University of Virginia
Vice President for Research
Institutional Review Board for the Social and Behavior Sciences
Post Approval Monitoring and Education Program
Administrative Guidance

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Approved By: Senior Associate VP for Research	David J. Hudson DocuSigned by: David J. Hudson 01CFC73944F6482...
Approved By: IRB-SBS Director	Bronwyn Blackwood DocuSigned by: Bronwyn Blackwood F1D4B9F179F244B...
Approved By: Research Compliance Monitor	Andrea Ruhsam DocuSigned by: 9D8A8CC93DD8452...

Table of Contents

1. Levels of Compliance Review

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, PAM Advisory Committee members, and IRB-SBS Full Board 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 & 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

The post-approval monitor will assign a level of review for protocols, in consultation with IRB staff. Levels of review include:

- Annual Notification
- Investigator Self-Assessment (Optional Compliance Check-up)
- Full Review (remote and/or on-site)
    - Randomly selected
    - Directed selection
- Consent Process Observation

1. **Annual Notification**

   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.

2. **Investigator Self-Assessment (Optional Compliance Check-up tool)**

   The Principal Investigator may access the Compliance Check-up (a modified version of the Self-Assessment checklist) which includes links to educational material. Investigators can use this tool at any time to self-assess with regard to compliance practices for their study. When completed by the investigator, this tool is automatically submitted for record keeping, but review of the submissions is done in aggregate with the goal of creating educational material to address trends identified in the data. The Compliance Check-up tool includes a field for the investigator to reach out for help and an automated email will be sent to the compliance monitoring inbox so a compliance monitor may respond. Principal Investigators will also be encouraged to utilize this self-assessment checklist on an annual basis, and an email with the link to the Compliance Check-up tool is sent through iProtocol following completion of the annual notification process.

3. **Full Review (remote and/or on-site)**

   Review Process Steps:

   1) **Investigator Self-Review:** The Principal Investigator will receive a Self-assessment checklist to complete within a set period as the first step of the review. The PI will submit the completed checklist, which is reviewed by the monitor.
   2) **Compliance Monitor Review:** As the second step, the monitor will review the study documents. Remote and/or 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 remote and/or on-site review. The PAM report for the study will include details related to that specific review.
   3) **Investigator and Compliance Monitor Meeting:** As the third step, the compliance monitor will meet (remote or in-person) with the PI and or study team to discuss the review findings and any recommended follow up actions. Follow-up may include educational activities, requirement for submission of a modification or protocol deviation, or an on-site review.
   4) **PAM Report:** The compliance monitor will write the PAM report to document the review, issues identified, and corrective and preventative action plans which were discussed with the PI/study team. The PAM Advisory committee with review the PAM report, vote on a compliance rating, and determine with further action is needed. If no

further action is needed per the committee, then a letter is sent to notify the PI, and this is the final step of the review.

Remote and/or 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:

- *Random selection of 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 below.
- *Directed selection of protocols reviewed as exempt, expedited or full board, for the following reasons:*
    - Requested: Request by IRB-SBS staff, IRB Chair, study team member, or other sources as an educational tool, or where compliance concerns have been raised.
    - Complaint: Receipt of a complaint by a research participant which raises safety or compliance concerns.
    - Change Concerns: Continuing review or reports from other sources suggest that changes may have occurred without IRB approval.
    - Past History: Protocols conducted by an investigator who had previous instances of noncompliance.
    - Expired 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.
    - Increased Risks: Protocols involving vulnerable populations, or unusual levels or types of risks to subjects.

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 full review activities will be tracked using an electronic format similar to the example in the PAM Record Tracking Spreadsheet available in the AG Appendix.

1.1 Annual Notification

OBJECTIVE

The objective of this guidance is to define the procedure for the administrative check-in of protocols as part of IRB-SBS requirements for investigators.

RESPONSIBILITY

IRB staff members will be responsible for the automated administrative check-in procedure (annual notification) and the post-approval monitor will be responsible for follow-up on any identified compliance issues.

PROCEDURE

All protocols that do not have a requirement for continuing review will undergo an annual administrative check-in.

The Principal Investigator will receive an automated notice annually for exempt determination protocols and prior to approval expiration for expedited protocols (generally one year after project approval) to submit a check-in form, with instructions to submit the form in a timely manner. 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.

