

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:

PROTOCOL NO.:

SPONSOR:

INVESTIGATOR:

SITE(S):

**STUDY-RELATED
PHONE NUMBER(S):**

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.

[Add the following statement only if the study protocol expressly allows the enrollment of subjects not capable of consenting for themselves:] A person who takes part in a research study is called a research or study subject. In this consent form “you” always refers to the research subject. If you are a legally authorized representative, please remember that “you” means the research (study) subject.

SUMMARY

[The summary section should summarize for the subject what the informed consent process will tell them, including:

- How research differs from regular health care.*
- The rights and responsibilities of research subjects.*
- Information subjects should have before joining a research study.]*

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this form carefully. To be in a research study you must give your informed consent. “Informed consent” includes:

- Reading this consent form,

- Having the study doctor or staff explain the research study to you,
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study: *[remove any that do not apply]*

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- Other parts of this study may involve experimental (investigational) drugs or procedures, that are being tested for a certain condition or illness. An investigational *[drug, device, vaccine]* is one that has not been approved by the U.S. Food & Drug Administration (FDA).
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study. Taking part in a research study could affect your current or future insurance coverage.

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the research;
- What drug or device or procedures will be used;
- Any possible benefits to you;
- The possible risks to you;
- The other medical procedures, drugs or devices that could be used instead of being in this research study; and
- How problems will be treated during the study and after the study is over.

Sample only; cannot be used without Board approval.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

[In simple language, explain the following:

- *Why the research is being done*
- *What the experimental components are]*

PROCEDURES

[In simple language and in a simple bullet format, explain the following:

- *The tests and procedures that will be done*
- *Which procedures/drugs are standard care and which are for research purposes only*
- *Whether a placebo or sham procedure will be involved*
- *The chances of being assigned to various study arms*
- *The method of assignment (random, etc.)]*

RISKS AND DISCOMFORTS

[In simple language and in a simple bullet format (whenever possible), explain the possible risks and discomforts: Start with the side effects for the experimental drugs, devices or procedures. List, for example:

- *most common*
- *less common*
- *rare]*

[Follow with risks and side effects for all drugs, devices or procedures used in the study.]

There may be side effects that are not known at this time.

[Include any risks relative to pregnancy for both men and women. For example:]

Women who are pregnant or nursing a child may not take part in this study. Before entering the study, you and your study doctor must agree on the method of birth control you will use during the entire study. If you think that you have gotten pregnant during the study, you must tell your study doctor immediately. Pregnant women will be taken out of the study.

Men who are in this research study should not get a sexual partner pregnant while taking the study drug *[If applicable also add the following:]* and for *[specify amount of time]* after the last dose of study drug. The effect of the study drug on sperm is not known.

[Or other pregnancy language supplied by sponsor—rewrite, if necessary, to simplify]

Your condition may not get better or may get worse during this study.

[If study drug is taken home, insert this or similar language:]

Only you should take the study drug. It must be kept out of the reach of children or anyone else who may not be able to read or understand the label.

NEW INFORMATION

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS

[In simple language indicate the possible benefit for both the subject and future patients.]

Your *[name of condition]* may improve while you are in this study; however, this cannot be promised. The results of this study may help people with *[insert name of condition]* in the future.

[or]

It cannot be promised that you will receive any medical benefits from being in this study.

COSTS

[In simple language state:

- *What will be billed to the subject or to their insurance*
- *Who pays if insurance does not (do not use exculpatory language).]*

[For example:]

[Sponsor Name] will provide the study *[drug/device]* free of charge during this study. Procedures that are done only for the study, such as extra lab tests will not be billed to you or your insurance company.

You or your insurance company may be billed for:

- *Any standard medical care given during this research study.*
- *[list other costs as necessary]*

Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include the costs of treating side effects. Otherwise, you might have unexpected expenses from being in this study.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

PAYMENT FOR PARTICIPATION

[Include this section only if subjects will be paid or if the sponsor requires subjects to be told that they will not be paid.]

You will be paid \$_____ for each completed study visit. If you do not finish the study, you will be paid only for the visits you have completed.

ALTERNATIVE TREATMENT

If you decide not to enter this study, there is other care available to you, such as *[List the major ones such as drugs / devices / procedures / supportive]*. The study doctor will discuss these with you. You do not have to be in this study to be treated for *[disease, condition, symptoms]*.

[Or]

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

[Use the following authorization format if the site is collecting health information, is a covered entity under HIPAA and is not using a separate HIPAA authorization form.]

