device or product, investigators may request a waiver or an alteration of the process of informed consent. In order to do this, they will complete VA Central IRB Form 112a, Request for Waiver or Alteration of the Informed Consent Process (Attachment 2) as part of the Principal Investigator/Study Chair New Project Application process.

7.7.2 Investigators should only complete the VA Central IRB Form 112a if their research meets one of the following criteria:

- 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 one or more of the following:
  - Public benefit or service programs
  - Procedures for obtaining benefits or services under those programs
  - Possible changes in or alternatives to those programs or procedures
• Possible changes in methods or levels of payment for benefits or services under those programs

OR

• The research meets all of the following criteria:
  • The research involves no more than minimal tangible or intangible risk to the participants
  • The waiver or alteration will not adversely affect the rights and welfare of the participants
  • The research could not be carried out without the waiver or alteration
  • Whenever appropriate, the participants are to be provided with additional pertinent information after participation

7.7.3 Even if a waiver or alteration of the informed consent process is granted, the VA Central IRB may still require other conditions of the investigator, such as additional information security measures.

7.8 Requesting a Waiver for Documentation of Informed Consent.

7.8.1 Investigators may request a waiver of the requirement to obtain a signed informed consent document. To do this, they must complete VA Central IRB Form 112b, Request for Waiver of Documentation of Informed Consent (Attachment 3), and submit it as part of the Principal Investigator/Study Chair New Application Process.

7.8.2 Investigators should not request such a waiver unless their research meets one of the following criteria:
  • The research involves no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

OR

• That the only record linking the participant and the research would be the consent document and the principal risk to the participant would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the subject with the research and the participant's wishes will govern. If the participant wants to be linked with the research, the participant will be offered an informed consent form for signature.

7.8.4 Even if a waiver of the requirement to obtain a signed consent form is granted, the VA Central IRB may still require other conditions of the investigator, such as providing subjects with an information sheet or other documentation about the research.
7.8.5 An investigator may request a waiver of the requirement to maintain a master list of all subjects in conjunction with the request for a waiver of documentation of informed consent by providing appropriate justification on the applicable portion of the VA Central IRB Form 112b.

7.8.5.1 The VA Central IRB will consider the waiver requests separately, even though one form is used for the request. The waiver for documentation of informed consent will be considered first. Only if the VA Central IRB approves the request for the waiver of documentation of informed consent is approved with the IRB consider the request for waiver of the requirement to maintain the master list of subjects.

7.8.5.2 The VA Central IRB may waive the requirement for an investigator to maintain a master list of subjects only if a waiver of documentation of informed consent was approved and the IRB determines that including the subjects on such a master list poses a potential risk to the subjects from a breach of confidentiality.

7.9 Requesting a Waiver of Informed Consent for Recruitment Purposes Only.

7.9.1 If an investigator intends to obtain identifiable private information for use in recruitment of participants, a request for waiver of informed consent and a request for waiver of the requirement for HIPAA authorization under the HIPAA Privacy rule must both be submitted if applicable. Please see VA Central IRB SOP 124, VA Central IRB HIPAA Responsibilities, for HIPAA waiver requirements.

7.9.2 The only exception to the requirement for requesting a waiver of the informed consent requirement for recruitment purposes only is if a participant previously gave permission to be contacted for future research purposes, such as if the identifiable information was obtained from a registry set up to promote future research. In this case, the VA Central IRB may want confirmation from the registry or will want to see a sample IRB-approved consent form that was used for the registry indicating this permission was solicited and granted.

7.10 Review of Informed Consent Process by the VA Central IRB.

7.10.1 When reviewing the informed consent process as part of the approval process for a study the VA Central IRB must ensure the following:

- Sufficient opportunity is provided for the subject to consider whether or not to participate in a project and to read the informed consent document before it is signed and dated
- The possibility for coercion or undue influence is minimized
- Surrogate consent is only accepted if the potential participant is incompetent, a minor, or has an impaired decision-making capacity as determined and documented in the person's medical record in a signed and dated progress note

Supersedes version dated August 8, 2011
• Information is provided in language understandable to the subject
• The process does not include any exculpatory language
• The informed consent document contains all basic required elements, as well as any additional elements required depending on the study.

7.10.2 When reviewing requests for waiver or alteration of the informed consent process or when reviewing requests for waiver of the requirement for documentation of informed consent, to include waiving the requirement to maintain a master list of subjects, the VA Central IRB must ensure that all the applicable approval criteria for the requested waiver or alteration are met for the specific study. Upon approval of a requested waiver, the VA Central IRB Co-Chair, or Designated Reviewer for projects reviewed under expedited review procedures, signs the applicable VA Central IRB Form 112a or 112b. The review of the approval criteria will also be documented in the meeting minutes for projects reviewed at a convened meeting and the signed VA Central IRB 112a or 112b will be referenced in the letter to the investigator.

