

### **A Statement of Ethical and Legal Principles**

The voluntary consent of human subjects is absolutely essential to participation in research. This means that persons, except as indicated (e.g., minors), should have legal capacity to give consent, and should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress or other ulterior form of constraint or coercion. Individuals should have sufficient knowledge and comprehension of the elements of the subject matter involved in research to enable the subjects to exercise a free power of choice without undue inducement or element of force. This requires that before the acceptance of an affirmative decision by the subject to participate and provide consent by signature, the nature, duration and purpose of the activity should be clearly delineated. Furthermore, the method and means by which research is to be conducted should be made clear along with inconveniences and hazards to be expected within reason. The effects upon the subject's health or person which may come from his or her participation in the procedure or activity shall be revealed. It should also be made known to the subject that he or she is free to withdraw consent and to discontinue participation in the procedure or activity at any time without prejudice.

Informed consent is documented through the use of an approved legally effective consent form which is signed by the subject or his/her authorized legal representative and the investigator and witness (when appropriate) as necessary. The duty and responsibility for ascertaining the quality of the consent rests upon each investigator who initiates, directs or engages in research, and this duty and responsibility may not be delegated to another with impunity. Cooperative activities involving other institutions will be implemented only after both or all have conducted an independent review of those aspects of the project or activity which may involve human subjects in accordance with this Institutional General Assurance.

The research or related activity shall be such as to yield fruitful results for the good of society, unprocurable by other means or methods of study, and not random or unnecessary in nature. Furthermore, human subject research activity is to be conducted to avoid all unnecessary physical, psychological, legal and social harm.

No research developments or related activity shall be conducted where therein is an *a priori* reason to believe that death or disabling injury will occur. Additionally, the degree or risk to be taken shall never exceed the humanitarian importance of the problem to be solved by the procedure or activity.

Proper preparation shall be made and adequate facilities shall be provided to protect the subject against even remote possibilities of harm, injury, disability, or death. The procedures or activities shall be conducted only by qualified investigators and the highest degree of skill and care should be required of those who conduct or engage in the procedure or activity through all stages. During the course of the procedure or activity, the human subject shall be at liberty to

bring participation to an end at any time. Additionally, during the course of the procedure or activity, the investigator in charge must be prepared to terminate the activity at any stage if he/she has probable cause to believe, in the exercise of good faith, superior skill and careful judgment required of him/her, that continuation is likely to result in harm, injury, disability or death to the subject. This includes cases where the research *per se* has revealed good cause for termination of a subject's participation.

### GUIDELINES FOR PREPARING THE INFORMED CONSENT FORM

The Informed Consent Form (ICF) is the means by which a subject learns exactly what s/he will experience while participating in a research study. **The ICF shall be clearly and simply written. Medical terminology utilized shall be explained in layman's terms.** Use the information provided below as a guideline to develop a custom-designed ICF appropriate to your study.

It is required that when constructing the ICF document for your research study, the author begin with the SDHIRB template, and incorporate information into it provided by the sponsor. A minimum of size 12 font must be used.

**Text that is highlighted in green is required and must be included verbatim.**

**Information in *blue italics* is provided to help ensure you consent contains all required elements, and should be deleted.**

The pages of the ICF shall be numbered at the bottom right as \*Page \_ of \_\*. The HIPAA Authorization and the Research Subject's Bill of Rights are the last three pages of the ICF. SDH IRB will add the IRB Study Number to the bottom left side of the footer once the study is approved.

**PLEASE INSERT INSTITUTION LETTERHEAD**

Informed Consent Form for Research Study Entitled

**[Complete Title of Study]**

*Title on the ICF shall match that on the protocol.*

**Principal Investigator  
(Study Doctor):**

Bill Smith, MD  
123 4<sup>th</sup> Street, Suite #5  
City, State, Zip Code  
24 hour telephone number, including area code

**Sub-Investigator(s):**

*(It is the preference of the SDHIRB that Sub-Investigators NOT be listed on the ICF. However, study sponsors may require that they be listed.)*

**Study Sponsor:**

A Good Research Company  
678 9<sup>th</sup> Street  
City, State, Zip Code

**Daytime Phone Number:  
After Hours Number:**

**Sponsor Protocol #:**

**IRB Study #**

*IRB will add Study # once the study is approved*

**INTRODUCTION:**

*Separate the sections of the ICF with appropriate titles in all caps and bold print.*

You are being asked to participate in a research study examining \_\_\_\_\_. You were selected as a possible participant in this study because \_\_\_\_\_. There will be approximately \_\_\_\_\_ participants in this study. It is anticipated that \_\_\_\_\_ participants will be enrolled at \_\_\_\_\_. This study is being sponsored by \_\_\_\_\_.