The Protocol Manager (IRB-SBS Staff member) will review the check-in responses, closing projects as appropriate. Protocol issues which require follow-up, such as a need for a modification submission, will be forwarded to the appropriate IRB-SBS staff member. The project will be referred by the IRB-SBS staff member to the post-approval monitor if the need for a directed selection Full Review is identified.

1.2 Investigator Self-assessment (Optional Compliance Check-up)

OBJECTIVE

The objective of this guidance is to define the procedure for use of the Optional Compliance Check-up, investigator self-assessment tool as a component of the post-approval monitoring program.

RESPONSIBILITY

The post-approval monitor will be responsible for the oversight of the data from the Optional Compliance Check-up, investigator self-assessment tool.

PROCEDURE

Investigator self-assessment (Optional Compliance Check-up)

Submission of the Optional Compliance Check-up (investigator self-assessment) checklist is not required. The Principal Investigator (and if applicable, the Faculty Advisor) may access the Compliance Check-up, which includes links to educational material, at any time to self-assess compliance practices for their study.

When completed by the investigator, this tool is automatically submitted for record keeping, but review of the submissions is done in aggregate with the goal of creating educational material to address trends identified in the data. The Compliance Check-up tool includes a field for the investigator to reach out for help and an automated email will be sent to the compliance monitoring inbox so a compliance monitor may respond. Investigators can use this tool to prepare for a compliance assessment.

Principal Investigators will also be encouraged to utilize this self-assessment checklist on an annual basis, and an email with the link to the Compliance Check-up tool is sent through iProtocol following completion of the annual notification process.

1.3 Full Review (remote and/or on-site)

OBJECTIVE

To define the procedure to prepare for and conduct post-approval monitoring full reviews 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 the full review process as needed.

PROCEDURES

A Full Review (remote and/or on-site) may be performed on protocols which have met exempt criteria, or have had an expedited or full committee approval, for the following reasons:

- *Random selection of 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 below.

- *Directed selection of protocols reviewed as exempt, expedited or full board, for the following reasons:*
    - Requested: Request by IRB-SBS staff, IRB Chair, study team member, or other sources as an educational tool, or where compliance concerns have been raised.
    - Complaint: Receipt of a complaint by a research participant which raises safety or compliance concerns.
    - Change Concerns: Continuing review or reports from other sources suggest that changes may have occurred without IRB approval.
    - Past History: Protocols conducted by an investigator who had previous instances of noncompliance.
    - Expired 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.
    - Increased Risks: Protocols involving vulnerable populations, or unusual levels or types of risks to subjects.

Review Process Steps 1-4:

1. Investigator Self-Review:
   Random Selection:

   The monitor will select a random batch of approximately 5 studies from a list of currently active studies generated from the iProtocol database. Random selection is assisted by the use of "Research Randomizer" a publicly available website that generates random numbers. Study batches should generally include 1 full board study, 2 expedited studies and 2 exempt studies for review, although this is not a required criteria for the randomly selected batches. Studies which were selected for random review in the past two years should not be re-reviewed for random selection within that 24-month grace period. Full board studies which will have a continuation in the next 30 days or have completed a continuation in the last 30 days may be skipped for review (as the board will or did review the study recently). The randomly selected studies will be logged in the full review tracking spreadsheet by the monitor.

   The PI will be emailed a notification of selection letter with the link to complete the online self-assessment tool as the first step of the PAM full review process. Randomly selected studies will have approximately 30 days (4-5 weeks) to complete the online self-assessment tool. The PI will receive an automated email one week (as the first reminder) after the initial email if the online self-assessment tool has not been completed. The monitor will email the PI (and faculty advisor or study contact) as a second reminder if the online self-assessment tool has not been completed after 2 weeks. The monitor will email a final reminder to the PI the week before the deadline if the online self-assessment tool still has not been completed.

   Directed Selection:

   The monitor will be notified that a specific study (or investigator study portfolio) should be reviewed for one of the reasons listed above or for another legitimate concern. The directed selection study will be logged in the full review tracking spreadsheet by the monitor. The PI will be emailed a notification of selection letter with the link to complete the self-assessment tool as the first step of the PAM full review process. Directed selection studies will have approximately 14-30 days (2-5 weeks) to complete the online self-assessment tool.

