The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Quality Improvement Activities in Human Research Protection/Audits

1.0 PURPOSE

This procedure establishes the process to develop and maintain a culture of protection of human participants in research by assessing whether the various elements of The Christ Hospital (TCH) Human Research Protection Program (HRPP) are effective in protecting human participants in research.

2.0 POLICY

Under the direction of the Institutional Official and in collaboration with TCH HRPP, the Institutional Review Board (IRB) shall perform Quality Assurance (QA) and Quality Improvement (QI) reviews of research involving human subjects at TCH to measure and improve the effectiveness of, and compliance with, organizational policies, procedures, and applicable federal, state and local laws.

3.0 SCOPE

Quality Assurance and Quality 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.

4.0 RESPONSIBILITY

The following components of The Christ Hospital Human Research Protection Program will conduct Quality Assurance and Quality Improvement monitoring activities.

4.1 Human Research Protection Program

The Christ Hospital HRPP will:

4.1.1 Assess active, ongoing IRB-approved studies for compliance with approved protocols and with hospital policies and federal regulations;
4.1.2 Perform Quality Assurance reviews of selected studies and monitor the informed consent process for selected studies;
4.1.3 Monitor the functioning of the IRB for efficiency and compliance with federal regulations and hospital policy;
4.1.4 Develop strategies for improving the quality of research through educational and training programs.

4.2 Institutional Review Board

The IRB will conduct study reviews including, but not limited to:

4.2.1.1 IRB File Reviews including review of study files, meeting minutes, and other relevant documentation to identify areas for improvement.

4.2.1.2 On-Site Reviews focused on assessment of:

4.2.1.2.1 Roles, responsibilities, and training of research team members,

4.2.1.2.2 Suitability of the facility to conduct research including regulatory and IRB compliance, pharmacy operations, recruitment and eligibility of research participants, and the consenting process, and

4.2.1.2.3 Regulatory file review for protocol adherence through source documentation and data collection, adverse events, file security, and other relevant aspects of the study.

4.2.1.3 For Cause Reviews at the request of the IRB and/or Institutional Official. Rationale of For Cause Reviews may include concerns regarding compliance, protocol adherence, or subject safety. The review may either be scheduled or unscheduled and may involve full review or focus on specific concerns.

4.2.1.4 Informed Consent Process Observations to assist researchers in ensuring that adequate informed consent is provided to study participants and/or potential study participants, and can be performed in conjunction with other types of reviews. During informed consent reviews, auditors may:

4.2.1.4.1 Observe the consenting process,

4.2.1.4.2 Verify that the person consenting the research participant is qualified and designated by the PI, and

4.2.1.4.3 Verify that the consent document is appropriately signed and dated, and that a copy is given to the research participant.

4.2.1.5 Contract & Funding Agreement Reviews performed by TCH Legal Counsel for consistency with AAHRPP Elements I.8.A - I.8.E, as applicable, to the research.

5.0 SELECTION OF STUDIES

Research studies will be selected for Quality Assurance and/or Quality Improvement review primarily from among studies meeting one or all the following characteristics:

5.1 Monitoring not performed by the study sponsor or another safety monitoring organization;
5.2 Presents greater than minimal risk to participants;
5.3 Involves investigator-initiated research;
5.4 Enrolls vulnerable populations including TCH employees and students, cognitively impaired participants, pregnant women, fetuses, neonates and children;

5.5 Involves potential for conflict of interest;
5.6 Undergoing review for any reason as requested by the IRB or Institutional Official.

6.0 NON-COMPLIANCE

Any non-compliance identified during a review will be reported to the appropriate officials for further procedures as described in IRB SOP 3.06 Compliance with Human Subjects Regulations/IRB Requirements/Determinations.

7.0 OTHER QUALITY ASSURANCE/IMPROVEMENT ACTIVITIES

The Christ Hospital HRPP will also perform the following QA/QI activities:

7.1 Assess the functioning of the IRB and its compliance with applicable regulations and IRB and institutional policy, not less than annually;
7.2 Identify areas where researchers, IRB members, and HRPP staff would benefit from training activities and educational materials;
7.3 Hold meetings with the Lindner Center at least quarterly to discuss and review any applicable audit results with the IRB chairman and/or IRB administration, along with any areas of concern in procedures;
7.4 Identify research practices, which, if shared among similar researchers, could improve the quality of research;
7.5 Ensure that personnel are available to assist researchers who request help with research methods, protecting vulnerable subjects, record keeping practices, or research-related problems, and direct them to resources to aid in the design and/or conduct of safe research.

8.0 QUALITY ASSURANCE / QUALITY IMPROVEMENT OUTCOMES

To evaluate the effectiveness of TCH HRPP, the IRB chairman and IRB office staff shall conduct an annual review of IRB activities. Evaluation criteria shall include:

8.1 The number of protocols reviewed in the preceding year and the proportion of active IRB protocols represented by recent-year protocol reviews;
8.2 Whether any Quality Improvement activities resulted in regulatory investigations or actions by the IRB, and whether such investigations accomplished the following:
- 8.2.1 Assisted investigators with improving their research processes,
- 8.2.2 Protected the integrity of research by identifying and correcting significant deficiencies in approved research protocols,
- 8.2.3 Promoted human subject protections through the conduct of ethical research;
- 8.2.4 Improved IRB or IRB office processes, and/or
- 8.2.5 Identified topics for research education and training;

8.3 Quality Assurance activities performed by TCH IRB throughout the preceding year;
8.4 Recommendations for continued Quality Assurance and Quality Improvement activities.

