**Consent Form for Participation in a Research Study**

**Title of Study (use same title as submitted to IRB)**

**Description of the research and your participation**

You are invited to participate in a research study conducted by (insert the name of the Principal Investigator here). The purpose of this research is (explain using language which can be easily understood by the subject).

Your participation will involve (describe the procedures to be followed).

**Risks and discomforts**

There are no known risks associated with this research. OR There are certain risks or discomforts associated with this research. They include (describe any reasonably foreseeable risks or discomforts to the participant. You may also describe the measures you will take to minimize these risks and discomforts.)

**Potential benefits**

There are no known benefits to you that would result from your participation in this research. OR (Describe any benefits to the participant and to others that may reasonably be expected from the research.) This research may help us to understand (brief statement, if appropriate).

**Voluntary participation**

Your participation in this research study is voluntary. You may choose not to participate and you may withdraw your consent to participate at any time. You will not be penalized in any way should you decide not to participate or to withdraw from this study.

**AUTHORIZATION TO USE AND DISCLOSE 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 doctor 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 doctor will get personal information about you. This may include information that might identify you. The study doctor 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 doctor and staff. They might see the research information during and after the study.

**Who might get this information?**

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 results of this research may be published in scientific journals or presented at medical meeting, 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 review 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 other marker, but be informative and accurate]*

You may withdraw or take 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.

Describe the extent to which confidentiality of records identifying the participant will be maintained.

If appropriate, precede the description with:

*We will do everything we can to protect your privacy.*

If appropriate, follow the description with:

*Your identity will not be revealed in any publication resulting from this study.*

**Contact information**

If you have any questions or concerns about this study or if any problems arise, please contact (insert Principal Investigator’s name here) at (location name at XXX-XXX-XXXX. If you have any questions or concerns about your rights as a research participant, please contact the CHRISTUS Health IRB at 469-282-2686 or via email at christus.irb@christushealth.org.

A copy of this consent form will be given to you.

**Consent**

**I have read this consent form and have been given the opportunity to ask questions. I give my consent to participate in this study.**

Participant’s signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**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.

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**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.