Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #10 Rev. 0	Post-Approval Monitoring	Date Effective: 1.21.2019
Approved by IRB Chair	*R. Shuane*	Date 1/21/2019
Approved by RP Director	*Chris Mumm Mumdum*	Date 1/21/2019

PURPOSE

To describe Post-Approval Monitoring (PAM) selection procedures, monitoring, and follow-up education.

GENERAL DESCRIPTION

The IRB's priority is to protect human participants in research and ensuring that research is conducted in accordance with federal, state, and University policies. Post-Approval Monitoring attends to this policy by observing and interviewing Principal Investigators (PIs) to determine the safety and compliance of procedures in studies using human participants.

RESPONSIBILITY

Execution of SOP: IRB Chair, IRB Administrator, Principal Investigator (PI)/Study Personnel, Research Protections (RP) Staff.

PROCEDURES

Selection of Studies for Post-Approval Monitoring

1. All studies reviewed by the IRB are subject to PAM. Selection may be driven by for cause and not-for cause reviews.
2. For cause reviews:
   a. Studies may be identified for a PAM review based on the following criteria:
      i. Noncompliance by the PI
      ii. An adverse or unanticipated event is reported that may imply a review of the approved procedures
      iii. Allegations of misconduct or subject complaint
      iv. Repeated failure to follow IRB deadlines, requirements or procedures
      v. The IRB of record in a multi-site project requests a PAM review of the local site
      vi. Other circumstances where the IRB requests PAM, with approval by the IRB Chair
3. Not for cause reviews:

    a. Studies will be randomly selected by IRB administrators

    b. Reviews of one study will not be conducted more often than annually

    c. When appropriate, several studies by same PI may be selected for one PAM visit, such as

        i. Logistics support multiple reviews for one visit

        ii. Studies are related or connected

4. PAM reviews are conducted with (at least) one member of the IRB Administration and one voting member of the IRB.

    a. If needed, a nonmember of the IRB who has specific expertise related to the study may be asked to join.

Communicating with PI's

1. Once a study is selected for PAM, Research Protections Staff will alert PI by email notification, requesting a response within 10 business days. If PI is a student, the faculty advisor (FA) will be copied.

    a. If PI does not respond within 10 business days, a reminder email will be sent, asking PIs to respond within 5 business days.

    b. If PI does not respond to reminder email, a final reminder email will be sent, this time copying the PIs department chair.

2. PI schedules PAM Visit, for roughly one hour. If PI is a student, the FA must be present during the PAM Visit.

3. Following PAM Visit, PIs will be sent a PAM Report within 10 business days, detailing all observations, positive comments, and areas for improvement.

4. PIs will sign the PAM Report and return it via email and/or schedule a meeting with Research Protections to discuss or dispute comments. Unresolved disputes may be appealed according to Policy 209.

5. PIs are responsible for implementing any changes mandated in the PAM Report and contacting Research Protections for additional resources and educational materials.

PAM Preparation

1. RP Staff member reviews the approved protocol for selected study, noting potential areas of focus, such as:

    a. Data storage and retention

    b. Informed consent form and process

    c. History of any subject complaints, withdrawals

    d. Recruitment and accrual history

    e. Procedures and location of procedures

2. The PI prepares for the visit:

a. Documentation such as informed consent form, debriefing, and assent, are the currently approved versions
b. Procedures and locations are in accordance with the approved IRB
c. Personnel on the project are listed in the IRB and have completed all required training
d. If additional requirements such as GCP, DoD, etc. are applicable, the PI can show compliance

Post-Approval Monitoring Visit
1. IRB administrators/members conducting PAM (also called Monitors) meet PI and faculty advisor (if PI is a student) either where procedures take place or where records are kept.
2. PAM is comprised of documentation review, a review of the consent procedure, and if applicable, a demonstration of study procedures.
3. Once Monitors conduct the review and answer any questions from the PI, the visit is complete.

PAM Report and Follow up
1. PAM Report is completed by the Monitors and sent to the PI within 10 business days of the visit
   a. The report summarizes what was reviewed, highlights, and areas where education or revisions are required
   b. The PI may be asked to respond to the report in addition to an acknowledgement if a specific action is required, such as additional training or a modification to the study
      i. The PI will be given a target date for completion; failure to meet the target date may result in noncompliance
2. The IRB Chair is briefed on the visit at the next available weekly Chair meeting
3. Other institutional review bodies (e.g., the IACUC, IBC or COI) may be notified of the PAM results if any findings indicate additional review may be needed
4. The IRB will be provided a summary of PAM activities for the previous 30 days at the next monthly meeting
   a. If needed, the IRB is briefed on findings from the visit where noncompliance was discovered

SUPPORT PROCESSES AND PROCEDURES
SOP#3, Continuing Review
SOP#7, Noncompliance

REFERENCES

45 CFR Part 46.10p(g)