INFORMED CONSENT FORM

to Participate in Research, and

AUTHORIZATION

to Collect, Use, and Disclose Protected Health Information (PHI)

If this study seeks to enroll people who cannot consent for themselves (e.g. potential subjects who are (a) children or (b) incapacitated adults) you may want to include a descriptive box at the beginning of the consent helping the reader understand the tense of the study. For example, the consent may refer to the subject as “you” throughout the consent. If a parent is reading the consent however, “you” may actually be the child rather than the parent reading the consent. For more information visit: http://irb.ufl.edu/docs/st-youyourchild.docx.

INTRODUCTION

Name of person seeking your consent: ____________________________________________

Place of employment & position: ______________________________________________

Please read this form which describes the study in some detail. A member of the research team will 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 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, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")
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://research.ufl.edu/research/pdf/irb_2.pdf

3. Who do you call if you have questions 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:

Principal Investigator:

Other research staff: <if appropriate, otherwise delete>

4. Who is paying for this research study?

The sponsor of this study is Examples: (1) University of Florida - 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.

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.

If this study involves an FDA regulated drug or device (see http://irb.ufl.edu/docs/st-clinicaltrials.gov.docx for more information about if your study qualified), then add the following language:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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" means procedures that would normally be used as part of the treatment for patients with a particular problem.

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 involves the use of the subject’s Social Security Number for any reason other than payment to the subject, please inform the subject in this section and apply for an exception from the Privacy Office (telephone 352-273-5094 or http://privacy.ufl.edu/pdf/PrivacyPolicyProcedures.pdf - Page 29)

You also must insert the following language after informing the subject that you will use the Social Security Number:

Your Social Security Number will be collected because the University is specifically permitted by law to do so, or because the University must collect it in order to perform its legal duties and responsibilities under the study. If you have questions about the collection and use of Social Security Numbers, please visit: http://privacy.ufl.edu/SSNPrivacy.html

NOTE 2 TO PRINCIPAL INVESTIGATOR:

If your research uses any drugs or devices that are being used in a manner not previously approved by the FDA. This includes not only IND drugs or experimental devices, but also using approved drugs or devices in unapproved manners or for unapproved conditions. If so, you must include a statement that specifically indicates these items.
NOTE 3 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)
4. Genetic Testing

If you have any questions now or at any time during the study, please contact one of the research team members listed 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 be involved, including 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?

   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
   MRI **Special Note:** Women of childbearing potential require a pregnancy test before undergoing an MRI
   Radiation or radioactive materials.
   HIV Testing

   Genetic Testing – If genetic testing is being performed in your study, insert the standardized language available at: http://irb.ufl.edu/docs/st-gina.doc in this section.

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

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 affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

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 one of the research team members listed in question 3 of this 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 new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in 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, the Principal Investigator listed in question 3 of this form 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 one of the research team members listed in question 3 of this form. 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?

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?
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 (http://irb.ufl.edu/docs/coststemplate.doc) to find the appropriate language to cut and paste here.

http://irb.ufl.edu/docs/coststemplate.doc

For PIs in the Health Science Center

Does this project require ANY technical/professional services including, but not limited to, the following:

- blood draws
- tissue samples
- tests
- procedures
- examinations
- evaluations

☐ NO
☐ YES – Per UF clinical research fiscal compliance policy, standards, and procedures, your study must be evaluated for fiscal and billing risk by the Research Administration and Compliance (RAC) office (COM-RESEARCH-ADMIN-COMP-L@LISTS.UFL.EDU).

This requirement applies regardless of who is paying for the services and applies even if your study is not classified as a “Clinical Trial”.

To obtain your billing plan approval, email the Research Administration and Compliance (RAC) office (COM-RESEARCH-ADMIN-COMP-L@LISTS.UFL.EDU) or call 273-5398. Learn more at: http://ctc.health.ufl.edu/index.shtml.

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 more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. If the payments total $600 or more or you are a nonresident alien, payment will be processed through the University of Florida Accounts Payable department and the University must report the amount you received to the Internal Revenue Service (IRS). If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html

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/injurycoststemplate.doc)

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:
Investigator must list/describe the protected health information that will be created, used and shared with others to determine the subject's eligibility for the study and information obtained through the course of the study. The list/description must contain sufficient specificity to identify the information in a specific and meaningful fashion. The following list provides examples and categories for investigators to consider listing here. As a general rule, the more sensitive the information, the more specifically it should be described (that is, HIV results). You should only request information that is consistent with your protocol (for example, do not request mental health records if they are not pertinent to your study objectives).

- Complete past medical history to determine eligibility criteria
- Information about HIV/AIDS
- Information about hepatitis infection (inflammation of the liver)
- Information about sexually transmitted diseases
- Information about other diseases that must be reported to Public Health authorities such as those caused by infection
- Records of physical exams
- Laboratory, x-ray, MRI, and other test results
- Diaries and questionnaires
- Records about study medications or drugs
- Records about study devices
- Information related to your mental health condition
- Complete past medical history (there are some studies that use the first statement, but the medical history is kept as a part of the study and not for the sole purpose of determining eligibility criteria)
- Ability or potential ability to conceive a child
- Your social security number for compensation purposes

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.
18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

Investigator must list each purpose for the collection, use and sharing of the protected health information. The investigator should list as one purpose, the same purpose statement contained in the informed consent (Reference Item 5). Additionally, the investigator may list all additional purposes. The following, non-exhaustive list of possible purposes provides examples and categories for investigators to consider listing here:

- to determine the effectiveness of the study drug (device, or procedure) in treating ___
- to evaluate a possible new use for the study drug (device, or procedure)
- to determine the causes or effects of the study condition ____

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida 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).

Investigator must provide an exhaustive list of the names or other specific identification of any other persons or classes of persons who may collect, use or disclose the information and who will come into direct contact with the subject. For example, named local independent Data Safety Monitoring Board (“DSMB”), named outside collaborators involved in the study, or any other persons or specific classes of persons who will be in any way collecting, using, or disclosing the subjects protected health information. Be cautious here, it is better to be over rather than under-inclusive.
20. **Once collected or used, who may your protected health information be shared with?**

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- North Florida/South Georgia VHS
- Your insurance company for purposes of obtaining payment

*Investigator must provide an exhaustive list of any additional names or other specific identification of the persons or classes of persons to whom the protected health information will be disclosed, who are not already listed above. For example, an external Review Board or consultant, such as an external DSMB. Persons or classes of persons listed here should only be those outside the University, Shands, or the Malcom Randall VA Medical center (Gainesville).*

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. **If you agree to take part in this research study, how long will your protected health information be used and shared with others?**

Your PHI will be used and shared with others <insert time period>

*Investigator may input (1) “until the end of study”, (2) enter a specific date, (3) “For” X “number of years after the study closes”, or (4) “Your PHI will be collected until the end of the study. This information will be used and disclosed forever since it will be stored for an indefinite period of time in a secure database.” If you allow subjects to withdraw, you may wish to add the following sentence: “If you withdraw your permission for the use and sharing of your PHI, then your information will be removed from the database.”*

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use
and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.
See the Informed Consent instructions at http://irb.ufl.edu/docs/icf-instruct.doc; 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 alternative to being in the study; and how the participant’s protected health information will be collected, used, and shared with others:

________________________________________  
Signature of Person Obtaining Consent and Authorization  
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 protected health information will be collected, used and shared with others. 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 questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

________________________________________  
Signature of Person Consenting and Authorizing  
Date

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