The Christ Hospital

 **Study Information Sheet – Expedited Template – Instructions**

***Please remove instruction pages prior to submitting the study information sheet for IRB review and approval.***

This study information sheet template is designed to help you draft and finalize a study information sheet which is compliant with federal regulations and institutional expectations. Study information sheets provide information to research subjects to ensure they can understand the research and make an informed, voluntary decision whether to participate. This study information sheet is intended for use when a study is not exempt. IRB members will carefully review the document you submit to ensure that all required elements and language are included.

**Important notes**

* The template and the suggested language within are suggestions only (in most cases), meant to provide a guideline for language which might be acceptable.
* The templates and language should be customized carefully for each individual study to facilitate subjects’ clear understanding of the research.
* The following sections must include the mandatory language provided in the study information sheet, unless otherwise approved by the IRB. Please see the Informed Consent Document Checklist for details.
	+ Important Information
	+ How will my information be protected?
	+ Will my information be used for research in the future?
	+ What will you do with my genetic information? *first paragraph only; the second paragraph should be customized for your study*
	+ Who will pay for my treatment if I am injured?
	+ Who should I call with questions or problems?
	+ What financial interest does the researcher have?
* Studies which already have a template consent form or information sheet provided by a sponsor or funding agency are welcome and encouraged to utilize those templates. In those situations, investigators should utilize the Informed Consent Document Checklist to ensure all requirements, including required language for TCH-affiliated research, has been included in the study information sheet. TCH IRB staff will compare the submitted consent form or information sheet to the checklist during the pre-review process to ensure compliance will all requirements.

**Using the template**

* Instructions to you are in brackets. Be sure to address each item and remove all bracketed 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 regulations, your consent form should begin with a concise presentation of information, referred to as Important Information. If your consent is very short, there is no need to begin with the concise presentation. For example, if your consent is only two pages long, a concise presentation will only serve to lengthen the document.
* If a section does not apply to your study, please remove it.
* 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).

**Comprehensibility**

* Use simple language, at least 8th grade level, or language that is appropriate to the specific subject population. 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 TCH IRB.*

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**THE CHRIST HOSPITAL**

 **STUDY INFORMATION SHEET FOR RESEARCH**

**[IRB #]**

**[Insert Protocol Title]**

**[Insert Sponsor Name and Sponsor Protocol Number]**

**[Insert Principal Investigator and Sub-Investigators]**

**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].

**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 [insert appropriate entity (e.g., university, hospital)].

This form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

**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 (i.e., eighth grade level).

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 University/Departmental affiliation]. It is funded by [Insert Sponsor or funding agency name].

**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 taking part in this study.

**WHAT WILL HAPPEN DURING THE STUDY?**

If you agree to be in the study, you will do the following things:

[Insert explanation of all activities/tests that are included in the study (e.g., assignment to study groups, study visits, surveys and questionnaires, focus groups, audio or video recordings, etc.) using language understandable to the subject (i.e., eighth grade level). Include the following:

* Where the activities are performed and how frequently they are performed
* The expected amount of time each activity and/or visit will last
* Indicate the length or duration of subject participation
* Identify which activities are experimental and which are standard

[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 activities completed in the study (e.g., physical, psychological, social, legal) using language understandable to the subject (i.e., eighth grade level). Examples of risk statements include:

* A risk of completing the survey is being uncomfortable answering the questions.
* There is a risk of possible loss of confidentiality.]

[Insert an explanation of measures that will be employed to minimize the risks 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.]

An additional risk is the accidental loss of confidentiality. [Insert Institution, study doctor, and 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.

[\*\***If all risks are described on page 1 (#5), or if the only risk is loss of confidentiality, remove this section from the document\*\*]**

**Pregnancy Risks / Risk to Fetus For Women of Childbearing Potential: [If applicable]**

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 Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, the principal investigator of this study, include:

• hormonal contraceptives (birth control pills, patches),

• barrier methods (condoms, diaphragms),

• intrauterine devices (IUDs), and/or

• surgical sterilization (tubal ligation or hysterectomy).

Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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 applicable]**

 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.

**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 Payment section.]

[\*\***If there is no direct benefit to the subject per page 1 (#4), remove this section from the document\*\*]**

**WILL I RECEIVE MY RESULTS?**

[If 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 wellbeing. [If applicable, insert a description 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 wellbeing. 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 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 wellbeing; however, we will not share any of these research results with you.

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

**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. [Include the following, if applicable, “and databases in which results may be stored.” Also, 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) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the [Insert “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., who may need to access your medical and/or research records.

[If the study is an FDA-regulated or NIH-funded clinical trial, insert the following:] 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.

[If the study is NIH funded, you automatically receive a Certificate of Confidentiality, and must include this section. If the study is not NIH funded but the study has obtained or intends to obtain one, insert the following as appropriate:] For the protection of your privacy, this research is covered by a Certificate of Confidentiality 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
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 this is not applicable to the research, remove this section from the document\*\*]**

**WILL I BE PAID TO PARTICIPATE?**

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

[\*\***If no payment is available per page 1 (#8), remove this section from the document\*\*]**

**WILL IT COST ME ANYTHING TO PARTICIPATE? [Insert Insurance coverage and patient liability]**

Taking part in this study may lead to added costs to you or your insurance company where applicable. You or your insurance company will be responsible for the following costs: [Insert a list of the activities, tests, office visits, etc. for which the subject or the subject’s insurance is responsible. Include what is considered standard of care activities.]. You will not be responsible for these study-specific costs: [Insert a list of the activities, tests, visits, etc. for which the study will pay.

[\*\***If there are no added costs to subjects per page 1 (#7), remove this section from the document\*\*]**

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

[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. 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.

[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.]

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

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

[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.

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

**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]. If you cannot reach the researcher during regular business hours (i.e., 8 a.m. to 5 p.m.), please contact [insert contact]. After business hours, please call [Insert alternate number and person/title the subject should request].

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

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 subjects may be re-contacted in the future:] If you agree, we may contact you after your participation is over to request additional information. 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.

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

**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 in writing]. [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 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**:

\*If applicable\* [If the study involves individuals who cannot consent for themselves, include the following:]

**Participant’s Printed Name:**

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

**Signature of LAR**: **Date:**