# **INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR**

**FOR COMPLETION OF THE INFORMED CONSENT**

Attached is a copy of the Informed Consent template that has been approved by the NorthBay Healthcare Institutional Review Board (IRB).

Complete the Informed Consent form by replacing the instructions in “red” with information as appropriate for your protocol. The “black” text is strongly recommended and should remain intact if applicable.

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

TITLE

**Principal investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Co-investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Facility Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

This is a clinical trial (a type of research study). Clinical trials include only participants who choose to take part. Please take time to make your decision. Discuss it with your family and friends.

This consent 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. Read every page carefully and make sure that all your questions are answered to your satisfaction. [STATE IF APPLICABLE: The study doctor is being paid to conduct this study.]

**Why have I been asked to take part in this research study, and who is conducting it?**

You have been invited to take part in this research study because you have [INSERT DIAGNOSIS AND MAY INCLUDE EXTENT OF DISEASE]. This study is being conducted by [INSERT SPONSOR/COOPERATIVE GROUP NAME].

**Why is this research study being done?**

The reason for doing this study is to compare the effects, good and bad, of [INSERT TREATMENT(s)]. We want to see if giving the [INSERT TREATMENT(s)] will help [INSERT WHAT THEY ARE TRYING TO DO, e.g. PREVENT THE CANCER FROM COMING BACK]. We will also learn more about any side effects you experience.

This study is being done because [INSERT REASON].

[FOR A COMPARATIVE STUDY THE FOLLOWING PARAGRAPH CAN BE INSERTED INTO THE TEXT AT THIS POINT.]

At the present time we do not know which of these treatments is better for [INSERT DISEASE] you have.

**How many people will take part in the study?**

About [insert number of participants] [insert males and/or females] will take part in the study in the United States.

**What is involved in the study?**

[THIS SECTION SHOULD DESCRIBE THE FREQUENCY OF VISITS, TESTS, EXAMS, OR PROCEDURES, AND NOTE WHICH ONES ARE EXPERIMENTAL. THE ITALICIZED SECTIONS SHOULD CONTAIN THE INFORMATION APPROPRIATE TO THAT SECTION. INDICATE HOW MUCH OF THE SUBJECT’S TIME WILL BE INVOLVED. DESCRIBE PHYSICAL REQUIREMENTS: VENIPUNCTURE, EXERCISES, OR USE OF SPECIAL MEDICAL DEVICES. IF A PLACEBO IS ADMINISTERED OR DISPENSED TO A PORTION OF THE SUBJECTS INVOLVED, ALL SUBJECTS SHALL BE INFORMED OF SUCH FACT.]

*Before you begin the study***.**

First we will need to find out whether or not you are able to be on the study. You will be asked to give information about your medical history and undergo the exams and tests listed below. If you have had any of them recently, your doctor may decide not to repeat them. These exams and tests include:

[insert exams and tests]

*While you are participating in the study***.**

[IN THIS SECTION THERE SHOULD BE A DESCRIPTION OF THE TREATMENT, PROCEDURES FOR THE TREATMENT AND LENGTH OF TIME EACH TREATMENT TAKES.]

[IF RANDOMIZATION IS BEING USED FOR GROUP ASSIGNMENT, THE FOLLOWING PARAGRAPH CAN BE INSERTED INTO THE TEXT AT THIS POINT.]

You will be put into one of the study groups mentioned above through a process called randomization. Randomization means that you are put into a group by chance, like flipping a coin. Neither you nor your doctor will choose what group you will be in. The group will be chosen by computer.

**How long will I be in the study?**

Your treatment will last [insert time period].

We would like to keep track of your medical condition for [Insert how long follow-up will continue once the participant is off the treatment portion of the study. e.g. “THE REST OF YOUR LIFE TO LOOK AT THE LONG-TERM EFFECTS OF THE STUDY”]. However, your doctor may take you off the study drugs if one of the following happens:

* the study treatment does not work for your [INSERT DISEASE];
* you develop a serious side effect that you cannot tolerate or that cannot be controlled with other medications or treatments;
* your health gets worse;
* you are unable to meet the requirements of the study (for example, you cannot take the medicine as prescribed or cannot return for follow-up visits);
* new information becomes available about the study drugs or other treatments for [INSERT DISEASE] become available.

In addition, your participation in this study may be ended because [insert sponsor/group] finds it necessary to limit or stop the study.

**What are the risks of the study?**

There are risks involved in taking the [INSERT “DRUG(s)” or “TREATMENT(s)”] in this study, and there may be side effects. Most of these are listed below, but they will vary from person to person. Your doctor may be able to give you other medications to make some of the side effects less bothersome.

Many side effects go away shortly after the [INSERT “DRUG(s)” or “TREATMENT(s)”] are stopped, but in some cases, side effects may be very serious, long-lasting, and/or life-threatening. Talk with your study doctor about this. If you want to read more about the study [INSERT “DRUG(s)” or “TREATMENT(s)”], please ask your doctor [INSERT “OR PHARMACIST” IF DRUGS] for more information:”

**Side effects that are *likely* to occur from your therapy:**

[LIST COMMON SIDE EFFECTS]

**In addition, it is *possible* you may experience one or more of the following during your therapy:**

[LIST OTHER LESS COMMON SIDE EFFECTS]



**In *rare* circumstances, you may experience:** [LIST RARE SIDE EFFECTS]

There may be other side effects that we cannot predict. During your screening for this trial, one of the study staff gave you information about the benefits and risks of your participation. You should discuss these risks and side effects with the researcher, [INSERT NAME OF PHYSICIAN AND PHONE NUMBER], or your regular doctor.

