| Title of Study: : Clinical Data Collection for Patients Seen in the War Related Illness and Injury Study Center | |
|---|---|
| Principal Investigator: J. Wesson Ashford, MD, PhD | VAMC: VA Palo Alto HCS |

Are you participating in any other research studies? _____ yes _____no

**What is this research about?**

You are invited to participate in **a research study** on the effects of combat related injuries and illnesses. A component of the War Related Illness and Injury Study Center (WRIISC) is to study injuries and illnesses that result from combat and determine better methods to treat such illnesses and injuries. To do this, the WRIISC team will be gathering clinical data to create a data base. This data base will be used to provide valuable information to WRIISC researchers as they pursue better treatments for combat illnesses and injuries.

As a patient of the War Related Illness and Injury Study Center, you have undergone many diagnostic tests related to you particular illness or injury. The WRIISC team is requesting your consent to include the results of these tests in the WRIISC database which will be analyzed and used to present information to the professional medical community via medical conferences and written materials such as journal articles. You will not be required to undergo any additional tests. Your data will be de-identified and stored on a VA computer server that is protected by a VA firewall.

**What is expected of me? (Procedures)**

If you decide to participate, you will be asked to fill out some self-report questionnaires. Beyond this, you will not be asked to do anything further than what you have already gone through in your clinical appointments. You will only be asked to read and agree to this form so we can have your permission to look at your clinical data. The data for this research study is the clinical data you have already provided as a WRIISC patient. Your participation, at this point, only includes approximately 55 minutes for this consent form and the questionnaires.

**What are the possible risks or discomforts?**

The risk associated with this study is the possibility of a loss or unauthorized disclosure of your clinical tests results. The WRIISC team will take every precaution to protect your data including removing identifying information from your data and storing it on a VA server that is administered by VA Office of Information and Technology employees and protected by the VA firewall. Because some questions on the self-report questionnaires may be combat-related or address illnesses or problems you might have, you may feel a certain level of psychological discomfort by answering these questions. You maintain the right to refuse to answer any of these questions.

**Will I benefit from the study?**

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY. However, your data may contribute to new treatments for combat related illnesses and injuries. Your decision whether or not to participate in this study will not affect your medical care.

**What are my alternatives to being in this study?**

Since this study is not a form of treatment per se, the alternative to participation in this study is not to participate.

**Will I get paid?**

There is no payment for participation in this study.

**Do I have to be in this study?**

Participation is voluntary and a decision not to participate will not result in any penalty or loss of benefits to which the participant may be entitled.

**Can I change my mind later and stop being in this study?**

You can withdraw from the study at any time without penalty or loss of benefits to which they may be entitled. You have the right to refuse to answer particular questions.

**Will my information be protected from the public?**

We will keep your name and all the information you tell us in this study as confidential as possible. We may include your data in published materials from this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information.

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## Authorization To Use Your Health Information For Research Purposes

The HIPAA (Health Insurance Portability & Accountability Act) allows you to control how health information about you is used. You have been asked to take part in the study listed above and this form provides an explanation about the use and disclosure of your health information and asks for your permission to use and share your individual health information.

### What is the purpose of this study?

The primary purpose of this research program is to study on the effects of combat related injuries and illnesses. A component of the War Related Illness and Injury Study Center (WRIISC) is to study injuries and illnesses that result from combat and determine better methods to treat such illnesses and injuries. To do this, the WRIISC team will be gathering clinical data to create a data base. This data base will be used to provide valuable information to WRIISC researchers as they pursue better treatments for combat illnesses and injuries.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, personal information or your identity will not be disclosed.

