

**The Christ Hospital IRB**

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**Reviewed By:** Steve Roberts, MD

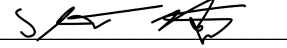
**Approved By:** Steve Roberts, MD

(I.5.A, I.5.B)

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## STANDARD OPERATING PROCEDURE

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### Quality Improvement Activities in Human Research Protection/Audits

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#### POLICY:

The Christ Hospital IRB will undergo quality assurance and improvement review to measure and improve the effectiveness of and compliance with organizational policies, procedures as well as applicable federal, state and local laws. These activities are designed to develop a culture of protection of human participants in research by assessing whether the various elements of the HRPP are effective at protecting research participants.

#### APPLICABILITY

Quality assurance and improvement activities are applied to all researchers, departments and units engaged in IRB-approved human subjects' research, including those whose research is conducted at off site locations.

The HRPP will:

- assess active, ongoing IRB approved studies for compliance with approved protocols and with hospital policies and federal regulations
- perform quality assurance reviews of selected studies and monitor the informed consent process for selected studies.
- monitor the functioning of the IRB for efficiency and compliance with federal regulations and hospital policy.
- develop strategies for improving the quality of research through educational and training programs.

#### QUALITY ASSURANCE MONITORING ACTIVITIES

The IRB will conduct study reviews which will include but not be limited to:

- IRB File Review – This includes a review of study files, meeting minutes and other relevant documentation in order to identify areas for improvement.
- On Site Reviews – The focus of the review includes an assessment of the roles, responsibilities and training of research team members, suitability of the facility to conduct research including pharmacy operations, regulatory and IRB compliance, recruitment, eligibility and consenting process, case review for protocol adherence through source documentation and data collection, adverse events, file security, and other relevant aspects of the study.

- Informed Consent Review – This review helps researchers in assuring that adequate informed consent is provided to participants in studies and can be performed in conjunction with other reviews. Auditors may observe the consenting process; verify that the person consenting the subject is qualified and designated by the PI; verify that the consent document is appropriately signed and dated, and a copy was given to the participant.
- For Cause Review – This type of review is performed at the request of the IRB and/or Institutional Official. Reasons for this request may include: specific concerns regarding compliance, protocol adherence, or subject safety. The review may be either scheduled or unscheduled and may involve full review or focus on specific concerns.
- Contract Review – This type of review is performed by the IRB Chairman and/or Institutional Official. Reasons for this request are to verify that the contracts contribute to the protection of research participants in sponsored studies.

Selection of Studies to Review – Research studies will be chosen for QA/QI review primarily from among studies meeting one or all of the following characteristics:

- Not receiving study monitoring by the study sponsor or another organization
- Present greater than minimal risk to participants
- Involve investigator-initiated research
- Enroll vulnerable populations, including TCH employees and students, cognitively-impaired participants, pregnant women/fetuses/neonates and children.
- Have potential for conflict of interest
- Are requested by the IRB or Institutional Official

Any non-compliance which is identified during the course of the review will be reported to the appropriate officials for further procedures in keeping with IRB policy 3.06 *Compliance with Human Subjects Regulations/IRB Requirements/Determinations*

#### OTHER QUALITY ASSURANCE ACTIVITIES

The following QA/QI activities will also occur:

- Assess the functioning of the IRB and its compliance with regulations and policy, not less annually
- Identify areas where researchers, IRB members and HRPP staff can benefit from training activities and educational materials
- Quarterly meetings with The Lindner Center will discuss and review audit results with the IRB Chairman and staff. Any areas of concern in procedures will also be discussed
- Identify research practices, which, if shared among similar researchers could improve the quality of research
- Have personnel available to assist researchers who request help with research methods, protecting vulnerable subjects, record keeping practices, or research related problems and to direct them to resources that may assist them in designing or conducting research safely.