   The PI will receive an automated email one week (as the first reminder) after the initial email if the online self-assessment tool has not been completed. The monitor will email the PI (and faculty advisor or study contact) as a second reminder if the online self-assessment tool has not been completed after 2 weeks. The monitor will email a final reminder to the PI the week before the deadline if the online self-assessment tool still has not been completed.

   For situations in which the directed selection could potentially involve safety concerns, the monitor may implement a shorter deadline for completion and more frequent contact with the PI/study team with the support/recommendation of HRPP leadership.

For both randomly or directed selection studies, if no response is received by the PI/study team after approximately 4 weeks from the initial notification, the Associate Vice President for Research may send a letter via email to the investigator asking him/her to contact the Research Compliance Monitor. Failure to contact the monitor within approximately two weeks after the letter is sent may result in temporarily closing the protocol to enrollment.

If subject enrollment has not occurred at the time of initial notification of the PI, the monitor may defer the visit and contact the study team again every 6-12 months until subjects have been enrolled. Additionally, if the study team requests to close the study, the compliance monitor may excuse the PAM visit.

2. Compliance Monitor Review:

Randomly Selected or Directed Selection Studies: As the second step of the review process, the PI/study team will receive an automated email at the completion/submission of the investigator self-assessment tool to schedule a visit date in the next 30 days with the compliance monitor. The compliance monitor will receive an automated email that the PI/study team has completed the self-assessment and that the PI/study team should be reaching out to schedule a visit in the next 30 days.

Please note that for directed selection studies the deadline for a scheduled visit date may be decreased or warrant an unannounced arrival with the support/recommendation of HRPP leadership.

The PI will receive an email from the compliance monitor after one week (as the first reminder) to schedule the visit if this has not been completed. The monitor will again email the PI (and faculty advisor or study contact) as a second reminder if the visit has still not been scheduled after 2 weeks. The monitor will email a final reminder to the PI the week before the deadline if the visit still has not been completed.

Generally, this scheduled visit will be a remote visit to discuss the follow up with the PI from the PAM review (see step 3 for details). However, the visit can be done in person if requested by the study team or if the need for an in-person visit is identified during the review. Prior to the visit, the monitor will review the completed investigator self-assessment tool and review the study documents. Remote and/or 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 remote and/or on-site review. The PAM report for the study will include details related to that specific review.

If no response is received by the PI/study team after approximately 4 weeks from the initial notification to schedule a visit with the compliance monitor, the Associate Vice President for Research may send a letter via email to the investigator asking him/her to contact the Research

Compliance Monitor. Failure to contact the monitor within approximately two weeks after the letter is sent may result in temporarily closing the protocol to enrollment.

3. Investigator and Compliance Monitor Meeting:

   Randomly Selected or Directed Selection Studies: As the third step in the PAM full review process, the compliance monitor will meet (remote or in-person) with the PI/study team to discuss the review findings and any recommended follow up actions. Follow-up may include educational activities, requirement for submission of a modification or reporting a protocol deviation, or an on-site PAM review. The compliance monitor may suggest solutions and Corrective and Preventative Action (CAPA) plans if the study team is open to guidance, but these suggestions will be identified as separate from requirements. For example, the compliance monitor may identify an issue during the PAM visit for which a CAPA plan is required, but if the study team requests, the compliance monitor can suggest a specific idea for the CAPA plan.

4. PAM Report:

   Randomly Selected or Directed Selection Studies: Following the meeting, the compliance monitor will write the PAM report to document the review, issues identified, and corrective and preventative action plans which were discussed with the PI/study team. Generally, the compliance monitor will provide the PI/study team with a draft of the PAM Report prior to review by the PAM Advisory Committee and allow the PI to make comments, however, this is a courtesy and not required. The PAM Advisory Committee with review the PAM report, vote on a compliance rating, and determine what, if any, further action is needed. If the PAM Advisory Committee determines that additional action is required of the PI/study team, then the compliance monitor will act in support and cooperation with HRPP leadership to communicate those requirements with the PI/study team. If no further action is needed per the committee, then a PAM Letter is sent to notify the PI, and this is the final step of the review.

