Subject Name: _____ **Date** _____

Title of Study: _____

Principal Investigator: _____ **VAMC:** _____

UF Institutional Review Board
UNIVERSITY of FLORIDA

<For IRB use only>

INFORMED CONSENT FORM
to Participate in Research

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

This is a research study of
<insert one phrase or sentence, e.g. "a new drug to treat …" or "how a new monitor works'" or "the function of certain blood cells" etc.>.

Could participating in this study offer any direct benefits to you? <Yes or No>, as described on page <enter page #>.

Could participating cause you any discomforts or are there any risks to you? <Yes or No>, as described on page <enter page #>.

Subject Name: _____ **Date** _____

Title of Study: _____

Principal Investigator: _____ **VAMC:** _____

Please read this form which describes the study in some detail. I or one of my co-workers will also describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any VA or other benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, concerns, complaints, wish to discuss problems or talk to someone independent of the research staff, obtain information, or offer input, please call either of the following offices: (1) the University of Florida Institutional Review Board (IRB) office at (352) 273-9600; or (2) the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 374-6069. If you decide to take part in this study, please sign this form on page <enter page #>.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

For PI Use:

Participant Social Security Number: _____

SSN should be written on this consent form by the research team prior to scanning into the VHA health record; if the subject does not have a VHA health record, this requirement is N/A.

2. What is the Title of this research study?

Grants and IRB projects must have EXACT same title or you must submit DSR's title verification form from
http://rgp.ufl.edu/research/pdf/irb_2.pdf

3. Who can you call if you have questionsconcerns, or complaints about this research study?

Include a telephone number where subjects can reach a person who can help them after hours and on weekends and holidays. If applicable include a qualified clinician responsible for study-related healthcare decisions. If that person is not the Principal Investigator, include the following:

Contact information for emergencies after hours or on weekends or holidays:

4. Who is paying for this research study?

The sponsor of this study is *Examples: (1) VHA - only if there is no other support. (2) your sponsor's name, but only if funding has been **obtained**. (3) **NIH Grants:** If the NIH is the sponsor, you must submit a copy of the grant with the IRB submission This information must be consistent with information in the IQ.*

5. Why is this research study being done?

The purpose of this research study is to

You are being asked to be in this research study because
Include both sentences or a similar alternative. Be sure to describe the experimental purpose of the study in terms the subject will understand.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

Normal clinical care is medical or other treatment or services that you would receive even if you did not participate in this research study.

If the protocol will involve normal/usual care, clearly describe the normal/usual care and include the following:
Your health care provider, who may also be the investigator of this research study, will provide and monitor your usual care, alert you if there are any issues with this care and determine if discomforts or problems you may have are related to the usual care. You should discuss the risks and benefits of your usual care with your healthcare provider.

7. What will be done only because you are in this research study?

Describe any screening, baseline, treatment, and end-of-study assessments that are being done only for research purposes. If a procedure that is normally used in health care would not normally be part of the treatment for the subjects in your study, that procedure is considered a research procedure and a full description of the procedure and its risks should be included in the Consent Form.

***NOTE 1 TO PRINCIPAL INVESTIGATOR**:*

If your research uses any drugs or devices that are being used in a manner not previously approved by the FDA(ncluding not only IND drugs or experimental devices, but also using approved drugs or devices in unapproved manners or for unapproved conditions) you must include a statement that specifically identifies these items.

***NOTE 2 TO PRINCIPAL INVESTIGATOR**:*

If your research involves any of the following, See ICF Standardized Language at http://irb.ufl.edu/irb01/forms6.htm :

1. *Placebo and/or randomization*
2. *HIV Testing*
3. *Magnetic Resonance Imaging (MRI)(SEPARATE DOCUMENT)*
4. *Genetic Testing*

<insert name of PI> and the research team conducting the research procedures described above, will monitor how you do during the research. If you have any questions about the research procedures now or at any time during the study, please contact <insert name of PI> in question 3 of this form.

