

**Subject Name:** \_\_\_\_\_ **SSN:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Title of Study:** \_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_ **VAMC: Tuscaloosa**

**Co-Investigators:** \_\_\_\_\_ **Version Date:** \_\_\_\_\_

We are asking you to volunteer to take part in a research study at the Tuscaloosa Veterans Affairs Medical Center (TVAMC) it is important that you read and understand the information on this form. The sponsor (financial source) for this study is \_\_\_\_\_.

[This entire document must read in first person]

**PURPOSE**

[SECTION I Content: Introduce the subject to the nature of the research, why it relates to his condition, and make a specific purpose statement:]

**The purpose of this research is ...**

[When referring to medical terms that are commonly abbreviated, write out the full name the first time you mention it in the text. When using statistics, indicate the number out of 100 or more, instead of A percent.]

State length of study and the number of participants.

**SECTION II. DESCRIPTION OF THE STUDY INCLUDING PROCEDURES TO BE USED.**

[SECTION III. DESCRIPTION OF ANY PROCEDURES THAT MAY RESULT IN DISCOMFORT OR INCONVENIENCE.]

[Title these sections:] **PROCEDURES** - [They may be combined or addressed separately.]

[Content:]

1. [Start this section with:] **If you consent to participate in this research study ...**
2. [Give a step by step description of the procedures from selection of patients through follow-up. Identify phases, if appropriate.]

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3. [Discuss experimental procedures (do not call them investigational procedures). Focus on invasive techniques, restriction of normal activities, long term follow-up, and possibility of receiving inactive materials.]
4. [Make a clear distinction between procedures which are necessary because of the study and those which would be required as part of the subject's usual care. This includes increases in time, complexity, discomfort, and/or prolongation of hospitalization or hospitalization entirely for research purposes.]
5. [If the study involves random assignment, the nature and probability of group assignment must be specified:]  
**Using a procedure like flipping a coin, you will have a 1 in \_\_\_\_\_ chance of receiving a sugar pill instead of \_\_\_\_\_.**
6. [If the subject and/or treating physician are to be kept blind to group assignment, this fact must be included.]
7. [When appropriate, the subject's approximate length of involvement in the study shall be indicated.]
8. [The number of times a procedure is repeated shall be noted.]
9. [The duration of lengthy procedures, including questionnaires, should be indicated. This may be summarized for procedures done as a group.]
10. [If blood is withdrawn, both the frequency of the procedure and the total amount of blood should be indicated in metric measures, followed by teaspoons, tablespoons, ounces, pints, etc., as appropriate. For studies involving a large number of samples to be drawn over an extended time interval, an estimate can be given.]
11. [For women of child bearing age:]  
[If pregnant subjects are to be excluded, the following statement is required for all women of child-bearing age:]  
**Since this research may have bad effects on an unborn child and should not be done during pregnancy, it is necessary that a pregnancy test be done first. To your knowledge, you are not pregnant at the present time.**  
[if the research extends over more than several days, add a statement to indicate the following:]  
**You also agree to avoid becoming pregnant (use contraceptives, take precautions against becoming pregnant, etc.) during this study.**
12. [For studies involving investigational (experimental) drugs, or procedures, the following statements must be included:]
  - (a) **Because this is a new (drug, procedure) we do not know all of its bad effects. You should contact (name of the VA investigator) at (phone, location) if you have any bad effects. Include this information about the investigator here even if it is repeated elsewhere.**
  - (b) **We can not guarantee that you will be able to continue receiving this (drug, device, procedure) after this study is over.**

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13. [Describe anything unusual about this study that is not covered above.]
14. [List the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.]

[SECTION IV. EXPECTED RISKS OF STUDY]

[Title this section:] **RISKS** - [You may combine Sections III and IV and title them)

**DISCOMFORTS AND RISKS**

[All risks stated in consent form must be stated in the protocol and vice versa. Include physical, psychological, social and economic risks.]

[Content:]

1. [State any known risks, inconveniences, or side effects, with at least a rough estimate of number per 100, 1000, etc. of likelihood for severe events such as, coma, death, hemorrhage, etc.]
2. [If blood is to be drawn, include the following risks:] **Pain, bruising, and rarely, fainting or infection.**
3. [Discuss any measures taken to minimize hazards.]
4. [Note that risks can not be predicted.]
5. [Include the effects these risks will have on the person's health or person as a result of participating in the research study.]
6. when appropriate disclose:
  - A statement that the particular treatment or procedure might involve risks to the participant, which were currently unforeseeable.
  - A statement that if the participant was or became pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which were currently unforeseeable
  - Anticipated circumstances under which the participant's participation might be terminated by the investigator without regard to the participant's consent.

