



Participant Name: _____ Date: _____

Title of Study: _____ [Insert study title] _____

Principal Investigator: _____ [Name, degrees, & phone number] _____ VA Facility: Baltimore 512

STUDY No: [Please include the UMB protocol number only]

Comment [v1]: Note that Study Title and PI name & contact info are inserted into the header.

SPONSOR: [delete if not applicable]

REMOVE ALL THE INSTRUCTIONS IN BLUE OR RED BEFORE SUBMITTING. REMOVE ITALICS EXCEPT WHERE NECESSARY TO CLEARLY INFORM THE PARTICIPANT.

REMOVE YELLOW HIGHLIGHTS.

THE FINAL VERSION SHOULD BE IN BLACK, IN A CONSISTENT FONT (Times new Roman 12), GRAMMATICALLY CORRECT AND WITHOUT SPELLING ERRORS.

Comment [jlm2]:
This template incorporates the IRB's March 2012 revisions plus clarifies and prompts for specific VA items. These VA-specific additional items are in RED.

- Add a statement here to let the participant know that this is a **research study**, participation is voluntary, they can ask questions at any time, and if they are consenting for someone else- a child or someone unable to provide consent themselves- then the word "you" means that person.
- Include a statement identifying the VA Maryland Health Care System (VAMHCS). This is to explain the acronym VAMHCS, used throughout the ICF, but also to clarify with the participant the VAMHCS' role (will occur completely or partially at the VAMHCS, will be conducted by VAMHCS researchers, is being paid for by the VA [including the BREF], etc.)

YOU SHOULD NOT SIMPLY COPY-PASTE YOUR CONTENT FROM THE UMB ICF.

This template contains many blue bullet points as prompts for you to consider. The final consent form can remain in bullet points or can be in paragraph format. Clarity for the participant is the foremost consideration.

Generally, black text must remain in the final ICF.

Generally, italicized text is actual language to be used if applicable. REMOVE THE ITALIZATION UNLESS NECESSARY FOR THE PARTICULAR STUDY.

Yellow highlights indicate where information needs to be filled in to required statements.

PURPOSE OF STUDY

- Explain the purpose of the research project.
- If an investigational drug or device is being used and an IND/IDE has been obtained, please describe and state that the FDA is allowing the use of this in the study
- Please state if a placebo is being used.
- Explain how/why the potential participant qualifies for the study and inform him/her why he/she is being asked to participate in the study.
- Do not include inclusion/exclusion criteria in consent form unless the criteria are directly relevant to the subject's decision making, e.g., safety issues, excluded medications, changes in behavior such as alcohol use.
- State the number of participants at this site and in total if this is a multi-center study



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- If this is a “collaborative study” with the University of Maryland or other collaborators, state that this is a “collaborative” study that will combine VA research activities and VA data with [University of Maryland] research activities and [University of Maryland] data.

PROCEDURES

- Briefly explain in lay terms the study design, as well as the procedures the participant will undergo if he/she agrees to join the study.
- Explain how treatment groups will be assigned.
- If randomization will determine treatment assignment, explain it in readily understandable terms. It is suggested that randomization means that treatment will be determined by chance like drawing a card, drawing a number, or flipping a coin. **For example:** *The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an _____ [equal/one in three/etc.] chance of being given each treatment. [For double-blinded studies add] Neither you nor the study doctor will know which treatment you are getting. [For single blinded studies add] You will not be told which treatment you are getting, however your study doctor will know.*
- Specify the number of required hospital visits, clinic visits, inpatient or outpatient actual time commitment involved in participation.
- Specify where procedures/visits will take place (at the VAMHCS v. at UMMS). It may be advisable to include a “Study Activities Chart” depicting the location of the activities in this ICF.
- If a separate UM ICF will be signed for the UM portions of the study, explain this to the participant and summarize the UM portion of the study.
- State the expected duration of participant’s participation.
- Clearly state the amount of blood to be drawn at each visit and the total amount to be drawn over the course of the study (in household measures, i.e. teaspoons).
- Clarify what will be done to the participant solely for research purposes and/or what is experimental in the project (including a detailed description of the investigational agent or device, if applicable). Differentiate “research” from “usual care.”
- If the study procedures are long and complex and include several steps, a bulleted format and short paragraphs is recommended. A flow chart or table could be included in the consent form to enhance the participant’s ability to understand the procedures.