7.11 The Use of Deception in Human Subjects Research.

7.11.1 When a study proposes to use deception as part of the study design, the PI/SC must submit a VA Central IRB Form 112a to request an alteration in the informed consent process since, by definition, the use of deception precludes providing fully informed consent to the potential participants. As part of the alteration request, the PI/SC must provide the following information:

• Justification for the use of the deception based on the study's significant prospective scientific, education, or applied value and an explanation as to why equally effective non-deceptive alternative procedures are not feasible.
• A description of the measures that will be taken at the conclusion of the study to debrief participants and fully explain the nature of the deception, to include allowing participants to withdraw their data, or provide explicit justification for withholding such information.

7.11.2 In reviewing such requests for alteration of the informed consent process, the VA Central IRB will take the following into consideration:

• The scientific value and validity of the research
• The efficacy of alternative procedures
• That the deception does not extend to influencing the participant's willingness to participate in the research
• The possibility of physical or psychological harm to include stress, including but not limited to loss of self-esteem, embarrassment, and guilt
• That the deception is not used to facilitate unwanted and inappropriate invasions of the participant's privacy
• That the deception is the least amount possible and that the informed consent document reveals as much as possible to participants regarding the
procedures in the study without threatening the ability of the researcher to test the hypothesis of the study
• Whether the measures proposed by the PI/SC at the end of the study to explain the deception and alleviate discomfort on the part of the participants are adequate or the request to withhold such information is justified.

7.12 Research Involving Collection of Data From Voice, Video, or Photographs

7.12.1 Informed consent must be obtained from research participants prior to taking photographs or making voice or video recordings that will be used for research purposes. The informed consent form must contain a discussion of why photographs and/or video and/or voice recordings are being taken for research, who will have access to them, and what their disposition will be after the research is completed.

7.12.2 VA Form 10-3203, Consent for Use of Picture and/or Voice must be used when the research participant is a patient (either an inpatient or outpatient) and signed and dated by the participant prior to the taking of the photographs or recordings. This is required even if the IRB has otherwise waived documentation of informed consent. The signed and dated VA Form 10-3203 must be placed in the participant’s medical record along with the signed and dated informed consent form if applicable. Investigators who plan to take photographs or video/voice recordings of research subjects who are patients must complete and submit a VA Form 10-3203 to the VA Central IRB for approval as part of the PI/SC application package and any LSI Application packages as applicable.

7.13 Use of VA Form 10-5345, Request for and Authorization to Release Medical Records or Health Information. This form must be included as part of the approved study package as applicable per the study design if the study includes the disclosure of medical records or health information, including pictures, video, and voice recordings, to another individual. This form can be part of the approved PI/SC application as the form to be used or as a model document to be used by local sites in submitting the actual forms to be used in the disclosure process.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

8.3 45 CFR 46, Department of Health and Human Services, Protection of Human Subjects

8.4 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards

8.6 VHA Handbook 1605.01, Privacy and Release of Information

8.7 VHA Handbook 1907.01, Health Information Management and Health Records

8.8 American Psychological Association Guidelines for Research Involving Deception

3 Attachments
1. VA Form 10-1086 as modified by the VA Central IRB, Investigator Guidelines and Template for Preparing an Informed Consent Form
2. VA Central IRB Form 112a, Request for Waiver or Alteration of the Informed Consent Process
3. VA Central IRB Form 112b, Request for Waiver of Documentation of Informed Consent

I have read and approved the content of this SOP.

K. Lynn Cates, MD
Director, PRIDE

Date: 12/12/11

Supersedes version dated August 8, 2011
Investigator Guidelines and Template: Preparing an Informed Consent Form

Notes to the Investigator: Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research participant. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act.

The procedures used in obtaining informed consent should be designed to educate potential participants in language that they can understand. The informed consent document should be considered a teaching tool. Therefore, informed consent language and its documentation (especially explanation of the project's purpose, duration, experimental procedures, alternatives, risks, and benefits) needs to be written in "lay language", (i.e. understandable to the people being asked to participate). Avoid the use of medical terms or technical jargon.

If an investigator proposes to use a participant population that does not speak or read English, a copy of the translated document, as well as the English version, needs to be forwarded to the VA Central IRB for approval.

The written presentation of information is used to document the basis for consent and for the participants' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

For projects falling under the Cooperative Studies Program (CSP), a separate consent will usually be required for any substantial sub-studies, such as for genetic analysis or for collecting tissue to be part of the CSP VA Genomic Medicine Program. (Please consult the CSP Guidelines for the Planning and Conduct of Cooperative Studies at [www.csp.gov/pdf/guide.pdf](http://www.csp.gov/pdf/guide.pdf)).

For projects involving the informed consent of VA employees, investigators need to carefully review the template and not include any elements that may not pertain to these types of studies, such as statements involving usual care, alternate treatments, or current relationships with participant's health care providers.

