

Name:

Date:

Title of Study: (enter IRB# and title here)

Principal Investigator: (enter name of PI here)

VAMC: Dayton (552)

Purpose of study and how long it will last:

You are invited to participate in a research study of *(insert general statement about study)*. The purpose of this study is to *(Give brief statement of purpose in language understandable to the subject, e.g., sixth grade level)*. *(If the study involves the use of an investigational drug or device, state that that means it is not approved by the Food and Drug Administration)*.

Description of the study including procedures to be used:

If you agree to participate, you will be one of *(single number, not range)* subjects who will be participating in this research *(locally and nationally, if multi-center study)*.

If you agree to be in the study, you will do the following things:

(In language understandable to the subject, give in detail, preferably in chronological order, all procedures, including surveys, focus groups, etc., which will be employed in the study, including where they will be performed, their frequency, and the total duration of the study. Identify any experimental and standard procedures. Describe the extent to which confidentiality of records identifying the subject will be maintained. If blood is to be drawn, explain how and from where the blood will be drawn, e.g., "from a vein in your arm." Indicate the total number of times blood will be drawn, the amount of blood to be drawn each time, and the total amount of blood to be drawn over the course of the study. Translate the amount to be drawn to common measures, such as teaspoonfuls or cupfuls). This section must contain procedures for the orderly termination of a subject's participation in the protocol.

Risks:

(Define the risks of each of the procedures to be employed in the study. Give the side effects of all medications to be given to the subjects for the purpose of the study. Describe any procedures that may result in discomfort or inconvenience.)

While on the study, the risks are *(explain each, including their likelihood-a grid can be used or numbering each to correlate with the ways you will minimize the risk):*

(e.g.: The risks of completing the survey are being uncomfortable answering the questions.)

(e.g.: The risks of possible loss of confidentiality)

(e.g.: The risks of drawing blood include, pain, bruising, and rarely, infection.)

(e.g.: The side effects associated with taking Cimetidine are mild diarrhea, confusion,)

(As appropriate)

There also may be other side effects that we cannot predict *OR* This study may involve currently unforeseeable risks to you and to an embryo or fetus if you should become pregnant.

(Give measures that will be employed to minimize the risks and side effects listed above.)

(e.g.: While completing the survey, you can tell the researcher that you feel uncomfortable or do not care to answer a particular question.)

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(e.g.: Blood will be drawn by experienced technicians and whenever possible it will be obtained at a time when blood is being obtained for other tests your doctor has ordered.)

(e.g.: While you are receiving Cimetidine, you will be questioned weekly about possible side effects; your blood and kidney function will be monitored by the blood tests we are obtaining.)

Benefits:

The benefits to participation are *(list or state if there are no benefits)* either personally or to others from the research.

There are no direct benefits to you from your participation in this research study. However, the knowledge gained from this study may help others should the results prove useful.

Treatment with _____ may improve _____. This may provide relief from symptoms and improve your quality of life. However, neither of these benefits is guaranteed.

Alternate Courses of Action or treatment:

Instead of being in the study, you have these options: *(As appropriate, give alternative course of treatment and information associated with that treatment.)*

Statement of Use of Research Results:

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

(As appropriate) You will be told about new information that may affect your health, welfare, or willingness to stay in the study. This study may be terminated by *(Sponsor/Investigator)* if *(Give reason for premature termination)*.

Special Circumstances:

Tissue Banking-Suggested Consent Inclusions: (Off-site Tissue Banks must be approved by Central Office)

As this is a research institution, specimens obtained in medical situations may later be used for research purposes. The investigator intends to include specimens taken from you along with other specimens that may also be used in an attempt to develop products to be sold, and it is not the intention of the investigator to enter into an agreement with you to become partners in sharing the profits or losses in the sale of those products.

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1. *If the specimen will be used for future research and will allow the participant the choice of how the specimen will be used (any research, research by the PI or other researchers, genetic analysis, research related to a specific area.)*
2. *If the research results of reuse of the specimen will be conveyed to the participant*
3. *If the participant is re-contacted after the original study is completed*

By initialing below, you are agreeing to the following:

1. Your blood and tissue sample(s) may be kept by the _____ for later use in research projects whose aim is to learn about, prevent and/or treat _____.
 Yes No Initials _____ Date _____
2. Your blood and tissue sample(s) may be kept and used for research about other health problems (for example _____)
 Yes No Initials _____ Date _____
3. I am requesting contact prior to any future research.
 Yes No Initials _____ Date _____

Confidentiality:

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the investigator and his/her research associates, the study sponsor.

In addition, organizations and agencies responsible for assuring the safety of human subjects in research may also view your research records. These include: the Wright State University Institutional Review Board or its designees, the VA Research and Development Committee or its designees, The VA Office of Research Oversight, the VA Office of Research & Development, the government Accountability Office, the Office of Human Research Protections, and, when applicable, the Food and Drug Administration (when medications or medical devices are involved), the National Institutes of Health (when they provide funding), and the National Cancer Institute (when they provide funding).

Research Subject Costs:

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Each of the following items should be included if applicable: (Number 3 is always applicable.)

1. List any additional costs to the subject that may result from participation in the study. If not applicable, then use this statement:

There will be no costs to you for any of the treatment or testing done as part of this research study. Eligibility for medical care at a VA Medical Center is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.

2. The study is sponsored by _____.

3. You will not be required to pay for medical care or services received as a participant in a VA research project except as follows:

Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

Compensation: (Always include #2)

1. You (will/will not) receive payment for taking part in this study (include details and any conditions of payment).
2. The VA medical facilities shall provide necessary medical treatment to a research subject injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This does not apply to: (1) treatment for injuries due to noncompliance by a subject with study procedures; or (2) research conducted for VA under a contract with an individual or a non-VA institution.
3. Financial compensation for research-related injuries is not available, except through legal action. By signing this form, you do not give up your legal rights to seek such compensation through the courts.

Further Information:

1. If disclosing a financial conflict of interest, it should be entered here.
2. If obtaining a Certificate of Confidentiality enter the information here.

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The following should appear on the last page of the consent (adjust page breaks accordingly):

RESEARCH SUBJECT'S RIGHTS:

Participation in this study is entirely voluntary. You may refuse to participate. 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. You will receive a copy of this consent form.

In case there are medical problems or questions, Dr. _____ may be called at _____ during the day and Dr. _____ at _____ after hours. If any medical problems occur in connection with this study, the VA will provide emergency care. *(Obtain answers to questions about the research.)*

If you have any questions regarding your rights as a study subject, you may contact Jack M. Bernstein, M.D. (Coordinator for Research & Development, Dayton VAMC) at (937) 262-3393 *(Obtain answers to questions about the research from someone not associated with the protocol)*, Patient Representative, Dayton VAMC at (937) 268-6511, ext. 2164 *(Voice concern or complaints about the research)*, and/or Robyn Wilks (IRB Coordinator at (937) 775-4462 *(Voice concern or complaints about the research from someone not associated with the protocol)*).

For studies that contain an FDA regulated product-this statement is required:

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.

The study has been explained to me and all of my questions have been answered. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained.

Subject's Signature_____
Printed Name of Subject_____
Date_____
SSAN_____
Signature of Person Obtaining Consent_____
Printed Name of Person Obtaining Consent_____
Date

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