The Christ Hospital

**Informed Consent Document Template – Instructions**

***Please remove instructions pages prior to submitting your informed consent document for IRB review and approval.***

This informed consent document template is designed to help you draft and finalize an informed consent document which is compliant with federal regulations and institutional expectations. Informed consent documents provide information to research subjects to ensure they can understand the research and make an informed, voluntary decision whether to participate. IRB members will carefully review the informed consent document you submit to ensure that all required elements and language are included.

**Using the template**

* Instructions to you are in brackets and are highlighted in gray. Be sure to address each highlighted item and to remove all bracketed/highlighted template instructions before submission.
* Be sure that formatting and grammar are consistent throughout the document. Font choice and size are up to you and should be chosen based on your specific subject population; however, please be sure both are consistent throughout. Be careful not to use font in specific sections to over or underemphasize the information provided. For example, don’t use bold or larger font in the payment section, or smaller font in the risks section.
* Per federal regulation, 45 CFR 46.116(a)(5)(i)), your consent form should begin with a concise presentation of information, referred to as Important Information.
* Some sections in the template may be removed if they are not applicable to your research. Only sections that are listed as such in the template may be removed without prior IRB approval. If you have any questions, please contact the IRB Office.
* Where the suggested language does not adequately address your study or uses more complex words than is appropriate for your subject population, please customize the language carefully.
* Make use of images, lists, and tables where appropriate to clarify procedures.
* Review your final version carefully for consistency with other study documents (e.g., Questionnaires, protocol).
* Do not alter the document header in any way.

**Comprehensibility**

Language throughout the consent should be customized carefully for each individual study to facilitate subjects’ clear understanding of the research.

* Use simple language, approximately 6th grade reading level, or language that is appropriate to the specific subject population. The IRB recognizes that some consent forms are of such a technical nature that it may not be possible to keep to a 6th grade reading level. You can edit the suggested language to improve readability.
* Consider the environment and context in which the consent is presented to a potential research subject.
* As much as possible, avoid the use of or replace complicated or medical/technical language with lay language to ease subject comprehension. For instance, use *action* instead of *intervention.*
* Write in second person so as to not be interpreted as suggestive or coercive.
* Define any abbreviations and acronyms.
* Use short, simple and direct sentences.

The following resources are publicly available for suggested lay terms and testing the readability of consent forms:

1. CDC Plain language Thesaurus <http://www.plainlanguage.gov/populartopics/health_literacy/thesaurus_v-10.doc>
2. CDC Everyday Words for Public Health Communication <https://www.cdc.gov/other/pdf/everydaywords-060216-final.pdf>
3. Glossary of Clinical Trials Terms - <https://clinicaltrials.gov/ct2/info/glossary>
4. Federal Plain Language Guidance <http://www.plainlanguage.gov/howto/quickreference/quicktips.cfm>
5. Document Checklist for Plain Language - <http://www.plainlanguage.gov/howto/quickreference/checklist.cfm>
6. Readability calculator - <https://www.online-utility.org/english/readability_test_and_improve.jsp>

*Questions or suggestions regarding this template should be sent to the IRB Office.*

***IMPORTANT! - Please remove these two instructions pages prior to submitting your informed consent document for IRB review and approval.***

**THE CHRIST HOSPITAL**

 **INFORMED CONSENT STATEMENT FOR RESEARCH**

**IRB #: [Insert IRB Number]**

**Protocol Title: [Insert Protocol Title]**

**Sponsor: [Insert Sponsor Name]**

**Principal Investigator: [Insert Principal Investigator Name]**

**Phone Number (24-Hour Contact Number): [Insert 24-Hour Contact Number}**

**About this research**

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve medical treatment in the future. [Insert why patient is being selected, i.e., You were selected as a possible participant because you have been diagnosed with...].

**Taking part in this research study is voluntary**

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with The Christ Hospital Health Network or the study doctor.

This consent form will give you information about the study to help you decide whether or not you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

**SUMMARY OF THE RESEARCH**

Detailed explanations of the research can be found following this section.

