

**WILLIAM BEAUMONT ARMY MEDICAL CENTER (WBAMC)**  
**RESEARCH STUDY AGREEMENT**  
WBAMC Protocol #\_\_\_\_\_ entitled “???”

**INTRODUCTION:**

We have asked you to take part in a research study at WBAMC because ??? As this is a research study, there are several facts that we would like you to know up front:

- a) Your decision to take part in this study is voluntary.
- b) You may withdraw from this study or any part of this study at any time. If you choose not to participate or if you withdraw from the study, your decision will not affect your eligibility for care, **your military career status** (*insert the bold portion only if your study population is strictly active duty soldiers, otherwise delete*), or any other benefits to which you are entitled
- c) After you read this agreement, we will answer all your questions until you understand your part in this study.
- d) You may take this agreement home with you and return it when you are ready to make your decision.
- e) We will ask you some basic questions to be sure that you completely understand your involvement in this study.

**PURPOSE OF STUDY:**

We will attempt to determine (hypothesis/reason for the study):

- a)
- b)
- c)
- d)

**EXPECTED LENGTH OF YOUR PARTICIPATION:**

Your part will include (*how many visits and/or follow-ups, establish time periods [i.e. total period of participation is two hrs including filling out the forms and study visits]*).

- a) Establish what procedures will be encountered during each visit/follow-up
- b) Be specific

**PROCEDURES TO BE FOLLOWED:**

- a) Establish the study design (i.e. This is a double-blind, prospective, randomized study, this is a survey, etc). **Add the following if the study is double blinded, prospective, and/or randomized:**
  - 1) Double blind means that you and your doctor will not know to which treatment group you are assigned.
  - 2) Prospective means future or soon to be. This means that the results of our research may make a difference in the future.
  - 3) Randomized means that you will be assigned to a group by chance. This is like flipping a coin. You have a 50/50 chance of receiving the dummy drug.
- b) Provide step-by-step guidance on what the patient can expect (*i.e. a) you will complete an informed consent document, b) you will be randomly assigned, etc.*)
- c) After you complete the (*list the event, i.e. last visit, survey, etc*) follow up, your part in the study will be finished.

## RESEARCH STUDY AGREEMENT (Continued)

STUDY TITLE:

### **REASONABLY PREDICTABLE RISKS OR DISCOMFORTS:**

Although unlikely, there is a small possibility that you may feel some discomfort (*explain where, in what area of the body?*). There is also a possible loss of privacy and/or confidentiality.

*INSERT APPENDIX A IF BLOOD SAMPLES ARE TO BE DRAWN*

*INSERT APPENDIX B IF ABSENCE OF PREGNANCY IS REQUIRED*

### **NON-PREDICTABLE RISKS:**

Although unlikely, conditions may occur during your part in this study that are not predictable. However, we will conduct all procedures in a safe and ethical manner. We will always follow the best available medical practice.

*INSERT APPENDIX C IF THERE MAY BE CIRCUMSTANCES WHERE TERMINATION OF PARTICIPATION WITHOUT CONSENT WOULD BE NECESSARY*

### **BENEFITS OF YOUR PARTICIPATION IN THIS STUDY:**

By taking part in this study, you will not receive any additional medical benefits beyond standard treatment. This is the best medical care available. However, information that is learned from your part may help us provide better medical care for patients in the future.

### **PAYMENTS THAT MAY RESULT FROM PARTICIPATION IN THIS STUDY:**

We will not charge you for taking part in this study. You will not receive any type of payment for your part in this study.

### **OTHER PROCEDURES OR COURSES OF TREATMENT:**

You may choose not to take part in this study or you may choose to withdraw from this study at any time. If you choose not to take part, your medical care will not be affected. You will continue to receive treatment which is standard of care.

### **NUMBER OF PARTICIPANTS IN THIS STUDY:**

There will be about (*how many??*) subjects in this study.

### **MAINTAINING CONFIDENTIALITY:**

While being treated as a patient at WBAMC, you are given copies of the Privacy Act Statement (DD Form 2005) and the Health Insurance Portability and Accountability Act Statement (HIPAA). These documents tell you how the privacy of your health information is protected. You are given an opportunity to look at these forms and ask questions about them. You are also given copies of them.

Information gained during your part in this study may be published in medical articles, discussed in educational settings, and used to improve our understanding of medical science. In all cases where this information will be used, you will in no way be personally identified.

**RESEARCH STUDY AGREEMENT (Continued)**

STUDY TITLE:

The WBAMC Institutional Review Board (IRB), a committee established to ensure the protection of study participants, and other government agencies may review your records, as part of their normal duties.

Complete confidentiality cannot be guaranteed, particularly for military subjects. It may be required that information regarding your health status be reported to appropriate medical or command authorities. In addition, we may be obligated to release information as a result of a court order(s).

