OBJECTIVE
To define the procedures utilized to prepare a report of findings for each review performed.

RESPONSIBILITY
The Research Compliance Monitors are responsible for preparing a report for each review performed.

PROCEDURES
1. Prepare the final report using information gathered during the review.

2. Structure of the PAM reports.
   The heading of the PAM report should include the following information:
   • The IRB-SBS number and title of the research study
   • The name of the principal investigator and faculty advisor
   • The name of the project manager/laboratory manager
   • The date on which the review was conducted.

   The introduction of the PAM report should include but not be limited to the following:
   • 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 review
   • Information regarding IRB of record if not UVA IRB-HSR

   The body of the PAM report should include summaries of the topics covered in the review, such as:
   • 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

   Recommendations shall be made for findings, as indicated. Resources for accessing further information will be offered.

   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 is made by the Research Compliance Monitor based on the number and severity of compliance issues found.
REFERENCES:
Post Approval Monitoring Report Form 1-7A