The results of the QA/QI 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.

9.0 PROCEDURE

9.1 IRB File Review by IRB Office

The Institutional Review Board Office shall:

9.1.1.1 Randomly select a study that meets the criteria in Section 5.0 above for an IRB record review.
9.1.1.2 Perform the review using the "IRB Record Internal Audit Checklist".
9.1.1.3 Provide a summary of the findings of the review to the IRB chair.

9.2 On Site Review or For Cause Review

During an On Site review or For Cause review, the IRB office and the investigator shall perform the following responsibilities.

9.2.1 **Institutional Review Board Office**

9.2.1.1 Schedules an appointment approximately 1 week in advance (if applicable) to review the research files with the Investigator or study coordinator.
9.2.1.2 Request a list of patients enrolled in the study from the investigator including information on locating the appropriate patient records (e.g., patient's date of birth, medical record number, date of study enrollment). Patients shall be randomly selected and the patients' research records will be reviewed as appropriate.
9.2.1.3 Conducts the IRB audit utilizing the Post-Approval Audit Checklist.
9.2.1.4 Provides a summary of the audit findings to the IRB chair for review prior to distribution to IRB members and the investigator. Note: The summary may not contain any patient identifiers.
9.2.1.5 Presents audit findings to the IRB members at the next convened IRB meeting.
9.2.1.6 Retains documentation of the audit and subsequent action as indicated, as applicable, in the IRB meeting minutes.
9.2.1.7 Sends a copy of the audit findings to the Investigator.
9.2.1.8 Retains a copy of the audit with any follow-up information in the study file and in the audit file.

9.2.2 **Investigator**

9.2.2.1 Responds promptly to IRB office requests for arranging audit of the regulatory files.
9.2.2.2 Provides a quiet area for the record review.
9.2.2.3 Makes himself/herself or a study coordinator available to answer questions during the review.
9.2.2.4 Reviews the findings of the audit and responds to requests from the IRB in writing, if requested.

9.3 Informed Consent (IC) Process Observation

9.3.1 Institutional Review Board Office

9.3.1.1 Notifies the investigator and/or study coordinator of the intent to observe the IC process.

9.3.1.2 Coordinates date and time of the observation with the investigator or study coordinator

9.3.1.3 Performs observation of the IC process and completes the "Consent Process Observation Checklist". The observation shall only take place under the conditions that:

9.3.1.3.1 The subject is informed of the observation, and

9.3.1.3.2 The observation may only be performed if the subject's verbal consent is obtained to allow observation of the IC process.

9.3.1.4 Provides a summary of the findings of the observation to the IRB chair for review prior to distribution to IRB members and the investigator.

9.3.1.5 Presents a summary of the findings of the observation to the IRB members at the next convened IRB meeting and takes action as indicated and applicable.

9.3.1.6 Sends a copy of the findings of the observation to the investigator.

9.3.1.7 Retains documentation of the findings of the observation in the IRB minutes record.

9.3.1.8 Retains a copy of the "Consent Process Observation Checklist" and communications with the investigator in the IRB audit file.

9.3.2 Investigator

9.3.2.1 Responds promptly to IRB office requests for arranging observation of the IC process.

9.3.2.2 Coordinates date and time of observation with IRB office staff.

9.3.2.3 Reviews the findings of the observation and responds to requests from the IRB office in writing, if requested.

9.4 Contract and Funding Agreement Review

9.4.1 Investigator and/or Designee

9.4.1.1 Uploads the fully executed (FE) Clinical Trial Agreement/Funding Agreement to the main protocol page in Mentor IRB.

9.4.1.2 Completes the "Contract & Funding Agreement Checklist", then uploads the document to the main protocol page in Mentor IRB.

9.4.1.3 Facilitates any subsequent revisions requested by Legal Counsel and uploads the revised fully executed (FE) Clinical Trial Agreement/Funding Agreement to the main protocol page in Mentor IRB.

9.4.2 Institutional Review Board Office

9.4.2.1 Assigns the Contract and Funding Agreement Review Checklist to the designated TCH Legal Counsel in Mentor IRB.

9.4.2.2 Communicates any findings of non-adherence with AAHRPP standards to the investigator and/or institutional signatory for revision.

9.4.2.3 Communicates any revisions subsequently requested by Legal Counsel to the investigator and/or institutional signatory.

9.4.2.4 Uploads the revised fully executed (FE) Clinical Trial Agreement/Funding Agreement to the main protocol page in Mentor IRB.

9.4.3 **TCH Legal Counsel**

9.4.3.1 Completes the "Contract and Funding Agreement Review Checklist*"* in Mentor IRB to confirm consistency between the Agreement and AAHRPP Elements I.8.A - I.8.E, as applicable, to the research.

9.4.3.2 If determined that the Agreement does not align with all applicable AAHRPP Elements I.8.A - I.8.E, documents required remediation and any suggested language for revision.

10.0 REFERENCES

10.1 IRB Standard Operating Procedures

10.1.1 SOP 2.14 - Compensation or Medical Treatment if Injury Occurs During Participation in Research Conducted at The Christ Hospital

10.1.2 SOP 3.06 - Compliance with Human Subjects Regulations/IRB Requirements/Determinations.

10.1.3 SOP 3.13 - Expectations for Research Sponsors & Contracts

10.2 Code of Federal Regulations

10.2.1 U.S. Department of Health and Human Services (HHS) 45 CFR 46.109(e)

10.2.2 U.S. Food and Drug Administration (FDA) 21 CFR 56.109(f)

10.3 AAHRPP Domains and Elements I.8.A - I.8.E