8. How long will you be in this research study?

Provide specific information about the time commitment expected if the individual chooses to participate. State how long subjects will actively participate in study interactions or interventions, including long-term follow-up. Include how long a study session will last, how often and where study sessions will be held, and how long follow-up will last..

9. How many people are expected to take part in this research study?

Provide specific information about how many people are expected to participate in this research, including not only locally but also at all sites if the study is being conducted at multiple centers. This is important because it helps the subject understand how many people are being exposed to the risks and benefits of the study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

Clearly define and describe which potential risks are related to the research and, therefore, must be discussed with the research team, versus those associated solely with usual care provided by the subject's health care provider. Risks that do not result from the research, but that result solely from treatments or services described in Q6 above should not be described in the consent form.

In general, use at least one paragraph for each risk, and put the risks in order from greatest risk or most frequent risk to least risk or least frequent risk. Thus, in a drug study, the risk of venipuncture should come after the risks of the drug.
If your research includes any of the items below please download Standardized Text from the IRB website at: http://irb.ufl.edu/irb01/forms.htm#standard
Venipuncture
Reproductive Risks (SEPARATE DOCUMENT)
*MRI **Special Note:** Women of childbearing potential require a pregnancy test before undergoing an MRI*
Radiation or radioactive materials
HIV Testing
Genetic Testing
Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

Other possible risks to you may include: *(address: psychological, social, economic, and/or legal risks if they are a part of the research).*

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform <insert name of PI> (listed in question 3 of this consent form) or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of any new information that may become available and might affect your decision to remain in this study. This includes, but is not limited to, information that may affect your safety, well-being or medical care.

If you wish to discuss the risks or discomforts described above or any discomforts you may experience, please ask questions now or call the PI or contact person listed in question 3 of this form.

11a. What are the potential benefits to you for taking part in this research study ?

You must state one of the following:

1. There is no direct benefit to you for participating in this research study.
(Note to researcher: If your Protocol states there is no benefit you must make the same statement here.)

2. You may or may not benefit from participating in this research study. The possible benefits are... (Researcher to insert possible benefits the subject might receive)

3. You will directly benefit from participating in this research study by... (Researcher to insert benefits the subject will definitely receive. Note that it is a rare study where benefits can be stated with absolute confidence.)"

*Do **NOT** put information about payment or compensation in this section. This section is primarily for information about **health** or other, non-financial benefit.*

*Do **NOT** overstate benefits because this may be inadvertently coercive. In general, you should not claim that a benefit **will** occur, but rather that it **may** occur and that any benefit cannot be guaranteed.*

11b. How could others possibly benefit from this study?

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, <insert name of PI> may benefit if the results of this study are presented at scientific meetings or in scientific journals.

<If any conflict of interest exists, include appropriate language here>

12. What other choices do you have if you do not want to be in this study?

For treatment studies: Specific Alternatives to participation should be listed. List standard of care, whether the experimental treatment or therapy can be obtained without being in the study, and/or other available treatments or medications.

For non-treatment studies, add the following: The option to taking part in this study is doing nothing. If you do not want to take part in this study, tell the Principal Investigator and do not sign this Informed Consent Form.

Student subjects. There are two options for this. Download the appropriate text from http://irb.ufl.edu/docs/st-stud.doc

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If appropriate, describe in the box above the consequences of a subject's decision to withdraw and procedures for orderly termination of participation by the subject.

If you decide to withdraw your consent to participate in this study for any reason, please contact <insert name of PI or study coordinator> at <phone number>. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study.

NOTE 1 - use of already collected data:
If subjects withdraw from the research, they should have the right to withdraw ***completely*** *from the study, including the withdraw/removal of any their identifiable*

information. Sometimes this isn't feasible – such as if the research already relies on the data because it has been analyzed and published. In the event that the researcher, sponsor, or other entity (e.g. FDA) intends to retain the data despite subject withdraw, you should (1) inform subjects in this section of this possibility, and (2) de-identify the data if possible (removal of all identifiers as defined by HIPAA, including dates). This information must be consistent with information included in the HIPAA Authorization.

