The Christ Hospital IRB
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Number: 2.01
Effective Date: 06/08
Revision Date: 12/25

STANDARD OPERATING PROCEDURE

Guidelines for New Protocol Submission

1.0 PURPOSE

This procedure establishes the process of submitting documentation for proposed new research activities involving human participants for review by The Christ Hospital Institutional Review Board.

2.0 POLICY

All new research projects submitted for review to The Christ Hospital Institutional Review Board (TCH IRB) must be submitted in Mentor IRB including projects for which TCH IRB will serve as the IRB of Record, and those projects for which The Christ Hospital will rely on an external IRB.

3.0 RESPONSIBILITY

3.1 The Principal Investigator (PI) of a research study is ultimately responsible for assuring compliance with institutional and IRB policies and procedures and any applicable regulations governing their specific research project (e.g., U.S. Department of Health and Human Services (HHS) 45 CFR 46; U.S. Food and Drug Administration (FDA) 21 CFR 50 regulations).

3.2 Prior to submission, if applicable, all principal investigators, research staff, and other key research personnel that have direct physical contact with research participants (e.g., consenting) must be credentialed through the Medical Staff Office prior to study activation/final approval. Investigators or research staff who require new access to TCHHN records must request access by submitting a Service Request to the Service Desk Digital Workplace (DWP).

4.0 PROCEDURE

4.1 The Christ Hospital as the IRB of Record

When TCH serves as the IRB of Record, the principal investigator or authorized designee must create a new protocol submission in the web-based IRB submission system, Mentor IRB. The following items must be completed and/or uploaded in Mentor IRB, as applicable to the research.

4.1.1 Application (Mentor Smart form), which may include the following, as applicable:

4.1.1.1 Request for Full or Partial Waiver of HIPAA Authorization

4.1.1.2 Waiver of Informed Consent Request

4.1.1.3 Waiver of Documentation of Informed Consent Request
4.1.1.4 Investigational Drug Information
4.1.1.5 Investigational Device Information

4.1.2 Informed Consent documents, such as:
4.1.2.1 Informed Consent using the TCH template
4.1.2.2 The HHS-approved sample consent document (when available)

4.1.3 Protocol/Clinical Investigation Plan (CIP), such as:
4.1.3.1 Sponsor-approved protocol
4.1.3.2 Complete HHS-approved protocol (when available)

4.1.4 Electronic Signature Affidavit for the principal investigator and/or authorized research coordinator(s)

4.1.5 FDA documentation for investigational products

4.1.6 Recruitment/Advertising Materials

4.1.7 Investigator's Brochure

4.1.8 Instructions for Use

4.1.9 Any relevant grant applications or clinical trial agreements

4.1.10 Data Collection Materials

4.1.11 Investigator Qualifications and FCOI Disclosures, as applicable
4.1.11.1 CITI certificates of completion/transcripts for the required CITI courses for all investigators and other key research personnel including training in Human Subjects Research (HSR) and Good Clinical Practice (GCP), or approved alternative, as applicable to the research; transcripts of required CITI training must reflect completion within the most recent three years
4.1.11.2 Most recent CV/Resume for all investigators and other key research personnel
4.1.11.3 Medical or Nursing licenses for all investigators and other key research personnel, as applicable
4.1.11.4 Financial Conflict of Interest (FCOI) disclosure form for all investigators and other key research personnel, completed less than 12 months prior to review (required for funded/sponsored research)

4.2 Reliance on an External IRB

When requesting TCH to rely on an external IRB to serve as the IRB of Record, the principal investigator or authorized designee must create a new protocol submission in the web-based IRB submission system, Mentor IRB and select "Reliance Agreement (External IRB)" as the Review Type on the application. The following items must be completed and/or uploaded in Mentor IRB, as applicable to the research.

4.2.1 Application (Mentor Smart form), which may include the following as applicable:
4.2.1.1 Request for Full or Partial Waiver of HIPAA Authorization
4.2.1.2 Investigational Device or Drug Information

4.2.2 Informed Consent documents, such as:
4.2.2.1 Informed Consent including TCH local context information
4.2.2.2 Stand-alone HIPAA Authorization (if not utilizing a combined consent)

4.2.3 Protocol/Clinical Investigation Plan (CIP), such as:
- 4.2.3.1 Sponsor-approved protocol
- 4.2.3.2 Complete HHS-approved protocol (when available)

4.2.4 Electronic Signature Affidavit for the principal investigator and/or authorized research coordinator(s)
4.2.5 TCHHN-specific Recruitment/Advertising Materials
4.2.6 Investigator's Brochure
4.2.7 Instructions for Use
4.2.8 Any relevant grant applications or clinical trial agreements
4.2.9 Investigator Qualifications and FCOI Disclosures, as applicable
- 4.2.9.1 CITI certificates of completion for the required CITI courses for all investigators and other key research personnel including training in Human Subjects Research (HSR) and Good Clinical Practice (GCP), or approved alternative, as applicable to the research; transcripts of required CITI training must reflect completion within the most recent three years
- 4.2.9.2 Most recent CV/Resume for all investigators and other key research personnel
- 4.2.9.3 Medical or Nursing licenses for all investigators and other key research personnel, as applicable
- 4.2.9.4 Annual Financial Conflict of Interest (FCOI) disclosure form for all investigators and other key research personnel, completed less than 12 months prior to review (required for funded/sponsored research)

4.3 Submission Deadline

To allow sufficient time for administrative review and institutional clearances, the submission deadline for new research projects is 21 days prior to the next convened meeting of TCH IRB. IRB review includes an initial review fee for industry-sponsored research studies submitted for full board, expedited, and local context/reliance review. This fee is invoiced through The Christ Hospital Accounting Department.

5.0 REFERENCES

5.1 IRB Reference Manuals:
- 5.1.1 RM 02 - IRB Review of Proposed Research Studies
- 5.1.2 RM 07 - Research Protocol and Consent - Format and Requirements
- 5.1.3 RM 10 – Conflicts of Interest
- 5.1.4 RM 16 – Informed Consent

5.2 Code of Federal Regulations
- 5.2.1 U.S. Department of Health and Human Services (HHS)
  - 5.2.1.1 45 CFR 46.109(b)
  - 5.2.1.2 45 CFR 46.116
- 5.2.2 U.S. Food and Drug Administration (FDA)
  - 5.2.2.1 21 CFR 50.25
  - 5.2.2.2 21 CFR 56.109(b)

5.3 AAHRPP Domains & Elements: Element III.2.A