**PURPOSE OF THE STUDY:**

*State specifically and clearly the purpose of the study. Include the goals the study is designed to discover or establish.*

**STUDY PROCEDURES:**

If you decide to participate in this research study, the study doctor (and staff) will \_\_\_\_.

*Describe what will happen if subjects elect to participate:*

- a. *Detail all study procedures that will be performed and at what point during subjects' participation the procedures will occur*
  - a. *Notify subjects which research procedures, etc. are considered experimental or investigational and which are not. If investigational products are involved include the statement "Investigational means not approved by the US Food and Drug Administration (FDA)."*
  - b. *Specify which procedures are study-specific vs. standard of care.*
  - c. *Include randomization procedure(s), if appropriate (i.e., "you will be randomized (chosen at random, like the flip of a coin) to be in one of two groups ..."*
- b. *Explain the duration of study procedures and their frequency. Include the total duration of participation.*
- c. *Indicate the expected duration of the subject's participation in this research study.*

**RISKS OF STUDY PARTICIPATION:**

*Give a description of any reasonably foreseeable risks or discomforts to the subjects. The preferred format of the "RISKS" section is to have a small introduction paragraph followed by the specific risks listed in bullet format. Please use terminology that can be easily understood by subjects. If you must use medical terminology, please list risks using the non-medical term followed by the medical term in parenthesis as "hives (urticaria)".*

- *If applicable, (i.e., drug study in which anaphylactic reactions are possible), include "other unknown risks/reactions may occur which could be life threatening."*
- *If applicable, (i.e., data collection study), you may state, "there is no risk associated with your participation in this study other than a possible loss of confidentiality".*
- *If applicable, you may include a statement such as "You will sign a separate consent form for the surgical procedure and should discuss the risks, benefits, and alternatives of the procedure with your doctor."*
- *If applicable, include "Exposure to radiation may increase your risk for developing cancer."*
- *Please use the term "side effect" instead of "adverse event", unless defined*

*If appropriate, include:*

**If you are a woman who is able to become pregnant:** You must use an effective method to ensure that you do not become pregnant during the study. The study doctor or study nurse will discuss the study approved methods with you. If you are or become pregnant, the treatment involved in this study may involve risks to you or the fetus, which are currently unknown. If appropriate, you agree to be tested for pregnancy to assure that you are not pregnant. Although

urine pregnancy tests are a good method for detecting pregnancy, they are not perfect. It is possible that you could be pregnant even with a negative pregnancy test – especially if you had unprotected intercourse within a week of the urine pregnancy test. If you become pregnant during the course of this study, you must notify the study doctor immediately.

You must not participate in this study if you are breastfeeding. The treatment involved in this study may involve risks to a breastfeeding baby, some of which may be unknown.

**BENEFITS OF STUDY PARTICIPATION:**

*Give a description of any reasonably expected benefits to the subject or others, which may be reasonably expected from the research.*

*Include:* It is possible that you may receive no benefit from participating in this research.

- *If applicable, include:* Information collected from the subjects receiving placebo is as important as from those receiving (*specify investigational material*).
- *If there is no potential benefit to the subject (i.e., data collection study), include* “You will not personally benefit from your participation in this study; however, your participation in this study may help others in the future.”

**ALTERNATIVES TO STUDY PARTICIPATION:**

*Give a description of any appropriate alternative procedures or courses of treatment that may be advantageous to the subject and the important potential benefits and risks of those procedures. If the study does not involve treatment, it is acceptable to state “your alternative to participating in this study is to not participate in this study.”*

**PAYMENT FOR STUDY PARTICIPATION:**

*Clearly explain the pro-rated compensation that will be provided to the subjects, including a timeframe of when they can expect payment. If no compensation is given, include the statement: You will not be paid for your participation in this study.*

*If applicable, include:*

You may be required to report income from this study to the IRS as taxable income.

**COSTS RELATED TO STUDY PARTICIPATION:**

*Outline specifically what costs the study subject might expect to pay:*

- a. *State whether procedures required by the protocol are considered routine care for the subject’s condition and therefore, those costs are to be paid by the subject or whether*

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*procedures are specific to the protocol and therefore, the subject (or third party) is not responsible for those costs.*

- b. *State whether the cost for investigational drugs, devices, or specific procedures are the responsibility of the subject. If the study does not add any costs to the subject's care, (i.e., data collection study), state, "There will not be any cost to you related to your participation in this study." This paragraph must be complete, and include all possible contingencies.*

*If applicable, include:* Normal treatment costs will be billed to you or your insurance carrier. You will be responsible for any co-pay, co-insurance or deductible.

