TITLE: **[Full title as listed on the IRB application]**

PRINCIPAL INVESTIGATOR(S): **[Principal Investigator name and credentials]**
[Principal Investigator address]
[Principal Investigator telephone number]

SUB- INVESTIGATOR(S):

SPONSOR *(if applicable)*: **[Sponsor name]**
[Sponsor address]
[Sponsor telephone number]

- **Instructional text appears in red and must be removed prior to submission to the IRB.**
- **Red text in parentheses [ ] should be replaced with information from your study, e.g., [your name here]**

Site(s): - Address (es)
Study Related Contact Information - (Phone Number)

Introduction

You are being asked to take part in a research study. This consent form is only a part of the informed consent process. It will give you detailed *written* information about what will take place during the study.

Take the time to read this form carefully. After reading this form and having this study explained to you by someone conducting the research, you can decide if you want to participate in it.

You may have questions this form does not answer. If you do not understand something about the research study or if you have any additional questions, please ask the researcher for an explanation before you sign this form.

If you choose to participate in this research study, then you should sign this *consent* form. If you do not want to take part in this research study, you should not sign this form. Your decision whether or not to participate will have no effect on your [medical care, academic standing, job status, etc. (insert the appropriate phrase)].

Why is this research study being done?

The purpose of this study is to:

- Describe the purpose of the study;
- Clearly state why the subject is being ask to participate;
- Include the number of subjects expected to participate at the local site and in the entire study if it is being conducted at multiple sites.

When applicable, describe:

- Whether or not the drugs/devices/procedures are being used in ways that are not FDA approved;
- The use of placebo and how individuals would be assigned to a group;
- Whether or not all participants will receive the same therapy;
- The process of randomization (i.e., flipping a coin, 50/50 chance).

What does this study involve?

If you agree to participate in this research study, you will be asked to do the following:

- Describe the procedures, in order and in detail; Chronological descriptions are most helpful.
- Use lay language (written at an eighth grade level); Simplify symbols and medical language to lay terminology throughout the consent.
- Use short sentences and short paragraphs;
- Use subheadings and bulleted items;
- Describe which procedures are experimental and which are standard clinical procedures/treatments;
- Describe the time required to participate and length of study; consider inserting a chart or calendar; a visual layout can be most helpful in long term studies for most participants.
- For Labs: (state what specimens will be collected and the estimated amount) e.g., the number of tablespoons of blood to be drawn.
- If samples will be saved for future research (see Tissue Sampling for Research).

Use the following sub-section below if applicable to your study:

- Women of Childbearing Potential

REPRODUCTIVE RISKS:

FEMALES:

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you breast-feed during this study, you or your child may be exposed to known/unknown risk (or state specific risk)

To confirm to the extent medically possible that you are not pregnant, you will be asked to have a pregnancy test done before beginning the research study. You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed study investigation. The study investigator will discuss acceptable methods to prevent pregnancy with you. You must accept the risk that pregnancy could still result despite the responsible use of the reliable method(s) of birth control discussed with you. If you become pregnant which may result in you being withdrawn from the study.

MALES:

Effects of [the drug] on the male reproductive system are unknown. Measures to prevent pregnancy should be taken while you are participating in the study. Your study doctor will discuss acceptable methods to prevent pregnancy with you.

MEN WHO CAN FATHER A CHILD

The effects of _____on sperm and sperm production are not known. Like other chemotherapies, _____ may cause temporary or permanent sterility (inability to make someone pregnant). If appropriate, you may want to consider storing sperm in a sperm bank before receiving treatment on this study.

Use the following sub-section below if applicable to your study:

- Tissue Banking for Research

Research using tissue samples are an important way to try to understand human disease. You have been given this information because the investigators want to include your tissues in a research project and because they want to save the samples for future research. There are several things you should know before allowing your tissue sample to be studied.

Your tissue will be stored (insert how samples will be stored- and if appropriate how samples will be linked) e.g., under diagnosis and medical or code number and unlinked)

If linked: You have the right to refuse to allow your tissue to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research.

If unlinked: Because your tissue samples will not be linked to your name after they are stored, you cannot withdraw your consent to the use of the samples after they are taken.

Optional:

The results of the study of your sample will be used for research purposes only and you will not be told the results of the tests.

Or

You will be told the results of the test(s) that are part of your clinical care, but you will not be told

the results of the research test, or any future research test.

___ I consent to my samples being saved for future research

___ I **do not** consent to my samples being saved for future research

Use the following sub-section below if applicable to your study:

↳ Genetic testing (current study or future research)

Tissue Sampling for Genetic Testing

As part of the analysis on your samples, the sponsor (name) will/may do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearances and biochemistry, gene sequencing, genetic landmarks, individual and family medical histories, and reactions to medications and responses to treatment. Genetic research raises certain questions about informing you about any results. Possible risk of knowing results include: anxiety; other psychological distress; and the possibility of health/life insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

If investigators will not share the research results with the participants then the following language should be added:

The result of the study or your samples from this project will be used for research purposes only, and you will not be told the results of the tests.

What are the possible risks, side effects, and discomforts of this research study?

