CONSENT TO PARTICIPATE IN RESEARCH

PROTOCOL TITLE:

SPONSOR:

INVESTIGATOR: name & phone number

SITE: name, address, phone number

NCT #: if this trial is not registered on ClinicalTrials.gov mark as N/A

INTRODUCTION

Suggested text:
You are asked to participate in a research study conducted by [*insert names and degrees of all investigators*], from the [*insert affiliation*] at the [*insert facility]*. You have been asked to participate in this study because [*explain succinctly and simply why the prospective subject is eligible to participate*]. [*If appropriate, state the approximate number of subjects involved in the study.*] *[Add a statement as to the patient's duration of participation in the study.]* Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

Guidelines:
⇒ *Use simple language.*
⇒ *Be concise.*
⇒ *Use the pronoun "you" consistently throughout (except for the "Signature of Research Subject" on the last page).*
⇒ *If subjects must be patients with a specific disease/condition, and if they must have tried standard treatments without good results, say so in clear terms. For example: "You qualify to participate in this project because you have breast cancer that has not responded well to standard treatment (or that has recurred, in spite of standard treatment)."*

- **PURPOSE OF THE STUDY**

[*State what the study is designed to discover or establish.*]

- **PROCEDURES**

Suggested text:
If you volunteer to participate in this study, we would ask you to do the following things:

Guidelines:
⇒ *Describe the procedures chronologically using lay language, short sentences and short paragraphs. The use of subheadings will help to organize this section and increase readability. Distinguish which procedures are experimental and which are standard clinical treatments.*
⇒ *Define and explain medical and scientific terms .in ordinary language (for example, describing the amount of blood to be drawn in terms of teaspoons or tablespoons).*
⇒ *Specify the subject's assignment to study groups, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of the procedures to be done, etc.*
⇒ *For research involving randomization of subjects into different arms of studies, specify the randomization procedures.*
⇒ *For research involving the use of placebo, clearly define the term of placebo.*

- **POTENTIAL RISKS AND DISCOMFORTS**

Guidelines:
⇒ *Identify each intervention with a subheading and then describe any reasonable foreseeable risks, discomforts, inconveniences, and how these will be managed.*
⇒ *In addition to physiological risks/discomforts, describe any psychological, social, legal, or financial risks that might result from participating in the research.*
⇒ *If there are significant physical or psychological risks to participation that might cause the researcher to terminate the study, please describe them.*
⇒ *Include a statement regarding possible unforeseeable risks.*
⇒ *Include a statement that there may be potential risk to an embryo or fetus, if applicable.*

- **ANTICIPATED BENEFITS TO SUBJECTS**

Suggested text:
Based on experience with this [*drug, procedure, device, etc.*] in [*animals, patients with similar disorders*], researchers believe it may be of benefit to subjects with your condition [*or, it may be as good as standard therapy but with fewer side effects*]. Of course, because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. The potential benefits may include:
[*Describe the anticipated benefits to subjects resulting from their participation in the research.*]

Guidelines:

⇒ *If , there is no likelihood that participants will benefit directly from their participation in the research, say so in clear terms. For example: "You should not expect your condition to improve as a result of participating in this research" or "This research is not being done to improve your condition or health. You have the right to refuse to participate in this study."*

⇒ *Do not include financial rewards for participating in this section; that will be addressed later.*

- **ANTICIPATED BENEFITS TO SOCIETY**

[*State the anticipated benefits, if any, to science or society expected from the research; do not be presumptuous.*]

- **ALTERNATIVES TO PARTICIPATION**

Guidelines:

⇒ *Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subjects decide whether or not to participate in the study. If applicable, explain why these procedures are being withheld. If there are no efficacious alternatives, state that an alternative is not to participate in the study.*

⇒ *If the prospective subjects are suffering from a terminal illness, and there are no alternative treatments available, you should say so; but add that treatment of symptoms and pain control are available through hospice, home health care, clinics, private physicians, etc. In other words, avoid suggesting that participation in the research is the only way to obtain medical care and attention.*

⇒ *If prospective subjects have a chronic, progressive disorder, for which no treatment had been demonstrated to be safe and effective, say that, as well. But also describe opportunities for managing symptoms, improving ability to function, etc. so that it does not appear that the patient will be abandoned if he/she does not agree to participate in the research.*

- **PAYMENT FOR PARTICIPATION**

(Note: If this does not apply to your research, please omit this entry and delete the heading.)

Guidelines:

⇒ *State whether the subject will be paid or offered other benefits (e.g., free care). If not, state so.*

⇒ *If the subject will receive payment, describe remuneration amount, when payment is scheduled, and proration schedule should the subject decide to withdraw or is withdrawn by the investigator.*

⇒ *If the subject will be reimbursed for expenses such as parking, bus/taxi, baby-sitter, travel companion/assistant, etc., list payment rates.*

⇒ *You normally should pay the entire amount that would be due at the end of the protocol to subjects who discontinue participation for reasons other than a wish to withdraw (e.g., intercurrent illness, severe side effects).*

- **FINANCIAL OBLIGATION**

(Note: If there is no financial obligation of the subject, please say so.)