***ADD THE FOLLOWING STATEMENT IF AN INVESTIGATIONAL DRUG OR DEVICE IS TO BE STUDIED*** “Since the investigational (state name of drug or device) will be used in this study, it may be necessary for personnel in the Food and Drug Administration and other regulatory agencies to review this information.”

***INSERT APPENDIX E REGARDING USE OF STUDY SAMPLES***

***INSERT APPENDIX F IF PHOTOGRAPHS ARE TO BE TAKEN***

**SIGNIFICANT FINDINGS:**

During this study, your doctor will inform you of any significant findings which may influence your willingness to continue taking part in this study. Upon request, we will provide you results of this study.

**ENTITLEMENT TO CARE:**

If physical injury occurs because of procedures used in this study, your medical care, if necessary, will be limited to what is authorized for DOD health care beneficiaries. Taking part in this study will not change ongoing medical benefits for military beneficiaries. You will continue to receive all necessary or future medical treatment should you experience illness or injury as a result of this study.

**WHOM TO CONTACT:**

The principal investigator in this study is (principal investigator). He/she can be reached at (915) (phone number). You may request the names and professional status of other investigators associated with this study.

**AGREEMENT STATEMENT**

I, \_\_\_\_\_ ,  
(Please print your name)

have passed my 18th birthday and am freely willing to volunteer to take part in this clinical research study.

I have been given a reasonable opportunity to ask questions and to discuss my concerns about this research study.



## RESEARCH STUDY AGREEMENT (Continued)

STUDY TITLE:

### *APPENDIX A*

#### **BLOOD SAMPLES TO BE DRAWN:**

*State the reason for the blood draw, how much will be taken and how often [i.e. 1 tsp, etc.], and add the following “Blood drawing can be painful. In some cases, bleeding may occur for a short time on top of or under the skin. Although rarely occurring, blood drawing can cause blood clots to develop inside of blood vessels and can also cause skin infections or internal infections.”*

### *APPENDIX B*

#### **ABSENCE OF PREGNANCY IS REQUIRED:**

As a female subject, you must not be pregnant and you must not become pregnant during the course of this study. Medications, vaccinations or other procedures that may be used in this study can be a significant risk to you or your fetus if you are pregnant. You cannot participate in this study if there is a possibility that you are pregnant (late period and/or intercourse without birth control) unless absence of pregnancy is determined. If you think there is a possibility that you may be pregnant, you must be tested and determined to be non-pregnant before participating in this study. Pregnancy testing and reporting will be performed under strict privacy and confidentiality guidelines and results will be made available only to you and/or your doctor. You can avoid becoming pregnant by either abstaining from sexual relations or using a birth control method. Condoms, diaphragms, birth controls pills, IUDs, or sperm killing products are not 100% effective in preventing pregnancy. The only way to completely avoid drug-associated risks to a fetus is to not become pregnant or not participate in this study. If you become pregnant while participating in this study, you must immediately withdraw from this study and seek medical attention. Upon completing your participation in this study, you should avoid becoming pregnant for at least 30 days since pregnancy during this time may create a potential risk to the fetus.

### *APPENDIX C*

#### **TERMINATION OF PARTICIPATION WITHOUT YOUR CONSENT:**

*Explain these conditions.*

- (a) Health conditions that may occur in which your continued participation would possibly be dangerous are:
- (b) Other conditions which might occur that would make your continued participation detrimental are:

### *APPENDIX D*

**ASSENT OF A CHILD** *(applicable for children capable of understanding nature and consequences of the study):*

The study was explained to me in a way that I could understand. I was able to ask questions about anything I did not understand. I understand what the study is about and I agree to be in the study.

### *APPENDIX E*

## RESEARCH STUDY AGREEMENT (Continued)

STUDY TITLE:

### **USE OF STUDY SAMPLES:**

Upon completion of this study, the (specify sample type) that you provide for this study (will) (will not) be stored for use in future research studies. In either case, you will not be personally identified in any publications of the research study results. Cell lines or products derived from cell lines that may be developed from samples that you provide for this or future studies will become the property of the federal government. By participating in this study, you assign your right of ownership of the cell lines or products derived from cell lines to the federal government.

### *APPENDIX F*

### **PHOTOGRAPHS:**

If photographs are to be taken, describe the purpose of the photographs and what actions will be taken to protect the identity of the participant.

### **NOTES**

- The title of the research study must be identical to the protocol title.
- Please address the highlighted portions and be as specific as possible. All other areas of the consent are templates, as required by regulations - some may apply, others may not. Please delete those paragraphs that do not apply to your study.
- Be brief as possible without omitting essential information.
- Avoid redundancy
- **EXPLAIN ALL MEDICAL TERMINOLOGY IN LAY TERMS (AVOID MEDICAL JARGON). THE CONSENT MUST BE TAILORED TO AN 8TH GRADE READING LEVEL**