1. POLICY

The primary purpose of these procedures is to assess and enhance the protection of human subjects involved in research by providing education to Investigators and research team members and determining that proper procedures are followed regarding the conduct of Human Subjects Research. Additionally, these procedures are used for directed monitoring.

These policies and procedures apply to all Human Subjects Research protocols approved, or exempted by the Purdue HRPP or the Purdue University Institutional Review Board (IRB). The monitoring process may also be conducted on any protocols for which Purdue University's IRB has responsibility for oversight. These procedures apply to all research protocols.

2. DEFINITIONS

2.1 *Directed Monitoring.* Monitoring activities conducted on a "for-cause" basis which include, but are not limited to, reported complaints and request by the IRB due to anomalies related to a protocol.

2.2 *Monitor.* An Office of Research and Partnerships Post-Approval Monitor, a Protocol Analyst, IRB Administrator, IRB Chair, IRB Associate Chair, IRB Member, or a team consisting of any of the preceding who are selected to conduct monitoring activities.

2.3 *Random Selection Procedure.* Manner of selection based on review type without Investigator identifiers.

3. PROCEDURES

3.1 Protocol Selection

3.1.1 Reasons for selection to undergo post-approval monitoring include:

(a) For cause selection which includes reported complaints and/or requests by the convened IRB of record.

(b) Projects where continuing review or reports from other sources have indicated that material changes may have occurred without IRB approval.

(c) Projects conducted by an Investigator who had previous instances of noncompliance.

(d) Projects involving vulnerable populations that raise cause for concern.

(e) Complex projects involving unusual levels or types of risks to subjects.

(f) Upon request by the Investigator.

(g) In response to inquiries from external regulatory agencies.

(h) Random selection procedure.

3.1.2 The decision to initiate directed Post-Approval Monitoring (PAM) may be made by an IRB Chair, IRB Associate Chair, HRPP Director, or IRB Administrator, but all, collectively must be informed unless a conflict of interest is cited.

3.2 Who Conducts Monitoring Activities

3.2.1 Post-Approval Monitoring activities are generally conducted by a Post-Approval Monitor (assigned EVPRP staff member), Protocol Analyst, and/or the IRB Administrator under the guidance of the HRPP Director and/or Institutional Official.

3.2.2 In addition to the above referenced personnel, IRB Chairs, IRB Associate Chairs, and IRB Members may be selected to conduct or assist with monitoring activities on the basis of expertise.

3.3 Monitoring Procedures for Research Protocols

3.3.1 Once a protocol is selected for monitoring, the Monitor conducting the visit will contact the Investigator notifying them that their protocol has been selected for review and to expect a second contact within the next five (5) business days to schedule the visit. Information about the monitoring program and what will be reviewed will be provided.

3.3.2 Within five (5) business days after the initial contact with the Investigator, the Monitor will contact the Investigator to schedule the visit. If the Investigator has a conflict with the proposed visit schedule, she or he may request the visit be rescheduled. The Investigator may elect to have key personnel from the research team present.

3.3.3 Prior to the visit, the Monitor will verify the research team's training, review the protocol, and prepare the monitoring materials as required.

3.3.4 On the day of the visit, the Monitor will conduct an introductory meeting with the Investigator and research team. At this meeting, the Monitor will inform the Investigator if the visit is for directed Monitoring. The Monitor will interview the Investigator and other research team present about their

procedures and will ask for a verification of security procedures. Additionally, the Monitor will address any questions from the Investigator and research team.

3.3.5 After the interview(s) the Monitor will review the requested materials and request any additional materials from the Investigator

3.3.6 The Monitor will prepare a draft report and provide it to the Investigator within fifteen (15) business days.

3.3.7 The Monitor will conduct a debriefing interview with the Investigator and research team and provide an overview of preliminary findings and answer any questions that may occur.

3.3.8 The Investigator will have fifteen (15) business days to respond to the draft report and advise of changes. If no response is forthcoming in that time frame, the report will be considered to be accurate and will be finalized. If for some reason the Investigator cannot respond within the fifteen (15) business day time frame, she or he can request an extension.

3.4 Reporting Monitoring Results

3.4.1 The Monitor will submit the final report to the IRB Chair, IRB Associate Chair, HRPP Director, or the IRB Administrator.). The final report may include recommendations for corrective actions. The IRB Chair or Associate Chair reviews the final report and may request revisions to the research protocol from the Investigator based on the information and recommendations provided.

3.4.2 If the monitoring uncovers serious or continuing noncompliance, the matter will be handled in accordance with the procedures outlined in SOP 408: Noncompliance.

3.4.3 The final report will be filed in the Investigator's protocol file maintained in the HRPP office as well as in the Monitor's database.

3.4.4 No less than twice per year, a report of recent PAM processing will be provided to the IRB for inclusion at a fully convened meeting.

3.5 Additional Monitoring Procedures

3.5.1 Due to the diversity of research, monitoring procedures must remain flexible to accommodate the various research procedures utilized in protocols. The Monitor will have the discretion to skip procedures and/or questions identified on the Monitoring Form if they are inappropriate for

the research design and the reasons for conducting the monitoring activities (e.g. random, directed, etc.).

3.5.2 In some situations, observation of the consent process with subjects and/or the research procedures may be required.

4. RESPONSIBILITY

Monitor is responsible for conducting monitoring activities including, but not limited to, Random Selection Procedures, notification of Investigators, scheduling site visits, conducting interviews, conducting document reviews and drafting timely reports.

The IRB Chair (or his/her designee) may serve as the original reviewer of Post Approval Monitoring Reports.

The HRPP Director and IRB Administrator coordinate the monitoring activities, receive and route PAM reports, and supervise the HRPP and Office of Research and Partnerships Post-Approval Monitoring staff involved in the process.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.108, 46.109

21 CFR 56

6. REFERENCES TO OTHER APPLICABLE SOPs

304 Continuing Review

408 Noncompliance