**Consent and Authorization Form for Research Study**



**Approved by Institutional Review Board**

|  |
| --- |
| Study Title: |
| Name of Investigator: |
| Phone Number: |
| Study Sponsor: |

1. **Why have I been asked to take part in this research study?**

You have been invited to take part in a research study (the “Research Study” or “Study”) being done by Legacy Health. You have been invited because

The purpose of this Consent Form is to give you information about the Research Study; then you can decide whether you would like to take part.

1. **Who is doing the study?**
2. **Why is this study being done?**

*(If applicable:)* The usual approach to care for is .

The purpose of this Research Study is to      . *(Provide a brief description of why the study is being done. Use the names and types of drugs/agents/interventions where indicated. Describe what is experimental about this study.)*

The length of time you will be in the Study is      . *(Include both active treatment/study and follow-up times.)*

*[Indicate how many research subjects will be taking part at Legacy, and if this a multi-site study indicate how many other sites will be involved and what is the total number of research subjects across the country.]*

1. **What will happen if I take part in this Study?**

Before you start the study:

During the study:

*(Note the extra tests and procedures that are not standard of care, including required specimen collection.)*

*(If applicable, use sub-head:* What are the study groups?

* *(Describe and/or diagram, and describe randomization.)*
* *(If applicable, describe use of placebo; include statement about whether or not and when the subject will learn if they received placebo.)*

1. **What are the possible side effects and risks from being in the study?**

There are possible risks, side-effects or discomforts that might happen if you take part in the Study; these have been explained to you. You have had a chance to ask your doctor and staff all the questions you have about the risks in this Research Study.

Those risks, side-effects and discomforts include:      . *(Should include both physical and non-physical risks, including more time in hospital, private questions being asked, etc.)*

*(If applicable:* The tables below show the most common and the most serious side effects that researchers know about.)

*[If applicable:* The treatments or procedures in this Study may also have risks that are not known at this time. You have had a chance to talk with your doctor and the staff about possible unknown risks.]

Reproductive Risks (Information on Pregnancy / Birth Control

*[If applicable:* The treatment in this study may have risks to a pregnant woman, an unborn human fetus or a breastfeeding child. So if you are pregnant, planning to become pregnant or father a baby, or breastfeeding, you cannot take part in this Study.]

*(If women should not become pregnant during the course of the study:)* To lower your chance of getting pregnant while in the Study, you will need to use an effective method of birth control. Check with the study doctor about what types of birth control to use while in the study. If you now use a method of birth control, the study doctor or study staff can tell you whether it is alright for use during this study.

If you become pregnant during this study, you should tell the study doctor as soon as possible.

1. **What are the possible benefits of this study?**

You may or may not personally benefit from being in this Study. But, by being a research participant, you may add to new information which helps other people in the future.]

1. **What are my other choices if I do not take part in this study?**

*[For studies involving medical interventions:*Talk with your doctor about other treatments or procedures that are available. These include \_\_\_\_\_\_\_\_ *(briefly state the options available*). You also have the choice to not get any treatment for your condition. You have had the chance to ask questions about the options with your doctor and other health care providers.]

*[For studies comparing approved procedures, drugs or devices, or for studies involved in off label uses of drugs or devices:* The treatment involved in this Research Study may also available to you without taking part in the Study. Talk to your doctor about what might be best for you.]

*[For questionnaires and other non-medical interventions, this section is not needed*.)

1. **What are the costs of taking part in this study?**

*[If applicable:* The costs of the following medicines, devices, and procedures in this Study will be paid by the Study Sponsor:      .]

Except for the costs listed above, you may have to pay for other medicines, devices, supplies and/or care that are part of this Research Study. [*Optional*: Those costs include:     .] Legacy Health will first bill your health insurance for such costs. If your insurance does not pay, or pays only a part of the costs, Legacy Health may bill you for any unpaid amounts.

1. **Will I be paid for being in this study?**

The sponsor will pay you for taking part in the Research Study. You will be given      .

*Or*

You will not receive any sort of payment for taking part in the Research Study.

1. **What happens if I am injured or hurt because I took part in this study?**

If you have an injury or illness, you should seek medical care for it and tell the study doctor.

*[For those studies involving potential physical risk, including simple procedures such as blood draw*: If you become sick or hurt while taking part in this Research Study, medical treatment will be available; this might be first aid, emergency treatment or follow-up care as needed. Legacy Health will bill your health insurance for the cost of such care. If your insurance does not pay for that care, or pays only a part of the cost, Legacy Health may bill you for any unpaid amounts. By providing or making available medical care for injuries or illness, Legacy Health and the people doing this Research Study are not admitting fault for injury or illness.