1.3.1 Documentation of Findings in the Post-Approval Monitoring Report

The Compliance Monitor will prepare the PAM Report using information gathered during the review.

The structure of the PAM reports may include the following information:

The heading of the PAM report:

- The IRB-SBS number and title of the research study
- The name of the principal investigator (and faculty advisor, if applicable)
- The date on which the Investigator and Compliance Monitor Meeting following the review was conducted.

The introduction of the PAM report:

- A brief summary of the research study
- Source of funding
- Dates of initial and most recent IRB approvals
- The number of subjects approved and currently enrolled in the study
- The type/level of IRB review
- Information regarding IRB of record

The body of the PAM report:

- IRB approvals and correspondence
- Informed consent documentation
- Subject selection criteria
- Study procedures and verification of protocol compliance
- Recording/reporting of adverse events
- Compliance with approved confidentiality/data security procedures

Requirements/Recommendations/Suggestions shall be made for findings, as indicated. Resources for accessing further information will be offered if needed.

The general comment section reflects the Research Compliance Monitor's overall assessment of the findings and the study team's response. An initial education and follow-up recommendation can be made by the Research Compliance Monitor based on the number and severity of compliance issues found.

1.4 Consent Process Review

OBJECTIVE

To define the purpose and procedures for observation and review of the informed consent process.

RESPONSIBILITY

The Research Compliance Monitor will be responsible for informed consent monitoring when the need for observation of the process is identified.

PROCEDURE

1. In reviewing the adequacy of informed consent procedures for proposed research, the IRB may determine that impartial observation of the consent process is required in order to reduce the possibility of coercion or undue influence, ensure that the approved consent process is being followed, and ensure that subjects are truly giving informed consent. Examples for which observation of the informed consent process may be needed:
    - High risk studies
    - Research involving particularly complicated procedures or interventions
    - Studies enrolling highly vulnerable populations
    - Research conducted by study team members with minimal experience in obtaining informed consent from potential study participants
    - Other situations when the IRB has concerns that the consent process may not be/is not being conducted appropriately
2. IRB members or IRB administrative staff may request consent monitoring. The investigator will be notified by the IRB of the requirement for consent monitoring.
3. Consent process review will be conducted by the UVA Post-approval Monitoring & Education staff and/or IRB administrative staff.
4. Prior to the start of the consent process, the reviewer will obtain verbal permission to be present from the potential subject.
5. An example of the Consent Process Review Checklist is available in the AG Appendix for elements to be evaluated during the consent process observation.
6. A report of the observation of informed consent process will be submitted to the PAM Advisory Committee.

2. Post-Approval Monitoring Advisory Committee

OBJECTIVE

To define the purpose and function of the IRB-SBS PAM Advisory Committee.

RESPONSIBILITY

The IRB-SBS Research Compliance Monitor will be responsible for creating the PAM Reports that are submitted to the PAM Advisory Committee for review. The PAM Advisory Committee is responsible for discussing the findings, determination of further action required by the study team (if applicable) and issuing a compliance rating for each study.

The IRB-SBS PAM Advisory Committee membership consists of the following members:

- IRB-SBS Community Member
- IRB-SBS Associate Director
- IRB-SBS Director
- IRB-SBS Chair
- Senior Associate Vice President for Research
- IRB-HSR Research Compliance Monitor
- IRB-SBS Research Compliance Monitor and Educator

PROCEDURE

1. The PAM Advisory Committee will meet prior to the second IRB-SBS full board meeting of each month to review monitoring and educational material as noted on the meeting agenda.

2. The PAM Advisory Committee meeting agenda, with the PAM Reports to be discussed at the meeting, will be submitted via email to the group by the Research Compliance Monitor a week prior to the meeting date.

3. During the committee meetings, the group will review the agenda and each PAM Report considering the following:
    - Additional recommendations and/or educational needs for that specific study team.
    - Findings that the study team should report to the IRB-SBS Full Board to be addressed.
    - Suggestions for policy, educational programming, and/or procedural changes.

4. Following discussion of each PAM Report, the IRB-SBS PAM Advisory Committee will then vote to assign a compliance rating for that study. The ratings will be used for internal reporting to the IRB-SBS and for statistical reporting. The PI/study team will be notified of the compliance rating assigned to their study in the PAM Letter.

