1 PURPOSE

1.1 This guidance establishes the process to conduct quality improvement of the Sharp HealthCare (SHC) Human Research Protection Program (HRPP).

1.2 The guidance begins the first business day of each quarter.

1.3 The guidance ends when all assessments have been completed and if needed, acted upon.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY STATEMENT

3.1 The goal of the quality improvement plan is to achieve and maintain compliance and to achieving targeted levels of quality, efficiency, and effectiveness of the HRPP.

3.2 Objectives of the quality improvement program are to improve compliance of investigators with their responsibilities.

3.3 The measures of the quality improvement program are defined in *FORM: Investigator Quality Improvement Assessment (HRP-233)*.

3.4 The Institutional Review Board (IRB) can accept audits conducted by external organizations to SHC and internal departments (e.g., Internal Audit Services department) to fulfill auditing requirements.

4 RESPONSIBILITIES

4.1 The investigators or their designee are to complete IRB assigned Quality Improvement Assessments. The IRB specialists ensure completion and review assessments.

5 PROCEDURE

5.1 The IRB Specialists complete *TEMPLATE: Letter: Investigator Quality Improvement Assessment (HRP-534);* attach it to *FORM: Investigator Quality Improvement Assessment (HRP-233);* send to at least six investigators quarterly; and manage the process.

5.2 The frequency of assessments or more focused assessment on one or more aspects of the study will be determined by the IRB Specialists, the Director of Research, or the IRB committee. The requirement to increase the frequency of assessments or conduct a more focused assessment might be based on considerations including but not limited to:

- 5.2.1.1 Involvement of vulnerable populations
- 5.2.1.2 Level of risk
- 5.2.1.3 Phase 1 or Phase 2 studies
- 5.2.1.4 Involvement of Food and Drug Administration (FDA) approved drugs for which there has been a new safety warning issued, or change in the labeling that indicates increased risks
- 5.2.1.5 Issues of study non-compliance or history of site or investigator non-compliance
- 5.2.1.6 Data confidentiality or security concerns

5.3 Investigators or their designee are to complete *FORM: Investigator Quality Improvement Assessment (HRP-233)* within 30 days of assignment. The completed form is to be attached to *FORM: Alerts and Updates (HRP-226)* and uploaded to the Revision Log via IRBANA.

5.4 The IRB Specialists will review the completed assessments *(CHECKLIST: Investigator Quality Improvement Checklist [HRP-433]).*

5.5 If the results of any assessments demonstrate regulatory non-compliance, high variability, or are outside institutional performance targets, the assessment will be added to the next IRB agenda and the IRB committee will review and determine appropriate actions.

5.5.1 Possible range of actions or restrictions considered by the IRB may include:

- 5.5.1.1 Investigator education
- 5.5.1.2 Modification of the information disclosed during the consent process

5.5.1.3 Notification of current participants when such information might relate to participants' willingness to continue to take part in the research
5.5.1.4 Modification of the continuing review schedule
5.5.1.5 Monitoring of the consent process
5.5.1.6 Monitoring of the research
5.5.1.7 Referral to institution's administration
5.5.1.8 Requiring current participants to re-consent to participation
5.5.1.9 Providing additional information to past participation
5.5.1.10 Suspension of SHC IRB approval of the research
5.5.1.11 Modification of the protocol
5.5.1.12 Termination of the protocol
5.5.1.12.1 Any suspensions or terminations of SHC IRB approval are to be sent to the investigator using *TEMPLATE: Letter*:: *Suspension or Termination of IRB Approval (HRP-515)*.

5.6 The IRB Specialists notify the investigators of any IRB required actions and timeline for compliance with requested action.
5.6.1 The investigator is to provide a written notification to the IRB Specialists that the required actions have been completed and the outcome of those actions.
5.6.2 The outcome/s of the required actions will be evaluated by the IRB committee at the next regular IRB meeting. IRB requested actions determined insufficient for adequate participant protection will be escalated to a higher level action and may result in termination of the SHC IRB approval.
5.6.3 The IRB Specialists maintain a database of completed Quality Improvement Assessments, actions and outcomes *(DATABASE: Investigator Quality Improvement Log [HRP-633])*.
5.6.3.1 Annually, the Quality Improvement Assessment database will be reviewed by the IRB committee, Director of Research, and or the Institutional Official to assess whether targeted actions were adequate for enduring quality improvement and to assess for any systematic quality or compliance issues.
5.6.3.1.1 Systematic quality or compliance issues may result in policy or guidance revision or HRPP education.

6 MATERIALS

6.1 FORM: Alerts and Updates (HRP-226)
6.2 FORM: Investigator Quality Improvement Assessment (HRP-233)
6.3 CHECKLIST: Investigator Quality Improvement Checklist (HRP-433)
6.4 TEMPLATE: Letter: Investigator Quality Improvement Assessment (HRP-534)
6.5 TEMPLATE: Letter: Suspension or Termination of IRB Approval (HRP-515)
6.6 DATABASE: Investigator Quality Improvement Log (HRP-633)

7 REFERENCES

7.1 None

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