Add the following to the section “What are the costs of taking part in this study?” immediately prior to “You will not be paid for taking part in this research study”

However, if you are a VA study participant you or your insurance 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, these co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

Add the following to the section “What happens if I am injured or hurt because I took part in this study?” after “If you have no insurance, you would be responsible for any costs” and before “if you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a research study”

However, if you are a VA study participant then the VA (not you or your insurance) will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Palo Alto VAMC or arrangements may be made for contracted care at another facility. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at (650) 493-5000 # 64948.

If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call the Stanford Institutional Review Board at (650)-724-7141.

Add the following to the section “Who will see my medical information?”

This privacy permit is called a Certificate of Confidentiality. In addition to help protecting your study records if there is a court case, the Certificate of Confidentiality also does not allow researchers to release research information identifying you to other people not connected with the study unless you allow it except in a few situations, such as if required by law.

Your study doctors will put information about your participation in this study in your VA medical record for your safety. It is important for other health care providers taking care of you to know any study drugs or study treatments you are receiving.

*The following will be added to the bulleted list of agencies who may see records*

-The VA officer of the Inspector General (OIG)

 -The VA Office of Research Oversight (ORD)

Add the following to the section “Where can I get more information?”

**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 principal investigator Harlan A. Pinto, MD at 650-380-3543.

**Injury Notification:** If you feel you have been hurt by being a part of this study, please contact the principal investigator, Harlan A. Pinto, MD at 650-380-3543.

**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, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

**Appointment Contact:** If you need to change your appointment, please contact Ms. Lisa Zhou at 650-4935000 x 63463

**Alternate Contact:** If you cannot reach the principal investigator, please contact Ms. Lisa Zhou at 650-4935000 x 63463

Add the Experimental Subject’s Bill of Rights prior to the signature section:

**EXPERIMENTAL SUBJECT’S BILL OF RIGHTS**

As a research participant you have the following rights. These rights include but are not limited to the participant's 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 signed and dated 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.

Signature Lines:

RESEARCH PARTICIPANT’S SIGNATURE AND DATE:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Participant’s signature (or legally authorized representative)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Date of signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of person(s) conducting the informed consent discussion

\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Date of signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Name of person(s) conducting the informed consent discussion

Add the withdrawal paragraph after the signature lines:

**WITHDRAWAL FROM STUDY**

If you first agree to participate and then you change your mind, you are free to withdraw your consent and stop your participation at any time. If you decide to withdraw from the study, you will not lose any benefits to which you would otherwise be entitled [(if applicable) and your decision will not affect your ability to receive medical care for your condition].

If you want to stop being in the study you should tell the investigators or study staff. You can do this by phone by calling Harlan A. Pinto, MD at (650) 858-3931

If you withdraw from the study, or the study medication is stopped for any reason,

you must return all study-related supplies, including unused study drug.

The investigators may also withdraw you from the study and the study medication may be stopped without your consent for one or more of the following reasons:

* + Failure to follow the instructions of the investigators and/or study staff.
	+ The investigators decide that continuing your participation could be harmful to you.
	+ Pregnancy (if applicable).
	+ You need treatment not allowed in the study.
	+ The study is cancelled.
	+ Other administrative reasons.
	+ Unanticipated circumstances.