**Risks related to pregnancy:** You should ***not*** become pregnant or make someone else pregnant while on this study because the [INSERT “DRUG(s)” or “TREATMENT(s)”] can affect an unborn baby. Ask for counseling and more information about preventing pregnancy if this applies to you. Also, you should not nurse your baby while on this study. Some of the [INSERT “DRUG(s)” or “TREATMENT(s)”] used in the study may make you unable to have children in the future.

**Are there benefits to taking part in this study**

We cannot guarantee you will benefit if you take part in this study. The treatment you receive may even be harmful. Your doctors feel that your participation in this study will give you at least as good a chance as you might expect from other treatments. We hope the information learned from this study will benefit other patients with [INSERT DISEASE].

**What other treatment options are there?**

Instead of being in the study, you can decide to have:

* [LIST TREATMENT(s)]
* No treatment

You can get treatment for [INSERT DISEASE] even if you do not take part in this study. All of the treatment on this study may be available at this center or at other locations. Please talk with your doctor about these and other options before you enter the study and about other options that may become available during the trial.

**What are the costs?**

Taking part in this study may lead to added costs to you or your insurance company due to [INSERT TEST(s)/PROCEDURE(s) THAT APPLY]. Please ask about any expected added costs or health insurance problems.

If you are injured or become ill from taking part in this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to pay you in the event of injury. You or your insurance company will be charged for continuing medical care and/or hospitalization.

You will not be paid for taking part in this study. [OR INSERT COMPENSATION]

You are not being asked to waive any legal rights.

**Do I have to be a part of the study?**

You may choose to either take part or not to take part in this research study.

If you have any questions about the study, you will have a chance to talk to one of the study staff. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers. You may also wish to discuss this matter with a relative, a friend, or your regular doctor.

**What are my rights as a study participant?**

Even after you agree to take part in this study, you may withdraw at any time. Before withdrawing, you should notify one of the people involved with this research. This will allow that person or someone else supervising the research to inform you of any medical risks associated with withdrawing from the study. You can choose to withdraw in one of two ways. First, you can stop your study treatment, but still allow your study doctor to follow your care. Second, you can stop your study treatment and not have any further contact with the study staff. Either way, there will be no penalty to you.

Your decision will not affect your routine medical treatment, your relationship with those treating you, or your relationship with this institution. If you withdraw from the study therapy, you will still be offered all available care that suits your needs and medical condition.

Your doctor will tell you if any new information about the study develops that may affect your health, welfare or willingness to stay on the study. You may be asked to sign another consent form at that time.

**Who can I call if I have questions or problems?**

If you have any further questions about the study or if you think you have experienced a research-related illness or injury, contact [INSERT PRINCIPAL INVESTIGATOR NAME] at [INSERT PHONE NUMBER].

If you have any questions regarding the way in which this study is being conducted, or your rights as a research subject, contact the NorthBay Healthcare Institutional Review Board at (707) 624-7001.

**How will information about me be kept private?**

We will try to keep personal information as private as we can. We cannot guarantee absolute privacy. Your personal information may be disclosed if required by law. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include the groups listed below.

* The Food and Drug Administration (FDA)
* [ LIST OTHERS SUCH AS SPONSOR, DATA GROUP, ETC]

Your research records will include things such as your medical history, results of your blood tests and exams, reports from your surgery and treatment, and reports of your office visits. Your medical records for this study may be sent by facsimile transmission (FAX machine). It is possible, although unlikely, that your records could be sent to the wrong machine in error. If we publish the information we learn from this study in a medical journal, you will not be identified by name or in any other way. Your Protected Health Information (PHI) may be released until the end of the research study.

**By signing this statement, I agree to the release of my Protected Health Information (PHI) to the above listed agencies for the period of time specified (refer to Section: How long will I be in the study?). However, I also understand that I may revoke this authorization to release my PHI, in writing, at any time.**

Participant’s Name

Participant’s Signature Date

**STATEMENT FOR THE PARTICIPANT**

By signing this form, you are showing that you have read this Informed Consent to Participate in Research or it has been read to you. Please do not sign this form unless you understand what is in this form, including the risks described, and all your questions have been answered satisfactorily. Remember that you may withdraw your agreement to be in this study at any time. By signing this form, you are showing that you have freely and voluntarily agreed to the requirements of the study and that you want to take part in this study. You will receive copies of this form and the Experimental Subject's Bill of Rights. All oral and written information and discussion about this study has been provided in English or in another language in which you are fluent.

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Participant's Name*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Participant's Signature Date*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Witness’ Name*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Witness’ Signature Date*

**STATEMENT OF THE INVESTIGATOR**

***This patient has been evaluated for participation in this clinical trial. The risks, benefits and alternative treatment were explained to the patient. The patient agrees to participate in this protocol.***

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Investigator's Signature Date*