1. PURPOSE
   1. This policy guides the investigator in what documents need to be maintained and be audit ready. The Principal Investigator is responsible for the study records to contain the IRB regulatory documents submitted and approved by the IRB of Record, as well as signed and dated consent forms and study documents that related to the conduct of the study as approved by the IRB.
2. REVISIONS FROM PREVIOUS VERSION
   1. None
3. POLICY
   1. The policy applies to the Principal Investigator (PI) and his/her/their study team that will prepare for a routine or for-cause audit. The study team consists of those individuals named on the IRB approved protocol.
4. RESPONSIBILITIES
   1. HSPP QA Team
5. PROCEDURE
   1. Work Space
      1. The PI shall be asked to provide a space for the Senior Analysts to review research records and arrange for research staff to be available during the routine or For-Cause review to assist with access to records/documents and provide answers to questions regarding the conduct of the selected study.
   2. Study Documents to be Reviewed
      1. Regulatory Files
         1. Initial submission, with IRB approval letter
         2. Protocol and amendments/modifications, with IRB approval letters
         3. Consents and amendments/modifications, with IRB approval letters
         4. Advertisements, with IRB approval letters
         5. Continuing reviews, with IRB approval letters
         6. Reported adverse events
         7. Correspondence (e.g., IRB debriefing letters, investigator responses to the IRB, emails)
         8. Training and education of staff related to the study

Subject Recruitment and Enrollment

* + 1. Appropriate recruitment of subjects with respect to protocol specific inclusion/exclusion criteria (i.e., enrollment and screening logs)Informed Consent Forms
       1. Location (i.e., confidentiality, limited access, separate from study data)
       2. Signed consents equal the number of enrolled subjects
       3. Content of signed consents corresponds to IRB-approved versions
       4. Proper execution of each informed consent (i.e., signed before study activities)
       5. Documentation of the consent process
       6. Determination of any enrollment during lapse in IRB approval
    2. Data
       1. Location (i.e., confidentiality, limited access)
       2. Compliant with HIPAA
       3. Source documentation of protocol-specific study procedures, interventions, study visits, follow-up, adverse events, and unanticipated problems (e.g., CRFs, computer generated study visit forms)

Subject Safety

Immediate action by the Executive Director and notification of the Institutional Official would take place in the event of suspected subject safety risks, possible research misconduct, or concerns with the audit findings or process.

* 1. Non Compliance

Findings of non-compliance, continuing non compliance

* + 1. If the audit identifies non-compliance, such as lack of oversight, deliberate falsification or omission, failure to comply with the requirements and determinations of the IRB, or significant and/or frequent protocol violations or deviations, the Senior Analyst will include the finding(s) in the report to the Executive Committee. These findings will be shared with the Principal Investigator at the completion of the audit during the exit interview.
    2. Please refer to the audit checklists for a more detailed description of the documents that will be reviewed.

1. MATERIALS
   1. HRP-024 – SOP - Reportable New Information
   2. HRP-026 – SOP – Suspension or Termination Issued Outside of Convened IRB
   3. HRP-101 – SOP – Human Research Protection Program Plan
   4. HRP-430a - CHECKLIST - Investigator Quality Improvement Assessment - Drug, Devices, Clinical Trial
   5. HRP-430b – CHECKLIST – Investigator Quality Improvement Assessment – Participant File
   6. HRP-430c – CHECKLIST – Investigator Quality Improvement Assessment – Biomedical Research
   7. HRP-430d – CHECKLIST – Investigator Quality Improvement Assessment – Social Behavioral Research
   8. HRP-430e – CHECKLIST – Investigator Quality Improvement Assessment – Humanitarian Use Device

1. REFERENCES

None