OBJECTIVE
To define the procedure to prepare for and conduct on-site review of IRB-SBS approved protocols.

RESPONSIBILITY
The Research Compliance Monitor will be primarily responsible for the execution of this administrative guidance. IRB-SBS administrative staff may assist with on-site review as needed.

PROCEDURES
1. Prior to conducting the post-approval monitoring visit, review the IRB database for protocol information and events, such as:
   - Dates of initial protocol review and approval by the IRB-SBS
   - Nature and approval dates of any modifications to the IRB-SBS approved protocol
   - The most recent IRB-SBS approved protocol, ancillary documents and informed consent form

3. At the site visit, the monitor will use the Investigator Interview Tool, the On-Site Assessment Checklist, and/or the Consent Verification Checklist to audit regulatory documentation and protocol adherence. These checklists are intended as a guide. Depending on the level of review, type of protocol, and reason for review, the visit’s activities may include use of only certain portions of the checklists.

4. At the conclusion of the visit, the monitor will meet briefly with the PI or project coordinator to provide initial feedback and one-on-one education. A report will be written, and findings will be disseminated according to AG 1-8, Dissemination of PAM Findings.

REFERENCES:
1-5A Investigator Interview Tool
1-5B On-Site Assessment Checklist
1-5C Consent Verification Checklist
1-7A Post Approval Monitoring Report Form
1-8 Dissemination of PAM Findings

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