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 reports that are submitted to the PAM Advisory Committee and the IRB-SBS for review.

PROCEDURE:

1. Individual PAM reports will be categorized and disseminated per the following:

   Category 1: Regulatory documents and source documentation are complete and protocol compliance is consistent with good clinical practice:
   - Submit the post-approval monitoring report, along with a category 1 transmittal letter via electronic mail to the study team (study team consists of Principal Investigator and, as applicable, Faculty Advisor and Laboratory/Project Manager), and the IRB of record.
   - PI response is optional.
   - Enter the findings of the post approval monitoring review into the Post Approval Monitoring Record.
   - Submit the preliminary PAM report and the PI response (if any), to the IRB-SBS PAM Advisory Committee (and the IRB of record if needed) one week prior to their monthly meeting.
   - Ratings (exceptional or satisfactory) will be assigned by the IRB-SBS PAM Advisory Committee.

   Category 2: Deviations noted, education and/or follow-up review may be required; continued non-compliance may be observed:
   - Submit a preliminary post-approval monitoring report, along with a Category 2 transmittal letter via electronic mail to the study team (study team consists of Principal Investigator and, as applicable, Faculty Advisor and Laboratory/Project Manager) and the IRB of record.
• PI response (if requested) 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 of receipt, or re-negotiated a response time with a Research Compliance Monitor, contact may be made by the latter via email or telephone call. The PI may be asked if they have received the letter/PAM report and had a chance to review it. The PI may also be told that if no response is made within 5 working days, another letter will be sent and copied to the 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.

• The monitor will enter the findings of the post approval monitoring review into the Post Approval Monitoring Record.

• The monitor will submit the preliminary PAM report and the PI response to the IRB-SBS PAM Advisory Committee one week prior to their monthly meeting. The PI response will also be sent to the IRB of record.

• Rating will be confirmed by the PAM Advisory Committee, which may choose to select category 3 if there are concerns regarding subject safety.

Category 3: Serious 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 concerns of subject safety. If the status is changed, the IRB-SBS Director or designee will be notified.

• Monitors will submit a PAM report, along with a Category 3 transmittal letter via electronic mail, to the study team (study team consists of Principal Investigator and, as applicable Faculty Advisor and Laboratory/Project Manager), the Sr. Associate VP for Research, IRB-SBS Director and Chair or designee, and consultant (if applicable).

• 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 Research 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 the Research Compliance Monitor does not receive a response, findings will be considered by the Sr. Associate VP without PI input. This step will already have been completed 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 Research Compliance Monitors, 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 Monitors, 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 investigator 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. The IRB-SBS PAM Advisory Committee will use a primary reviewer to present the information to the full IRB of record.

• Following the IRB-SBS PAM Advisory Committee meeting, the IRB-SBS Chair will present the information to the full IRB-SBS (if IRB-SBS is the IRB of record) at the next scheduled full IRB meeting.

• The IRB of record will make further recommendations for action.

• The Research Compliance Monitor will enter the findings of the post-approval monitoring review into the Post Approval Monitoring Record.

2. Aggregate PAM reports will be disseminated as follows:

• Monthly to the IRB-SBS PAM Advisory Committee - all reviews completed the previous month. These reports will be grouped in a packet and distributed with the meeting agenda.

3. Recommendations made by the PAM IRB-HSR Advisory Committee will be disseminated as follows:

• Recommendations 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 messenger mail and will be copied to the applicable department chair. The letter will also be sent to the IRB-SBS chair or IRB of record.

4. The findings and the rating of the post approval monitoring review will be entered into the Post-Approval Monitoring Record.

5. An aggregate summary of all reviews shall be sent to the full IRB every year.

REFERENCES:
1-8A Transmittal letter –category 1
1-8B VPR letter – category 1 exceptional
1-8C VPR letter - category 1 satisfactory
1-8D Transmittal letter-category 2
1-8E VPR letter- category 2
1-8F Transmittal letter –category 3