DIRECTIONS FOR USE OF THIS TEMPLATE:

- Do not adjust the bottom margin or use the footer. The footer has been reserved for use by the VA Central IRB.
- Complete the header with the requested information (i.e., title of study and PI name).
- Read the guidelines for each section and then complete as applicable for your project. If using the guidelines as a template, please be sure and delete the template guidelines, which are in red print and/or italics.
- The document should be written in the second person, i.e., “You are invited to participate.” Phrases such as “I understand...” or “You understand...” are not appropriate as they can be interpreted as suggestive and can constitute coercive influence over a subject.
• No informed consent may contain 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 or the Institution from liability for negligence.
• The document should be written at an appropriate grade level for the group of participants, usually no higher than the 8th grade level based on an electronic grade level scoring system, which is available with most word processing systems. The VA Central IRB may consider higher reading grade levels based on the populations targeted in the study.
• The consent form should include all the section headings indicated in the template unless otherwise indicated.
• The VA Central IRB does not accept informed consent documents that include the HIPAA authorization as part of the document. These must be submitted separately.
• Check for spelling, typographical, and grammatical errors.

The template is meant as a guide for you to prepare a custom template for your study. The descriptions provided in each section are included to assist you in writing a consent document meeting all current requirements. The guidance provided is consistent with VA and federal consent document criteria. You need to be cognizant of any state and local laws impacting on the informed consent process and include these requirements as well. It is your responsibility to ensure that you have included all applicable sections and explanations in the document based on the project design.

TIPS ON WRITING AN INFORMED CONSENT THAT MEETS READABILITY REQUIREMENTS

When you are having difficulty getting a consent form to the 8th grade reading level, here are some tips on how to make the informed consent document more reader friendly:

• Use as few words with three or more syllables as possible.
• Break all compound sentences into two short sentences.
• Use simple, declarative statements where possible.
• Change all passive voice sentences to active voice.
• Avoid using technical terms as much as possible. If you must use them, explain what they mean in lay language.
• Treat events in chronologic order in the procedures section.
• Restrict descriptions of procedures to those things the participants will actually experience.
INTRODUCTION

Include the following verbatim:

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

BACKGROUND AND PURPOSE

Briefly inform the participant of the following. Include at a minimum all the items listed below that are applicable to your study. These bullets should be addressed in separate paragraphs with sub-headings as needed to maintain organizational clarity.

- Why the research is being done. State what is being studied, e.g., With this research we hope to learn.... State what the study is designed to discover or establish.
- Why human participants are being asked to take part. (If there is a condition or circumstance that makes the person eligible for the study, include this here.)
- Why current therapies are not satisfactory and/or why an alternate treatment approach will be used (if applicable).
- If a drug or device used in the project has or has not been approved by the Food and Drug Administration for the specific use being evaluated in the project.
- The number of participants who will be enrolled in the project locally and nationwide (if multisite).

SUBJECT'S IDENTIFICATION
RESEARCH CONSENT FORM
Version Date: (To be filled in by investigator)

Participant Name: ___________________________ Date: __________
Title of Study: ______________________________
Principal Investigator: ________________________ VA Facility: __________
Principal Investigator for Multisite Study: ____________________________

- Who will be conducting the study and who is sponsoring it.

DURATION OF THE RESEARCH

Explain the expected duration of the entire study. The participants must also be informed of their individual time commitment for participation in the total study, including long-term follow-up e.g., This research study is expected to take approximately X years, months, days. Your individual participation in the project will take X days, weeks, months, years, etc.

In the STUDY PROCEDURES section that follows, explain the participant’s time involved for each procedure or interaction.

STUDY PROCEDURES

If you decide to take part in this study, this is what will happen: The investigator must provide a detailed description of the following as applicable.

- A chronological explanation of the procedures that will be performed, distinguishing which procedures are experimental (to include the use of investigational drugs and devices) which are considered standard treatment, and which are being done solely for the purposes of the research
- Clearly indicate who is overseeing a procedure, the study team or the subject’s health care provider as part of usual care so it is clear to the participant who is responsible for the following:
  o Explaining the potential risks and benefits of the treatment or service to the subject
  o Providing the treatment or service
  o Monitoring the treatment or service as applicable
  o Defining whether adverse events result from usual care or research
  o Alerting the subject if there is a problem with the treatment or service
  o Documenting the subject’s clinical course while receiving the treatment or service
- For research involving randomization of participants into different study arms, specify the randomization process, explaining it in lay language.
- A full explanation of all responsibilities and expectations of the participant. Include applicable points from the list that follows and/or add your own per study requirements:

SUBJECT’S IDENTIFICATION
RESEARCH CONSENT FORM
Version Date: (To be filled in by investigator)

Participant Name: __________________________ Date: ____________

Title of Study: ________________________________

Principal Investigator: __________________________ VA Facility: ____________

Principal Investigator for Multisite Study: ____________

- Take the study drug as instructed. (If device, explain what is required for study compliance).
- Keep your study appointments. If it you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you might be pregnant or might have gotten your partner pregnant.
- Keep the study drug in a safe place for your use only and away from children.
- Fill out your diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this research, as well as that of the other studies.