If you decide to participate in this research study, you should know that there may be risks. You should discuss these risks with the research staff before making a decision to participate. The known or expected risks are:

↳ List the risks in bullet format

As with any research study, there may be additional risks that are unknown or unexpected.

↳ With drug studies involving a multi-drug regimen, list the side effects associated with the entire regimen rather than providing separate information for each individual medication.

Whenever possible, you should estimate the probability that a side effect will occur. Words such as "common," "likely," "occasionally," or "rare" may be used when it is not desirable to use numerical estimates (i.e. you will likely experience some bruising and soreness at the place where the blood is taken).

- Be sure to include risks of being in a placebo or observation group.
- Sample wording:
    - We cannot be sure how your body will respond to the [drug, placebo, procedure, etc.] used in this study. The researchers will discuss possible side effects and the chances that they will happen. Unknown side effects may happen. Side effects may range from minor discomfort, or may be so severe as to result in death (indicate highest severity level if death is not applicable). You should report any side effects to the researcher.
- Discuss any potential effects the research study may have on reproductive potential or to a fetus.
    - Describe foreseeable risks to a fetus.
    - Describe any required pregnancy testing and actions that may be taken if the participant becomes pregnant.
    - Describe any affect participation in the study could have on sperm or egg production.
    - If the research involves pregnant women or women capable of becoming pregnant and the risk profile of the research procedures on an embryo or fetus are not well known, end with the statement: This research may cause harm or injury to an embryo or fetus in ways currently not known.

What are the possible benefits from taking part in this research study?

State the direct benefits, or the possibility of direct benefits, that are likely for research participants. If there are no direct benefits, state:
There is no direct benefit to you from being in this study.

Describe any potential general and social benefits that the research study may have. The following statement may be adequate:
If you take part in this study, you may help other people with [disease/condition] in the future.

What treatments or procedures are available if I decide not to take part in this research study?

- Explain alternative treatments in lay language;
- Explain whether or not the drugs/device/procedures can be obtained in a non-research setting;
- Offer the option that another alternative to being in the study is not to participate at all. A description as to what will happen to the subject if he/she elects not to participate (i.e. natural course of a disease) should also be included.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Describe any additional costs to the participant or to the participant's insurance company that may be incurred due to their participation in the study. Clearly delineate any additional procedures or testing that would be different between "standard of care" treatment and what is required solely for purposes of the research study. This section may be deleted if the study involves no costs to anyone.

Financial Consideration:

Will I be paid if I take part in this research study?

Please clearly state if the study participant will receive any acknowledgement for participation (payment) for participation in the research study. If study participants will receive any acknowledgement for participation, the amount and conditions of payment (including subjects that withdraw early) must be described. Payment and schedule of payments to the participants in the research study should be set forth in the informed consent form. The payment should be appropriate only for the level of risk, population recruited, and the commitment/time involved. It must not be excessive so as to induce participation only for financial gain. Patient withdrawal from a study will only be paid prorated for visits completed and not at the end of the study period.

What if I am injured as a result of being in this study?

This section is required for studies involving more than minimal risk. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Below are sample statements which can be used, depending upon the study. Choose the most relevant statement or compose a statement that is appropriate for the type of study being conducted.

1. You may be exposed to risk of injury from participation in this study. If injury occurs, treatment will, in most cases, be available. Such treatment will be at your expense, the expense of the sponsor or the expense of your insurance carrier. In the event of physical or psychological injury, BayCare Health System and its hospitals will not provide reimbursement for such injuries or any other compensation (such as for lost wages). The hospital will provide the medical and ancillary services ordered by your doctor at the established charges for those services. No money will be provided by the sponsor or the physicians as compensation for a trial-related injury. You are not waiving any legal rights; nor are you releasing BayCare Health System, its hospitals, or doctor from liability for responsibility for negligence related/unrelated to the nature and risk of the treatment. If you are injured while in the study, you should contact ___name of P.I.)_____ at ___(Phone #)____.

2. Researcher composed statement relevant to the type of study being conducted and the level of risk involved.

Include the following language verbatim:

Conflict of Interest Statement

Conflict of Interest *See instructions for whether or not this statement is needed in the informed consent. If not, remove the heading and paragraph.

This study involves a conflict of interest because: _____ will be compensated for your participation. This compensation is used to pay for the costs of doing this study. If you want to know, please ask the investigator how: _____ will benefit by your participation in the study.

The Institutional Review Board for BayCare Health System has reviewed the possibility of a financial conflict of interest and believes that the possible benefit to the person leading the research is not likely to affect your safety and/or the scientific quality of the study.

What are my rights as a study participant?

As a research study participant you have the right:

- To be told about the nature and purpose of the study;
- To be given an explanation of exactly what will be done in the study;
- To be given a description of potential risks, discomforts, or benefits that can reasonably be expected;
- To be informed of any appropriate alternatives to the study, including, if appropriate, any drugs or devices that might help you, along with their potential risks, discomforts, and benefits;
- To ask questions you may have about the study;
- To decide whether or not to be in the study without anyone misleading or deceiving you;
- To stop taking part in the study at any time; and
- To receive a copy of this consent form.

