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]

KEY INFORMATION

This section should include the following information in a concise presentation:

1. The fact that consent is being sought for research and that participation is voluntary.

2. The purpose(s) of the research, expected duration of the prospective subject's participation, and procedures to be followed in the research.

3. The reasonably foreseeable risks or discomforts to the prospective subject.

4. The benefits to the prospective subject or others that may reasonably be expected from the research.

5. Appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the prospective subject.

The information presented in this section may be discussed in greater detail later in the consent form.

INTRODUCTION

Suggested text:
You are being 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.

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 will 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."

For Federally-Funded Research:

Please include one of the following statements (required):

- ⇒ *A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or*
- ⇒ *A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.* (Please call the IRB office if you choose to include this statement.)

Please include any of the following items (as appropriate):

- ⇒ *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit AND whether the subject will or will not share in this commercial profit.*
- ⇒ *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
- ⇒ *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*

HIPAA[1] authorization to use and disclose individual health information for research purposes

a. Purpose: As a research participant, you authorize the Principal Investigator and the researcher's staff to use and disclose your individual health information for the purpose of research directly related to **[*insert appropriate disease*]** for conducting the research study entitled:

[1] HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.

b. Individual Health Information to be Used or Disclosed: Your individual health information that may be used or disclosed to conduct this research includes: demographic information (e.g., age, date of birth, sex, weight), medical history (e.g., diagnosis, complications with prior treatment), physical examination findings, and laboratory test. (e.g., blood tests, biopsy results).

c. Parties Who May Disclose your Individual Health Information: The researcher and the researcher's staff may obtain your individual health information from:

[*insert hospital(s) or individuals who may obtain their information here)*] where you have received treatment.

d. Parties Who May Receive or Use Your Individual Health Information: The individual health information disclosed by parties listed in item c and information disclosed by you during the course of the research may be received and used by the following parties:

- **[*insert your facility or organization*]**
- **U.S. government agencies that are responsible for overseeing research such as the Food and**
- **Drug Administration (FDA) and the Office of Human Research Protections (OHRP)**
- **Study Sponsor: [insert sponsor name if applicable] and its study monitors, representatives, collaborators, affiliates and licensees**
- **HCA-HealthONE Institutional Review Board as a group**

e. Right to Refuse to Sign this Authorization: You do not have to sign this Authorization. If you decide not to sign the Authorization, you will not be allowed to participate in this study or receive any research-related treatment that is provided through the study. However, your decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

f. Right to Revoke: You can change your mind and withdraw this authorization at any time by sending a written notice to the Principal Investigator to inform the researcher of your decision. If you withdraw this authorization, the researcher may only use and disclose the protected health information already collected for this research study. In addition, your records may continue to be collected and reviewed if you experienced an adverse event (a bad side effect) and to complete monitoring of study-related visits that have already occurred. No further health information about you will be collected by or disclosed to the researcher for this study. If you revoke your authorization, you will no longer be able to participate in this study.

g. Potential for Re-disclosure: You individual health information disclosed under this authorization may be subject to re-disclosure outside the research study and no longer protected. Examples include potential disclosures for law enforcement purposes,

mandated reporting or abuse or neglect, judicial proceedings, health oversight activities and public health measures.

h. **[*edit as appropriate*]** This authorization does not have an expiration date.

i. You have the right to see and copy your records. However, if you sign this form, you will not be able to find out what treatment (arm) you were on until after all participants finish the study.

You may revoke your authorization at any time by sending a written request to your study doctor at the **[*physician address or organization address*]**. If you revoke your authorization, your participation in the study will end and the study personnel will stop collecting medical information from you. In addition, study personnel will stop using your information and will stop disclosing your information, except to the extent study personnel have relied on information that has already been collected from you. For example, the study personnel may need to use or disclose information obtained before you revoked your authorization in order to preserve the scientific integrity of the study.

SIGNATURE OF RESEARCH SUBJECT

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. ***(remove LAR line and references below if not applicable)***

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 PERSON OBTAINING CONSENT

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

_____
Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date