If the site is not collecting health information, is not a covered entity under HIPAA or is using a separate HIPAA authorization form, use the "Confidentiality" text that follows, rather than the authorization text below.

California sites: This entire HIPAA section plus authorization statement should be placed at the end of the consent form following a page break and must include its own set of signature lines.]

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

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

[Select additional from below, as appropriate.]

- Information gathered for 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?

The study doctor and the study staff. They may also share the research information with *[enter SMO name]*, an agent for the study doctor *[if no SMO, delete this sentence]*.

Who might get this information?

The sponsor of this research. “Sponsor” means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information 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, and
- Western Institutional Review Board[®] (WIRB[®])

[Add any institutional names above WIRB.]

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

- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

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

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

- Yes, but this permission will not stop automatically.
- This permission will be good until [date] *[required in CA, IN, WA, and WI]*.

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 stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

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

There is a risk that your information will be given to others without your permission.

Confidentiality *[Use the following confidentiality text if the site is not collecting health information, is not a covered entity under HIPAA or is using a separate HIPAA authorization form.]*

Study information collected about you will be given to the sponsor. “Sponsor” means any persons or companies that are working for or with the sponsor, or owned by the sponsor.

It will also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the study *[drug or device]* may be considered for approval. Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the sponsor;
- *[delete the following if no CRO or SMO]*
- *[CRO name]*, an agent for the sponsor;
- *[SMO name]*, an agent for the study doctor;

[Add any institutional names above WIRB.]

and may be looked at and/or copied for research or regulatory purposes by:

- the FDA,
- Department of Health and Human Services (DHHS) agencies,
- governmental agencies in other countries, and
- Western Institutional Review Board® (WIRB®).

Total confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be given out during those presentations.

COMPENSATION FOR INJURY

[Example:]

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance will be billed for this treatment. The sponsor will pay any charges that your insurance does not cover. No other payment is routinely available from the study doctor or sponsor.

[or other language supplied by sponsor, simplified.]

VOLUNTARY PARTICIPATION AND WITHDRAWAL

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 for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- *[if the protocol lists specific reasons, insert them here];*
- or for any other reason.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some of the end of study procedures done.

SOURCE OF FUNDING FOR THE STUDY

The sponsor *[name]* will pay for this research study. *[Or other wording, as appropriate].*

QUESTIONS

Contact *[name]* at *[number(s)]* for any of the following reasons:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who independently review research.

WIRB will not be able to answer some types of questions, such as questions about appointment times. You may contact WIRB if you cannot reach the research team or if you want to talk to someone else.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

CONSENT

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be 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 *[remove if you used a Confidentiality section rather than an Authorization section above]*.

By signing this consent form, I have not given up any of my legal rights.

[Example signature block for research involving adults able to consent, minors, and adults who lack the capacity to consent:]

Consent and Assent Instructions:

Consent: Subjects 18 years and older must sign on the subject line below

Consent is provided by the Legally Authorized Representative for adult subjects unable to consent

For subjects under 18, consent is provided by the parent or guardian

Assent: Is not required for subjects 6 years and younger

Verbal assent is required for subjects ages 7 through [14] years using the Assent section below [and the Information Sheet for Children].

Verbal assent is required for subjects ages [15] through [17] years using the Assent section below [and the Information Sheet for Adolescents].

Subject Name (printed)

CONSENT SIGNATURE:

Signature of Subject (18 years and older)

Date

Signature of Legally Authorized Representative,
Parent or Guardian (when applicable)

Date

Authority of Subject's Legally Authorized Representative or Relationship to Subject

Signature of Person Conducting Informed
Consent Discussion

Date

ASSENT SECTION For Subjects Ages [7] - [17]:

Statement of person conducting assent discussion:

1. I have explained all aspects of the research to the subject to the best of his or her ability to understand.
2. I have answered all the questions of the subject relating to this research.
3. The subject agrees to be in the research.
4. I believe the subject's decision to enroll is voluntary.
5. The study doctor and study staff agree to respect the subject's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Signature of Person Conducting
Assent Discussion

Date

Statement of Parent or Guardian:

My child appears to understand the research to the best of his or her ability and has agreed to participate.

Signature of Parent or Guardian

Date

ASSENT SIGNATURES, For Adult Subjects with a Legally Authorized Representative:

Assent:

For adult subjects who have a legally authorized representative, I confirm that:

- I have explained the study to the extent compatible with the subject's understanding, and the subject has agreed to be in the study.

OR

The subject is not able to assent due to lack of mental capacity.

Signature of Person Conducting Assent Discussion Date

Ver. 12-23-2009