The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Continuing Review

1. PURPOSE

This procedure establishes the process to conduct continuing review of approved human subject research protocols for purposes of renewal of the IRB approval period.

1.1 The process begins when the Principal Investigator (PI) submits documentation for consideration of renewal of the IRB approval period to the IRB Office.

1.2 The process ends with the notification of study closure from the PI or IRB determination of the approval period resulting in:

1.2.1 Renewal of IRB approval period for an IRB-determined time frame

1.2.2 Renewal disapproval, or

1.2.3 Study expiration: All research-related activity must cease unless the IRB deems that it is in the best interests of individual subjects to continue participating in the research interventions or interactions.

2. SCOPE

The scope of this policy includes research protocols for which TCH IRB serves as the IRB of Record.

3. POLICY

3.1 Continuing Review

The IRB must conduct continuing review of applicable approved human subject research protocols for purposes of renewal of the IRB approval period. Review must occur within one (1) year from the date of last approval. The IRB may conduct continuing review using the expedited procedure for research that otherwise would not require continuing review under 46.109(f)(1), but these continuing review activities must be documented and rationale for this review provided under 46.115(a)(3).

The determination of the length of the approval period, if applicable, is documented in the reviewer checklist, and if reviewed by the convened board, in the minutes. The study expires on the expiration date specified on the approval letter. Continuing review must occur prior to the expiration date.

For ease of tracking, the expiration date of applicable studies is set for the first day of the month of the following year that approval was granted (i.e., if approval is granted on January 9, 2024 the expiration date will fall on the January 1, 2025). If continuing review and reapproval does not occur before the expiration date of IRB approval for all applicable studies, all research-related activity must cease unless the IRB finds that it is in the best

interests of individual subjects to continue participating in the research interventions or interactions. Continuing review of applicable studies is required until the study is closed in the Mentor IRB system.

Review of a change in a protocol (i.e. modification or amendment) does not alter the date by which continuing review must occur because continuing review is review of the full protocol, not simply a change to it.

3.1.1 Research studies that require continuing review include:
- **3.1.1.1** Research subject to the pre-2018 Common Rule Requirements (approved on or prior to January 20, 2019);
- **3.1.1.2** All Research subject to FDA regulation;
- **3.1.1.3** Non-FDA-regulated research initially approved by the convened IRB (full board) AND subject to the Final Rule 45 CFR 46 (approved after January 20, 2019).

3.1.2 Research that does not require continuing review (subject to the Final Rule 45 CFR 46) include:
- **3.1.2.1** Research that has progressed to the point where it only involves one or both of the following criteria:
- **3.1.2.2** Data analysis, including analysis of identifiable private information or identifiable biospecimens;
- **3.1.2.3** Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

3.1.3 Minimal risk research originally approved by the expedited review mechanism prior to January 20, 2019, and involving one or both of the following criteria:
- **3.1.3.1** Exempt research requiring limited IRB review;
- **3.1.3.2** Transitioned Research that meets the criteria set forth in 3.3.1, 3.3.2, and 3.3.2 of this Standard Operating Procedure:
  - **3.1.3.2.1** Research deemed by the chairman as Transitioned Research applies to either:
    - **3.1.3.2.1.1** Full board studies that no longer involve subject intervention/interaction; the IRB will evaluate the need for continuing review at the time of the next scheduled continuing review, or
    - **3.1.3.2.1.2** Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care, or data analysis including analysis of identifiable private information or identifiable biospecimens;

3.1.4 Minimal risk research studies originally approved by the expedited review mechanism under the pre-2018 Common Rule Requirements on or after to January 20, 2019.

3.2 Administrative Check-In / Status Update

TCH IRB is responsible for continued oversight of all human subjects' research, even when formal continuing review is not required. Eligible research projects not subject to continuing

review will receive a ***biennial administrative check-in / status update.*** The status update is required ***every two years*** through Mentor IRB and is reviewed by the IRB chairman or designee. This process ascertains the status of each protocol and verifies that no unapproved changes or unreported problems have occurred. Researchers receive notification of an upcoming status check in advance of the biennial period "expiration" date. The informed consent document(s), if applicable to the research, will automatically update to the biennial check-in date. Failure to respond to the administrative check-in request shall result in a process hold on future submissions.

Note: Subsequent review by the IRB may be required in cases where relevant information provided by study personnel, or otherwise discovered, which subjects the study to review by the IRB.

4. RESPONSIBILITY

4.1 Principal Investigator

The Principal Investigator is required to keep track of approval periods and must submit required Continuing Review or Status Update documentation or notification of study closure prior to expiration in the timeframe set forth by this Standard Operating Procedure.

4.2 IRB Office

The IRB office facilitates appropriate review of all submitted documentation and relays IRB determination to the PI.

4.3 IRB Chair

The IRB chairman serves as primary reviewer or assigns a designee.

4.4 IRB

The IRB reviews submission documentation and makes a determination regarding renewal of IRB approval period.

