1. PURPOSE
   1. This SOP ensures that the investigator has the opportunity to provide an overview on how the IRB approved protocol is being conducted. This allows the QA/QI team to listen and observe to see if the description on how the study is being conducted mirrors the IRB approved protocol.
2. REVISIONS FROM PREVIOUS VERSION
   1. None
3. POLICY
   1. This applies to the Principal Investigator (PI) who has the overall responsibility on conducting the study as approved by the IRB of Record. At the initial interview, the HSPP Analysts may make the inquiries listed in this SOP, or similar ones. This is not a comprehensive list, as the questions may vary according to specific protocol details.
4. RESPONSIBILITIES
   1. HSPP QA Team
5. PROCEDURE
   1. The on-site review of the requested protocol begins with an initial interview.
      1. The PI is encouraged to invite his/her Co-investigator(s), study coordinator(s), and any other personnel named on the protocol.
   2. HSPP analysts may ask the following questions, or similar ones:
      1. How is your study conducted?
      2. How are subjects recruited?
      3. What is the informed consent process?
      4. Where do you document the consent process?
      5. What staff is involved in study activities, and what are their roles and qualifications?
      6. How many subjects were approved by the IRB?
      7. How many subjects are currently enrolled?
      8. What source documents are available to support the conduct of the study?
      9. Is this the only performance site?
      10. Where are the original signed and dated consent forms stored?
      11. Who determines that subjects were eligible for the study?
      12. Who evaluates research data for the safety of subjects?
      13. How frequently is the research data reviewed for safety?
      14. Have there been any serious adverse events or unanticipated events, and have they been reported to the local IRB and sponsor (if applicable)?
      15. Where are study medications/investigational drugs/investigational devices stored and dispensed (if applicable)?
      16. Has there been a lapse in IRB approval? If so, why?
      17. If there was a lapse in IRB approval, what study procedures were conducted?
6. MATERIALS
   1. HRP-025-SOP-Directed Review (For Cause) Audits
   2. HRP-024 – Reportable New Information
   3. HRP-026 – SOP – Suspension or Termination Issued Outside of Convened IRB
   4. HRP-101 – SOP – Human Research Protection Program Plan
   5. HRP-430a - CHECKLIST - Investigator Quality Improvement Assessment - Drug, Devices, Clinical Trial
   6. HRP-430b – CHECKLIST – Investigator Quality Improvement Assessment – Participant File
   7. HRP-430c – CHECKLIST – Investigator Quality Improvement Assessment – Biomedical Research
   8. HRP-430d – CHECKLIST – Investigator Quality Improvement Assessment – Social Behavioral Research
   9. HRP-430e – CHECKLIST – Investigator Quality Improvement Assessment – Humanitarian Use Device
7. REFERENCES

None