RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

**TITLE:**

**VCU IRB PROTOCOL NUMBER:**

**INVESTIGATOR:**

**SPONSOR: [*if no sponsor for this research, delete this field*]**

*[This template is based on a drug or device research study.* ***The same elements/sections are required*** *for other research studies (psychology, sociology, etc.). See Social-Behavioral Consent Template on VCU IRB Web site.]*

[Instructions and comments are in italics and []. Block and delete most after reading and following if needed. Find “drug name” and replace the initial use of the term with the actual generic name of the drug if it exists and any brand, chemical, or slang name you will be using later in the consent. Subsequent replacement of “drug name” may be with the generic, brand, chemical, or slang name of the drug, in a consistent manner. Find “disease name” and replace with the actual disease or condition. Delete those sections that are not applicable.]

Please ask the study doctor or the study staff to explain any information in this consent document that is not clear to you. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

*[Include if appropriate]* In this consent form, “you” always refers to the research participant. If you are a legally authorized representative, please remember that “you” refers to the study participant.

**PURPOSE OF THE STUDY**

*[What follows are only examples. If they are not applicable, remove the language and explain the purpose of the study.]*

*[Option 1]* The purpose of this research study is to test the safety, tolerability, and effectiveness of the drug name when used to treat disease name. You are being asked to participate in this study because you have been diagnosed with disease name, and may meet the study entry requirements.

*[Option 2]* Disease causes symptoms or condition, which may involve *[insert short discussion of how or why the drug might affect the disease or condition. Cannot promise efficacy or safety. Alter the wording if the study has a different purpose, for example, is limited only to safety and tolerability, no efficacy.]*

**DESCRIPTION OF THE STUDY**

*[What follows is an example. If not applicable, remove this language and provide a description of the study.]*

Drug name is an investigational drug, which means it has not been approved by the U. S. Food and Drug Administration (FDA). In this study, drug name will be compared to , an approved drug, and to placebo (a look-alike inactive substance). [*or other, depending on design]*

Your participation in this study will last up to *[insert* *length of time]*. Approximately *[insert* *how many]* individuals will participate in this study.

Significant new findings developed during the course of the research *[Insert new findings such as additional risks or discomforts]* which may relate to your willingness to continue participation will be provided to you.

# PROCEDURES

***[If any of the treatments or procedures have not been well studied, include a statement that the treatment or procedure might involve risks to the participant, which are currently unforeseeable.]***

*[What follows is an example.* *Your narrative must include any invasive and/or non-standard procedures, and any procedures that are experimental.]*

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered.

At your first study visit (Visit 1), your medical history will be taken and a physical exam will be performed. This exam will include measurements of your weight and vital signs (pulse, blood pressure and temperature). Blood and urine samples will be collected for routine lab tests. Approximately 1 to 2 tablespoons of blood will be collected*. [If done, mention pregnancy test at this time.]*

*Ex:* Women of childbearing potential will have a pregnancy test done.

*[If tests are done that require reporting of positive results to the Health Department (e.g. hepatitis, HIV, STDs), these must be mentioned, along with that information.]*

*Ex:* Your blood sample will also be tested for hepatitis and HIV. Virginia state law requires the study staff to report the results of positive tests for hepatitis and HIV to a local health agency.

You will have an electrocardiogram (ECG - tracing of the electrical activity of the heart).

*[If random]*

You will be randomly assigned (like the flip of a coin) to receive either or *. [Can also list as bullets if several arms.]*

You have chance in of being assigned to placebo, and chance in of receiving . *[Or can say],* You have an equal chance of being assigned to any one of the groups.

*[If double blind]*

Neither you nor the study doctor will know which study drug *(or procedure or treatment, etc.)* you are receiving. This information is available to the study doctor if needed in an emergency. This is done (blinding) so that a fair evaluation of results may be made.

*[If single blind] [Be sure the procedure discussion does not “blow the blind”]*

You will not know which study drug you are receiving. This is done (blinding) so that a fair evaluation of results may be made.

*[If visits are frequent, complicated, or involve varying activities, consider inserting a table in this section, or providing a pull out table as an appendix]*

Visit 2 will take place after Visit 1. Your vital signs will be measured, and ................ If you qualify for the study, you will be given study drug and you will be instructed on how to take your study drug.

Visits 3 through 6 will be scheduled at . At each visit except Visit 6, your vital signs will be checked, and ................ You will be asked about your health since the last visit. You will receive a new supply of study drug and ................................

Visit 6, the last visit, will include a physical exam, ECG and blood and urine samples for lab tests. You will be asked about your overall experience with the study drug.

At each visit, you should bring all of your remaining study drug supply to the research clinic.

**RISKS AND DISCOMFORTS**

*[What follows is only an example.]*

*[If there are more than 3-4 side effects in a list, please present in a vertical, bulleted format for ease of reading. Also please use the non-technical meaning, rather than a medical term (ex, use “gas” instead of “flatulence”, or “weakness” instead of “asthenia”)] Ex:*

Possible side effects associated with the use of drug name include:

* headache
* dizziness
* sleepiness
* nausea
* indigestion

Allergic reaction todrug name is possible. Severe allergic reactions can be life threatening.

*[Or side effect information supplied by the sponsor]*

***[If any of the treatments or procedures have not been well studied in pregnant women, include a statement that the treatment or procedure might involve risks to*** *the participant* *(if applicable, insert: or to the embryo or fetus, if the participant is or may become pregnant)* *that are currently unforeseeable.]*

*[Include risks and side effects for each comparator drug, if any].*

*[IF APPLICABLE]*

*[For women only studies]*

As the study procedures might injure an unborn child, pregnant women may not participate. Women who might become pregnant should use a medically accepted form of birth control such as total abstinence, birth control pills, an IUD, diaphragm, progesterone injections or implants, or condoms plus a spermicide. Methods of birth control other than total abstinence are not 100% effective, and should a women become pregnant there is a risk of injury to an unborn child. For similar reasons, women who are nursing an infant may not participate.

*[For studies with women and men]*

As the study procedures might injure an unborn child, pregnant women may not participate. Women who might become pregnant should use a medically accepted form of birth control such as total abstinence, birth control pills, an IUD, diaphragm, progesterone injections or implants, or condoms plus a spermicide. Methods of birth control other than total abstinence are not 100% effective, and should a women become pregnant there is a risk of injury to an unborn child. For similar reasons, women who are nursing an infant may not participate.

For men, the study procedures might increase the risks for birth defects of any child conceived during treatment and several months after treatment is stopped. Men in this study who have the potential of fathering children should be aware of this possibility and consider using a medically accepted form of birth control.

*[For men only studies]*

For men, the study procedures might increase the risks for birth defects of any child conceived during treatment and several months after treatment is stopped. Men in this study who have the potential of fathering children should be aware of this possibility and consider using a medically accepted form of birth control. For men this would include total abstinence and condoms plus a spermicide, or for the female partner, birth control pills, an IUD, diaphragm, progesterone injections or implants. Methods of birth control other than total abstinence are not 100% effective, and should a women become pregnant there is a risk of injury to an unborn child.

*[List risks of other procedures if needed especially any invasive procedure (ex, if study required tympanocentesis, or endoscopy, or endometrial biopsy, etc.). Also include imaging and x-ray studies if in excess of what would be done as part of standard treatment.]*

*[If a treatment study, include]*

Your condition may not get better or may become worse while you are in this study.

*[If study drug is taken home, include]*

Only the study participant can take the study drug. It must be kept out of the reach of children and persons who may not be able to read or understand the label.

**USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION**

*[If study involves use of Protected Health Information (PHI), include this section unless 1) the study does not involve the use or disclosure of protected health information or 2) a separate authorization form will be utilized. Edit the content of this section appropriately. For more information, see the HIPAA for research webpage at* <http://www.research.vcu.edu/human_research/hipaa-guidance.htm>*]*

**Authority to Request Protected Health Information**

The following people and/or groups may request my Protected Health Information:

|  |  |
| --- | --- |
| * Principal Investigator and Research Staff | * Study Sponsor |
| * Research Collaborators | * Institutional Review Boards |
| * Data Safety Monitoring Boards | * Government/Health Agencies |
| * Others as Required by Law |  |

### Authority to Release Protected Health Information

The VCU Health System (VCUHS) may release the information identified in this authorization from my medical records and provide this information to:

|  |  |
| --- | --- |
| * Health Care Providers at the VCUHS | * Principal Investigator and Research Staff |
| * Study Sponsor | * Research Collaborators |
| * Data Coordinators | * Institutional Review Boards |
| * Data Safety Monitoring Boards | * Government/Health Agencies |
| * Others as Required by Law |  |

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

**Type of Information that may be Released**

*[This section to be filled-out by the Principal Investigator – double click on the boxes to insert a check]*

The following types of information may be used for the conduct of this research:

|  |  |  |  |
| --- | --- | --- | --- |
| Complete health record | Diagnosis & treatment codes | | Discharge summary |
| History and physical exam | Consultation reports | | Progress notes |
| Laboratory test results | X-ray reports | | X-ray films / images |
| Photographs, videotapes | Complete billing record | | Itemized bill |
| Information about drug or alcohol abuse | | Information about Hepatitis B or C tests | |
| Information about psychiatric care | | Information about sexually transmitted diseases | |
| Other (specify): | | | |

### Right to Revoke Authorization and Re-disclosure

You may change your mind and revoke (take back) the right to use your protected health information at any time. Even if you revoke this Authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

**BENEFITS TO YOU AND OTHERS**

*[What follows are examples. If not applicable, remove this language and describe any benefits to the participants and others, which may reasonably be expected from the research.]*

There is no guarantee that you will receive any medical benefits from being in this study.

*[If not a treatment study]* This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. The information from this research study may lead to a better treatment in the future for people with disease name. You may benefit from the physical exams, ECGs, lab tests, and other study procedures.

*[Include if appropriate]* Please be aware that the investigative team and the University may receive money for the conduct of this study.

**COSTS**

Study drug will be provided by the sponsor. There are no charges for the study visits. *[Or other list as appropriate] [If will be billed for any additional costs, need to tell them, also that insurance may not pay for research charge.]*

**PAYMENT FOR PARTICIPATION**

*[Only need to have if are paying, or the protocol says must inform are not paying. Use*

*straightforward language and always include the per visit amount.]*

*Ex:* You will be paid $\_\_\_\_\_ if you complete all scheduled study visits. If you withdraw from the study before completion, you will be paid $\_\_\_\_\_ per completed study visit. Total payments within one calendar year that exceed $600 will require the University to annually report these payments to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

**ALTERNATIVE TREATMENT**

If you decide not to enter this study, there are other treatments available. These include *[List of major drugs and/or therapies]*. The study doctor will discuss these with you. You do not have to participate in this study to be treated for [*disease name*].

*[If not a treatment study - Remove “Treatment” from section title and add]*  Your alternative is not to participate in this study.

**CONFIDENTIALITY *[section updated June 2014]***

Potentially identifiable information about you will consist of *[List e.g., tissue samples, surveys, interview notes and recordings, audiotapes of consultations and interviews, and data abstracted from the medical record]*.

*[If this is NOT clinical research or is not a clinical trial]*

Data is being collected only for research purposes.

*[If this is a clinical research study that has the potential for clinical billing or is a clinical trial or research information will be placed in the medical record at VCUHS]*

It will be noted in your protected electronic medical record at VCU Health System that you are in this clinical trial. Information about the study including any medications you may receive will be noted in the record. This information is protected just as any of your other medical records are protected.

*[Note how the data will be identified, stored and protected and destroyed. Please review VCU policy, State and FDA regulations and sponsor requirements regarding retention of records. As appropriate to this study add information regarding retention in this section]. Ex:* Your data will be identified by ID numbers and birthdates, not names, and stored separately from medical records in a locked research area. All personal identifying information will be kept in password protected files and these files will be deleted *note time frame]*. Other records *[Note which ones]* will be kept in a locked file cabinet for *[Note time frame]* after the study ends and will be destroyed at that time. *[Note which files]* will be kept indefinitely. Access to research data will be limited to study personnel. A data and safety monitoring plan is established.

*[If there is the potential for you to discover suspected child or elder abuse, as an employee of an institution of higher education in Virginia, you are obligated to report this. Include a statement indicating the requirement to report. If there is the potential for any participant to disclose that they may cause injury to themselves or others, you should state in this section that you are required by law to report that information to the appropriate authorities.]. Ex:*  We will not tell anyone the answers your child gives us. But, if your child tells us that someone is hurting her or him, or that she might hurt herself or someone else, the law says that we have to let people in authority know so they can protect your child.

VCU and the VCU Health System have established secure databases to help with monitoring and oversight of clinical research. Your information may be maintained in these databases but are only accessible to individuals working on this study or VCU/VCUHS officials who have access for specific research related tasks. Identifiable information in these are not released outside VCU unless stated in this consent or required by law. Personal information about you might be shared with or copied by authorized officials of the Federal Food and Drug Administration or the Department of Health and Human Services.

*[If research is conducted in foreign countries include the following statement:]* If the research is conducted in foreign countries (where a study drug or device may be considered for approval), personal information pertaining to you may be shared or copied by authorized agents of governmental agencies in those countries.

*[Include this language in its entirety (required by the FDA) if this study is a clinical trial]* A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/), as required by U.S. Law.  This Web site will not include information that can identify you.  At most, the Website will include a summary of the results.  You can search this Web site at anytime.

*[If research will have a Certificate of Confidentiality from the NIH, insert the following:]*

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

*[If you intend to make voluntary disclosure about things such as child abuse, intent to hurt self or others, or other voluntary disclosures. include language such as the following.]* The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. [State here the conditions under which voluntary disclosure would be made. If no voluntary disclosures will be made, the researchers should so state.]

Although results of this research may be presented at meetings or in publications, identifiable personal information pertaining to participants will not be disclosed.

**DATA REGISTRIES**

*[Consider implementing the following layered levels of consent if a registry is being created or you will be contributing to an existing registry. Layers may not be required, although participants may feel they have more control over their participation. If utilizing these layers, your registry must have provisions for respecting them.]*

1. I give permission for my data/tissue samples to be stored and used for research related to [*insert topic*]

YES \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NO \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. I give permission for my data/tissue samples to be stored and used for future research about other health problems.

YES \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NO \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3. I give permission for my data/tissue samples to be stored; however, I want to be contacted prior to any future use of my data/tissue samples for research.

YES \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NO \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**GENETIC TESTING**

*[Only need to have if genetic testing is involved.]*

***[For Multi-center protocols (not initiated at VCU)]***

*[Include a description of the research plan with attention to the special concerns raised by genetic testing. (These concerns may be inferred from the section on VCU-initiated protocols below.) Investigators may need to modify the proposed informed consent form in order to provide this information. If participants may make choices concerning the use of their samples, these should be indicated in a check-off format (see below). Investigators should take care, however, that the modified informed consent form reflects that the actual research plan. This may be difficult if the research plan is vague.]*

***[For VCU-initiated protocols, the following issues should be addressed]***

**Background information:** The research involves genetic testing. Genetic testing may reveal information about the likelihood that a person or his or her relatives may develop certain diseases. Genetic testing may reveal information about who is related to whom. If known to employers or insurance companies, the results of genetic testing might affect a person's ability to obtain a job or health or life insurance.

Current and future studies: *[Consider implementing the following layered levels of consent:]*

1. My blood/tissue samples may be stored and used for future research about [*insert topic*].

YES NO

initial initial

1. My blood/tissue samples may be stored and used for future research about other health problems (for example, heart disease, osteoporosis, diabetes, etc.)

YES NO

initial initial

**Future contact concerning further genetic testing research:** *[Describe the circumstances under which participants might be contacted in the future concerning further participation in this or related genetic testing research. Consider offering the participant the option of opting out of such contacts at this time with a Yes/No response to a question formatted like those above.]*

**Future contact concerning genetic testing results:** *[If planned or possible future genetic testing results are unlikely to have clinical implications, then a statement that the results will not be made available to participants may be appropriate. If results might be of clinical significance, then describe the circumstances and procedures by which participants would receive results. Describe how participants might access genetic counseling for assistance in understanding the implications of genetic testing results, and whether this might involve costs to participants. Investigators should be aware that federal regulations, in general, require that testing results used in clinical management must have been obtained in a CLIA-certified laboratory.]*

**Withdrawal of genetic testing consent:** *[Describe whether and how participants might in the future request to have test results and/or samples withdrawn in order to prevent further analysis, reporting, and/or testing.]*

**Confidentiality:** *[Describe the extent to which genetic testing r*esults *will remain confidential and special precautions, if any, to protect confidentiality.]*

**COMPENSATION FOR INJURY or ILLNESS** *[This element is required for greater than minimal risk research as per §46.116(a)(6) and 21CFR50. It is not required, and generally not appropriate, for expedited research; no waiver of this element needs to be requested]*

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study.

To help avoid research-related injury or illness it is very important to follow all study directions.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL**

Your participation in this study is voluntary. You may decide to not participate in this study. Your decision not to take part will involve no penalty or loss of benefits to which you are otherwise entitled. If you do participate, you may freely withdraw from the study at any time. Your decision to with draw will involve no penalty or loss of benefits to which you are otherwise entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent. The reasons might include:

* the study doctor thinks it necessary for your health or safety;
* you have not followed study instructions;
* the sponsor has stopped the study; or
* administrative reasons require your withdrawal.

If you leave the study before the final regularly scheduled visit, *[Insert any consequences of a participant’s decision to withdraw from the research (i.e., side effects of tapering off of study drug(s),condition may worsen)) and procedures for orderly termination of participation by the subject (i.e., tapering off of study drug(s), follow-up visits with study team or patient’s physician).*]

**QUESTIONS**

If you have any questions, complaints, or concerns about your participation in this research, contact:

**[*Insert name and contact information of contact person for study*]**

and/or

**[*Insert name and contact information of additional contact person for study – (optional)*]**

*[List the name of the contact person and his/her contact information here. The contact person should be a full-time faculty or staff person. More than one contact may be listed. Give name and role of primary contact first.* ***Use bold type and larger font for names and contact information.****]*

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

If you have general questions about your rights as a participant in this or any other research, you may contact:

Office of Research

Virginia Commonwealth University

800 East Leigh Street, Suite 3000

P.O. Box 980568

Richmond, VA 23298

Telephone: (804) 827-2157

Contact this number for general questions, concerns, or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. General information about participation in research studies can also be found at <http://www.research.vcu.edu/irb/volunteers.htm>.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

# CONSENT

*[Change consent to permission if parents or legal guardian are agreeing to child’s participation. Add “My child” language as needed]*

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered.

By signing this consent form, I have not waived any of the legal rights or benefits, to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form once I have agreed to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Name, printed

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Signature Date

***[NOTE: DELETE THE PARENT OR LEGAL GUARDIAN LINES UNLESS THE STUDY ALLOWS FOR THE ENROLLMENT OF CHILDREN]* 1**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Parent or Legal Guardian

(Printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent or Legal Guardian Signature Date

***[NOTE: DELETE THE LEGALLY AUTHORIZED REPRESENTATIVE LINES UNLESS THE STUDY ALLOWS FOR THE INVOLVEMENT OF ADULTS WHO ARE UNABLE TO PROVIDE CONSENT]* 2**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Legally Authorized Representative

(Printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Legally Authorized Representative Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Conducting Informed Consent

Discussion / Witness 3

(Printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Conducting Informed Consent Date

Discussion / Witness

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Signature (if different from above) Date 4

1 *[If the study allows for the involvement of children, the permission of BOTH parents is required for certain categories of research unless one is deceased, unknown, incompetent, or only one parent has legal responsibility for care and custody. The categories of research are: (a) research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition (45.CFR 46.406) or (b) research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children. (45.CFR 46.407) Include lines for BOTH parents to print their names and lines for BOTH signatures and date if the research involves one of the two categories listed above.]*

2 *[If the study allows for the involvement of adults who are unable to provide consent, the consent of a legally authorized representative is required.]*

3*[A witness to the signature of a research participant is required by VA Code. If the witness is to be someone other than the person conducting the informed consent discussion, include a line for the witness to print his/her name and lines for signature and date.]*

4 *[The purpose of this signature is to ensure that the principal investigator is aware of who has been enrolled in studies. The principal investigator’s signature date need not correspond to that of subject or witness, but should be provided after both the subject and witness have signed.]*