For studies involving banked specimens, participants should be informed of the following:

Comment [jlm3]: Carefully consider all points of the VA “collaborative studies” program when answering this and other related questions in this template.

As you put your project into CICERO and complete the research informed consent form(s), keep in mind how you will “split out” or describe VA v. UM/collaborator activities.

- Will you have a single VA ICF that clearly describes what is VA and what is UM?
- Will you have TWO ICFs: a VA consent form for the VA portion of the study (with a mention of the UM portion) and a UM consent form for the UM portion of the study (with a mention of the VA portion)? (The participant would sign both)
- Will you have TWO ICFs: Identical ICFs with one done in UM-templated format and one done in VA-templated format with one site designated as the “coordinating center”? (VA participants will sign the VA form and UM participants will sign the UM form).
- There may be other possibilities as well.

The ICF, protocol, HIPAA authorization, and CICERO must all be consistent with each other.

Comment [jlm4]: This must be very clear for collaborative studies.

Comment [jlm5]: This is a collaborative studies consideration.



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- Will the collected specimens be used for future research and if so, what area of research (research specified in the consent form; research conducted by the Investigator only; research conducted by other investigators; research related to specific diseases)?
- Will the specimens be used to generate a cell line for genetic testing?
- Will the specimens be stored without any identifiers and if so, will they be linked specimens or unlinked specimens? If linked, will the specimens and all links to clinical data be destroyed or removed from the bank upon the participant's request?
- Will the research results be conveyed to the participant and/or health care provider?
- Will the participants be contacted after the completion of the original research?
- Could biologic specimens obtained be part of, or lead to the development of, a commercially valuable product?
- If the specimens are to be retained after the end of the study for future research, where the specimens will be retained, who will have access to them, and how long they will be retained.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to: [For all clinical trials, describe any responsibilities of the subject. Delete this section if the research is not a clinical trial.]

POTENTIAL RISKS/DISCOMFORTS:

- Describe any foreseeable risks or discomforts to the participant that are related only to the research in clear simple terms.
- Risks should be stated by the severity and likelihood, or they should be compared with natural risks that are understood by most patients. Use categories such as likely, less likely, unlikely, and/or rare.
- Along with physical risks, be sure to consider social, psychological, legal, and economic risks.
- All consent forms should list the risk of the potential for the loss/breach of confidentiality.
- There may be risks to the participant which are currently unforeseeable unless the risk profile of all research-related interventions is well known and the research involves no investigational drugs or devices. If there are unforeseeable risks, please include the following statement:



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There may be risks in this study which are not yet known.

- In addition, please state how all risks will be minimized. For example, state, if applicable:
“Loss of confidentiality will be minimized by storing data in a secure location such as a locked office and locked cabinet.” and/or “Electronic data will be password-protected.”

If applicable -

- Include pregnancy and/or male and female fertility risks to the adult. *[If the research involves pregnant women or women of child-bearing potential and involves an investigational product or procedures whose risk profile in pregnancy is not well known, add] If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown.*
- *[For research that involves risks to an embryo or fetus] The procedures involved in this research may harm a pregnancy or unborn child in the following ways: _____ . You should not become pregnant or father a baby while on this research study.*
- Include any risks to a nursing infant if applicable.

POTENTIAL BENEFITS

- If the participant will not benefit from participation, clearly state:
You will not benefit directly from your participation in this study.
- If there is the potential for the participant to receive benefit state:
You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. State the potential personal or societal benefits of participation.
- Do not overstate direct benefits to participants when it is not realistic to expect benefits. If applicable, state possible general benefits for science or other patients with similar diseases, or for the population at large (if applicable). However, do not state such benefits if the person who will be consenting is a surrogate for the research subject, and should not be considering those benefits.
- **For research involving children, the following statement in the parental consent must be included: “You need to decide if your child’s participation in this research study is in your child’s best interest.”** NOTE: Research involving children is not



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permitted at the VA without a waiver from VA Central Office (CRADO). (A request for a CRADO waiver cannot be submitted to VA Central Office until after IRB and RDC approvals have been obtained).