- A summary of the different people with whom the participant will interact.
- An explanation of when and where the research will be done.
- How often the procedures will be performed and how long each procedure will take.
- Type and frequency of safety monitoring during and after the study.
- If applicable, include information regarding pregnancy testing for women of childbearing potential and indicate the frequency of pregnancy testing.
- If the study includes surveys or questionnaires, include a statement that the participant is free to skip any questions that he/she would prefer not to answer.

If applicable, state if the subject will receive a report of the aggregate results or any results specific to the subject.

POSSIBLE RISKS OR DISCOMFORTS

Suggested wording that can be modified based on the type of research you are proposing to conduct: Any procedure has possible risks and discomforts. The procedures in this study may cause all, some or none of the risks or side effects listed. Rare, unknown, or unforeseeable (unexpected) risks also may occur.

SUBJECT’S IDENTIFICATION

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Identify each intervention with a subheading and then describe any reasonable foreseeable risks, discomforts, and inconveniences, and how these will be managed. Include the probability of the risks, especially those that are likely and those that are rare but serious.

In addition to physiological risks/discomforts, describe any psychological, social, legal, or financial risks that might result from participating in the research, to include risks inherent in genetic analysis and tissue banking if applicable.

If there are any significant risks to participation that might cause the researcher to withdraw the participant or terminate the study, these should be described.

Give measures which will be employed to minimize the described risks, discomforts, and inconveniences.

For studies involving possible reproductive risks, please include a section that includes the following:

- State any known risks in pregnancy, either to mother or child.
- State that there may be unforeseeable (unanticipated) risks to the participant (or to the embryo or fetus) if the participant is pregnant or becomes pregnant during the study.
- List the acceptable methods of birth control for this research study. Describe what action will occur in the event of pregnancy, e.g., follow-up of pregnancy outcome, immediate withdrawal from the study, etc.
- Describe if there is any effect on sperm count or the motility of sperm or other reproductive risks associated with fathering a child.
- Describe if there are any known risks to gametes.

Include the following information verbatim:

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

**POTENTIAL BENEFITS**

This section must describe any potential benefits to the participant or to others which may reasonably be expected from the research. **DO NOT include any payment to be offered to participants for taking part.** The description of benefits to the participant should be clear and not overstated in order to avoid the appearance of undue influence or coercion. If no direct benefit is anticipated, this should be stated. If research results will be given to the participant, this should be stated.

**SUBJECT'S IDENTIFICATION**
Some examples on how to complete this section follow:

We can't promise that you will get any benefits from taking part in this research study. However, possible benefits may include <<list benefits>>.

OR

There are no direct benefits to you from your taking part in this research study. However, the information we get from this study might help us treat future patients.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

Describe alternative procedures or courses of treatment. To enable a rational choice about participating in the research study, individuals should be aware of the full range of options available to them, including palliative or comfort care (if applicable).

Example: You may choose not to participate in this study. If this is your decision, there are other choices such as <<list alternatives>>.

If standard therapy is part of the research study, the participant must be told he or she can receive it outside of participation in the study.

If there are no alternatives, such as if the only alternative is not to participate, this section should not be included in the informed consent form.

You may discuss these options with your doctor.

CONFIDENTIALITY

Describe the procedures used to maintain the confidentiality of the records and data pertaining to the participant, how the participant's privacy will be protected, and who may inspect the records.

If you are collecting Social Security numbers, inform participants of this fact and why. Tell participants whether they can withhold their Social Security number and still participate.

SUBJECT'S IDENTIFICATION

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MAR 2006
Participant Name: ___________________________ Date: __________

Title of Study: ________________________________

Principal Investigator: __________________________ VA Facility: ________________

Principal Investigator for Multisite Study: ________________

Example: Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- Indicate how records are kept, e.g., locked in filing cabinets, on computers protected with passwords, who will have access, etc.
- For large multi-site studies, discuss the number and nature of the sites and what if any information will be shared among sites.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

We will not share your records or identify you unless we have to by law. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. (If the study involves a product regulated by the FDA, the Food and Drug Administration should be included in the above list)

If applicable, please provide a description of the Certificate of Confidentiality and any voluntary disclosure plan, or the potential for disclosures required by law, e.g., elder abuse, child abuse, study participants posing a danger to themselves or others, etc.)

Example: We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. By law, information can still be released if we find or suspect child abuse, elder abuse, an intent to harm yourself or others, or if you have an infectious disease that State or Federal law requires us to report. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.

