# INFORMED CONSENT AND AUTHORIZATION FOR PARTICIPATION IN RESEARCH

**Instructions (DO NOT INCLUDE THIS INFORMATION IN YOUR ASSENT):**

* **Font must be Times New Roman and at least at 12 point.**
* **Must be paginated.**
* **Bottom margin must be at least 1 inch.**
* **All footer information must be either on the left side of the page or the middle.**
* **A version number and date must be included in the footer of the document**
* **If the text below is in blue, this language must be used exactly as written.**
* **Use language that the average person is likely to understand (no higher than sixth grade-level). Define any technical terms and/or acronyms. For guidance, see IRB Document 118.9, “**[**Glossary of Lay Terms for Use in Preparing Consent Forms**](http://www.creighton.edu/fileadmin/user/ResearchCompliance/IRB/Policies_and_Procedures/118_9_Glossary_of_Lay_Terms_for_Use_in_Preparing_Consent_Forms.pdf)**”.**
* **Write using second person (i.e., subject addressed as “you” and clinical investigators as “I/we”).**

**TITLE OF RESEARCH:**

**IRB NUMBER:**

**SPONSOR PROTOCOL NUMBER:**

**INVESTIGATOR NAME:**

**INVESTIGATOR ADDRESS:**

**INVESTIGATOR PHONE NUMBER:**

**SPONSOR:**

You are being asked to take part in this clinical research study at **(Insert Name of Facility)**. This consent form explains why this research study is being done and what your role will be if you choose to take part. This form also describes the possible risks connected with being in this study. After reviewing this information with the person responsible for your enrollment, you should know enough to be able to make an informed decision about whether you want to take part in the study.

You are being asked to take part in this study because **(Insert the reason the subject is being approached for study participation)**.

## PURPOSE OF STUDY

The goal of this research study is **(Insert brief paragraph about the study purpose).**

## LENGTH OF STUDY AND NUMBER OF PARTICIPANTS

**Include a sentence explaining how many total participants will be enrolled in the study and how many will be enrolled at the local study site. If the investigator will see subjects at multiple locations indicate where the subjects will be enrolled. Please include a statement of how long participation is expected (I.E., how long the study lasts for each subject).**

## **DESCRIPTION OF STUDY**

This is an **(Insert type of study – e.g., investigational, observational) study. Provide a one to two sentence summary of the study.**

***Insert a detailed description of the study. Where applicable, include an explanation of study treatments, study groups, study visits, and what is required at each visit, questionnaires, assessments, length of treatment/study phase, end of study activities, follow-up visits, etc. Be as detailed as possible.***

## RISKS, SIDE EFFECTS, AND DISCOMFORTS TO PARTICIPANTS

While in this study, you are at risk for side effects. These side effects will vary from person to person. At each treatment visit, you will be asked about your experience with side effects. The most commonly occurring side effects are listed in this form, as are rare but serious side effects that the **(include the name of the investigational product or device)** is known to cause. You should discuss these possible side effects with the study investigator. You may also want to ask about uncommon side effects that have been observed in small numbers of subjects but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases, side effects may be serious, long lasting, or permanent, and may even cause hospitalization and/or death.

## POSSIBLE SIDE EFFECTS

**INSERT A COMPREHENSIVE LIST OF ALL SIDE EFFECTS – include those related to treatment, lab procedures, blood draws, questionnaires, radiation, and general side effects etc. Every procedure/treatment should be listed along with any associated side effects. In addition to physiological risks/discomforts, describe psychological, emotional, financial, social, and legal risks that might result.**

## RADIATION RISKS

**When applicable, indicate radiation risk and exposure comparison to daily life and/or routine medical care. If not more than usual care, the following language should be used:**

Although you will undergo some tests involving ionizing radiation in this protocol, they are the same you would undergo if you were not in this study, and at the same frequency. Therefore, this study does not involve any additional radiation risk for you.