**IN CASE OF RESEARCH-RELATED INJURY:**

*Give a description of how a research-related injury should be reported to the study personnel and how related costs will be managed.*

*For example:* If you are injured as a result of your participation in this study, you should ask your study doctor for more information. If this happens, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third party coverage. There are no plans to provide other compensation beyond that which is listed in this informed consent document. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.

**CONFIDENTIALITY:**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential. *Describe any procedures that the research team will use to protect a subject's confidentiality.*

As required by law, the medical records of participants will be made available to the appropriate agencies regulating this research, including the United States Food and Drug Administration (FDA), the St. David's HealthCare Institutional Review Board, and \_\_\_ *(fill in the name of the sponsoring company)*. Any publication of this research will not identify you. The attached Authorization to Use and Disclose Personal Health Information describes how your study related information will be used and disclosed.

**DISCLOSURE OF INFORMATION:**

Any significant new findings that develop during the course of the research that may relate to your willingness to participate will be provided to you.

You will be given a signed and dated copy of this consent form to keep.

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*If applicable, include “The study doctor and/or this facility will be receiving payment from \_\_\_\_\_ (fill in the name of the sponsoring company) for services provided in connection with the study.”*

*For all applicable clinical investigations governed by the FDA initiated on or after March 7, 2012, this exact statement (no deviations or rewording allowed) is now required by FDA regulation. Please remove if not applicable: 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.*

*This statement should be included for trials of drugs and biologics which are controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulations, and for trials of devices which are controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric post market surveillance studies. It is your responsibility to confirm with the study sponsor that the trial will be registered with the Web site.*

**WHOM TO CONTACT:**

If you have questions, experience problems during the course of the study, or to report a research-related injury, contact:

*PI Name*

*Address*

*24-hour telephone number, including area code*

**If you have questions regarding your rights as a study subject, contact:**

Matthew C. Cowperthwaite, PhD, Chair  
St. David’s HealthCare Institutional Review Board (SDHIRB)  
St. David’s Medical Center  
919 East 32<sup>nd</sup> Street  
Austin, Texas 78705  
Phone: (512) 544-2626  
E-mail: [sdhp.irb@stdavids.com](mailto:sdhp.irb@stdavids.com)

The SDHIRB is a group of medical and non-medical professionals representing St. David’s HealthCare Austin-area hospitals and medical staff that review and approve or disapprove research involving people by following the FDA rules. This group is also required by the FDA to do periodic review of ongoing research studies.

**WITHDRAWAL OR TERMINATION FROM PARTICIPATION:**

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Your decision whether or not to participate in this study is voluntary. You may refuse to participate in the study or may withdraw from the study at any time without penalty or loss of benefits and without affecting your present or future medical care.

Your doctor or the sponsor of this study may stop your participation in this study at any time if it is in your best interest medically, you need additional medication, the study plan is violated, you experience a research-related injury, or for administrative reasons.

*Describe any additional conditions and requirements for orderly termination of participation, or conditions under which the Investigator may terminate the subject's participation without his/her consent.*

**STATEMENT OF CONSENT TO PARTICIPATE:**

I understand the proposed research study and willingly consent to participate. I have had the opportunity to ask questions and receive answers about the study and my role in it. I understand that I do not waive any of my legal rights as a research subject by participating in this study.

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Printed Name of Subject

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Signature of Subject

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Date

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Signature of Person Explaining Consent

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Date

*If applicable, include the following signature line.*

I am the legal representative of the person being enrolled in this study. I understand the proposed treatment and willingly permit the study personnel to enter my ward into this study. The study personnel have explained the study to me. I have had the opportunity to ask questions and receive answers about the study. I understand that by signing this form I do not waive any of the legal rights of my ward.

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Signature of Legal Representative/Parent/Guardian

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Date

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*The entire Statement of Consent section (from section header through all signatures) should be on a single page. Please insert a page break, if necessary.*

## AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

A privacy rule has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your health information. This document called a HIPAA Authorization, explains how your health information will be used and disclosed for this study and describes your rights, including the right to see your health information.