**State need to keep medication in a location out of reach of children.**

[SECTION V. EXPECTED BENEFITS OF STUDY]

[Title this section:] **BENEFITS**

[Content:]

1. [Describe any potential benefits to the subject, society, or future patients with similar conditions. This section should answer the question of how the benefits outweigh the risks and discomforts. It should indicate how fruitful results could not be obtained by other methods or at random. The subject should have a clear understanding of why the experiment is justified, without being coerced.]

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2. [If there are no clear benefits to this subject, include the following:]  
**You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others.**

[SECTION VI. ALTERNATIVE THERAPY OR DIAGNOSTIC TEST]

[Title this section:] **OTHER TREATMENT AVAILABLE**

[Content:]

1. [Discuss the consequences of not being involved in the study including whether and how the evaluation/treatment received would be different.]
2. [Where appropriate, include the consequences of a subject's decision to withdraw from the research.]
3. [Where appropriate, include the set procedure for safe and orderly termination of participation when abrupt termination would impose risks.]

[SECTION VII. USE OF RESEARCH RESULTS]

[Title this section:] **RESEARCH RESULTS**

[Content:]

[Consider the statements below, as applicable. The wording should be changed only for substantive reasons and without changing the meaning. The intent of the statements and all parts of the statements should be retained.]

1. **We will let you and your physician know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study.**
2. [If using scales which elicit information concerning suicidal intent, depression, or other major clinical findings, indicate when the primary physician will be notified.]
3. [Include a statement that indicates who will have possession of questionnaires, videos, audio cassettes, who else will have access to them, how they will be secured, and the timing and method of coding and disposal.]

**CONFIDENTIALITY**

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. Your medical records will be maintained according to this medical center's confidentiality requirements. Your physician will treat your identity with professional standards of confidentiality. However, there is a possibility that the

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Food and Drug Administration, other federal oversight agencies, \_\_\_\_\_ (SPONSOR), and/or the VA Institutional Review Board (IRB) may inspect your records. A copy of this consent form will be placed in your medical record.

### **WITHDRAWAL FROM STUDY**

You are not required to take part in this study: your participation is entirely voluntary. You can refuse to participate now or you can withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to withdraw from this study, you should contact \_\_\_\_\_ (investigator). Discontinuation will in no way affect or jeopardize the quality of care you receive now, or in the future, at this institution or your right to participate in other studies. The investigator or your doctor may also withdraw you without your consent, for medical or administrative reasons, in a study not terminated. Any significant new findings that develop during the course of the research study that, in the opinion of the investigator, may affect your willingness to continue to participate, will be provided to you as soon as possible.

### **COST TO SUBJECT FOR PARTICIPATION IN RESEARCH**

There will be no costs to you for any of the treatment or testing done as part of this study. Eligibility for medical care is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study. Depending on your veteran status, you might have to pay co-payments for medical care and services provided by VA. (The Sponsor) \_\_\_\_\_ has donated the medication used in this study, so there will be no cost to you for the study medication. There is no guarantee that the medicines you will receive during this study will be continued after the study is completed. You will continue to receive \_\_\_\_\_ if your physician decides that it is the most appropriate treatment.

### **PAYMENT FOR PARTICIPATION IN THE RESEARCH**

List payment for participation or no payment clause. List the schedule of payments for partial participation. Payment statement must include amount received by patient at each visit and total payment along with when patient will receive payment. For example: Patient will receive payment at the end of each completed visit or payment for each completed visit will be mailed to patient within two weeks after completing visit.

### **INJURY COMPENSATION CLAUSE**

Should you be injured as a result of participation in this research project, which has been approved by the Tuscaloosa VA Institutional Review Board (IRB) and Research and Development Committee and conducted under the supervision of one or more VA employees, the Tuscaloosa VA Medical Center will provide you with necessary medical care for those injuries. This care is governed by Federal regulations and VA policy. This does not apply to injuries due to noncompliance by you (i.e., not following study procedures and instructions). In addition, any care received outside the VA is not paid for without prior

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approval (i.e. approved fee-basis service). You do not waive any liability rights for personal injury by signing this form.

