The Christ Hospital IRB
Submitted By: Erica Jones, CIP
Approved By: Steve Roberts, MD

Number: 2.01
Effective Date: 06/08
Revision Date: 09/22

STANDARD OPERATING PROCEDURE

Guidelines for New Protocol Submission

1.0 PURPOSE

This procedure establishes the process of submitting documentation of proposed new research activities involving human subjects 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 TCH IRB 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 TCH IRB policies and procedures and any applicable regulations governing their specific research project (e.g., Department of Health and Human Services (DHHS) 45 CFR 46; Food and Drug Administration (FDA) 21 CFR 50 regulations).

3.2 Prior to submission, if applicable, all principal investigators, other key research personnel and research staff that have direct physical contact with subjects (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 following documents 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):

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

4.1.2 Informed Consent Documents, such as:
   a. Informed Consent using the TCH template
   b. The HHS-approved sample consent document (when available)

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

4.1.4 Electronic Signature Affidavit for all investigators and other key research personnel

4.1.5 Financial Conflict of Interest (FCOI) Affidavit (Mentor Smart form) or Disclosure of Financial Interest form (on a case-by-case basis) for all investigators and other key research personnel

4.1.6 FDA documentation for investigational devices

4.1.7 Recruitment/Advertising Materials

4.1.8 Investigator's Brochure

4.1.9 Instructions for Use

4.1.10 Any relevant grant applications

4.1.11 Data Collection Materials

4.1.12 Investigator Qualifications
   a. 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; transcripts of required CITI training must reflect 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

4.2 Reliance on an External IRB

When TCH will rely on an external IRB to serve as the IRB of record, the following documents must be submitted for TCH IRB review in Mentor IRB. Review type for these submissions should be selected as "Reliance Agreement (External IRB)." The following documents must be completed and/or uploaded, as applicable to the research:

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

4.2.2 Informed Consent Documents, such as:
   a. Informed Consent including TCH local context information
   b. The HHS-approved sample consent document (when available)
   c. Stand-alone HIPAA Authorization (if not utilizing a combined consent)

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

4.2.4 Electronic Signature Affidavit for all investigators and other key research personnel

4.2.4 Financial Conflict of Interest (FCOI) Affidavit (Mentor Smart form) or Disclosure of Financial Interest form (on a case-by-case basis) for all investigators and other key research personnel

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

4.2.9 Investigator Qualifications

a. 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; transcripts of required CITI training must reflect 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

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. There is 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 DOCUMENTS

5.1 Informed Consent (TCH template)
5.2 Stand-alone HIPAA Authorization (TCH template)
5.3 Financial Conflict of Interest (FCOI) Statement (Mentor Smart form)
5.4 Disclosure of Financial Interest form

6.0 DEFINITIONS

Not applicable

7.0 REFERENCES

7.1 Reference Manuals: RM 02; RM 07; RM 10; RM 16
7.2 Code of Federal Regulations: 45 CFR 46.109(b); 45 CFR 46.116; 21 CFR 50.25; 21 CFR 56.109(b)
7.3 AAHRPP Standards: III.2.A