If the research is a clinical trial subject to FDA regulation, the following statement must be included:

SUBJECT'S IDENTIFICATION

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COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants: Include a statement that veteran-participants will not be required to pay for care received as a participant in a VA research study except as follows:

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

If participants must bear any additional costs (e.g. transportation, time away from work, health costs, etc.) it must be disclosed in this section. Any such costs must be consistent with Federal laws concerning veterans’ eligibility for medical care and treatment.

Payment Offered for Participation: If payment is being offered for participation in the study, a separate subheading must be included with the following information. (If there is no payment being offered for participation, this should be so stated.)

- State whether the payment will be financial or something else such as a gift card, etc.
- If the payment is financial, describe the amount the participants will be paid, when payment is scheduled, how the payment will be disbursed, and the pro-rated amount the participant will receive should the participant decide to withdraw from the study or is withdrawn by the investigator.
- If the participant is reimbursed for certain expenses like transportation and parking, list the reimbursement rates.
- State who will be disbursing the payments. Due to limitations in the Financial Management System, payments made to subjects through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount. This information and the fact that the SSN of the subject will be used for this purpose must be included in the informed consent form.

Note: VA policy prohibits paying human subjects to participate in research when the research is integrated with a patient’s medical care and when it makes no special demands on the patient beyond those of usual medical care. Any payment offered should be commensurate with the
time and inconvenience of the participant incurred by the participant that they otherwise would not have incurred, as well as to cover travel expenses.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

For all studies, including minimal risk studies, the following information must be included:

Include this statement verbatim: Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures.

Note: The VA may not provide necessary medical care for treatment for injuries in research conducted for VA under contract with an individual or non-VA organization. If this is the case, this exception must be included in the above paragraph.

Include specific information about whom the participant should contact in case of a research-related injury. This should include name(s), telephone number(s), and when the person(s) listed may be contacted.

A number with 24-hour availability must be provided. If the number is a pager or the hospital operator, include further instructions for contacting the appropriate individual.

Example: If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: (List local site contacts)

DURING THE DAY:
Dr./Mr./Ms. ___________________________ at ___________________________ and

AFTER HOURS:
Dr./Mr./Ms. ___________________________ at ___________________________.

Emergency and ongoing medical treatment will be provided as needed.

For studies greater than minimal risk, the following additional information must be included:

SUBJECT’S IDENTIFICATION
Provide an explanation of whether any compensation is available should an injury occur.

In addition, provide 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.

Include this statement for all studies: You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

PARTICIPATION IS VOLUNTARY

State that participation is voluntary. Indicate that refusal to take part in the study will involve no penalty or loss of benefits to which the participant is otherwise entitled. If the participant is a VA employee or student, indicate that refusal to take part in the study will in no way influence their employment, ratings, subsequent recommendations, or academic progress as applicable. Also indicate that the participant may discontinue taking part at any time without any penalty or loss of benefits. If applicable, state that the participant may withdraw and still receive the same standard of care that he or she would otherwise have received.

Example: It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don’t take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

Explain any possible consequences of a participant’s decision to withdraw from the research. Describe any adverse effects on the participant’s health or welfare, or any extra follow-up that may be requested if the participant decides to withdraw from the study. Explain the procedures for an orderly termination of participation. Such an explanation may be omitted if there are no adverse consequences to withdrawal.

Indicate that for data already collected prior to the participant’s withdrawal, that the investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data. Also indicate that specimens already used cannot be withdrawn.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

SUBJECT’S IDENTIFICATION
Describe foreseeable circumstances under which the participant’s participation might be terminated by the investigator without regard to the participant's consent.

If the investigator might terminate participation of a participant, possible reasons should be listed and the procedures for an orderly termination of participation described. Include a description of any adverse effects on the participant’s health or welfare that may result, or any additional follow-up that may be requested, if the participant is withdrawn from the study.

PERSONS TO CONTACT ABOUT THIS STUDY

Explain whom participants should contact with any questions, complaints, and concerns about the research or related matters. Contact information for the investigator should be included for questions about the research. At least one of the contacts must be someone other than the investigator or other study personnel such as the local Patient Advocate. Make sure you inform all persons listed that they are points of contact for participants and ensure they are knowledgeable concerning the study. Document the contact as part of your research records.

In addition to the above, include the following statement verbatim: If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

SIGNIFICANT NEW FINDINGS (Include if Applicable)

State that new findings developed during the course of the research that may affect the participant’s willingness to continue participation will be provided to the participant. This section may be omitted if new information could not reasonably be used to alter participation (e.g., one-time interventions that are no greater than minimal risk).

