PURPOSE
To summarize the levels of review and protocol selection of the IRB-SBS post approval monitoring (PAM) component of the University of Virginia Human Research Protection Program.

RESPONSIBILITY
The Research Compliance Monitor will be responsible for the implementation of the Post Approval Monitoring and Education program. IRB-SBS staff and committee members may also be involved with aspects of the program and its protocol reviews.

POLICY
Purpose: The IRB-SBS PAM program serves to improve human research protection and the quality and integrity of research under the oversight of the University of Virginia IRB for Social and Behavioral Sciences.

The IRB-SBS PAM and education program has the following goals:
- Ensure adequate protection of research participants
- Verify that research is being conducted as approved by the IRB-SBS
- Ensure compliance with federal and state regulations as well as institutional policies
- Identify educational needs of researchers and provide resources to meet those needs
- Gather information for the continuing improvement of IRB-SBS processes

Confidentiality: Knowledge of assessment procedures and the content of any findings shall be kept appropriately confidential by all parties involved in the assessment.

PROCEDURE: LEVELS OF REVIEW
The post approval monitor will assign a level of review for protocols, in consultation with IRB staff. Levels of review include:
- Administrative check-in
- Investigator self-assessment
- IRB-directed self-assessment
- Full on-site review
- Consent process observation
1. **Administrative Check-in**
   All protocols that do not have a requirement for continuing review will undergo an annual administrative check-in. The Principal Investigator will receive a notice at a designated time point to complete a Protocol Status form. The check-in will remind PIs of their obligation to submit amendments and event reports, and will enable IRB staff to know if a protocol should be closed. See AG # 1-2 for specifics.

2. **Self-assessment**
   a. **Investigator self-assessment.** Submission of the Self-assessment checklist in this case is not required. The Principal Investigator will receive a Self-Assessment checklist when a full on-site review is scheduled. Investigators can use this tool to prepare for a full on-site review. In this case, the checklist is not used by the monitor during the review.

   Principal Investigators will also be encouraged to utilize the Self-assessment checklist on an annual basis, and to contact the monitor if questions arise.

   b. **IRB-directed self-assessment:** Through random selection, the Principal Investigator will receive a Self-assessment checklist to complete within a set period. The PI will submit the completed checklist, which is reviewed by the monitor. Follow-up may include suggested educational activities, requirement for submission of a modification, or a full on-site review.

   IRB-directed self-assessment may also be required when a PI has allowed a protocol to expire, and wishes to re-open the study.

3. **Full on-site review**
   On-site assessments may include review of the IRB-approved documents, modifications, participant records, and consent documents. The monitor, in consultation with IRB staff and/or members, may choose to perform only certain elements of the on-site review.

   On-site review may be performed on protocols which have met exempt criteria, or have had an expedited or full committee approval, for the following reasons:

   - Request by IRB-SBS staff, IRB Chair, study team member, or other sources as an educational tool, or where compliance concerns have been raised.
   - Receipt of a complaint by a research participant which raises safety or compliance concerns
   - Continuing review or reports from other sources suggest that changes may have occurred without IRB approval.
   - Protocols conducted by an investigator who had previous instances of noncompliance
   - Protocols involving vulnerable populations, or unusual levels or types of risks to subjects.
   - Random selection among those protocols reviewed as exempt, expedited or full board. Random post-approval monitoring reviews will be conducted no more
frequently than once every two years for investigators receiving a satisfactory rating, unless an audit is required or requested as noted above.

4. **Consent process observation**
   The researcher or monitor will complete a checklist during observation of the consent process, for one or more participants. When performed by the researcher as part of a directed self-assessment, the completed checklist will be submitted for review.

Protocol-specific review activities will be tracked using Table 1-1A, Post-Approval Monitoring Record.

**REFERENCES:**
1-1A Post-Approval Monitoring Record