Suggested text:

It is possible that your insurance will not pay for all of the treatments and tests you will receive if you participate in the research. That is because many insurance companies, HMOs, and health benefits plans do not cover experimental treatments. If that happens, the charges you will have to pay will be as follows: [P*rovide an itemized list.*]

Suggested **alternative** text:

Neither you nor your insurance company will be billed for your participation in this research.

Guidelines:

⇒ *If it is likely or even possible that procedures or tests the subjects will undergo will not be covered by their insurance, health benefits plan, or other third party payers, you should make this clear.*

⇒ *Itemize and estimate the charges that subjects participating in the research will be expected to pay if the charges are not paid by their insurance or other third payer.*

⇒ *If you have had enough experience with similar protocols to estimate which of the charges are likely to be covered, that information may be included, but be sure to make clear that that will not necessarily be true in each case.*

⇒ *Bills should not be submitted to third party payers without the written consent of the subject.*

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

(Note: This is a required element of informed consent for research involving more than minimal risk. If this does not apply to your research, please omit this entry and delete the heading.)

Your participation in this research is at your own risk. You will be responsible for the cost of treatment for any research related injury. HCA-HealthONE has not set aside funds to provide financial compensation for any injury suffered during this study. You are not waiving any legal claims, rights or remedies because of your participation in this research study.

- **PRIVACY AND CONFIDENTIALITY**

Suggested text:

The only people who will know that you are a research subject are members of the research team and, if appropriate, your physicians and nurses. No information about you, or provided by you during the research will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care);
- any threats that you make to harm yourself or others;
- information that a child has been subjected to abuse or neglect; or
- evidence of an infectious or contagious disease that endangers the public health will be reported to appropriate authorities.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audio-tape recordings of you will be used for educational purposes, your identity will be protected or disguised. [*Describe the subject's right to review/edit the tapes, who will have access, and when they will be erased. Describe how personal identities will be shielded, disguised, etc.*]

[***When the research records may be subject to inspection by FDA, a funding agency, or an industrial sponsor, you must add:***]

Authorized representatives of the Food and Drug Administration (FDA) [*or a funding agency, such as the National Institutes of Health*], the manufacturer of the drug [*or device*] being tested [*insert name of company*], and the HCA-HealthONE IRB may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

Guidelines:

⇒ *Give a brief description of how personal information, research data, and related records will be coded, stored, etc. to prevent access by unauthorized personnel.*

⇒ *Explain how specific consent will be solicited, if any other uses are contemplated.*

⇒ *If applicable, state if and when individual responses to survey questionnaires will be destroyed, following analyses of the data.*

- **PARTICIPATION AND WITHDRAWAL**

Suggested text:

Your participation in this research is VOLUNTARY. If you choose not to participate, that will not affect your relationship with [*facility*], or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at [*facility*].

- **CONSEQUENCES OF WITHDRAWAL**

(Note: If this does not apply to your research, please omit this entry and delete the heading.) [*Explain the consequences of a subject's decision to withdraw from the research and state whether withdrawal must be gradual, for reasons of safety.*]

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

Suggested text:
The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If you experience any of the following side effects [*list and describe*] or if you become ill during the research, you may have to drop out, even if you would like to continue. The investigator, [*insert name*], will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If you must drop out because the investigator asks you to (rather than because you have decided on your own to withdraw), you will be paid [*insert amount of payment or other remuneration*].

Guidelines:
⇒ *If subjects will be paid for participating in the research, it is important that they not lose that pay if they develop side effects or intercurrent illness, because you want them to feel free to report such matters.*
⇒ *Be sure that this aspect of terminating participation at the request of the PI is noted in the section on Payment for Participation, as well, and that the information in both sections is consistent.*
⇒ *Be sure to thoroughly explain the reasons/circumstances by which an investigator may withdraw a subject; if there are none, please omit this category.*

- **NEW FINDINGS**

During the course of the study, you will be informed of any significant new findings (either good or bad) that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

- **IDENTIFICATION OF INVESTIGATORS**

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact [i*dentify all personnel involved in the research as listed in the protocol under the following subheadings: Principal Investigator, Co-Investigator(s), and Participating Personnel. Include day phone numbers and addresses for all listed individuals. For greater than minimal risk studies, include night/emergency phone numbers.*]

- **RIGHTS OF RESEARCH SUBJECTS**

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the HCA-HealthONE Institutional Review Board (IRB) Administrative Office at 303-584-2300.

[For FDA regulated studies that are considered applicable clinical trials, the following statement is required *verbatim* effective 07MAR2012. If your study is not FDA regulated, please delete this paragraph]

"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."

SIGNATURE OF RESEARCH SUBJECT (*or legal representative – *if approved by IRB*)

I have read (or someone has read to me) and understand the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____
Name of Subject

_____
Name of Legal Representative (if applicable)

_____ _____
Signature of Subject (or Legal Representative if applicable) Date

SIGNATURE OF INVESTIGATOR

I have explained the research to the subject or his/her legal representative and answered all of his/her questions.

_____
Name of Investigator

_____ _____
Signature of Investigator Date (must be the same as subject's)