1. **Why is this research being done?**

[Insert a short, 1-2 sentence summary of the purpose of the research]

1. **What will happen to me during the study?**

[Insert a short, high-level summary of the procedures]

1. **How long will I participate?**

[Insert a description of the length or duration of subject participation]

1. **Will I benefit from the study?**

[Insert one of the following:]

We don’t expect you to receive any specific benefit from taking part in this study, but we hope to learn new information which will help people with your condition in the future.

**or**

It is possible that you may benefit from taking part in this study; however, there is no guarantee that it will help you.

1. **Will taking part expose me to risks?**

[For greater than minimal risk research, insert the following:] Taking part in this research may expose you to significant risks. We may not know or understand all the risks at this time. Some people may experience side effects or discomfort, some of which may be serious. It is very important that you understand the risks in this research study before you decide whether to participate.

**or**

[For minimal risk research, insert the following:] This research is considered no more than minimal risk, which means that there is no more expected risk to you than what you might experience during a typical day or during a routine physical exam.

1. **Do I have other treatment options besides taking part in this study?**

**[\*\*If this is not a treatment study, this section is not applicable to the research. Please remove this**

**section from the document\*\*]**

There may be other options for treatment of your [Insert applicable condition], [Insert alternative treatment(s), including medication changes or surgery], which you should discuss with your doctor.

1. **Will I be paid to participate?**

[Insert one of the following:]

You will not receive any payment for taking part in this study.

**or**

You will not be paid to participate, but payment for your time or travel is available if you decide to take part in this study.

1. **Will it cost me anything to participate?**

[Insert one of the following:]

There is no cost to you for taking part in this study.

**or**

You will not be responsible for any costs related to the research; however, you or your insurance company will still be responsible for the cost of your routine/standard medical care. [List routine/standard medical care costs here]

**or**

Taking part in this study may lead to additional costs to you or your insurance company. [List additional costs here]

***Please review the rest of this document for important details about these topics and additional things you should know before making a decision about whether to participate in this research.***

**EXPANDED DESCRIPTION OF THE RESEARCH**

**WHY IS THIS RESEARCH BEING DONE?**

The purpose of this study is to [Insert explanation for why the research is being completed using language understandable to the subject (sixth grade reading level). Explain if the study involves the use of an investigational drug or device, including that “investigational” means it is not approved by the Food and Drug Administration (FDA)].

You were selected as a possible participant because [Insert explanation regarding how the subject was identified]*.*

The study is being conducted by [Insert investigator(s) name(s) and Hospital/University/Departmental affiliation]. It is funded by [Insert Sponsor name, if any, and include if the Sponsor is also the manufacturer of the drug/device being studied, if applicable].

**HOW MANY PEOPLE WILL TAKE PART?**

If you agree to participate, you will be one of [Insert local number of subjects if the study involves only one site or insert local and national/international number of subjects if the study involves multiple sites. It may also be appropriate to include the number of subjects in different cohorts or groups, if applicable] participants who will be taking part in this research.

**WHAT WILL HAPPEN DURING THE STUDY?**

[Insert explanation of all procedures/tests that are included in the study (e.g., randomization, assignment to study groups, study visits, administration of study medications, X-rays or imaging, blood draws, surveys and questionnaires, focus groups, audio or video recordings, etc.) using language understandable to the subject (sixth grade reading level). Include the following:

* Where the procedures are performed and how frequently they are performed
* The expected amount of time each procedure and/or visit will last
* Indicate the length or duration of subject participation
* Identify which procedures are experimental and which are standard **\*this can be disclosed with an asterisk and footnote\***
* If blood is to be drawn, explain how and from where the blood will be drawn (e.g., from a vein in your arm) and indicate the total number of times blood will be drawn, the amount of blood to be drawn, and the total amount of blood to be drawn over the course of the study. Translate the amount of blood to be drawn to common measurement terms (e.g., teaspoons, cups)]
* If participation includes multiple study visits, include a table delineating procedures/tests at each visit.