## PREGNANCY-RELATED RISKS

**DEDICATE THIS SECTION TO PREGNANCY RELATED RISKS – (TAILOR THE BELOW STATEMENT TO FIT CURRENT STUDY – Please see the CHRISTUS Health approved pregnancy prevention statements)**

If you are pregnant or breastfeeding, you cannot **(or may not be able to)** take part in this study. You may be required to have a blood and/or urine test to see if you are pregnant before you begin study treatment. If you are sexually active, it is important that you not become pregnant or father a child during this study because this medication may be harmful to your unborn child. **You must discuss your pregnancy plans with your doctor before enrolling in this study; you must also agree to use the type and duration of precautions approved by your doctor for the entire time you receive this study treatment.** For women, if you become pregnant or have reason to believe you might be pregnant, please inform your doctor immediately. Once you are no longer receiving this study treatment, discuss with your doctor when it might be safe to become pregnant or become a new father.

This study may involve unpredictable or unknown risks to the participant.

**(Remove the below paragraph if research is not in Louisiana)**

Louisiana law requires us to set forth the known risks of a medical treatment, including the risks, if any, of death, brain damage, quadriplegia (paralysis in all arms and legs), paraplegia (paralysis of both legs), the loss or loss of function of any organ or limb, and disfiguring scars, which might be associated with a necessary procedure. Any clinical study carries with it risks of which we may be unaware at this time, including those listed in this paragraph. [These complications have never been seen with this investigational drug, and chemically related compounds have not been associated with any of these adverse effects.]

*The paragraph above should be included as required by Louisiana State Law in those informed consents for research that involves more than minimal risk. It should be removed when the study is non-treatment, like an observational study, record review, or survey. Do not alter this language without approval from CHRISTUS’s Legal office. Attach approval e-mail with the consent form in iRIS.*

## POTENTIAL BENEFITS

**INSERT A STATEMENT REGARDING THE BENEFITS OF STUDY PARTICIPATION**. Inform subjects that their condition may not improve or may get worse, despite participation in the research.

## ALTERNATE PROCEDURES OR TREATMENTS

You may choose to not take part in this study. **INSERT A STATEMENT REGARDING OTHER OPTIONS FOR TREATING THE CONDITION UNDER STUDY.** You may choose not to be treated at all.

## CONFLICT OF INTEREST

The CHRISTUS Health Conflict of Interest policy states that CHRISTUS Health Associates and/or Physicians may not serve as the study chair or co-chair on a research study if they have received funds that are greater than the amount allowed by the policy or own stock in the sponsoring or supporting companies. The Conflict of Interest policy and the IRB also require that you be told about significant financial relationships that the study staff and CHRISTUS Health officials may have with the study sponsor(s). At this time, no significant financial relationships with the study sponsor(s) have been disclosed by any of the study staff.

CHRISTUS Health may benefit from your participation and/or what is learned in this study

## CONFIDENTIALITY/PRIVACY

Your identity and your records will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. Confidentiality will be maintained during and after your participation in this study. However, there is no guarantee of absolute privacy. Federal agencies (such as the FDA and the OHRP), **(INSERT SPONSOR(S) NAME)** and the CHRISTUS Health IRB might review your record to collect data or to check that the research is being done safely and correctly. In some situations, the FDA or any of these regulatory agencies could be required to reveal the names of participants.

## COST OF PARTICIPATION AND COMPENSATION OF INJURY

If you suffer injury as a direct result of taking part in this study, CHRISTUS Health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You **(will or will not)** be reimbursed for expenses or compensated financially by CHRISTUS or **(INSERT SPONSOR(S) NAME)** for this injury. You may also contact the CHRISTUS Health IRB at **469-282-2686** with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the costs of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. The standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

## PAYMENT FOR PARTICIPATION AND/OR REIMBURSEMENT OF EXPENSES

**If the study is unfunded – please remove the below and include a statement that there is no compensation for participation in the research.**

**DISCUSS COMPENSATION IN THIS SECTION (TAILOR BELOW STATEMENT TO FIT STUDY)**

You may receive up to **(FILL IN MAXIMUM AMOUNT OF COMPENSATION)** in the form of **(FILL IN TYPE OF COMPENSATION IF APPLICABLE)** for study participation. You will only receive compensation if you are found eligible for study participation. No compensation will be provided for incomplete visits.