Example: Sometimes during the course of a research study, new information becomes available about the <<treatment/drug>> that is being studied that might change a person's decision to stay in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to

SUBJECT'S IDENTIFICATION
continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

PAYMENT TO INVESTIGATORS (Include if Applicable)

Describe any payments that are being made to investigators that could be construed as a potential conflict of interest. If a conflict of interest cannot be eliminated after the review by the VA Central IRB, the IRB may require that this section be included.

GENETIC RESEARCH (Include if Applicable)

- Describe in this section possible limits to individual confidentiality based on the technologies involved in the research.
- If a possible commercial product will be developed as part of this research, explain that the participant will not profit from any products or tests that might result based on research with their specimens.
- Clarify when and under what conditions research results of genetic testing will be conveyed to the participant, the participant's family, or the participant's physician.

Include the following statement verbatim:

Federal laws and policies provide you with protection from discrimination by health insurance companies, group health plans, and most employers based on your genetic information. A new federal law, the Genetic Information Nondiscrimination Act (GINA) generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information obtained from this research.
- Health insurance companies and group health plans may not use your genetic information obtained from this research when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

SUBJECT'S IDENTIFICATION
Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Reminder: Substantial sub-studies involving genetic research and analyses will require a separate consent form from the rest of the study. If this is the case, it should be so stated and reference made to the additional form.

FUTURE USE OF DATA AND RE-CONTACT

If any of the participant’s data are going to be retained after the study for future research, the following information must be provided to the participant:

- Where will the data be stored
- Who will have access to the data

If the subject is going to be re-contacted in the future about participating in future research, this must be specified. Describe the circumstances under which the participant would be re-contacted whether within the VA or outside the VA.

TISSUE BANKING (Include if Applicable)

If you are planning to store blood, tissues, or specimens of any kind for future research, tissue banking guidelines must be addressed. If you plan to store these samples anywhere except VA property, you must obtain a waiver from the VA Office of Research and Development.

A separate consent form will also be required for the collection of DNA for the sole purpose of adding the specimen to the CSP VA Genomic Medicine Program Biorepository.

Describe where the specimens will be stored, who will have access to them, and how long they will be retained.

Clarify when and under what conditions research results will be conveyed to the participant, the participant’s family, or the participant’s physician.

Explain if the participant will be re-contacted after the original project is complete. In addition to the above, specify why the tissue is being banked and the potential future uses. If applicable, you may want to give participants a choice of whether tissue can be banked. An example of providing the participants a choice is provided below:

SUBJECT’S IDENTIFICATION
Please read each sentence below, think about your choice, and mark "YES" or "NO". No matter what you decide to do, your decision will not affect your medical care or your participation in the study already described.

May the <<site>> or its research partners in this study retain your <<describe specimen (e.g., tissue, blood, urine, body fluid)>> specimen(s) after the end of the study for use in future research?

☐ YES My specimen(s) may be saved for future research as follows:

Check all restrictions that apply:

☐ None. My specimen may be used for any future research
☐ Only research by the current principal investigator
☐ Only research that does not involve genetic testing
☐ Only research that involves the disease or condition to which this study pertains

OR

☐ None of the above. The specimen may only be used under the following conditions:

☐ NO My specimen(s) must be destroyed at the end of this research study.

If yes, may the <<site>> or its research partners in this study keep your name and other identifying information with your specimen(s)?

☐ YES My personal identifiers and medical information can be kept with my specimen(s). All information will be kept secure and confidential.

☐ NO My name and identifiers must be removed from my specimen(s). My specimen(s) cannot be linked back to me.
If you gave consent for the specimen(s) to be used in future research by the <<site>> or its research partners, an Institutional Review Board (IRB) will review and approve each new study. The IRB may require that you be contacted for your consent prior to the use of the specimen(s) in a new study if it decides such consent is required for your protection.

You have the right to withdraw your consent in the future and have your specimen destroyed. You need to notify the investigator of your decision. If you decide to remove identifiers from your specimen(s), you will not be able to withdraw your specimen later because it cannot be linked back to you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The following language must be included verbatim unless otherwise indicated:

Dr./Mr./Ms. has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

You voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record if applicable.

I agree to participate in this research study as has been explained in this document.

<table>
<thead>
<tr>
<th>Participant’s Name</th>
<th>Participant’s Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name of person obtaining consent</th>
<th>Signature of person obtaining consent</th>
<th>Date</th>
</tr>
</thead>
</table>

SUBJECT’S IDENTIFICATION
RESEARCH CONSENT FORM
Version Date: (To be filled in by investigator)

Participant Name: __________________________ Date: __________
Title of Study: ____________________________________________
Principal Investigator: ___________________________ VA Facility: __________
Principal Investigator for Multisite Study: __________________________

Note: The use of a witness signature is optional. If the VA Central IRB determines that a witness signature is required, an additional line for the witness signature must be added above the name of the person obtaining consent. Usually, a witness is solely witnessing the signature of the participant but the VA Central IRB may determine that the witness must witness the entire consent process. A note should be added below the signature of the witness indicating what the role of the witness is.