[For research involving deception or incomplete disclosure, insert the following (or similar), as appropriate:]We are not able to provide you with the full purpose of the study at this time, but willprovide additional information at the conclusion of the study.

**WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?**

While participating in the study, the risks, side effects, and/or discomforts include:

[Insert explanation of the risks, side effects, and/or discomforts of each of the procedures completed in the study (e.g., physical, psychological, social, legal) using language understandable to the subject (i.e., sixth grade level). Include risks and side effects of all medications given to subjects for the purpose of the study, as well as the likelihood and frequency of the risks and/or side effects (e.g., rare, common, percentage).

Examples of risk/side effect statements include:

* There is a risk of possible loss of confidentiality.
* The risks of drawing blood include pain, bruising, and, rarely, infection.
* The side effects associated with taking [Insert study medication] are mild diarrhea, confusion, sleepiness, depression, anxiety, and headaches. In rare instances, side effects may include hair loss, rash, and a decrease in the number of red and white blood cells and blood platelets, which could cause fatigue and an increase in infection and/or bleeding.]

[Insert an explanation of measures that will be employed to minimize the risks and side effects listed above.]

**[If applicable**, include an explanation of any psychological, social, or medical services that may be required because of participation in the research (e.g., counseling, social support services, or medical services). If there are significant psychological risks to participation, the subject should be told under what conditions the researcher will terminate the study.

Examples include:

* While completing the survey, you can tell the researcher that you feel uncomfortable or that you do not want to answer a particular question.
* Blood will be drawn by experienced technicians and, whenever possible, it will be obtained at a time when blood is being drawn for other tests your doctor has ordered.
* While you are receiving [Insert study medication], you will be questioned weekly about possible side effects, and you will be monitored by the blood tests we are obtaining.]

There also may be other side effects that we cannot predict at this time.

An additional risk is the accidental loss of confidentiality. [Insert Institution, study doctor, research site, and/or sponsor] will take steps to protect your confidential information. However, there is always a risk that your confidential information could be improperly released or accessed.

**Pregnancy Risks / Risk to Fetus For Women of Childbearing Potential:**

[\*\***If this is not applicable to the research, remove this section from the document\*\*]**

Pregnant women will not be allowed to take part in this study. It is important not to be pregnant during the procedure or the duration of the study. If you are a woman of childbearing potential (if you have not reached menopause or have not had surgery to make you sterile), you must agree to use one or more of the following methods of contraception between the pre-operative screening visit and the hospital discharge follow-up visit.

Accepted methods of birth control approved by [insert PI name], the principal investigator of this study, include: [List accepted birth control methods, such as hormonal contraceptives, barrier methods, intrauterine devices (IUDs), and/or surgical sterilization.]

Dr. [insert PI name] will discuss these methods further with you and help you decide which may be best for you. If you are not following these guidelines while in this study, or if you think you may be pregnant prior to the end of this study, please tell your study doctor or any of the research staff immediately.

**FOR SEXUALLY ACTIVE MEN:**

[\*\***If this is not applicable to the research, remove this section from the document\*\*]**

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 [Insert PI name], 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.

**WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?**

The benefits to participation in the study that are reasonable to expect are [Insert a description of any direct benefit to the subject or benefit to others that may reasonably be expected from the research.] NOTE: Payment to subjects is not considered a benefit of participating in the study and should not be listed in this section. If applicable, list it under the *Will I be Paid to Participate* section.

**or**

Your participation in this trial is not expected to result in any direct benefits for you personally. [Insert a description of any direct benefit to the subject or benefit to others that may reasonably be expected from the research, such as “Information learned from this trial may result in new scientific information that may help other people with your condition in the future benefit other people with your condition.”]