5. Possible Compliance Ratings assigned by the IRB-SBS PAM Advisory Committee are as follows:
    - Exceptional – No findings and no further action required.
    - Satisfactory – No further action required in addition to what is noted on the PAM Report.
    - Unsatisfactory – Further actions required from the study team.
    - Major Concerns – Intervention from HRPP leadership required.

2.1. Dissemination of PAM Findings

OBJECTIVE

To define the possible outcomes of Post Approval Monitoring findings and the dissemination of the PAM report.

RESPONSIBILITY

The Research Compliance Monitor will be responsible for creating the PAM Reports that are submitted to the PAM Advisory Committee for review.

PROCEDURE

Individual PAM reports will be assigned a compliance review category by the compliance monitor prior the PAM Advisory Committee reviewing the PAM Report and assigning as compliance rating as follows:

Category 1: Compliance is consistent with good practice. Regulatory documents and source documentation are complete, and any identified issues are now resolved:

- Submit the PAM Report with the meeting agenda (and the PI response, if applicable), to the IRB-SBS PAM Advisory Committee one week prior to the monthly meeting.
- The PI response to the PAM Report is optional.
- Ratings (exceptional or satisfactory-no further action required in addition to what is noted on the PAM Report) will be assigned by the IRB-SBS PAM Advisory Committee.

- Following the meeting, the PAM Letter with the committee's assigned rating for the study will be sent via email to the PI/study team.
- For studies in category 1, where the rating does not require further action by the study team in addition to what is noted in the PAM Report, these PAM Letters will be batched and issued by the compliance monitor approximately every 6 months at the end of the fiscal year and end of the calendar year.

Category 2: Unresolved deviations noted; education and/or follow-up review may be required; study team may need guidance or support with development of a CAPA plan:

- The draft PAM Report will be sent to the study team for PI review/response.
- PI response (if applicable) will be required within 10 working days. The response should be made on the PAM report in the Resolution column. If investigators have not responded to the PAM report within 10 days, or re-negotiated a response time, the compliance monitor may reach out to the PI via email or telephone call to confirm PI receipt of the document. The PI may also be told that if no response is made within 5 working days, another letter will be sent and copied to their department chair. Finally, if appropriate, this letter to the PI and copy to the department chair will be sent via email. If the Research Compliance Monitor still does not receive a response, the issue will be referred to the IRB-SBS PAM Advisory Committee.
- Submit the PAM Report with the meeting agenda (and the PI response, if applicable), to the IRB-SBS PAM Advisory Committee one week prior to the monthly meeting.
- Ratings (satisfactory-no further action required, or unsatisfactory-study team actions required) will be assigned by the IRB-SBS PAM Advisory Committee.
- Following the meeting, the PAM Letter with the committee's assigned rating for the study, and any further required actions, will be sent via email to the PI/study team.
- The PAM Advisory Committee may choose to increase the compliance review category to category 3 if the committee has concerns regarding subject safety.

Category 3: Concerns regarding safety of subjects and/or possible serious non-compliance:

- Prior to or while formulating a written PAM report, the monitor may take their concerns to the Sr. Associate VP for Research. In addition, the IRB Chair and/or a consultant may be contacted for assistance with the review of the study. This consultant may be a specialist in the area of the research, or a regulatory specialist. The Sr. Associate VP for Research or IRB Chair may change the status of the study at any time (for example, place a hold on enrollment) due to potential concerns of subject safety. If the status is changed, the IRB-SBS Director or designee will be notified.

