**

Informed Consent Form

**INTRODUCTION**

You are being invited to take part in a research study. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

**BACKGROUND AND PURPOSE**

This research study is sponsored by

This research study is funded by

The Principal Investigator *\_\_\_\_\_\_\_\_\_\_\_\_* for this study:

receives financial support for the conduct of the research project from:

Specify:

receives personal income for(such as other work such as payments for lectures or for consultations):

Specify:

has a financial interest in (for example stocks):

Specify:

may receive royalties or money form patents related to the subject of the research

Specify:

A total of  subjects at  institutions will be asked to participate in this study. You will be one of approximately  subjects to be asked to participate at this location.

**STUDY PROCEDURES**

If you decide to take part in this study this is what will happen:

**DURATION OF THE RESEARCH**

This research study is expected to take approximately . Your individual participation in the project will take .

**POSSIBLE RISKS OR DISCOMFORTS**

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur. Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

There may be unknown risks or discomforts involved. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study.

Sometimes during the course of a research study, new information becomes available about that might change a person’s decision to stay in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your research doctor will arranges for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue. Potential benefits:

**POTENTIAL BENEFITS**

The benefits of participating in this study may be:

You may receive no benefit from participating, however, your participation may help the investigators better understand *.*

**ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH**

The following alternative procedures or treatments are available if you choose not to participate in this study :

**RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION**

**CONFIDENTIALITY**

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

We will include information about your study participation in your medical record.

If the study involves a product regulated by the FDA*,* there are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, [FDA, is checked above] and other study monitors may look at or copy portions of records that identify you.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**COSTS TO PARTICIPANTS AND PAYMENT**

You 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, you will still pay these co-payments for VA care and medications that are not part of this study.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

**MEDICAL TREATMENT AND COMPENSATION FOR INJURY**

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

The VA may not provide necessary medical care for treatment for injuries in research conducted for VA under contract with an individual or non-VA organization.

Insert names and contact telephone of subject(s) if the subject has a medical concern or gets hurt or sick as a result of taking part of this study:

**DURING THE DAY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_.**

**AFTER HOURS:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **at** \_\_\_\_\_\_\_\_\_\_\_\_.

**PARTICIPATION IS VOLUNTARY**

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don’t take part, you can still receive all usual care that is available to you.

If you are a VA employee,Refusal to take part in the study will in no way influence your employment, ratings, or subsequent recommendations,

If you are a student learner, or trainee, refusal to take part in the study will in no way influence your ratings, subsequent recommendations, or academic progress

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

**PERSONS TO CONTACT ABOUT THIS STUDY**

The investigator and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, you may speak with a member of the study staff:

Research Staff Member Name:

Research Staff Member Phone Number:

Members of the Institutional Review Board can also answer your questions and concerns about your rights as a research subject. The IRB office number is *.* Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

**GENETIC RESEARCH**

Federal laws and policies provide you with protection from discrimination by health insurance companies, group health plans, and most employers based on your genetic information.  A new federal law, the Genetic Information Nondiscrimination Act (GINA) generally will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information obtained from this research.
* Health insurance companies and group health plans may not use your genetic information obtained from this research when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

FUTURE USE OF DATA AND RE-CONTACT