IMPORTANT: The below signature block for Legally Authorized Representatives (LAR) is only used for populations unable to provide informed consent. Only use the LAR signature block in place of the participant's signature block if it has been explained in the new study application (subject to approval by the IRB) that these types of populations are going to be used in the study. Delete this if you do not plan to enroll participants using an LAR.

The participant is unable to give informed consent. I, as the legally authorized representative of the participant, give consent for their participation in this study.

<table>
<thead>
<tr>
<th>Name of Legally Authorized Representative</th>
<th>Signature of Legally Authorized Representative</th>
<th>Date</th>
</tr>
</thead>
<tbody>
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<td></td>
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<th>Name of person obtaining consent</th>
<th>Signature of person obtaining consent</th>
<th>Date</th>
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</table>

Indicate below your authority to act as the participant's legally authorized representative:

- [ ] Spouse
- [ ] Parent
- [ ] Adult Child (18 years of age or over) for his or her parent
- [ ] Adult Sibling (18 years of age or over)
- [ ] Grandparent
- [ ] Adult Grandchild
- [ ] Guardian appointed to make medical decisions for individuals who are incapacitated
- [ ] Other per local or state law

Specify: ____________________________

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RESEARCH CONSENT FORM
Version Date: (To be filled in by investigator)

Participant Name: ________________________________ Date: _________
Title of Study: ____________________________________________
Principal Investigator: __________________________ VA Facility: ________
Principal Investigator for Multisite Study: ________________________

NOTE: If a local site has local policies in regard to other signatures or annotations on the informed consent form, these should be documented as part of the local site investigator application and these changes justified within the application.

SUBJECT'S IDENTIFICATION

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VA Central IRB Template October 5, 2011
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Request for Waiver or Alteration of the Informed Consent Process

VA Central CIRB
VA Institutional Review Board for multisite Studies

This form must be included with all project applications when requesting a waiver or alteration of the informed consent process. This form cannot be used in research involving an FDA-regulated product or in research involving prisoners.

I. Project Identification

<table>
<thead>
<tr>
<th>Title of Project</th>
<th>Principal Investigator</th>
</tr>
</thead>
</table>

II. Type of Request

- Waiver of informed consent requirement for recruitment purposes only. Informed consent will be sought from participant prior to enrollment.
- Waiver of requirement to obtain informed consent
- Waiver or Alteration of one or more specific elements of the informed consent process

III. Criteria to be Eligible to Submit a Waiver or Alteration Request

*The principal investigator must check that the proposed research meets one of the following criteria in order to be eligible to submit a waiver or alteration request.*

| The research could not be practicably carried out without the waiver or alteration and
| The research is to be conducted by or subject to approval of state and local officials and is designed to study, evaluate, or otherwise examine procedures for obtaining benefits under public service programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.
| The research meets all of the following criteria for requesting a waiver or alteration of the informed consent process:
  - The research involves no more than minimal tangible or intangible risk to the participants.
  - The waiver or alteration will not adversely affect the rights and welfare of the participants.
  - The research could not practically be carried out without the waiver or alteration.
  - Whenever appropriate, the participants will be provided with additional pertinent information after participation.

III. Justification for Waiver or Alteration

*The principal investigator must provide a response for each of the items listed below if applicable.*

1. Describe why the research would not be possible without the waiver or alteration. If requesting an alteration in the informed consent process, describe how it will be altered.
2. If applicable, indicate the specific public benefit or service program, and the procedures or alternatives involved. Check □ if Not Applicable

3. Explain why the research for which the waiver or alteration is requested will involve no more than tangible or intangible risk.

4. Explain why the waiver or alteration will not adversely affect the rights and welfare of the participants.

5. If the participants will be provided additional pertinent information after their participation, describe the additional information and how it will be provided.

IV. Investigator Certification

By signature below, the principal investigator acknowledges the following:

1. This project involves no more than minimal risk to the participant. Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2. Even if the waiver or alteration is granted, the VA Central IRB may require other conditions, such as providing the subjects with an information sheet about the research.

3. Even though a waiver or alteration may be granted, I acknowledge that it is still my responsibility to ensure that the rights and welfare of the participants are protected in accordance with VA and other federal requirements.