*(If sponsor does offer compensation for injury related to study participation, explain that.)*

1. **What are my rights in this study?**

Taking part in this Research Study is voluntary; it is your choice. You are free to decide not to take part; and you can decide to stop taking part at any time. Your decision will not affect your relationship with or treatment at Legacy Health. It will also not lead to any penalty or loss of benefits that you would have outside of the Research Study.

You can decide to stop being in the study at any time. If you decide to stop for any reason, tell study doctor as soon as possible. If you are taking a study drug, the doctor can help you stop safely. Also, you can decide whether the study doctor can continue to collect your medical information for the study.

New information learned during the Research Study could affect whether you still want to take part. New findings will be explained to you, and your written agreement to stay in the study may be needed.

The study doctor may take you out of the study:

* If your health changes and the study is no longer in your best interest
* If new information becomes available that suggests the study is not right for you
* If you are not able to meet the study requirements
* If the study is stopped by the sponsor

*[For studies involving an implanted medical device*: However, your freedom to leave this Research Study may be limited if you receive an implanted medical device. If you decide to leave the Study, you will not be required to take part in research related follow-up. But if you chose to have the device removed, you or your health insurance company may need to pay for that procedure.]

1. **Who can answer my questions about this study?**

Talk to the study doctor and staff about any questions or concerns you have about this study. You should also tell them about any side effects you have. Call the study doctor  *(insert name of study doctor(s)* at *(insert telephone number).*

You have a right to know about the risks, benefits, alternative procedures, and your rights as a research participant. If at any time you believe you have not been well informed, or if you feel pressure to take part in the study even if you do not want to, you can talk to a Research Specialist. Legacy Health’s Research Regulatory Specialist is available by phone during weekday working hours (8:30 a.m. to 5:00 p.m.) at (503) 413-2474.

1. **Who will see my medical information?**

For this Research Study, your doctor and research staff will need information from your medical records. This information about you is called Protected Health Information (PHI). PHI includes any part of your health records that could be used to identify you, such as name, address, birth date, etc. With this Consent Form, you allow Legacy Health to use and share your PHI only for the purposes of this Research Study.

WHO: You authorize (give permission to) Legacy Health to provide your PHI to these people and agencies: *(e.g., person(s), classe(s) of persons or business or government entities.)*

FOR HOW LONG: You authorize (give permission to) Legacy Health to use and share your PHI for the purposes of this Research Study until: (e.g. *you cancel that permission at any time in writing; until the end of the research study; until the FDA approves the drug; for \_\_\_ (a specified length of time); for an unlimited period of time).*

We will keep your information as secure as we can. But once Legacy Health gives PHI to the people or agencies listed above, Legacy Health cannot guarantee they will keep it private. They might give PHI to other people who are not limited by the terms of this Consent Form; and it might be used in ways that you did not intend.

You may change your mind and cancel this authorization at any time. To cancel this authorization, you must write to:

Principal Investigator

Address

Phone

If you cancel this authorization, you may no longer be able to take part in the Study. But the information already collected by Legacy Health and *[Sponsor name]* may be used and shared as allowed by this authorization and consent form.

1. **Where can I get more information?**

*[For those studies listed on ClinicalTrials.gov:* A description of this clinical trial (research study) will be on the internet at http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not have any information that can identify you. At most, the website will include a report of the Study results. You can search this website at any time.]

Use the following text for all cancer-related studies:

For more information about cancer and cancer studies, visit the NCI Web site at [www.cancer.gov](http://www.cancer.gov/). You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

You will receive a copy of this Consent Form.

#### My signature agreeing to take part in this Research Study

I have read this Consent Form or had it read to me. I have talked about it with the study doctor, and my questions have been answered.

I agree to take part in this Research Study. I know I can change my mind and can stop being part of it at any time.

I also give my permission to Legacy Health to use and share my Protected Health Information (PHI) for the purposes of this Research Study, as described in this Consent Form.

Signature of Research Participant Date

Printed Name of Research Participant

Signature of Legal Representative of Research Participant Date (if applicable)

The research participant has been informed of the purpose and procedures of this Research Study. This includes the risks involved in the study and the use of Protected Health Information. The participant’s questions have been answered to the best of our ability. A copy of this Consent and Authorization has been given to the participant.

Signature of Investigator or Designee Date