1 PURPOSE

1.1 This guidance establishes the process for maintaining Sharp HealthCare (SHC) Institutional Review Board (IRB) documentation via its electronic filing system.

1.2 The guidance begins when new information is received by the SHC IRB Office.

1.3 The guidance ends when the SCH IRB electronic filing system has been updated with new information.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions are available via the Human Research Protection Program (HRPP) Change Log.

3 POLICY STATEMENT

3.1 The SHC IRB maintains documentation of their activities in compliance with the HRPP requirements. SHC IRB records include IRB protocol files, minutes for convened IRB meetings, and other documentation (see *GUIDANCE: IRB Records Retention [HRP-072]*).

3.2 The SHC IRB Office maintains an electronic filing system. SHC IRB meeting minutes and non-committee notifications documents are maintained electronically in a location accessible to SHC IRB Specialists, the Director of Research, and other HRPP staff as appropriate.

3.3 The SHC IRB maintains electronic records of all documents submitted for every protocol event. The filing system contains a search function for locating and retrieving protocols by sponsor protocol identifier, protocol title, name of Principal Investigator (PI), names of sub-investigators, review type, meeting date, internal funding source, sponsor, SHC IRB number, reviewer, or any combination of the above categories. Electronic copies of all materials submitted to the SHC IRB can be accessed through the IRB database on an event-by-event basis, thus all documents supporting each protocol event are accessible to reconstruct the entire history of a protocol.

4 RESPONSIBILITIES

4.1 SHC IRB Specialists are responsible for carrying out these procedures.

5 PROCEDURE

5.1 For new requests for approval, the SHC IRB electronic filing systems is updated to include the items listed below. A protocol file contains, as applicable to the research or other activity requiring SHC IRB or non-SHC IRB review, determination, approval, and/or oversight:

5.1.1 Designated IRB reviewer determinations of whether an activity is exempt human research or is not human research.

5.1.2 Notifications of emergency use of a test article and required supporting documentation.

5.1.3 *FORM: Initial IRB Review Application (HRP-211*) or *FORM: Initial Application for Reliance on Non-SHC IRB (HRP-211_CIRB)*

5.1.3.1 SHC IRB comments and investigator responses that occurred during SHC IRB review are included with each application. Comments and responses exchanged via fax or email are also filed electronically.

5.1.4 *FORM: Modification Request (HRP-213)*, submitted for modifications to approved research.

5.1.5 *FORM: Financial Disclosure Statement (HRP-220)* documents, when applicable (see *GUIDANCE: Financial Conflicts of Interest (HRP-055*).

5.1.6 *FORM: Continuation Request or Final Closure (HRP-212)* and *FORM: Principal Investigator Attestation (HRP-219)*, or *FORM: Administrative Status Update (HRP-216)* and, when applicable, *FORM: Principal Investigator Attestation (HRP-219_CIRB)*, submitted for continuing review of ongoing research activities.

5.1.7 The IRB-approved informed consent document(s). The protocol file includes all consent forms approved by the SHC IRB.

5.1.8 The IRB-approved assent form(s). If a study involves children from whom the investigators will obtain assent, copies of all assent forms approved by the SHC IRB will be included in the protocol file.

5.1.9 *WORKSHEET: Scientific or Scholarly Review (HRP-320)* for proposed research or changes to proposed research, when applicable, is included in the protocol file (see *GUIDANCE: Review of Scientific Merit and Organizational Feasibility (HRP-045)*).

5.1.10 Sponsor Materials. For investigational drug studies, the investigator's brochure(s), and sponsor's protocol, including current amended editions of these documents and all previous versions are included in the protocol file. For investigational devices, a report of prior investigations (e.g., via the device Instructions for Use or User Manual), and the sponsor's protocol are filed.

5.1.11 Advertisements, phone screening scripts and non-medical oral scripts, flyers, website, or other subject recruitment materials.

5.1.12 Questionnaires, surveys, interview scripts, diaries, or other documents used during the study.

5.1.13 Participant information sheets, brochures, and sponsor newsletters.

5.1.14 *FORM: Promptly Reportable Information (HRP-214)* and applicable supporting documentation submitted per *GUIDANCE: IRB Review of Promptly Reportable Information Items (HRP-024)* and *GUIDANCE: Prompt Reporting Requirements (HRP-027)*.

5.1.15 *FORM: Status Change Report (HRP-215)* with applicable supporting documentation submitted for changes in the enrollment status of research activities that are subject to periodic review requirements.