NOTE 2 – collecting additional / future data:

If you wish to collect additional follow up data from the subject after their withdrawal (e.g. collecting data from their standard medical treatment via chart review) you must obtain additional IRB approved consent from the subject before doing so. If you do not obtain specific informed consent from the subject to continue collecting data you may not access any private (e.g. medical records) or public (e.g. Social Security Death Index) for research purposes.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

An unexplained statement that the investigator or sponsor may withdraw subjects at any time is not adequate. A statement that the investigator may withdraw subjects if they "do not follow study procedures" is not appropriate; rather subjects may be withdrawn if they do not follow the instructions given to them by the investigator.

Note: If you have a sponsor's protocol, this information should be consistent with the information provided in the protocol.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

There will be no costs to you for any procedure, treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not being done only for this study (e.g., normal hospital and prescription expenses which are not part of the research study) will be charged to you or your insurance. These

costs may not be charged if you are a veteran and you are being treated at the North Florida/South Georgia Veterans Health System (NF/SG VHS), however some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study."

The appropriate consent language required for this question will be based on the specific terms and conditions agreed to by the institution and the sponsor. Go to the Study Costs Template to find the appropriate language to cut and paste here.

Study Costs Template (http://irb.ufl.edu/docs/coststemplate.doc)

15. Will you be paid for taking part in this study?

Compensation should be pro-rated if there is more than one study session. If there is only one session, and there are several difficult procedures, you may be required to prorate payment according to the procedures. You must specify the timing of compensation, such as will it occur after each study visit, halfway through study participation, after the subject has completed participation in the study, or after the study is completed. You should also specify how long it should take for payment to be remitted.

Add the following if applicable:

If you are paid for taking part in this study, your name and social security number will be reported to the appropriate <University> or <VA> employees for purposes of making and recording the payment. You are responsible for paying income taxes on any payments provided by the study. Any payment made to you on a VA-funded study, regardless of amount, will be reported to the Internal Revenue Service (IRS).f the payments total $600 or more, the University must report the amount you received to the Internal Revenue Service (IRS).

16. What if you are injured because of the study?

The appropriate consent language required by UF for this question will be based on the specific terms and conditions agreed to by UF and the sponsor. Go to the Injury Related Costs Template to find the appropriate language to cut and paste here.

Injury Related Costs Template (http://irb.ufl.edu/docs/injurycosttemplate.doc)

If you experience an injury or illness as a result of your participation in this VA approved research study, all medical treatment considered necessary by your physician (emergency as well as medical treatment beyond emergency) will be provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases the VA may approve private care for a non-veteran.

If you do not follow study procedures, you may be treated by the VA on the basis of your veteran's eligibility. If you are not a veteran and have not followed study procedures the VA can only provide limited care at your expense.

No additional money has been set aside for pain, suffering or any money losses you may suffer during your treatment. You have not waived any legal rights by signing this form.

In the event of a research-related injury, have questions about any discomforts that you experience while participating in this study or if you experience an adverse reaction, please immediately contact the Principal Investigator at <insert phone number> during the day and <insert phone number> after business hours. If you seek emergency hospitalization in a private hospital because you are unable to come to the VA, have a family or friend contact your study doctor so that the VA can coordinate care with the private hospital.

17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these

research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Certain federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), or the VA Office of the Inspector General (OIG), that oversee human subject research may also have the legal right to review your records. *[HIDDEN TEXT if this study involves a test article regulated by the FDA include the language: The Food & Drug Administration (FDA) could inspect your research records that include your medical record.]* Otherwise your research records will not be released without your permission unless required by law or a court order.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

Subject Name: _____ **Date** _____

Title of Study: _____

Principal Investigator: _____ **VAMC:** _____

SIGNATURES

See instructions; replace text below if subjects will not be competent adults.

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

_____ _____

Signature of Person Obtaining Consent Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your privacy will be protected. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting Date

In the unlocked section above please be sure to add any other pertinent signature sections if needed (legally authorized representative, Assent, etc). For more information read the Informed Consent instructions at
http://irb.ufl.edu/docs/icf-instruct.doc