- Receiving healthcare, payment, or other consideration for participation in a research study is not considered a benefit.

ALTERNATIVES TO PARTICIPATION

- Explain realistic alternatives to participation; specifically, state what treatment is available or that might be advantageous if participant declines to participate, include for example, approved standard of care, other research studies, palliative care, or no treatment.
- **[For clinical trials]** *The important risks and possible benefits of these alternatives are listed below: [Describe the important risks and potential benefits of the alternative procedures and courses of treatment.]*
- If the research does not involve a treatment intervention, state:
This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at the VA Maryland Health Care System (VAMHCS) will not be affected.

COSTS TO PARTICIPANTS

- Include the following statement that a participant will not be required to pay for care received as a participant in a VA research project except as follows:
“You will not be charged for any treatments or procedures that are performed for research purposes in 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.”
- Detail any additional costs to the participants which may result as a consequence of their participation in the study, for example, transportation, parking fees, time away from work, co-pays, deductibles, etc. Any such costs must be consistent with Federal laws concerning veterans' eligibility for medical care and treatment.
- If there are no costs to the participant, state:
It will not cost you anything to take part in this study.
- If you do not anticipate any financial support, and the project involves clinical procedures conducted primarily for research purposes, provide an explanation of the expected source of payment for these procedures (specifically state who will pay). **NOTE: VA participants cannot be responsible for payment.** Ensure that the language does not



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conflict with the CRADA or other contract. The IRB seeks reassurance that participants will not have undisclosed financial risks due to participation in the research study.

PAYMENT TO PARTICIPANTS

- Outline remuneration amount or other compensation and procedure, for example, check, gift certificate, transportation.
- If no compensation is to be offered, then state that participants will not be paid.
- If this study includes compensation to participants for their participation in the study which is in excess of \$600 in a calendar year, include a statement that informs participants that they will be responsible to report this income to the IRS.
- **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

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 Maryland Health Care System (VAMHCS) will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.

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. For example:]

DURING THE DAY:

Dr./Mr./Ms. _____ at _____ and

AFTER HOURS:

Dr. /Mr./Ms. _____ at _____.

Comment [v6]: This could be done in paragraph form, or other similar content from the UMB ICF as long as the information in the template is included.



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The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

CONFIDENTIALITY AND ACCESS TO RECORDS

- Explain whether or not the study will involve confidential information. If it does, briefly indicate who will have access to the information, whether or not it will be coded, what measures investigators will use to ensure the information is maintained in a confidential manner, whether or not the participant’s name or other identifier will be used, and how audio and video tapes will be stored and destroyed at the end of the study.
- If information requiring a Confidentiality Certificate is to be involved (i.e. illegal criminal behavior, drug use, physical abuse, sexually sensitive material, and HIV status), state the protections afforded by the Certificate. In the absence of a Certificate, state that the confidentiality of data will be maintained to the fullest extent permitted by law.
- Inform participants that study records will be considered confidential, and (if appropriate), that the participant’s name will not be used in reports or publications.
- Inform the participant if his/her information will be retained after the end of the study for future research, where the data will be stored, and who will have access to the data.
- Inform the participant if s/he will be re-contacted for future research whether within the VA or outside VA.
- **IF the data from the VA site will be combined with the UM site**, explain that the resultant data are to be used in a multi-site study that combines VA data with affiliate/collaborator data;
- **IF the UM is the “coordinating center”**, explain that the data will be disclosed to the UM where it will be combined and analyzed for the study.
- Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, the VAMHCS Office of Research Compliance and other representatives of this organization. Depending upon study-sponsorship, include a statement that study records can be reviewed by federal agencies, VA Office of Research & Development (ORD) (if VA-funded), private sponsor. Also include the following oversight bod(ies): VA Office of Research Oversight (ORO), VA Office of Inspector General (OIG), and Office of Human Research Protections (OHRP). **[Add to this list other organizations that**

Comment [Jlm7]: This is a collaborative study consideration.

Comment [Jlm8]: This is a collaborative study consideration.



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may have access to the subject's records such as the Food and Drug Administration, when the research is FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor's agent and other collaborating institutions.]