Compensation will be given according to the below payment structure **(FILL IN PER VISIT COMPENSATION SCHEME, if applicable).**

You will only receive compensation if you are found eligible for study participation. No compensation will be provided for incomplete visits.

* **This section should be reviewed by Office of Sponsored Programs and Research Finance for concurrence with CTA.**
* **A statement should be included indicating whether a subject is to be paid for participation or for reimbursement of expenses. It should explain how the payments will be dispersed over the course of the study and what the payments are being provided for [i.e., participation in the study, reimbursement for travel expenses, reimbursement for time lost from work, etc.].**
* **Payment should not be contingent upon completion of the entire study. Example: “You will receive $10.00 per study visit. This will be paid to you quarterly [4 times per year]. If you complete the entire study, you will be paid a total of $200.00. If you withdraw from the study early, you will be paid for the number of study visits you complete.”**
* **If payment for participation or reimbursement of expenses will not be provided, state that.**
* **Non-dollar amount “incentives” such as gift certificates, etc. should be included in this section.**
* **If there is a chance that total annual payment may reach $600, add: “Study payments that reach IRS limits of $600.00 in a calendar year will be reported to the IRS as required by law”.**

***The following must be included if participants are receiving payment for participation or reimbursement of expenses:***

Greenphire has been engaged by CHRISTUS Health to manage the reimbursement process.  You will be issued a Greenphire ClinCard, which is a debit card that your funds are loaded onto at the completion of a study visit.  When a visit is completed, funds will be approved and loaded onto your card.  The funds will be available within 1 business day and can be used at your discretion.  You will be issued one card for the duration of your participation.  You will be given instructions which will explain how to use your card. If your card is lost or stolen, you can contact the CHRISTUS Health study team for a replacement card.

Greenphire will collect information about you, including name, address, social security number, and date of birth.  All information is stored in a secure fashion and is deleted from the system once the study has been completed and the funds on the card have been exhausted.  Your information will not be shared with any third parties and will be kept completely confidential.  *Greenphire collects your social security number to permit the preparation of IRS-1099 form(s) for participants receiving $600 or more in any one calendar year, in accordance with Treasury Regulations, Sub-chapter A, Sec. 1.6041-1.*

By registering with the ClinCard system and using the ClinCard, you consent to participate in the ClinCard program.

## STUDY RELATED QUESTIONS

If you have questions concerning your participation in this study or if at any time you feel you have experienced a research-related injury or a reaction to a study drug, contact:

**Provide the contact name and information for the principal investigator.**

If you have any questions about your rights as a research subject, you may contact:

 CHRISTUS Health IRB

 919 Hidden Ridge Ave

 Irving, TX 75038

 469-282-2686

 christus.irb@christushealth.org

CHRISTUS Health IRB is a group of people who perform independent review of research. The study sponsor, the principal investigator, and sub-investigators are independently practicing physicians or employees of CHRISTUS Health System or the CHRISTUS Health IRB.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

## AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study investigator must get your authorization (permission) to use or give out any health information that might identify you.

### What information may be used and given to others?

If you choose to be in this study, the study investigator will get personal information about you. This may include information that might identify you. The study investigator may also get information about your health including:

* Medical and research records
* Records about phone calls
* Records about your study visits

**[Add additional items as appropriate, examples are below, delete if does not apply]**

* Information about HIV/AIDS\*
* Information about hepatitis infection
* Information about sexually transmitted diseases
* Information about other reportable infectious diseases
* Records of physical exams
* Laboratory, x-ray, and other test results
* Diaries and questionnaires
* Records about study medications
* Records about any study device you received
* Information related to diagnosis and treatment of a mental health condition
* Records about any study drug you received

\* Will not be disclosed without additional authorization from you.

### Who may use and give out information about you?

Information about your health may be used and given to others by the study investigator and staff. They might see the research information during and after the study.

