1. PURPOSE
   1. This policy guides the HSPP QA/QI team in the tasks of requesting and touring the facility to observe where the research is being conducted.
2. REVISIONS FROM PREVIOUS VERSION
   1. None
3. POLICY
   1. This policy applies tothe Principal Investigator (PI), Co-investigator(s), or study coordinator(s) that conduct the study activities to demonstrate that appropriate facilities and sufficient resources are available to conduct study activities and to determine where subjects are seen and where samples are obtained processed and stored. These tours will vary according to the description of study activities provided in the IRB approved protocol.
4. RESPONSIBILITIES
   1. HSPP QA Team
5. PROCEDURE
   1. Tour of facility
      1. The HSPP Analysts may ask the PI, Co-investigator(s), and/or study coordinator(s) the following questions:
         1. Where are the Informed Consent Forms locked and stored?
         2. Where does the consent process take place?
         3. Where are the regulatory documents for the study kept and maintained?
         4. Where are physical exams and/or study procedures conducted (if applicable)?
         5. Where are samples obtained, processed, and stored?
         6. Are samples stored with identifiable information? If yes, how is confidentiality maintained?
         7. Is the area where samples are obtained kept clean?
         8. Where are study medications/investigational drugs/investigational devices stored and dispensed (if applicable)?
         9. Are there any temperature logs regarding storage of the study medications/investigational drugs/investigational devices?
         10. Are there calibration and/or maintenance logs available for any equipment requiring calibration/maintenance?
         11. Where is the study equipment located?
         12. Where are the computer stations located? Is the area private and secure?
         13. Are study records maintained in a secure manner to protect confidentiality of subjects?
         14. Where are the source documents stored?
6. 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
7. REFERENCES

None