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

Number: 1.01
Effective Date: 02/09
Revised/Reviewed: 05/21

STANDARD OPERATING PROCEDURE

Continuing Review

1 PURPOSE

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

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

1.1.2 The process ends with the notification of Study Closure from the PI or IRB determination of the approval period resulting in:

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

1.1.2.2 Renewal Disapproval, or

1.1.2.3 Study Expiration

1.1.2.3.1 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 PREVIOUS VERSION

2.1 Revision- 01/13/2020

2.2 Revision- 05/10/21- Added details for fixed anniversary date; minor administrative changes and clarifications

3 POLICY

3.1 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 (1) one year from the date of approval. The IRB maintains a fixed anniversary date for the expiration of annual IRB approvals in order to keep the IRB approval period constant from year to year throughout the life of a research project. Therefore, when the IRB grants approval for one year at the time of each continuing review, and the IRB performs continuing review and re-approves (with or without conditions) the research within 30 days before the IRB approval period expires, the IRB may retain the anniversary of the expiration date of the initial IRB approval as the expiration date of each subsequent one-year approval period. For example, if an IRB conducts initial review of a research project and approves it without conditions on October 1, 2020 for one year, the IRB may conduct its first continuing review anytime between September 1 and October 1, 2021, and re-approve the research for another one-year period that expires on October 1, 2021. The same timing may be applied to each subsequent continuing review until the research activities involving human subjects are completed. If continuing review and re-approval 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 Study Closure Report/Final Report form has been submitted to the IRB Office.

3.1.1 Research studies that require continuing review include:

3.1.1.1 All 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:

3.1.2.1.1 Data analysis, including analysis of identifiable private information or identifiable biospecimens

3.1.2.1.2 Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

3.1.2.2 Minimal risk research originally approved by the expedited review mechanism prior to January 20, 2019, and involves one or both of the following criteria:

3.1.2.2.1 Exempt research requiring limited IRB review

3.1.2.2.2 Transitioned Research that meet the criteria set forth in 3.1.2.1, 3.1.2.2, and 3.1.2.3 of this Standard Operating Procedure

3.1.2.2.2.1 Research deemed by the chairman as Transitioned Research applies to either:

3.1.2.2.2.1.1 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

3.1.2.2.2.1.2 Data analysis, including analysis of identifiable private information or identifiable biospecimens; or

3.1.2.2.2.1.3 Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

3.1.2.3 Studies (minimal risk research) originally approved by the expedited review mechanism under the pre-2018 Common Rule Requirements on or after to January 20, 2019

4 RESPONSIBILITY

4.1 **Principal Investigator (PI)**- PI must submit required continuing review documentation or notification of study closure prior to expiration in the timeframe set forth by this Standard Operating Procedure.

4.2 **IRB Office**- Facilitates appropriate review of all submitted documentation and relays IRB determination to PI.

4.3 **IRB Chair**- Serves as primary reviewer or assigns designee.

4.4 **IRB**- Reviews submission documentation and makes determination regarding renewal of IRB approval period.

5 PROCEDURE

5.1 **Principal Investigator** submits the following documentation for review at least 21 days prior to the scheduled IRB meeting held prior to expiration:

- 5.1.1 Continuing Review Report Form
- 5.1.2 Current consent document for studies which remain active and enrolling subjects, or proposed consent document (if applicable)
- 5.1.3 Any proposed amendments to the research (if applicable)
- 5.1.4 Updated Disclosure of Financial Interest Form (if any new disclosures have occurred since last review)
- 5.1.5 Protocol Deviation Log (IND, IDE, and HDE studies only) as applicable, and
- 5.1.6 CITI Transcripts for all key study personnel documenting the educational requirement has been completed within the last three years (for studies that remain active and enrolling subjects only).

5.2 **IRB Office** performs the following:

- 5.2.1 Reviews all submitted documentation to assure completeness of the submission
- 5.2.2 Makes a determination regarding whether the research qualifies for expedited review or review by the convened IRB
- 5.2.3 Provides the documentation for review either to the:
  - 5.2.3.1 IRB Chair or designee for expedited review, or
  - 5.2.3.2 IRB members for convened review.
- 5.2.4 Documents IRB determination in the meeting minutes; then
  - 5.2.4.1 Issues one of the following determination letters:
    - 5.2.4.1.1 Approval letter and stamped approved consent document(s) to principal investigator
    - 5.2.4.1.2 Approval with contingencies letter and stamped approved consent document(s) to principal investigator, or
    - 5.2.4.1.3 Disapproval letter with IRB rationale to principal investigator, department head, and institutional official.
- 5.2.5 Updates electronic protocol log with determination and date
- 5.2.6 Files the submitted documents in the study folder

5.3 **IRB Chair** performs the following:

- 5.3.1 Primary review or appoints an experienced IRB member as designee to perform primary review utilizing the Continuing Review Checklist
  - 5.3.1.1 For studies that are applicable for the expedited review mechanism:
    - 5.3.1.1.1 Makes an approval determination and stamps consent documents (if applicable), or
    - 5.3.1.1.2 Makes a determination for the study to be reviewed by the convened board.
  - 5.3.1.2 For studies that are reviewed by the convened board:

5.3.1.2.1 Serves as primary reviewer, or appoints an experienced IRB member as designee to perform primary review utilizing the Continuing Review Checklist and gives recommendation.

5.4 **Convened IRB** performs the following:
- 5.4.1 Reviews the following documentation:
  - 5.4.1.1 Continuing Review Report,
  - 5.4.1.2 Current consent document for studies which remain active and enrolling subjects, or proposed consent document (if applicable),
  - 5.4.1.3 Any proposed amendments to the research (if applicable),
  - 5.4.1.4 Updated Disclosure of Financial Interest form (if any new disclosures have occurred since last review), and
  - 5.4.1.5 Protocol Deviation Log (IND, IDE, and HDE studies only), as applicable.
- 5.4.2 Makes one of the following determinations:
  - 5.4.2.1 Approved
    - 5.4.2.1.1 Makes 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
  - 5.2.1.1 Approved with modifications (contingently approve)
    - 5.2.1.1.1 Requests modifications, and
    - 5.2.1.1.2 Makes 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
  - 5.2.1.2 Disapproved
    - 5.2.1.2.1 Rationale is documented in the meeting minutes

6 DOCUMENTS
- 6.1 Continuing Review Report Form
- 6.2 Study Closure Report/Final Report form
- 6.3 Disclosure of Financial Interest form
- 6.4 Continuing Review Checklist

7 DEFINITIONS
- 7.1 See SOP 3.23 Definitions for definitions of double underlined terms.

8 REFERENCES
- 8.1 45 CFR 46.109(a)(d)(e)(f); 45 CFR 46.110; 45 CFR 46.111(a-d); and 46.115(a)(2, 3 & 8).
- 8.2 21 CFR 56.1069(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.