*Additional statements required:*

- *An explanation as to whether compensation is available if injury occurs*
- *If compensation is available when injury occurs, an explanation as to what it consists of and where further information could be obtained*
- *An explanation as to whether any medical treatment are available if injury occurs*
- *If medical treatments are available when injury occurs, an explanation as to what it consists of and where further information can be obtained.*

**NEW FINDINGS**

You and your physician will be informed if any important discoveries are made during this study which may affect you, your condition, or your willingness to participate in this study. Information obtained in this study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

**QUESTIONS**

If you have questions, concerns or complaints about your rights as a study participant, you may contact the Research Compliance Officer, Colleen Beall, DrPH, MSW, at (205) 554-2000, ext. 3200 or Institutional Review Board (IRB) Administrator who will have the IRB member subject representative contact you. The IRB Administrator can be reached at (205) 554-3675 (Tuscaloosa VA patients). If the IRB Administrator cannot be reached, contact the IRB Clerical Assistant at (205) 554-2000, ext. 3273 and she will direct your call to an IRB member. If you have questions regarding this study or the procedures, if you have unexpected reactions, or if you are injured and become ill as a result of participation in this study, please call (investigator) \_\_\_\_\_ at (205) 554-2000 ext. \_\_\_\_\_ or 1-888-269-3045, ext. \_\_\_\_ (toll free). You may also call the Tuscaloosa VA operator at (205) 554-2000 or 1-888-269-3045 (toll free) and have the operator page \_\_\_\_\_ (the investigator). If you are unable to reach Dr. \_\_\_\_\_ (the investigator) and need immediate medical assistance for a research-related injury, please call the Tuscaloosa VAMC hospital operator at 205-554-2000 or 1-888-269-3045 and ask for the Triage Nurse to obtain advice.

You may also call \_(name)\_\_\_ at \_(phone number)\_\_\_\_\_ for answers to pertinent questions about the research.

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RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above.

One of the above listed investigators has explained the study to you and answered all of your questions. 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 understand that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.**

The results of this study may be published, but your records will not be revealed unless required by law.

In case there are medical problems or you have questions, you have been told that you can call Dr. \_\_\_\_\_ at (205) 554-2000 ext. \_\_\_\_ during the day (or toll free 1-888-269-3045, ext. \_\_\_\_ ) and at (205) 554-2000 (have operator page Dr. \_\_\_\_\_) after hours. If any medical problems occur in connection with this study, the VA will provide emergency care in accordance with your eligibility.

I will receive a signed copy of this consent form.

\_\_\_\_\_  
 Subject's Signature Date

\_\_\_\_\_  
 Signature of Subject's legally-authorized representative\* Date Subject's legally-authorized representative (printed)  
 \*Only required if subject not competent.

\_\_\_\_\_  
 Signature of Witness\*\* Date Witness (printed)  
 \*\*A witness whose role is to witness the subject's or the subject's legally-authorized representative's signature

*NOTE, but only include if applicable: If the sponsor or IRB requires a witness to the consenting process in addition to the witness to the participant's signature and if the same person needed to serve both capacities, a note to that effect was placed under the witness's signature line.*

\_\_\_\_\_  
 Signature of Person Obtaining the Informed Consent Date Person Obtaining the Informed Consent (print)

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**Authorization for Release of Protected Health Information for Research Purposes (Health Insurance Portability and Accountability Act – HIPAA)**

You have been asked to be part of a research study under the direction of (investigator), and (his or her –**pick one or the other throughout this document**) research team. The purpose of this study is to determine \_\_\_\_\_. By signing this document, you will authorize the Veterans Health Administration (VHA) to provide (investigator) and (his or her) research team to access the following information about you: your name, social security number, date of birth, VA medical records (including records of substance abuse or dependence), laboratory tests, clinical visit data, and any medical records gathered from outside institutions under your consent.

If you do not sign this authorization, you will not be part of the study. This authorization has no expiration date.

You can revoke this authorization at any time. To revoke your authorization, you can write to (investigator) or you can ask a member of the research team to give you a form to revoke the authorization. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient.

If you revoke this authorization, (investigator) and (his or her) research team can continue to use information about you that has already been collected. No information will be collected after you revoke the authorization.

As part of the study, we may disclose your information gathered during the course of the study to \_\_\_\_\_, the company that is (*providing funding for or sponsoring*) this research study. We will not share any information with the sponsor unless the sponsor agrees to keep the information confidential and use it only for the purposes related to the study. Any information shared with the sponsor may no longer be protected under federal law.

This study includes the creation of a database of information that is secured on a computer by passwords to only allow (investigator) and (his or her) research team access to the database. By signing this authorization, you agree to allow the medical and personal information collected in this study to be added to that database.

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

By signing this consent form, you confirm that you have read this authorization form and have been given the opportunity to ask questions. If you have questions later, you can contact (investigator) or (his or her) research team. You will be given a signed copy of this consent form for your records. By signing this consent form you authorize the use of your identifiable information as described in this form.

\_\_\_\_\_  
Subject's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Subject's legally-authorized representative\*

\_\_\_\_\_  
Date

\_\_\_\_\_  
Subject's legally-authorized representative (printed)

\*Only required if subject not competent.