*[Researcher and Institution]* are working with *[Study Sponsor]* to study *[Name of Study Drug/Device]* to *[give purpose of the Study]*. By signing this Authorization, you allow *[Researcher and Institution]* to use your Personal Health Information to carry out this research study. Your Personal Health Information is information about you that could be used to identify you, such as your name, address, telephone number, photograph, date of birth, social security number, new and existing medical records, *[DNA samples and analyses, if applicable]*, or the types, dates, and results of various tests and procedures. This may include information in your medical record and information created or collected during the study.

By signing this Authorization, you allow *[Researcher and Institution]* to disclose your Personal Health Information to the St. David's HealthCare Institutional Review Board for this study and to *[Study Sponsor]*, including representatives who work on behalf of *[Study Sponsor]* to conduct the study. *[Study Sponsor]* will use this information to evaluate the safety and effectiveness of *[Name of Study Drug/Device]*. Your information may also be shared with the US Food and Drug Administration and health authorities in other countries.

The study data sent by *[Researcher and Institution]* to *[Study Sponsor]* generally does not include your name, address, social security number, or other identifier except possibly your date of birth. Instead, *[Researcher and Institution]* uses your initials and assigns a code number to your records sent to *[Study Sponsor]*. *[Provide brief description of the protected health information (PHI) data to be used or disclosed for the purposes of this study.]* However, your entire medical record may be reviewed and copied at the *[Researcher's site and/or Institution]* by *[Study Sponsor]* and/or its representatives, and regulatory authorities or other agencies overseeing this research. The purpose of these reviews is to assure that the study is being safely conducted, the study data are accurately collected, or for other uses allowed by law.

Your Personal Health Information may no longer be protected by the Privacy Rule once it is disclosed by the *[Researcher and Institution]*, although other confidentiality safeguards apply. Please refer to the Informed Consent document to see how *[Study Sponsor]* will treat your Personal Health Information confidentially. If you have questions about how your Personal Health Information will be protected, you can ask *[insert name of study personnel]*. *[Study Sponsor]* may add your Personal Health Information to research databases so that it can study better measures of safety and effectiveness, develop new medications or devices for other

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patients, expand their understanding of disease, or improve the efficiency of future clinical studies.

You have the right to see and copy your Personal Health Information related to the study for as long as this information is held by [Researcher and Institution]. However, to ensure the scientific integrity of the study, you agree that you may not be able to review some of your records related to the study until after the study has been completed.

You may cancel this Authorization at any time by sending a written notice to [Researcher] at the following address [insert address]. If you cancel this Authorization, [Researcher and Institution] will no longer use or disclose your Personal Health Information under the Authorization for this Study, unless the [Researcher and Institution] need to use or disclose some of your Personal Health Information to preserve the scientific integrity of the study. Information collected before you cancel this Authorization may still be disclosed to [Study Sponsor].

If you do not sign this Authorization, you cannot participate in the study. If you cancel this Authorization in the future, you will no longer be able to participate in the study.

This Authorization does not have an expiration (ending) date.

You will be given a copy of this form to keep.

\_\_\_\_\_  
Signature of Participant or Participant’s Legal Representative      Date

\_\_\_\_\_  
Printed Name of Participant or Participant’s Legal Representative

\_\_\_\_\_  
Signature of Witness      Date

\_\_\_\_\_  
Printed Name of Witness

If signed by a personal representative of the individual, describe the representative’s legal authority to act on behalf of the individual (e.g., father):

\_\_\_\_\_

**RESEARCH SUBJECT'S BILL OF RIGHTS**

What are your rights as a research subject?

Following is the *Research Subject's Bill of Rights*. Please read and keep this information for future reference. Although study staff may be available to answer any study related questions, those pertaining to the subject rights listed below should be addressed to the Chair of the St. David's HealthCare Review Board, Matthew C. Cowperthwaite, PhD, at (512) 544-2626.

1. To be told what the study is trying to find out.
2. To be told what will happen to you and whether any of the procedures, drugs, or devices are different from what would be used in regular practice.
3. To be told about the frequent and/or important risks, side effects or discomforts of the things that will happen to you for research purposes.
4. To be told if you can expect any benefit from participating, and, if so, what the benefit might be.
5. To be told the other choices you have and how they may be better or worse than being in the study.
6. To be allowed to ask questions about the study, both before agreeing to volunteer and during the study.
7. To be told what kind of medical treatment is available if you have any problems.
8. To refuse to participate in the study or to change your mind about participating after the study is started. This decision will not affect your right to receive the care you would receive if you were not in the study.
9. To receive a copy of the consent form.
10. To be free of pressure when deciding whether or not to participate in the study.

*For SDHIRB Use Only – Version Control*

initials: DDMMYY