### Who might get this information?

Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. [If no sponsor outside CHRISTUS Health, delete this section]

**For this study, "sponsor" also includes: [if no CRO or SMO, delete this line also]**

* **[insert CRO name, an agent for the sponsor]**
* **[Insert SMO name, an agent for the study investigator.]**

Information about you and your health, which might identify you, may be given to:

* The U.S. Food and Drug Administration (FDA)
* Department of Health and Human Services (DHHS) agencies
* Governmental agencies in other countries
* Governmental agencies to whom certain disease (reportable diseases) must be reported
* CHRISTUS Health Institutional Review Board
* [Add or delete from list to be accurate for your study]

### Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies. [Delete if not an FDA regulated study]

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The CHRISTUS Health IRB may review the information. The IRB is a group of people who perform independent reviews of research as required by regulations.

### What if I decide not to give permission to use and give out my health information?

By signing this consent form, you are giving permission to use and give out health information listed above for the purposes described above. If you refuse to give permission, you will not be able to participate in this research study.

### May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

### May I withdraw or revoke (cancel) my permission?

This permission will not stop automatically. ***OR***

This permission will be good until **[list a specific date if available, or end of study or another marker, but be informative and accurate]**

You may withdraw your permission to use and disclose your health information at any time. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information, which might identify you, will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

### Is my health information protected after it has *been* given to others?

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission. Your personal information may be disclosed if required by law.

Your records for this study may be sent by facsimile transmission (FAX machine) or electronically over the Internet. It is possible that your records could be sent to the wrong person. **[Delete if no FAX or Internet communications used]**

### ClinicalTrials.gov (if Applicable) – Remove if not applicable to the study

Information about this research study may be submitted to clinicaltrials.gov, a publicly available online database managed by the U.S. National Institutes of Health (NIH). None of your identifying information will be submitted to clinicaltrials.gov. If information from this study is submitted, none of it will be able to be directly linked to you.

## VOLUNTARY PARTICIPATION AND WITHDRAWAL

Participation in this study is voluntary. You may decide not to participate in this study, or you may withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled at this site. You will be informed of any significant new findings that develop during the investigation that may affect your willingness to continue in the study.

You should tell your study investigator about all of your past and present health conditions and allergies of which you are aware, and all drugs and medications which you are presently using.

Your participation in this study may be stopped at any time by the study investigator or the sponsor without your consent because:

* the study investigator thinks it is necessary for your health or safety;
* you have not followed study instructions;
* the sponsor has stopped the study; or
* Administrative reasons require your withdrawal.

If you leave the study before the final regularly scheduled visit, you may be asked by the study investigator to make a final visit for some need of study procedures.

## CONSENT/AUTHORIZATION (ADULT PARTICIPANTS ONLY)

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation have been answered. I freely consent to participate in the research study. I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above. By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

**Subject Signature Printed Name Date**

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**Authorized Representative**

***(When applicable)***

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**Authority of Subject's Legally Authorized Representative or Relationship to Subject**

**Person Obtaining Consent**

I have discussed this clinical research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Principal Investigator Printed Name Date**

**Or Person Obtaining Consent**

[ ]  Yes [ ]  No **Are you a CHRISTUS Health or CHRISTUS Health Affiliate employee?**

You will receive a signed and dated copy of the Voluntary Participation in a Clinical Research Study by a CHRISTUS Health or CHRISTUS Health Affiliate Employee form for your records.

**Witness to Consent\***

I was present during the explanation of the research to be performed under Protocol **(INSERT PROTOCOL NUMBER HERE)**. *\*A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Witness Signature Printed Name Date**

**Relationship to Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**TRANSLATOR**

I have translated the above informed consent as written (without additions or subtractions) into \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **(INSERT NAME OF LANGUAGE)** and assisted the people obtaining and providing consent by translating all questions and responses during the consent process for this participant.

**Name of Translator Signature of Translator Date**

 **Please check here if translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)**

**Signature of Witness to the Verbal Translation Date**

**(Other than Translator, Parent/Guardian, or Study Chair)**

**------------------------------Use the following only if applicable-----------------------------**

If this consent form is read to the subject because the subject (or legally authorized representative) is unable to read the form, an impartial witness must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information were explained, and the subject was given the opportunity to ask questions (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to participate in the research study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Impartial Witness Printed Name Date**

Note: This signature block cannot be used for translations into another language. A translated consent form, with the translation approved by the IRB, is necessary for enrolling subjects who do not speak English.