- The compliance monitor will submit a draft PAM report to the study team for PI review/response and copy the following individuals for awareness (if applicable): The Sr. Associate VP for Research, IRB-SBS Director and Chair or designee, and consultant.
- A written response from the PI will be required within 3 working days. If investigators have not responded within 3 days of receipt, contact will be made by the compliance monitor or Associate VP for Research via telephone call or email. The PI will be asked if they have received and reviewed the report, and will be asked to respond within 24 hours. If no response from the PI is received, findings will be considered by the Sr. Associate VP without PI input. – Please note, this step may have been completed already, if the study was first considered a category 2 and then changed to 3 by the IRB-SBS PAM Advisory Committee.
- The Sr. Associate VP for Research will call a meeting to be held within 3-7 working days after the preliminary report is sent to the PI. The following individuals may be invited (as determined by the Sr. Associate VP for Research) to the meeting: the compliance monitor, consultant(s) as appropriate, the Chair, Director and Associate Director of the IRB-SBS, the PI, other applicable parties. The preliminary report will be shared with all in attendance. The purpose of this meeting is to examine the concerns of subject safety. Possible outcomes of this meeting may include determining if the study should be closed, interventions stopped, additional information is needed, or the PAM audit process should continue as per category level 1 or 2. Minutes will be taken by the PAM Compliance Monitor, or another meeting attendee if they are absent. When issues related to the PI's lack of compliance indicate possible scientific misconduct, the Sr. Associate VP for Research will coordinate efforts to address these issues.
- If it is determined at the initial meeting, that concerns of subject safety or serious non-compliance remain and if the PI did not attend the initial meeting, the Sr. Associate VP for Research may contact the investigator and schedule a second meeting with the PI. The Sr. Associate VP for Research will determine additional attendees at this meeting as necessary. The purpose is to allow the PI the opportunity to discuss the concerns in person and for the Sr. Associate VP for Research to obtain additional information/clarifications. The Sr. Associate VP for Research or designee will document the outcome of this meeting and share this report with those in attendance at the previous meetings.
- All relevant information along with the written response from the PI will be presented to the IRB-SBS PAM Advisory Committee. Documents must be given to the IRB-SBS PAM Advisory Committee prior to their meeting to allow them time to review the reports. If time allows, submit the PAM Report with the meeting agenda (and the PI response, if applicable), to the IRB-SBS PAM Advisory Committee one week prior to the monthly meeting.
- Ratings (satisfactory-no further action required, unsatisfactory-study team actions required, or major concerns- intervention required) will be assigned by the IRB-SBS PAM Advisory Committee.

- Following the meeting, the PAM Letter with the committee's assigned rating for the study, and any further required actions, will be sent via email to the PI/study team with the support of HRPP leadership.
- Notification from the PAM Advisory Committee to the IRB-SBS Full Board:
    - Following the IRB-SBS PAM Advisory Committee meeting, the IRB-SBS Chair or designee will present the information to the IRB-SBS Full Board (if IRB-SBS is the IRB of record) at the next scheduled IRB-SBS Full Board Meeting.
    - The IRB-SBS will review recommendations made by the PAM Advisory Committee and may make further recommendations for action.
- Recommendations and required actions will be communicated via a letter to the study team from the Associate VP for Research (VPR), unless the IRB-SBS PAM Advisory Committee determines that the letter should come from both the VPR and the IRB-SBS. If the letter is to come from both, the Associate VP for Research and the Chair of IRB-SBS will sign the letter. The letter will be sent within 5 working days after the IRB-SBS PAM Advisory Committee meets (the fourth Wednesday of each month) via email and will be copied to the applicable department chair. The letter will also be sent to the IRB-SBS chair or IRB of record.

The PAM Advisory Committee findings and recommendations for each PAM Report will be recorded in the committee's agenda and/or meeting minutes. The ratings for each PAM Report will be entered into the Post-Approval Monitoring Record tracking spreadsheet.

2.2 Annual PAM Report to the IRB-SBS Full Board

OBJECTIVE

To define the method for sharing aggregate data on the Post-Approval Monitoring and Education Program with the IRB-SBS Full Board.

RESPONSIBILITY

The Research Compliance Monitor will be responsible for creating the Annual PAM Report that is submitted to the IRB-SBS Full Board for review.

PROCEDURE

An aggregate summary of data from all PAM reviews and research education initiatives shall be sent to the IRB-SBS Full Board every year in the Annual PAM Report. The compliance monitor will create the Annual PAM Report for the IRB-SBS from the data for the last fiscal year (July 1st of prior year through

June 30th of current year). The Annual PAM Report will be presented to the IRB-SBS Full Board at one of the two meetings in July. Additionally, the most recent Annual PAM Report will be published on the IRB-SBS PAM & Ed website in an effort to make the information available to the research community.