## QUALITY ASSURANCE OUTCOME

In order to evaluate the effectiveness of the HRPP, the IRB Chairman, Institutional Official and IRB staff will conduct an annual review. Evaluation criteria will include:

- The number of protocols reviewed in the preceding year and the proportion of active IRB protocols that represents.
- Whether any of these monitoring reports result in regulatory investigations or actions by the IRB
- Whether these investigations accomplished the following:
  - Assist investigators to improve their research processes
  - Protect the integrity of research by identifying and correcting significant deficiencies in approved research protocols.
  - Promote human subject protections through the conduct of ethical research
  - Improve IRB or IRB office processes
  - Identify topics for research education and training.
- Changes in HRPP to maximize its effectiveness or consistency across TCH
- Recommendations for continued quality assurance and improvement activities

The results of the QA projects will be shared with the Institutional Official and considered during the annual evaluation of IRB Office resources and development of the future needs of the Human Research Protection Program.

Results are submitted to the hospital's Performance Improvement Committee (PIC) for evaluation annually.

## PROCEDURE

### IRB OFFICE STAFF: On Site Review or For Cause Review

1. Requests a list of patients enrolled in the study from the investigator. The patient's date of birth, medical record number and date of study enrollment is requested in order to locate the appropriate records. Patients are randomly selected from the list and the medical record is requested from the Medical Records Department.
2. Schedules an appointment to review the research files with the investigator or study coordinator approximately 1 week in advance, if applicable.
3. If the IRB or Chair has determined that observation of the informed consent process is appropriate, also schedules a day/time that the IRB staff member may be present during the process. This observation may only be performed if the subject is informed of this observation and allows the person to be present during the consenting process.
4. Conducts the IRB audit utilizing the Study Audit form. If the consent process has been observed, a summary report is also included with the audit report. These reports may not contain any information that may identify the patient.
5. Provides a summary of the audit findings to the IRB Chair for review prior to distribution.
6. Presents audit findings to the IRB members at the next convened IRB meeting, and takes action as indicated, if applicable.

7. Sends a copy of the audit findings to the investigator.
8. Files audit documentation in the IRB minutes binder.
9. Files a copy of the audit with any follow-up information in the study file and in the AUDIT file.
10. After reviewing the report of observation of the informed consent process, the IRB may determine that a third-party advocate is required to be present to monitor and/or oversee the research procedures, including the informed consent process. A letter will be drafted as directed by the IRB Chair to the Investigator notifying him/her of the IRB's decision to have a patient advocate sign off on the consent form and to be present for study-related procedures.

#### INVESTIGATOR:

1. Responds promptly to request by the IRB office for arranging audit of the regulatory files.
2. Provides a quiet area for the record review (If a request is made to observe the informed consent process, arrangements are made for the IRB staff member and/or Chair to witness the process).
3. Makes himself/herself or a study coordinator available during the review to answer questions.
4. Reviews the findings of the audit and responds to requests from the monitor in writing if requested.
5. If a third party is requested as an advocate for obtaining consent and during study procedures, the investigator provides documentation that this will be accomplished.

#### CONTRACT AUDIT

##### IRB OFFICE STAFF:

1. Requests a fully executed copy of the study contract.
2. Sends a letter that is drafted as directed by the IRB Chair to the Investigator notifying him/her of the audit findings and any action required.
3. Files a copy of the audit with any follow-up information in the study file and in the audit file.

##### IRB CHAIR:

1. Conducts the contract audit utilizing the Contract Audit Checklist.
2. Presents audit findings to the IRB members at the next convened IRB meeting, and takes action as indicated, if applicable.

#### INVESTIGATOR:

1. Responds promptly to request by the IRB office for a fully executed copy of the study contract.

2. Makes himself/herself or a study coordinator available during the review to answer questions.
3. Reviews the findings of the audit and responds to requests from the IRB Chair in writing, if requested.

**REFERENCE:**

45 CFR 46.109(e); 21 CFR 56.109(f)

**REVISION HISTORY:**

Date Revised	Reason For Change	Revised By
03/15/18	Updated to reflect quarterly meetings with Lindner Center	Emily
03/16/21	Minor formatting changes, removed II.5.F AAHRPP Element	Erica