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 Christ Hospital (TCH) Institutional Review Board (IRB) for approval, it is necessary to adhere to the following guidelines carefully and completely. Non-conformance may result in unnecessary delays in IRB review and approval, and initiation of research.

All submission forms and templates are available on Mentor IRB or can be obtained by contacting the IRB Office by email at IRB_Office@thechristhospital.com. The forms are also located on the IRB page of The Christ Hospital website and the IRB SharePoint site.

7.1 Full Board Review Submission Documents

Full Board Review submissions must include the following documents, completed and uploaded in Mentor IRB, as applicable to the research:

1. E-application in Mentor IRB, which may include the following (as applicable):
    a. Request for Full or Partial Waiver of HIPAA Authorization
    b. Waiver of Informed Consent Request
    c. Waiver of Documentation of Informed Consent Request
    d. Investigational Drug Information
    e. Investigational Device Information
2. Informed Consent documents, such as:
    a. Informed Consent using the TCH template
    b. The HHS-approved sample consent document (when available)
3. Protocol/Clinical Investigation Plan (CIP), when applicable, such as:
    a. Sponsor-approved protocol
    b. Complete HHS-approved protocol (when available)
4. Electronic Signature Affidavit for all investigators and other key research personnel
5. Financial Conflict of Interest (FCOI) Affidavit (Mentor IRB) or Disclosure of Financial Interest form (on a case-by-case basis) for all investigators and other key research personnel
6. Documentation for FDA-regulated products

7. Recruitment/Advertising materials
8. Investigator's Brochure
9. Instructions for Use
10. Data collection materials
11. Investigator Qualifications
    a. Certificates of completion for the required CITI courses for all investigators and other key research personnel including
        i. Training in Human Subjects Research (HSR) and Good Clinical Practice (GCP), or approved alternative
        ii. Transcripts of required CITI training reflecting completion within the most recent three years
    b. Most recent CV for all investigators and other key research personnel
    c. Medical or nursing license for all investigators and other key research personnel, as applicable

For studies requiring Full Board review, all submission documents must be provided to the IRB office 21 days prior to the monthly convened IRB meeting.

7.2 Expedited Review Submission Documents

Expedited Review submissions must include the following documents, completed and uploaded in Mentor IRB, as applicable to the research:

1. E-application in Mentor IRB, which may include the following (as applicable):
    a. Request for Full or Partial Waiver of HIPAA Authorization
    b. Waiver of Informed Consent Request
    c. Waiver of Documentation of Informed Consent Request
2. Informed Consent Documents, such as:
    a. Informed Consent using the TCH template
    b. The HHS-approved sample consent document (when available)
3. Protocol/Clinical Investigation Plan (CIP), when applicable, such as:
    a. Sponsor-approved protocol
    b. Complete HHS-approved protocol (when available)
4. Electronic Signature Affidavit for all investigators and other key research personnel
5. Financial Conflict of Interest (FCOI) Affidavit (Mentor IRB) or Disclosure of Financial Interest form (on a case-by-case basis) for all investigators and other key research personnel
6. Documentation for FDA-regulated products
7. Recruitment/Advertising materials
8. Data collection materials
9. Investigator Qualifications
    a. Certificates of completion for the required CITI courses for all investigators and other key research personnel including
        i. Training in Human Subjects Research (HSR) and Good Clinical Practice (GCP), or approved alternative

ii. Transcripts of required CITI training reflecting completion within the most recent three years

b. Most recent CV for all investigators and other key research personnel
c. Medical or nursing license for all investigators and other key research personnel, as applicable

7.3 Expanded Description of Required Documentation

7.3.1 Application

The Christ Hospital IRB requires an application be completed in Mentor IRB for any proposed research project. The Mentor IRB system automatically generates the appropriate e-application depending on the submission type requested at the time of initial registration and generation of the IRB reference number. This number will be the reference number throughout life of the project. The application must be completed in its entirety prior to submitting to the IRB. Upon submission, a request for approval to proceed through IRB review will be automatically forwarded to the appropriate department director.

7.3.2 Informed Consent

Informed consent is one of the primary ethical requirements underpinning research involving humans. Informed consent reflects the basic principle of respect for persons.

Note that informed consent is an *ongoing process*, not a single event, designed to give individuals all relevant information needed to make the decision whether to participate in the research study or to continue participation in the research study. The informed consent 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 an ongoing meaningful exchange between the investigator and the potential research subject or study participant.