By signing this form, you will not give up any legal rights you may have as a research participant. You may choose not to take part in or leave the study at any time. If you choose to not to take part in or leave the study, your regular care will not be affected and you will not lose any of the benefits you would have received normally.

How will my confidentiality be maintained?

Offer a description as to how confidentiality of a subject's participation will be maintained. Consider the example statement below.

Your participation in this study will be kept as confidential as possible. Your identity will not be revealed. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity however will not be disclosed.

How is the privacy of my medical information maintained and what information about me may be released?

In addition to confidentiality of participation in a study, any study which collects health information on a subject also needs to describe how this information will be protected from improper access. This section may be modified or omitted if the research does not involve any health related information.

You have rights regarding the privacy of your medical information collected prior to and during this research study. This medical information is called Protected Health Information (PHI). Any PHI that is collected must be protected, as required by law. Only your written permission can allow the research staff to share this information with others who are involved in this research study.

Sharing this information with others may enable the researchers to

- carry out and evaluate the results of this study;
- ensure the study is correctly and safely performed;
- meet the reporting requirements of government agencies.

This information may *also* be shared with:

- The research team including the Principal Investigator, study coordinator, research nurses, and all other research staff. Do not list names because they may change over the course of the study.
- BayCare Health System Institutional Review Board
- The Sponsor of the study, [insert sponsor name]
- Food and Drug Administration (FDA).
- The Office for Human Research Protections in the U.S. Department of Health and Human Services.

Add the following if applicable, otherwise delete:

- Contract Research Organization, [insert CRO name]
- Outside Laboratories
- Data Analysis, Data Coordinator Centers
- Study Safety Monitors
- Drug Safety Monitoring Board

[Name of covered entity] is required by law to protect your health information. By signing this document, you authorize [name of covered entity] to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

The personal health information that may be used or disclosed (released) for this study includes:

- Complete as appropriate; provide a description of personal health information to be used or disclosed for the research project. The *PHI* may include, for example, all information in a medical record, results of physical examinations, medical history, laboratory tests, or certain health information indicating or relating to a particular condition.

There is no expiration date for the use or disclosure of your protected health information as it relates to your participation in this research study.

If you refuse to release your personal health information to the researchers of this study you will not be permitted to participate in this study. The non-study medical care and treatment for your medical condition will not be affected.

You may change your mind and withdraw your consent to release your protected health information at any time. *To withdraw your consent you must send* a letter to [insert Principal Investigator name and address: Once your consent is withdrawn:

- The research staff will stop collecting your medical information, but
- Any information that was collected before you withdrew your consent may still be used and shared as described above.

Can I withdraw my consent for participation in this research study?

You can withdraw from this research study at any time. If you decide to withdraw from the research study, you will still receive medical care. Clearly outline the study withdrawal procedures- these should be outlined in your protocol.

Different wording will be required if the study does not involve issues related to the subject medical care.

If I agree to participate in this research study, can I be removed from the study without my consent?

You may be removed from the research study if*:*

- Your condition changes;
- The researcher believes that is not in your best interest to stay in the study;
- You become ineligible to participate;
- Study instructions are not followed;
- The study is suspended or canceled;
- Add additional reasons as applicable, i.e. pregnancy

How can I get more information?

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should contact the investigator(s) listed on the first page of this consent document at the telephone number(s) given.

You will be told about new findings discovered during the course of this study that might influence your willingness to continue participation in the research study.

If at any time you want to discuss your participation in this study with someone who is not directly involved with the study, or if you feel undue pressure to enroll in or continue to participate in this study, you may contact the: BCHS IRB Office by telephone (727) 467-4577 or by writing -IRB Chairperson, c/o BayCare Health System Institutional Review Board, 2995 Drew St. East Building Clearwater, FL. 33579.

Statement of Consent and Authorization

This statement may need to be modified if the research does not involve a treatment plan.

I confirm that I have read the preceding information or it has been read to me. I confirm that I understand its contents. All my questions regarding this study and my participation in it have been answered to my satisfaction. I have been informed of the risks involved. I have been informed of my rights as a research subject. I understand that if I decide not to be part of this study or withdraw my consent, I will still receive treatment at (facility) or from the researcher. I will receive a copy of this signed and dated consent form. By signing this consent form, I give permission for the use and disclosure of my protected health information for the purposes of this study, and I have not waived any of the legal rights to which I otherwise would have as a subject in a research study.

_____

Subject's/Guardian's Signature* Date

_____

Subject's/Guardian's Printed Name

_____

Witness Signature **(only if required by sponsor)** Date

_____

Witness Printed Name

_____

Name of individual obtaining informed consent, if other than principal investigator

_____ _____

Signature of individual obtaining informed consent, if other than principal investigator Date

_____

Name of Principal Investigator Date

_____

Signature of Principal Investigator **(only if required by IRB)**

If this consent form is signed by a legal representative of the patient/research subject (for example, the parent, or legal guardian if the research subject is a minor), a description of such representative's authority to act for the patient/research subject must also be provided.

Provide description of authority:_____

_____