- **[For clinical trials, include]** The monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document you are authorizing this access.
- If HIV/Hepatitis/TB testing will be done, please add a statement that a positive result will be reported, as required under State law. *Note: There are many other reportable conditions. To see a list go to:* <http://www.cha.state.md.us/edcp/html/reprtabl.html>
- **[For FDA-regulated non-Phase I controlled trials add]** A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- Inform if the participant will receive a report of the aggregate results or any results specific to the participant.

State the following in this section. The following sentences contain statements required by the VAMHCS –

Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The “records control schedule” is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information at the VAMHCS will work to keep your personal information confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS “HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research”. However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.



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If you are a patient in the VAMHCS, the results of your medical tests for this study may be included in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS.

If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator <Insert Name of VA PI> at 410-605-7000 extension <Insert VA extension>.

- Please state either that there are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research, or state the consequences of a participant's decision to withdraw from the research. If the latter applies to this study, then please also state the procedures for orderly termination of participation by the participant. State that a written withdrawal is requested/required and to whom it should be sent.
- If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. [Note: The consent document cannot give the subject the option of having data removed.] If you agree, this data will be handled the same as research data. [Note: 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.]

If applicable please add the following –



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- “You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.”
- If the study includes students, staff or faculty, a statement must be included to state “If you are an employee or student, your employment status or academic standing at the VAMHCS will not be affected by your participation or non-participation in this study.”

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include *[add additional reasons why the subject may be withdrawn, if appropriate. For example: failure to follow instructions of the research staff, if the person in charge decides that the research study is no longer in your best interest.]* The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study.

Comment [v9]: This statement must remain in the ICF.

If you wish to confirm that this study is in fact IRB approved and is being conducted at the VAMHCS, you may contact **(list the name of one or more VA research team members here)** at 410-605-7000 extension **[insert the associated VA extension(s)]**.

Please read the University’s statement below.

Comment [v10]: This statement must remain in the ICF.

PLEASE CHOOSE ONE OF THE TWO STATEMENTS BELOW BASED ON THE RISK LEVEL OF YOUR STUDY. PLEASE BE SURE TO DELETE THE STATEMENT THAT IS NOT CHOSEN.

(Minimal Risk Studies)

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been



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reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland Baltimore. The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the UMB Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Office of Academic Affairs Regulatory Compliance
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

You may also contact the VAMHCS Human and Animal Research Protections Officer (HARPO). The contact information for the HARPO is:

VAMHCS Human and Animal Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
410-605-7000, extension 6512
Room 3D-158



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The VAMHCS Human and Animal Research Protections Officer may contact you in the future to ask you about your experiences with this research study.

(Greater than Minimal Risk Studies)

The University of Maryland Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the UMB Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Office of Academic Affairs Regulatory Compliance
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201

410-706-5037

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VAMHCS Human and Animal Research Protections Officer
Baltimore VA Medical Center



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Participant Name: _____ Date: _____

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Principal Investigator: *[Name, degrees, & phone number]* VA Facility: Baltimore 512

10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
410-605-7000, extension 6512
Room 3D-158

The VAMHCS Human and Animal Research Protections Officer may contact you in the future to ask you about your experiences with this research study.

Insert a page break. The signature page should be a separate page that contains all the signatures and the signing statement.



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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

Please incorporate all signature lines (below) which are applicable to your study **and delete all others.**

NOTE: Signature lines for the participant and the ‘person obtaining consent’ are required for all VA research studies. Additional signature lines, including the witness signature, may be required by the IRB.

NOTE: Children may not be enrolled in VA research unless you have obtained a waiver from the Chief Research & Development Officer at VA Office of R&D. Surrogate consent may not be obtained without special precautions.

Participant’s Signature

Signature of Parent/Guardian
(When applicable)

Date: _____

Relationship: _____

Date: _____



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Investigator or Designee Obtaining Consent
Signature

Date: _____

Signature of Parent/Guardian #2
*(When applicable, as required by CFRs-
requirements for permission by parents'
assent)*

Relationship: _____

Date: _____

Witness*
*(When applicable: **only if required by the
IRB**)*

Date: _____

**Witness is optional unless IRB required, participant is illiterate, or unable to sign. It may be prudent to include a witness line if your target population may need a witness to the signature.*