Unless the IRB has waived the requirement for consent to the research study or has specifically waived the requirement for a signed consent form, **an investigator may NOT involve an individual in a research study unless he/she has prospectively obtained the legally effective, written informed consent of the individual or the individual's legally authorized representative.** 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).

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. Refer to the TCH IRB Informed Consent template for specific guidelines.

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. (Ref. RM Section 16 Informed Consent; SOP 2.02 Informed Consent)

7.3.3 Research Protocol or Clinical Investigation Plan (CIP)

A research protocol or Clinical Investigation Plan (CIP) is the key document in a trial. It is a document developed by the research sponsor that describes the background, rationale, objectives, design, methodology, statistical considerations, and organization of a clinical research project. It should be designed in such a way as to optimize the scientific validity and reproducibility of the results of the study in accordance with current clinical knowledge and practice to fulfil the objectives of the investigation.

7.3.4 Electronic Signature Affidavit

The electronic signature affidavit is an assurance that the key research personnel acknowledge and understand their responsibilities in the research study.

7.3.5 Financial Conflict of Interest (FCOI) Affidavit

All investigators and key research personnel directly involved in research activities and/or interacting with research subjects must submit a FCOI Affidavit to disclose whether any of the financial interests/arrangements listed below apply to themselves or an immediate family member (e.g., a spouse, dependent child, or [other] members of their household) in relation to the study. The reporting period for any of the following financial interests/arrangements is 12 months preceding the date of disclosure.

a. Having been an executive, director, or employee of the sponsor of the study
b. Having received remuneration from a sponsor/funding agency when the aggregated value received during the 12-month period preceding the disclosure exceeds $5,000.
c. Having received reimbursed or sponsored travel that is related to investigator's responsibilities for this study
d. Having equity interests (e.g. stocks, stock options, or other ownership interests) of any value for a non-publicly traded company or that exceeds $5,000 for a publicly traded company during the 12-month period preceding the disclosure.

e. Having income related to intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights)
f. Having agreed to or plan to accept recruitment bonuses for enrolling subjects into the research
g. Receiving any significant payments of other sorts not aforementioned including monetary values more than $5,000 which may be in forms such as grants to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation, or honoraria

If a significant financial conflict exists, the IRB will approve a plan to manage the interest, as appropriate, to minimize the risk of imparting bias into the research. Management plans are typically tailored to the specific study and/or sponsor and the researcher's financial interests. (Ref. SOP 2.13 Financial Conflict of Interest)

7.3.6 Documentation for FDA-Regulated Products

For studies involving investigational drugs, biologics and food supplements, the IRB requires submission of documentation from either (1) the sponsor or FDA verifying the Investigational New Drug (IND) number or (2) the investigator providing the reason why an IND is not required.

For studies involving investigational medical devices, the IRB requires submission of documentation from (1) the FDA granting the Investigational Device Exemption (IDE), (2) the sponsor stating that the study is a non-significant risk device study and the basis for that determination, or (3) the sponsor as to why the investigation is exempt from the IDE requirements under 21 CFR § 812.2(c) (e.g., the PMA approval letter/number or 510(k) clearance letter/number).

7.3.7 Recruitment/Advertising Materials

All recruitment materials (e.g., advertisements, posters, flyers) must be reviewed and approved by the IRB prior to distribution. As part of sound study design, investigators should assess enrollment and recruitment practices for fairness and equitable selection. Investigators will provide information to the IRB to make these determinations. (Ref. SOP 2.10 Recruitment of Subjects in Research)

7.3.8 Investigator Brochure

The Investigator's Brochure is a comprehensive compilation of the clinical and nonclinical data on the investigational product (drug, supplement, device, or other product) that are relevant to the study and maintained by a drug developer or investigator. The Investigator Brochure contains the body of information about the investigational product obtained before and during a trial, is of critical importance throughout the development process, and updated with new information as the information becomes available.

7.3.9 Instructions for Use

The Instructions for Use is a device manual that is provided by the sponsor for device studies.

7.3.10 Data Collection Materials

Data collection materials must be reviewed and approved by the IRB prior to use. Common data collection materials include interview questions, focus group questions, observation sheets, surveys, questionnaires, and participant diaries.

7.3.11 Investigator Qualifications

To ensure investigators and research personnel are appropriately qualified, investigators and research staff must submit their current professional license showing the expiration date, curriculum vitae (CV) or resume, and CITI transcripts. The IRB requires CITI Human Subjects Research (HSR) and Good Clinical Practice (GCP) training, or approved alternative. Transcripts of required CITI training must reflect completion within the most recent three years. (Ref. SOP 3.12 Education of IRB Staff/Board Members/Investigators/Research Staff)