5.1.16 *FORM: Alerts and Updates (HRP-226)* submitted with Data and Safety Monitoring Board reports, Annual Progress reports, etc.

5.1.17 *FORM: Research Team Update (HRP-224)* and applicable supporting documentation related to the addition or removal of, and/or role changes for research team members.

5.1.18 Correspondence and communication between SHC IRB members, SHC IRB staff, investigators, research team members, sponsor representatives, etc.

5.1.19 Other SHC IRB correspondence related to the research.

5.1.20 Documentation of all actions of the SHC IRB, including approvals, disapprovals, waivers or alterations of consents and HIPAA authorizations (as documented in the protocol application forms).

5.1.21 The SHC IRB's approval and determination letters (e.g., Notice of Exempt Review for research subject to exempt review), and the SHC IRB's acknowledgement emails.

5.1.22 Monitoring visit reports or follow-up letters, including site initiation visits and study closeout visits, if any.

5.1.23 Expiration notices.

5.1.24 IRB approval or determination letters from collaborating institutions when SHC is the coordinating center for a multi-site study, or when data is being received at SHC. If the study is a multi-site study, with SHC as one of several participants, no other IRB approval is gathered or included from other participating sites.

5.1.25 IRB of Record initial approval or determination letter and associated documents, including waivers or alterations of consents and HIPAA authorizations, protocol, approved consent documents and approved HIPAA authorization, when relying on an external IRB for oversight. Other applicable forms and documentation specific to the reporting requirements outlined in *GUIDANCE: IRB of Record and Reliance Agreements (HRP-009)* for ongoing research activities.

5.1.26 Various HRPP forms, worksheets, and checklists including but not limited to those related to criteria for approval, informed consent content, exemption determination, expedited determination, human subjects research determination, engagement determination, and vulnerable population.

5.1.27 *FORM: Continuation Request or Final Closure Report (HRP-212*) submitted for closure of research activities that are subject to periodic review requirements.

5.1.28 Other applicable forms and documentation specific to any new or ongoing research activity.

5.2 Maintenance of and access to SHC IRB Records

5.2.1 All hard copy IRB records of active protocols are secured in closed filing cabinets in locked buildings with regular security patrols and alarms. Records of closed protocols are sent to an external vendor for long-term storage. Those materials can be obtained within 48 hours, or less, if necessary.

5.2.2 The IRB database resides on a secured server, with access limited to SHC IRB Specialists, the Director of Research, and other Sharp Center for Research staff, as appropriate.

5.2.3 Access to IRB records is routinely provided to the Director of Research, SHC IRB co-chairs, SHC IRB members, and SHC IRB Specialists to carry out HRPP operations. Research investigators are provided reasonable access to files related to their own research.

5.2.4 All other SHC access to SHC IRB records is limited to those with a legitimate need for access, such as Internal Audit, Office of Corporate Compliance, or Office of General Counsel. In addition, the Sharp Center for Research may allow access to IRB records by outside entities (e.g., monitors of sponsors of clinical trials) and agencies (e.g., regulatory agencies).

6 MATERIALS

6.1 GUIDANCE: IRB of Record and Reliance Agreements (HRP-009)
6.2 GUIDANCE: IRB Review of Promptly Reportable Information Items (HRP-024)
6.3 GUIDANCE: Prompt Reporting Requirements (HRP-027)
6.4 GUIDANCE: Review of Scientific Merit and Organizational Feasibility (HRP-045)
6.5 GUIDANCE: Financial Conflicts of Interest (HRP-055)
6.6 GUIDANCE: IRB Record Retention (HRP-072)
6.7 FORM: Initial IRB Review Application (HRP-211)
6.8 FORM: Initial Application for Reliance on Non-SHC IRB (HRP-211_CIRB)
6.9 FORM: Continuation Request or Final Closure Report (HRP-212)
6.10 FORM: Modification Request (HRP-213)
6.11 FORM: Promptly Reportable Information (HRP-214)
6.12 FORM: Status Change Report (HRP-215)
6.13 FORM: Administrative Status Update (HRP-216)
6.14 FORM: Principal Investigator Attestation (HRP-219)
6.15 FORM: Principal Investigator Attestation (HRP-219_CIRB)
6.16 FORM: Financial Disclosure Statement (HRP-220)
6.17 FORM: Research Team Update (HRP-224)
6.18 FORM: Alerts and Updates (HRP-226)
6.19 WORKSHEET: Scientific or Scholarly Review (HRP-320)

7 REFERENCES

7.1 None

This document is available on IRBANA or by contacting research@sharp.com.