**WILL I RECEIVE MY RESULTS?**

[\*\***If this is not applicable to the research, remove this section from the document\*\*]**

[If clinically relevant results will be returned, insert one of the following:] We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. [Insert a description of the types of research results which may be returned, under what circumstances subjects will be provided research results, and how subjects will be notified.] You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

**or**

We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, you can decide whether you want this information to be provided to you. [Insert a description of the types of research results which may be returned, under what circumstances subjects will be provided research results, and how subjects will be notified.]If you decide that you want this information, you may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions. Please initial one of the following options:

\_\_\_\_\_\_ Yes, I want to be provided with this information.

\_\_\_\_\_\_ I do NOT want to be provided with this information.

**or**

[If clinically relevant results will not be returned, insert the following:] We may learn things about you from the study activities which could be important to your health or to your treatment; however, we will not share this information with you.

**HOW WILL MY INFORMATION BE PROTECTED?**

Efforts will be made to keep your personal information confidential per HIPAA guidelines. Every attempt will be made to ensure that your personal information remains confidential, but we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study. All information will be de-identified before being released outside of The Christ Hospital [insert the following, if applicable, “and databases in which results may be stored.”]

[If audio or video recordings will be made, insert an explanation regarding who will have access to the recordings, if the recordings will be used for educational purposes, and when the recordings will be destroyed.]

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, The Christ Hospital Institutional Review Board or its designees, [Insert Sponsor name, if applicable], and (as allowed by law) and any state or federal agencies who may need to access your medical and /or research records (as allowed by law). [Insert the following as applicable:] State and federal agencies may include the [insert the following only as applicable: “Office for Human Research Protections (OHRP)” for federally-funded research, “Food and Drug Administration (FDA)” for FDA-regulated research and research involving positron-emission scanning, “National Cancer Institute (NCI)” for research funded or supported by NCI, and/or “National Institutes of Health (NIH)” for research funded or supported by NIH], etc.]

[Insert the following, if the study is an FDA-regulated and/or NIH-funded clinical trial AND the study is considered an Applicable Clinical Trial (ACT)\*:] A description of this clinical trial will be available on [**ClinicalTrials.gov**](http://clinicaltrials.gov/), as required by U.S. law. This website 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.

**\*see** [**Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT)**](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf) **at** [**https://prsinfo.clinicaltrials.gov/ACT\_Checklist.pdf**](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf)**.**

[Insert the following, if the study is NIH-funded or if the study has obtained or intends to obtain a Certificate of Confidentiality. A Certificate of Confidentiality is automatically granted to all NIH-funded trials.] For the protection of your privacy, this research is covered by a Certificate of Confidentiality [Insert where the Certificate of Confidentiality was obtained (i.e., for NIH-funded studies insert “from the National Institutes of Health”]. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

1. If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
2. if you consent to the disclosure, including for your medical treatment;
3. if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
4. for the purpose of auditing or program evaluation by the government or funding agency; and
5. [If FDA-regulated] if required by the federal Food and Drug Administration (FDA)

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent

to allow the researchers to release it.

**WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?**

[If the research involves the collection or use of identifiable private information or biospecimens, insert one of the following:]

Information or specimens collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we cannot ask for your additional consent. [If re-identification is possible (i.e. more than a theoretical risk), insert a statement to that effect and describe any risks.]

**or**

Information or specimens collected from you will not be used for future research studies or shared with other researchers for future research.

[If the research involves the storage and maintenance of identifiable private information or biospecimens for future use, please ensure the following are addressed: proposed use, collection and storage procedures, procedures for oversight of security and maintenance, who will have access, procedures to protect confidentiality, procedures for withdrawal, etc.]

[If specimens may be used for commercial profit, insert the following:] Specimens collected from you for this research may be used to develop products which could be sold in the future. The investigator does not plan to share any profits or losses from the sale of those products with you.

**WHAT WILL YOU DO WITH MY GENETIC INFORMATION?**

**[\*\*If this is not applicable to the research, remove this section from the document\*\*]**

[If the study involves genetic testing or the tracking of a particular disease or disorder in an individual’s family, insert the following:]This research follows the Genetic Information Nondiscrimination Act (GINA), a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to request the genetic information we get from this research and to discriminate against you based on your genetic information.

