Template Version 13: 08/11/16

- Instructional text should be removed prior to submission to the IRB.
- Text italicized and in parentheses ( ) should be replaced by information for your study e.g., *(Study Title)* and should then be un-italicized for the final draft.

TCH# (*protocol number, ex. 09-01)*

THE CHRIST HOSPITAL
INFORMED CONSENT AUTHORIZATION

(Study Title)

INVESTIGATOR INFORMATION

Principal Investigator: *(Principal Investigator Name*)

Co-Investigator: *(All Co-Investigator Names)*

Sponsor: *(Sponsor, if applicable)*

I. INTRODUCTION

Before you agree to participate in this medical research study, it is important that you understand the following explanation of the proposed procedures. This consent describes the purpose, procedures, benefits, risks, discomforts and precautions of this study. It also describes alternative procedures available, if applicable, and the right to withdraw from the study at any time. It is important that you understand that no guarantee or assurance can be made as to the results. You should also understand that refusal to participate in this study will not influence standard treatment for you. You should be sure that any questions you may have are answered to your satisfaction before agreeing to take part in this study. Should you agree to participate in this study and sign this consent form, your study doctor (or designee) will then ask you questions and will perform tests and procedures to see if you are eligible to participate in this study. You do not give up any legal rights by signing this form.

II. OBJECTIVES OF THE STUDY

You have been asked to participate in a medical research study, the purpose of which is to (*List the objectives that are sought by the performance of the study in this paragraph, i.e. evaluate/determine the safety and efficacy)*

III. PROCEDURES

SCREENING PROCEDURES:

(Describe any screening procedures. Certain clinical tests, such as HIV infection, may have State requirements regarding 1) the information that must be provided to the participant, 2) which organizations have access to the test results, and 3) whether a positive result has to be reported to the health department. Prospective subjects should be informed of any such requirements and how an unfavorable test result could affect employment or insurance before the test is conducted. (NOTE: Informed consent must be obtained prior to initiation of any clinical screening procedures that are performed solely for the purpose of determining eligibility for research).

STUDY PROCEDURES:

(*Describe the procedure and identify the experimental elements of the study. If the research is a medical device investigation, clearly state that the device is being used for research purposes. Use clear, simple language that can be understood by the subject (6th grade reading comprehension), followed by the technical details and nomenclature (when appropriate). If a medical device investigation, this section must also include an explanation of the nature of the device; an explanation of expected duration, and purpose of the study; an explanation of the scope of the investigation including the number of subjects involved.)*

IV. BENEFITS, RISKS AND PRECAUTIONS

BENEFITS: *List the potential benefits to the participant or potential benefits to others.*
Disclaimers can be listed at the end of the Benefits section.

RISKS: *List any possible side effects, discomforts and risks. When possible include their likely frequency. The risks enumerated should be confined to the risks of the investigation only, and does not include risks of the disease being treated/researched. Include a statement that the particular treatment or procedure may or may not involve risks to the subject, the embryo or fetus if the subject may become pregnant, or to the sperm if applicable, which are currently unforeseeable.*

LOSS OF CONFIDENTIALITY RISK
The potential risk with providing data from your medical record for this study includes a risk of loss of confidentiality. Every effort will be made to minimize this risk with secured systems and procedures that remove your identifiers such as date of birth, and full name from the data.

PRECAUTIONS: *Explain the safeguards and/or precautions that will be available should any of the stated adverse effects occur. Identify pregnancy test to be used. The Christ Hospital IRB requires a serum HCG. Indicate that contraception has been discussed with the female subject (and male if applicable) that has child bearing potential.*

The following are model paragraphs, <u>that can be used in the precaution section,</u> for subjects only where there is potential for pregnancy.

FOR WOMEN OF CHILD BEARING POTENTIAL:

A. You should understand that this *(treatment / drug)* may have an adverse reaction on a unborn child and should therefore not be given during pregnancy. It will be necessary that a serum pregnancy test be done first. To your knowledge, you are not pregnant at this time. If you become pregnant during the course of the study, you must immediately notify the investigator and you will be withdrawn from the study.

B. If you are a woman of child-bearing potential, you may not participate in this study unless, with the investigator's knowledge and approval, you are employing a form of birth control approved by Dr. *(principal investigator)*, the principal investigator directing this study. You should understand that pregnancy tests will be performed at weeks *(list weeks)* after treatment. You must agree to inform the investigator immediately if 1) you have any reason to suspect pregnancy; 2) if you find that the circumstances change and that there is now a risk of becoming pregnant; or 3) you stop using an approved form of birth control.

FOR SEXUALLY ACTIVE MEN:

C. If you are a man, you must understand that there may be sperm changes associated with the experimental treatment outlined in this study. You must understand that you are advised to use a form of birth control approved by Dr. *(principal investigator),* the principal investigator directing this study. This study may also temporarily or permanently impair fertility. You may discuss with your physician options and procedures for future reproduction that might be available prior to beginning treatment.

V. AVAILABILITY OF INFORMATION

Any questions, concerns or complaints that you may have concerning any aspect of this investigation or your rights as a subject will be answered by: (*principal investigator) at (telephone number)* or *(co- investigator) at (telephone number) or (research center) at (telephone number).*

If you have any **<u>medical</u>** questions pertaining to this study, you should contact your study physician.

You may also contact William Johnson at The Christ Hospital Department of Patient Relations at 513-585-0415 to discuss your rights as a research subject, or to obtain information or offer input.

