The Christ Hospital IRB
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IRB REFERENCE MANUAL
SECTION 07
RESEARCH PROTOCOL AND CONSENT -- FORMAT AND REQUIREMENTS

7.0 RESEARCH PROTOCOL AND CONSENT -- FORMAT AND REQUIREMENTS

When submitting a study to the TCH IRB for approval, it is necessary to adhere to the following guidelines carefully and completely. Non-conformance may result in unnecessary delay in the review, approval, and initiation of research.

For studies requiring full board review, all submission documents must be provided to the IRB Office 21 days prior to the scheduled meeting.

All submission forms and templates (#1-4 below in both lists) can be obtained by contacting the IRB Office by email at IRB_Office@thechristhospital.com or by phone at 513-585-2298. The forms are also located on the IRB page on The Christ Hospital website or the IRB SharePoint site.

Full Board Submission Documents

1. New Protocol Submission Checklist- Full Board Submission
2. Full Board Study Application
3. Informed consent utilizing TCH IRB Template
4. Disclosure of Financial Interest Form on PI and all key research personnel
5. Protocol
6. CITI Transcripts
7. Investigator's Brochure, if applicable
8. Investigator Brochure (drug studies)
9. Instructions for Use (device studies)
10. Recruitment Materials
11. Any relevant grant applications
12. FDA IDE Approval Letter (IDE studies)
13. FDA IND Approval Letter (IND studies)
14. Investigator Medical License, as applicable
15. Investigator CV
16. Any other relevant documentation

Expedited Review Submission Documents

1. New Protocol Submission Checklist- Expedited Submission
2. Expedited Study Application

3. Informed consent utilizing TCH IRB Template, Waiver of Informed Consent Form, or Waiver of Documentation of Informed Consent Form, as appropriate
4. Disclosure of Financial Interest Form on PI and all key research personnel
5. Protocol
6. CITI Transcripts
7. Recruitment Materials
8. Any relevant grant applications
9. Investigator Medical License, as applicable
10. Investigator CV
11. Any other relevant documentation

FORM AND TEMPLATE EXPANDED DESCRIPTION

1. New Protocol Submission Checklist

This checklist is for the benefit of the investigator to assure all required documents are submitted.

2. Study Application

The Christ Hospital IRB requires the appropriate Study Application be completed for any proposed research project. The IRB reference number for the project can be obtained by contacting the IRB Office. This number must also be used for all future correspondence regarding the study. The form must be completed in its entirety with all signatures secured prior to submitting to the IRB. Each new project must be approved by the appropriate department director.

3. Informed Consent

Informed consent is one of the primary ethical requirements underpinning research involving humans. It reflects the basic principle of respect for persons. It should always be remembered that informed consent is an ongoing process, not a single event. The informed consent process is designed to give individuals all of the relevant information that they need in order to decide whether to participate, or to continue participation, in a research study. The process should permit the potential research subject to ask questions and to exchange information freely with the study investigators. Moreover, investigators have an ethical and contractual responsibility to keep research subjects fully informed of any new information that may affect their willingness to continue study participation. Thus, rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and the potential research subject or study participant.

An investigator may NOT involve an individual into a research study unless he/she has obtained prospectively the legally effective, written informed consent of the individual or the individual's legally authorized representative (unless the IRB has granted exempt status to the research study or has specifically waived the requirement for a signed consent form). Note that verbal or telephone consent is not acceptable (unless the IRB has specifically waived the requirement for a signed consent form); nor is deferred consent (i.e., obtaining consent after the initiation of study procedures).

General Requirements for Informed Consent

1. A signed, written informed consent must be obtained from the individual, or the individual's legally authorized representative, before the individual can be involved in any procedures performed for research purposes (unless the IRB has specifically granted a waiver to obtain informed consent or a waiver to obtain a signed informed consent document).

2. The investigator must seek informed consent under circumstances that give the individual sufficient opportunity to consider whether to participate in the research study, and that minimize possible coercion or undue influence. Informed consent to participate in a research study should be sought at a time separate from obtaining informed consent for procedures performed for the medical management of the patient (i.e., non-research procedures).

3. For certain research studies (e.g., studies involving questionnaires, surveys) it may be practical and acceptable to mail the informed consent document to the potential subject and to have the signed document returned by mail. If this approach is taken, there must also be provisions for a telephone interaction between the potential subject and investigators so as to ensure that the informed consent process has been appropriately addressed. The cover letter accompanying the mailed informed consent document and survey or questionnaire materials must clearly address this telephone interaction. The procedures for ensuring an appropriate informed consent process when the consent form is mailed to potential research subjects should be addressed in the recruitment section of the corresponding IRB research protocol.

4. The information given to potential research subjects must be understandable to them.

5. The informed consent document may not include exculpatory language through which the potential research subject waives or appears to

waive any legal rights or releases; or which appears to release the investigator, the sponsor, the institution or their agents from liability for negligence.

6. The principal investigator of the research study is ultimately accountable for assuring that all aspects of the study are at all times in compliance with applicable federal regulations and IRB policies, including but not limited to the entire informed consent process and the instruction and oversight of individuals who may be involved in the process.

7. If the use of the short form of consent documentation is used, the IRB determines that:
    - The consent document states that the elements of disclosure required by regulations have been presented orally to the subject or the subject's legally authorized representative.
    - The written summary embodies the basic and required additional elements of disclosure.
    - There will be a witness to the oral presentation.
    - For subjects who do not speak English, the witness will be conversant in both English and the language of the subject.
    - The subject or the subject's legally authorized representative will sign and date the consent form.
    - The witness will sign (and date for FDA-regulated research) both the short form and a copy of the summary.
    - A copy of the signed and dated short form will be given to the subject or the representative.

The Informed Consent Document

A thoroughly written consent document is crucial to any research study. Very specific guidelines for the informed consent have been developed for studies at The Christ Hospital. Please refer to Informed Consent template for specific guidelines.

4. Disclosure of Financial Interest form

Each protocol submitted to the IRB for review must be accompanied by a Disclosure of Financial Interest Statement for each clinical investigator, sub-investigator, and all key research staff directly involved in the treatment or evaluation of research subjects in the study.