[For research involving biospecimens, insert the following, as appropriate:] We may use the specimens collected as a part of this study for whole genome sequencing, which involves mapping all of your DNA. [Insert a description including what information will be gained, how the information will be used and stored, any risks of whole genome sequencing, and whether the information will be provided back to the subject, and, if so, whether it may be clinically relevant.]

**WILL I BE PAID TO PARTICIPATE?**

**[\*\*If no payment is available per page 1 (#7), remove this section from the document\*\*]**

[Insert a description of the details and any conditions of payment, including if partial payment is applicable.]

**WILL IT COST ME ANYTHING TO PARTICIPATE?**

[\*\***If there are no added costs to subjects per page 1 (#8), remove this section from the document\*\*]**

**[Insurance coverage and patient liability should be discussed here]** **\*\*List cost(s) subject may have to pay\*\***

Taking part in this study may lead to added costs to you or your insurance company. You or your insurance company will be responsible for the following costs: [Insert a list of the procedures, tests, office visits, medications, etc. for which the subject or the subject’s insurance is responsible. If appropriate, state that all standard of care procedures, drugs, tests, etc., will be the responsibility of the subject or his/her insurance. Also, include what is considered standard of care procedures.]. You will not be responsible for these study-specific costs: [Insert a list of the procedures, tests, visits, medications, etc. for which the study will pay. If appropriate, include the following: “If during the study, [Insert name of study drug] becomes commercially available, you may have to pay for the amount of drug needed to complete the study.”] The [insert investigator name or Research Institute (i.e., The Lindner Center for Education and Research)] and/or a social worker from The Christ Hospital] will assist you, if necessary, in obtaining information in regards to your costs to participate in this study.

**WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?**

[\*\***If this is not applicable to the research, remove this section from the document\*\*]**

[If a source of funds for payment of treatment costs is NOT available, insert the following:] In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. (If you have a government insurer, your insurer will not be billed and you may be responsible for those costs. Costs not covered by your health care insurer will be your responsibility). Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

or

[If a source of funds for payment of treatment costs IS available, insert a description of the source and conditions for payment of those costs.]

**WHAT FINANCIAL INTEREST DOES THE RESEARCHER HAVE?**

[\*\***If this is not applicable to the research, remove this section from the document\*\*]**

[If an investigator has a financial interest in this research, insert the following:] One or more individuals involved in this research may benefit financially from this study. The Institutional Review Board (an ethics committee that helps protect people involved in research) has reviewed the possibility of financial benefit. The Board believes that the possible financial benefit is not likely to affect your safety and/or the scientific integrity of the study. If you would like more information, please ask the researchers or study staff.

**WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?**

For questions about the study or a research-related injury, contact the researcher, [Insert name of investigator], at [Insert telephone number]. After business hours, please call [Insert alternate number and person/title the subject should request (e.g., on-call physician)].

In the event of an emergency, you may contact [Insert name of investigator] at [Insert 24-hour emergency number].

[If this is an investigational drug study, insert the following:]If you are unable to reach the investigator at the above number(s) in an emergency, you may contact [insert emergency contact].

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact The Christ Hospital Patient Relations Department at 513-585-0415.

**WILL I BE CONTACTED ABOUT RESEARCH IN THE FUTURE?**

[\*\***If this is not applicable to the research, remove this section from the document\*\*]**

[If subjects may be re-contacted in the future, insert the following:] If you agree, we may contact you after your participation is over to request additional information or biospecimens. Please initial one of the following options:

\_\_\_\_\_\_ Yes, I agree to be contacted for the purpose of collecting additional health information and/or possibly additional biospecimens.

\_\_\_\_\_\_ I do NOT agree to be contacted for the purpose of collecting additional health information and/or possibly additional biospecimens.

**CAN I WITHDRAW FROM THE STUDY?**

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, [explain the procedure for withdraw from the study via written withdrawal]. [If withdrawal from the study prior to completion could pose risk to the subject, insert a description of what those risks might be and how orderly termination will occur.]