### What Personal Information Will Be Used or Shared?

By agreeing to this document, your give the parties listed below permission to access and use the following health information about you for this research:

| | | | |
|---|---|---|---|
| X | History and physical examination | | Discharge summary |
| X | Progress notes | X | X-ray and MR scans |
| X | Biological specimens (e.g. blood, tissue, urine, saliva) | | Photographs, videotapes, other images |
| X | Diagnostic/Laboratory test results | | HIV (testing or infection) records |

| | | | |
|---|---|---|---|
| X | Survey/Questionnaire responses | | Operative reports |
| X | Mental health (not psychotherapy) notes | X | Psychological test results |
| X | Drug abuse Information | X | Alcoholism or alcohol use information |
| | Billing records | X | Sickle cell anemia information |
| | Other records: | | |

## Who May Use or Share Your Health Information

- Departments within the VA Palo Alto Health Care System responsible for the oversight, administration, or conduct of the trial.
- The Protocol Director (John Wesson Ashford, MD, PhD), Co-Protocol Director, Ansgar Furst, PhD, Faculty Sponsor (Jerome Yesavage, MD) and members of the research team.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and other Stanford University Officials responsible for the oversight, administration, or conduct of the trial.

## Who May Receive and Use Your Health Information

The study team may need to share your information with the following parties as part of this research:

- Collaborating researchers at John Hopkins University (Dr. Susumu Mori's Laboratory) may receive the anonymized scans (no PHI) in order to analyze and process the resulting data.
- The imaging laboratories at Stanford University may receive the anonymized scans (no PHI) in order to analyze and process the resulting data.
- Researchers from other WRIISC locations, for approved analysis research protocols.
- The Office for Human Research Protections in the U.S. Department of Health and Human Services

We will protect your health information as required by all laws, however health information shared with others may no longer be protected by Federal laws or regulations and might be shared by the parties above.

## Do I have to agree to this form?

No. Agreeing to this form is voluntary. The VA may not condition treatment, payment, enrollment or eligibility for benefits based on agreeing to this form. If you decide not to agree to the form, you will not be able to take part in this study.

## If I agree now, can I decide later not to continue in the study?

Yes. You are free to take back your permission regarding the use and sharing of your health information and stop being in the study. If you take back your permission, the research team can continue to use information about you collected before you decided to take back your permission, but will not collect any information about you going forward.

To take back your permission, you must write a letter to the researchers telling them you want to take back your permission or you can ask a member of the research team to give you a form to complete to take back your permission. If you take back this permission, you will not be able to continue to take part in the research. You mail your written request to the researchers by sending to:

Dr. Ansgar Furst, 3801 Miranda Avenue (151Y), Palo Alto, CA 94304-1207.

## Does My Permission Expire?

Yes. Your information cannot be used forever. Your permission related to the use and sharing of your health information expires when this research study is completed or on December 31, 2040.

**Use of your information to contact you regarding future studies:**

The WRIISC and affiliated groups at the VA Palo Alto conduct studies on a variety of topics related to physical and psychological health. Please indicate below if you grant permission to contact you in the future regarding other studies for which you may be eligible to participate:

_____Yes, I grant permission to use my information to contact me in the future regarding other studies.

_____ No, I do not grant permission to use my information to contact me in the future regarding other studies. → **(*do not contact subject for future studies*)**

**Who can I talk to if I have questions about the research, problems related to the study or if I think I've been hurt by being a part of the study?**

**Appointment Contact:** If you need to change your appointment, please contact Ansgar Furst, PhD or a member of the research team at (650) 493-5000 x68652.

**Questions, Concerns, or Complaints:** If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director. You may contact Dr. Ashford now or later at (650) 493-5000 x64059.

**Alternate Contact:** If you cannot reach the Protocol Director, please call a member of the research team at (650) 493-5000 x68652.

If you think you have experienced a **research-related injury** call Dr. Furst at (650) 493-5000 x68652.

If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, and would like to speak with a VA representative who is independent of the research, call the Human Protections Administrator at (650) 493-5000 x 67593.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

**What are my rights if I take part in this study?**

You have the right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Please print a copy of this page for your records.

If you agree to participate in this research, please indicate this to the researcher.