5. PROCEDURE

5.1 Principal Investigator

The Principal Investigator or authorized designee performs the following:

5.1.1 Completes and submits a continuation form in Mentor IRB for review by the due date in Mentor IRB ensuring the following documents/files are attached for consideration:

5.1.1.1 FCOI Affidavit for all investigators and other key research personnel,

5.1.1.2 Protocol Deviation Log (IND, IDE, and HDE studies only) as applicable.

5.1.2 Ensures that all investigators and other key research personnel's Investigator Qualifications are still current in Mentor IRB, such as:

5.1.2.1 CITI Transcripts (completed within the last three years),

5.1.2.2 CV or Resumé,

5.1.2.3 Medical License and/or Nursing License, if applicable.

5.2 IRB Office

The IRB office performs the following:

5.2.1 Reviews all submitted documentation to assure completeness of the submission and completes the IRB Office: Continuing Review, or Status Update Checklist in Mentor IRB;

5.2.2 Makes a determination regarding whether the research qualifies for administrative check-in (status update), expedited review, or review by the convened IRB;

5.2.3 Assigns the submission for review in Mentor IRB to either the:

5.2.4 Administrative Review (Status Update) procedure,

5.2.5 IRB Chair or designee for expedited review, or

5.2.6 Full Board Panel for IRB members for convened review.

5.2.7 Documents IRB determination in either the:

5.2.7.1 Exempt/Expedited Panel / Chairman's Report for research reapproved by expedited review for review by the convened board at the next scheduled meeting; or

5.2.7.2 Meeting minutes for research reapproved by the convened board, then

5.2.7.2.1 Issues one of the following determination letters in Mentor IRB:

5.2.7.2.2 Approval letter to the principal investigator and any research coordinator;

5.2.7.2.3 Approval with contingencies letter to the principal investigator and any research coordinator; or

5.2.7.2.4 Disapproval letter with IRB rationale to the principal investigator, any research coordinator, department head, and institutional official.

5.2.8 Updates Mentor IRB protocol record with determination, approval date and expiration date;

5.2.9 Ensures all approved documents are appropriately linked on the main protocol page in Mentor IRB.

5.3 IRB Chair or Designee

The IRB chairman or designee performs the following:

5.3.1 Primary review, or appointment of an experienced IRB member as designee to perform primary review, utilizing the IRB:

5.3.1.1 Continuing Review Checklist, or

5.3.1.2 Review Study Status Update Checklist in Mentor IRB.

5.3.2 For studies applicable for the administrative review/status update mechanism:

5.3.2.1 Makes an approval determination in Mentor IRB, or

5.3.2.2 Makes a determination in Mentor IRB for the study to be reviewed by the convened board, if applicable.

5.3.2.3 For studies applicable for the expedited review mechanism:

5.3.2.3.1 Makes an approval determination in Mentor IRB, or

5.3.2.3.2 Makes a determination in Mentor IRB for the study to be reviewed by the convened board, if applicable.

5.3.2.4 For studies that are reviewed by the convened board:

5.3.2.4.1 Serves as primary reviewer, or

5.3.2.4.2 Appoints an experienced IRB member as designee to perform primary review utilizing the IRB: Continuing Review Checklist in Mentor IRB and gives recommendations.

5.4 Convened IRB

The convened IRB performs the following:

5.4.1 Reviews the following documentation:

5.4.1.1 Continuation form in Mentor IRB;

5.4.1.2 Current consent document(s) for studies which remain active and enrolling subjects, or which are closed to further enrollment but remain in the process of reconsenting subjects;

5.4.1.3 Any FCOI disclosed in the FCOI Affidavit in Mentor IRB;

5.4.1.4 Protocol Deviation Log (IND, IDE, and HDE studies only), as applicable; and

5.4.1.5 Current Investigator Qualifications to ensure compliance.

5.4.2 Makes one of the following determinations:

5.4.2.1 Approved with determination for frequency of subsequent review at intervals appropriate to the degree of risk posed to the subjects, but not less than once a year;

5.4.2.2 Approved with modifications (contingently approved) with determination for frequency of subsequent review at intervals appropriate to the degree of risk posed to the subjects, but not less than once a year;

5.4.2.3 Tabled (if major modifications are requested)

5.4.2.4 Disapproved with rationale documented in the IRB meeting minutes

6. DOCUMENTS

6.1 IRB: Review Study Status Update Checklist in Mentor IRB

6.2 Continuation form in Mentor IRB (electronic form)

6.3 IRB: Continuing Review Checklist in Mentor IRB (Protocol Survey)

6.4 FCOI Disclosure in Mentor IRB (electronic form)

7. DEFINITIONS

Not applicable

8. REFERENCES

8.1 45 CFR 46.109(a)(d)(e)(f); 45 CFR 46.110; 45 CFR 46.111; and 46.115(a)(2, 3 & 8).

8.2 21 CFR 56.109(f); 21 CFR 56.110(a)(b); 21 CFR 56.113.

8.3 63 FR 60364-60367

8.4 AAHRPP Standards II.2.E.2 and II.2.F.2