[If appropriate, insert the following:] Your participation may be terminated by the investigator without regard to your consent in the following circumstances: [Insert a description of when and why study participation may be terminated and how orderly termination will occur].

[Insert the following:] You will be told about new information that may affect your health, welfare, or willingness to stay in the study. This study may be terminated by [Insert Sponsor/investigator, as appropriate] if [Insert a reason for possible premature termination].

**PARTICIPANT’S CONSENT**

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this signed informed consent document to keep for my records. I agree to take part in this study.

**Participant’s Printed Name:**

**Participant’s Signature**: **Date**:

**Printed Name of Person Obtaining Consent:**

**Signature of Person Obtaining Consent**: **Date**:

**Participant’s Printed Name:**

[Note: IRB-approval is required for the use of a Legally Authorized Representative (LAR). This determination is made at the time of initial IRB-review. If not applicable to your patient population, this following portion may be deleted:]

**Printed Name of Legally Authorized Representative (LAR)**:

**Signature of LAR**: **Date:** \_

**Description of the LARs authority to act for the research participant:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**AUTHORIZATION FOR USE AND/OR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH**

I authorize the study investigator and The Christ Hospital to use and/or disclose my individually identifiable health information as described below for the research study described in this document.

I authorize the following person(s) or organization(s) to receive the information:

* The Christ Hospital Institutional Review Board, and The Christ Hospital and its employees and agents who review human research to protect the safety of research participants
* The US Food and Drug Administration (FDA) or any other governmental agency that oversees human research projects
* The Sponsor/Cooperative Group for this study, [insert name]
* The research organization that is managing this study, [insert name]
* [list any others who are identified in the protocol and need to receive or have access to PHI from this study]
* The Principal Investigators and sub-investigators of this research study, and the research staff
* My treating physician and consulting physicians associated with this research study.

The following individually identifiable health information may be used and/or disclosed: All medical records and other information concerning me which have been acquired in the past or are acquired during any treatment by The Christ Hospital or the study investigatorthat are reasonably needed or anticipated to be needed for my participation in this research study, including all medical records and other information created during and/or for the research study.

I authorize the release of any information contained in the above records concerning treatment of drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological condition and/or psychiatric/mental health treatment and/or HIV related conditions.

**Purpose or reason for the use and/or disclosure of the information**: To gather data needed for this research study as explained in the research study Informed Consent Document.

**Refusal to Sign this Authorization:** If you refuse to sign this Authorization, you will not be permitted to participate in this research study as explained in the research study Informed Consent Document.

**Re-disclosure:** I understand that the information used and/or disclosed as allowed by this Authorization could be re-disclosed by the person(s) or organization(s) receiving the information and, in those cases, may no longer be protected by Federal privacy law. However, if the information disclosed pursuant to this Authorization includes alcohol or drug treatment records, the person(s) or organization(s) receiving the information is hereby notified that this information has been disclosed from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit such person(s) or organization(s) from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2.

**Expiration:** This Authorization will expire at the end of the research study. The study does not end until all data have been collected, checked (or audited) and analyzed. Sometimes this can be years after your study visits have ended. For example, this could happen if the results of the study are filed with a regulatory agency like the Food and Drug Administration.

**Revocation:** I understand that I may revoke this Authorization at any time by notifying the study investigator in writing by sending a letter to the study investigatorat:

[insert PI name and mailing address]

I understand that if I revoke this Authorization, it will not affect the uses and disclosures of my information by The Christ Hospital or by the study investigator before receiving my revocation letter. I understand that information given to the sponsor or any other authorized individuals before I canceled this Authorization may still be used by them.

**Participant’s Printed Name:**

**Participant’s Signature**: **Date**:

[Note: IRB-approval is required for the use of a Legally Authorized Representative (LAR). This determination is made at the time of initial IRB-review. If not applicable to your patient population, this following portion may be deleted:]

**Printed Name of Legally Authorized Representative (LAR)**:

**Signature of LAR**: **Date:** \_

**Description of the LARs authority to act for the research participant:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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