Signature ___________________________ Date ____________

Section V of this form is for VA Central IRB use only.
### V. Review by VA Central IRB

*This section is to be completed by the VA Central IRB Co-Chair based upon the actions taken at a convened meeting of the VA Central IRB or during the expedited review process.*

This waiver request meets the below checked criteria for approval:

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<tr>
<td>☐</td>
<td>The research could not be practically carried out without the waiver or alteration and The research is to be conducted by or subject to approval of state and local officials and is designed to study, evaluate, or otherwise examine procedures for obtaining benefits under public service programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.</td>
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The research meets all of the following criteria for requesting a waiver or alteration of the informed consent process:

- The research involves no more than minimal tangible or intangible risk to the participants.
- The waiver or alteration will not adversely affect the rights and welfare of the participants.
- The research could not practically be carried out without the waiver or alteration.
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

The action taken regarding this waiver request is indicated by the box checked below:

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<tr>
<td>☐</td>
<td>The request for waiver of informed consent is approved for recruitment only.</td>
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<tr>
<td>☐</td>
<td>The request for waiver or alteration of the informed consent requirement is approved for this study as requested.</td>
</tr>
<tr>
<td>☐</td>
<td>The request for waiver of the informed consent requirement is approved only as indicated in the below remarks.</td>
</tr>
<tr>
<td>☐</td>
<td>The request for waiver or alteration of the informed consent requirement is not approved. The reasons for the disapproval are indicated in the remarks below.</td>
</tr>
</tbody>
</table>

**Remarks:**

Signature of VA Central IRB Co-Chair: [Signature]  
Date: [Date]
This form must be included with all project applications when requesting a waiver of documentation of informed consent. This type of waiver can be requested when using telephone, surveys, questionnaires, or when signing the informed consent form could have a negative consequence for the participant.

I. Project Identification

<table>
<thead>
<tr>
<th>Title of Project</th>
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<tr>
<th>Principal Investigator</th>
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II. Criteria to Submit Request for Waiver of Documentation of Informed Consent

The principal investigator must check that the proposed research meets one of the following criteria:

- The research involves no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

  or

- The only record linking the participant and the research would be the consent document and the principal risk to the participant would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research and the participant's wishes will govern.

  NOTE: This criterion cannot be used for FDA-regulated studies.

III. Portion(s) of Research for which Investigator is Requesting Waiver

The principal investigator must check one of the boxes below. If the second box is checked, the investigator must identify the portion(s) of the study for which the requested waiver applies:

(telephone survey, mailed questionnaire, etc.)

a. Indicate which interactions with subjects for which you are applying for the waiver:

- This waiver request applies to all interactions with subjects detailed in the study.

- This waiver request applies to the following interaction(s) with subjects:

  Are you also requesting a waiver of the requirement to maintain a master list of subjects?

- No. A master list of subjects will be maintained in accordance with VHA Handbook 1200.05.

- Yes. Maintaining a master lists of subjects poses a potential risk to subjects from a breach of confidentiality. If yes, additional justification must be provided below.
IV. Justification for Waiver

The principal investigator must provide justification that the portion(s) of the study for which waiver is requested meets waiver criteria as selected in Section II above. If also requesting a waiver of the requirement to maintain a master list of subjects, additional specific justification must be provided for this waiver request:

Justification for Waiving Documentation of Informed Consent (Specify Intervention):

If Applicable, Justification for Waiving Requirement to Maintain Master List of Subjects:

V. Investigator Certification

By signature below, the principal investigator acknowledges the following:

1. Even if the requested waiver(s) is(are) granted, the VA Central IRB may require other conditions, such as providing the participants with an information sheet about the research.

2. If I checked the second box in Section II, I acknowledge that each participant must be asked whether they want documentation linking them with the research, and the participant's wish will govern.

3. Even though the requested waiver(s) may be granted, I acknowledge that it is still my responsibility to ensure that there is an appropriate informed consent process and that the rights and welfare of the participants are protected in accordance with VA and other federal requirements.

__________________________
Signature

__________________________
Date

Section VI is for VA Central IRB use only.
VI. Review by VA Central IRB

This section is to be completed by the VA Central IRB Co-Chair based upon the actions taken at a convened meeting of the VA Central IRB or during the expedited review process.

This request meets the below checked criteria for approval of a waiver of documentation of informed consent:

☐ The research involves no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

**OR**

☐ The only record linking the participant and the research would be the consent document and the principal risk to the participant would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research and the participant’s wishes will govern.

The action taken regarding this waiver request is indicated by the box checked below:

☐ The request for waiver or documentation of informed consent requirement is approved for this study as requested.

☐ The request for waiver of the documentation of informed consent is approved only as indicated in the below remarks.

☐ The request for waiver of documentation of informed consent is not approved. The reasons for the disapproval are indicated in the remarks below.

Remarks:

If the request for a waiver of documentation of informed consent was approved and a request for waiver of the requirement to maintain a master list of subjects was also submitted, the action taken regarding this request is indicated below:

☐ Not applicable. No request for a waiver of the requirement to maintain a master list of subjects was submitted.

☐ Not Approved. A master list of subjects must still be maintained.

☐ Approved. Including subjects on a master list poses a potential risk to the subjects from a breach of confidentiality.

Remarks:

________________________________________  ____________________________
Signature of VA Central IRB Co-Chair                      Date: