APPROVED
Mmm dd, yyyy
WIRB®
Olympia, WA

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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:

PROTOCOL NR:
WIRB
VCU tracking number

SPONSOR:

INVESTIGATOR:

*This template is based on a drug or device research study. **The same elements / sections are required** for other research studies (psychology, sociology, etc.). They should be reworded to reflect the different circumstances of the research (i.e. less physical intervention, non-treatment, survey or questionnaire, etc.).*

Instructions are in italics ... Block and delete most after reading and following if needed. Find "drug name" *and replace with the actual drug name, and* "disease name" *and replace with the actual disease or condition.*

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. 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 subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

PURPOSE OF THE STUDY:
The purpose of this research study is to test the safety, tolerability, and effectiveness of the drug, 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.

[*Optional]* Disease causes symptoms or condition which may involve *[short discussion of how or why the drug might affect the disease or condition. Cannot promise efficacy or safety] Alter*

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the wording if the study has a different purpose, for example, is limited only to safety and tolerability, no efficacy.

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 *length of time* . Approximately *how many* subjects will participate in this study.

PROCEDURES

***[What follows is only an example] Your narrative must include any invasive and/or non-standard** procedures*

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 (eg 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"

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

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 to drug name is possible. Severe allergic reactions can be life-threatening.

[Or side effect information supplied by the sponsor]

There may be side effects which are unknown at this time.

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

If applicable:
Women who are pregnant or nursing a child may not participate in this study. Before entering this study, you and your study doctor must agree on the method of birth control you will use during the entire study. If you suspect that you have become pregnant during the study, you must

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notify the study doctor promptly. Pregnant women will be withdrawn from the study drug because the risks to a fetus from the study drug are not completely known.

Drawing blood from your arm may cause pain, bruising, lightheadedness, and, on rare occasions, infection.

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 subject 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.

You will be made aware of any significant new findings that may change your decision to remain in this study.

BENEFITS
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.

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 anything, need to tell them, also that insurance may not pay for research charges]*

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.

ALTERNATIVE TREATMENT

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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: This is not a treatment study. Your alternative is not to participate in this study.]

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What information may be used and given to others?

If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits

[board presenters to select additional from below as appropriate]

- Information obtained during this research about
  - HIV / AIDS
  - Hepatitis infection
  - Sexually transmitted diseases
  - Other reportable infectious diseases
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
  - The diagnosis and treatment of a mental health condition
- Records about any study drug you received
- Records about the study device

Who may use and give out information about you?

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. They may also share the information with [*insert SMO name,* an agent for the study doctor. *remove if no SMO]*

Who might get this information?

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Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.

For this study, "sponsor" also includes: [*if no CRO, delete this line also.]*

- [*insert CRO name,* an agent for the sponsor]

Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Virginia Commonwealth University
- The Western Institutional Review Board® (WIRB®)

[Pre-Board: Add any institutional names above WIRB]

Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by WIRB®. WIRB is a group of people who perform independent review of research as required by regulations.

What if I decide not to give permission to use and give out my health information?

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?

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You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically. *OR* this permission will be good until *[insert definite time limit if known]*

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

COMPENSATION FOR INJURY

In the event of physical and/or mental injury resulting from your participation in this research study, the Virginia Commonwealth University and the VCU Health System have no plan to provide long-term care or compensation.

If you are injured or if you become ill as a result of your participation in this study, contact your study doctor immediately. Your study doctor will arrange for short-term emergency care or 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 as a result of your participation in this study.

If the sponsor provides compensation for injury, include sponsor language as a separate paragraph. EX:
If you are injured or become ill as a result of participation in this study, contact the study doctor immediately. Emergency medical treatment will be provided by the study doctor. Your insurance will be billed for such treatment. The sponsor will pay any charges that your insurance does not cover. No other compensation is available from the study doctor or sponsor.

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VOLUNTARY PARTICIPATION AND WITHDRAWAL

[01]Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are 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, you may be asked by the study doctor to make a final visit for some of the end of study procedures.

QUESTIONS

In the future, you may have questions about your study participation. You may also have questions about a possible side effect, reaction to study medication, or a possible research-related injury. If you have any questions, contact:

Dr. _____
Address
Phone

If you have questions about your rights as a research subject, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789.

WIRB is a group of people who perform independent review of research.

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.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT *[Add "My child" language as needed]*

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I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered. I freely consent to participate in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

_____

Subject Name, printed

_____ _____

Subject Signature Date

[INCLUDE ASSENT, LAR LINES IF APPLY] [ALSO CAREGIVER IF APPLY]

_____ _____

Legally Authorized Representative Signature (if appropriate) Date

_____ _____

Signature of Person Conducting Informed Consent Discussion Date

_____ _____

Investigator Signature (if different from above) Date

_____ _____

Signature of Witness Date

---------- **Use the following only if applicable** ----------

If this consent form is read to the subject because the subject (or legally authorized representative) is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally

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authorized representative). The subject (or the subject's legally authorized representative) freely consented to participate in the research study. [adjust as needed]

_____ _____

Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

wirb/sponsor/wirb pro#/initials (this is our wirb "file signature" – wirb will add)

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