You must understand that the appropriate confidentiality will be maintained for all records but that the Food and Drug Administration, Department of Health and Human Services, the study sponsor, and The Christ Hospital Institutional Review Board may inspect the records.

You will be told about any new information that might change your decision to be in this study or continue participation. You may contact the investigator or any member of the study team at any time after your participation ends to find out if any new information about this study has become available.

VI. CONFIDENTIALITY

Research study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security and authorized access.

USE AND DISCLOSURE OF YOUR MEDICAL INFORMATION

By signing this form, you are authorizing the use and disclosure of your health information collected in connection with your participation with this research study. Your information will only be used in accordance with the provisions of this consent form and The Health Insurance Portability and Accountability Act (HIPAA) and other applicable law. If you decide to terminate your participation in the study, or if you are removed from the study by the protocol director, you may revoke your authorization, except to the extent that the law allows The Christ Hospital to continue using your information.

WHAT INFORMATION WILL BE USED OR DISCLOSED FOR THE RESEARCH STUDY?

The following information will be used and/or disclosed for this research study: *(Describe what information will be used and/or disclosed for this research study)*

WHO WILL DISCLOSE MY HEALTH INFORMATION FOR THIS RESEARCH STUDY?

The following parties are authorized to use and/or disclose your health information in connection with this research study: (*List who will be authorized to use and/or disclose the human participants' health information in connection with this research study)*

WHO MAY RECEIVE / USE THE INFORMATION?

The Principal Investigator(s) and their research team will use your health information for this research study. Your health information may be disclosed to the following for their use in connection with this research study: (*List who may receive/use the subjects' health information in connection with this research study including The Christ Hospital and/or its agents)*

Your health information may be re-disclosed if the individual or entity named above is not required by law to protect the privacy of the information.

CONFIDENTIALITY EXPIRATION
Your authorization for the use and/or disclosure of your health information will expire *(describe the expiration date or event, i.e., "at the end of the research study" or "continue indefinitely").*

WHEN ACCESS TO YOUR INFORMATION MAY BE LIMITED
You may not be allowed to see or copy certain information in your medical records collected in connection with your participation with this study while the research is in progress if the research includes treatment. When the research study is completed you will have access to inspect or copy your records with certain exceptions under applicable law.

HOW TO WITHDRAW FROM THE STUDY
You have the right to end this Authorization by withdrawing it, at anytime, in writing. Your withdrawal must be made in writing and sent to:
(List Principal Investigator)
(List Principal Investigator's mailing address)

MUST I SIGN THIS AUTHORIZATION?
You are not required to sign this Authorization and you may refuse to do so. If you decide not to sign this Authorization, it will not affect your healthcare but you will be unable to participate in this research study.

A description of this clinical trial will be available at ClinicalTrials.gov, as required by United States Law. This Web site will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

VII. ALTERNATIVE TREATMENT

You should understand that alternative treatment may be available such as *(list alternative treatment available),* but that the treatment that you are receiving is an attempt to give you at least as good a chance of response as is available to you by alternative treatments for your condition.

If any significant new findings are developed during the course of the study that might affect your willingness to continue to participate, your study doctor will provide that information to you.

VIII. COMPENSATION

If you are injured because of study participation, you will receive emergency medical care if needed and you will receive assistance in getting other medical care as needed. You or your insurance carrier will be billed for the cost of care, just as you would be billed for any other medical care. It is not The Christ Hospital's policy to pay compensation to research participants for injuries resulting from a study.

If you feel that you have been injured as a direct result of this research, you should contact your Dr. (*principal investigator) at (telephone number)* or Dr. (*co- investigator) at (telephone number).* You

may also contact William Johnson at The Christ Hospital, Director of Patient Relations at 513-585-0415 to discuss your concerns as a research subject.

(Please provide a schedule of payments if the study participant is receiving any monetary compensation)

IX. COSTS

(Outline the estimated cost of treatment and any additional testing that may be encountered and explain if these costs will be paid for by the sponsor, by insurance, or if the patient is responsible for payment. If hospitalization is required, give expected length of stay. Provide a schedule of payments if the study participant is receiving any monetary compensation)
The Study Sponsor agrees that if you suffer an injury as a result of a study procedure or the administration of use of the study drug, the study sponsor will pay all reasonable and necessary medical expenses to the extent that such expenses are not coved by the patients health insurance policy, by a government program or by any other third party.

X. THE RIGHT TO WITHDRAW

You should understand that your participation is voluntary and you are free to withdraw from this investigation at any time. Should you wish to withdraw, you are assured that standard therapy for your condition will remain available to you. Also, your refusal to participate will involve no penalty or loss of benefits to which you may be entitled. *(Please list the probable consequences of the subject's withdrawal from the study)*

If you are withdrawn from the study by the investigator, you will be informed of the reason for withdrawal (i.e., sponsor stopped study, patient failure to adhere to protocol, patient's best interest medically).

XI. WITNESSING AND SIGNATURES

SUBJECT: I have read, or someone has read to me, this informed consent document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or I have been informed I will receive) a copy of this form for my records and for future reference.

Subject: _____ Date: _____
Or
Legally Authorized
Representative: _____ Date: _____

PERSON OBTAINING INFORMED CONSENT: By signing this consent form, I attest that the information in the consent form and any other written information was accurately explained to, and to the best of my knowledge, understood by the subject or the subject's legally authorized

representative, and that informed consent was freely given by the subject or the subject's legally authorized representative.

Person Obtaining
Informed Consent: _____ Date: _____