OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #409.0 Revision 0	**TITLE: Post Approval Monitoring Program**	Effective Date: 1/19/2018
Approved By: OIRB Director	Signature *Linda Rota*	Date 1/19/2018
Approved By: IRB Chair	Signature	Date 1/19/2018

PURPOSE
To describe the policies and procedures for the post approval monitoring (PAM) component of The University of New Mexico Human Research Protections Program (HRPP).

REVISIONS FROM PREVIOUS VERSION
None

POLICY
The PAM program serves to improve human research protections and the quality and integrity of research under the oversight of the UNM IRB. The PAM program has three goals:
- Enhance protection of research participants,
- Improve quality of human research data, and
- Provide education to maintain compliance with HRPP regulations and policies.

The PAM program provides oversight and education relating to project start-up activities and on-going conduct of human research projects. It is designed to verify that research is being conducted as approved by the IRB and help ensure compliance with federal and state regulations and institutional policies. At the time of initial or subsequent review, the IRB reviewer (or full board) may recommend PAM activities for specific projects. PAM staff, in consultation with the Director and IRB Chair when appropriate, retain the right to modify the recommendation of the IRB reviewer based on resource allocation and other considerations. Designated OIRB staff conduct the PAM activities. For student projects, the student researcher should be involved in addition to the PI of record. The UNM HRPP intends to conduct PAM activities on at least 5% of all active projects on an annual basis.

RESPONSIBILITIES
Execution of SOP: OIRB Director, OIRB Staff, Principal Investigator (PI)/Project Team Personnel

PROCEDURE
PAM Activities

1. **Administrative check-in:** For projects that do not have continuing review, they may have an administrative check-in. OIRB staff send an email communication to the PI at a designated time point (based on the original data collection time line) to assess the status of the project including whether the project is still collecting data, had any adverse events, unanticipated problems involving risk or protocol deviations, and whether there are any new findings that may affect risk to participants. The check-in will remind PIs of their obligation to submit amendments and event

reports. Based on PI feedback, project time lines will be adjusted accordingly or the project will be closed by the OIRB.

2. **IRB directed self-assessment (full, informed consent documents only, or informed consent process only)**: OIRB staff sends the PI a self-assessment checklist to complete within a set period. The completed self-assessment is returned to and reviewed by the OIRB. Self-assessments may be limited to consent forms only or other limited scope to screen for potential quality issues. For a consent only assessment, the researcher may be informed to submit all signed consent/assent signature pages for all participants enrolled during a specified period.

3. **Full On-site Assessment:** Full assessments are conducted as per SOP 406 Directed and Self-Audits.

4. **Project Team review:** Projects with large project teams or special team training requirements (e.g. muscle biopsy, tDCS) may be selected for a project team review. The PI submits a current Project Team form and training certificates via IRBNet and OIRB staff will verify that all team members meet training requirements and have a current Conflict of Interest (COI) disclosure on file.

5. **Informed Consent Observation:** When a project is viewed as sensitive, high risk or when the IRB has concerns regarding the process for obtaining informed consent, the OIRB may request a consent observation. Consent observation may be requested for one or more participants. The OIRB informs the researcher(s) that consent observation is required and it is the responsibility of the researcher(s) to coordinate with the requestor.

Monitoring Process
1. Upon selection, the OIRB notifies the PI in writing regarding the selection of their project for PAM.
2. OIRB staff provide a timeline for completion of the PAM activities. Lack of response by the PI will be considered noncompliance with this policy and may result in a process hold on future submission(s), full audit or involvement of the Department Chair, Director or Associate Dean for Research.
3. The following documents may be requested and/or reviewed by OIRB staff: signed informed consent documents, signed HIPAA authorizations, CV and training documentation for project staff, regulatory documents, and participant research records including inclusion/exclusion confirmation documentation if appropriate, enrollment logs or any other relevant documents.

Outcomes
1. OIRB staff document the outcome of PAM activities and identify any areas of strength and/or need for improvement in research practices. This documentation is provided to the PI and the IRB Chairs. PAM outcomes may also be reported to Department Chairs and Center Directors as appropriate.
2. If a need for improvement in research practice is identified, OIRB staff provide education to the PI and project team (if applicable), suggest recommendations based on existing policies and procedures, and provide any relevant recordkeeping tools (e.g. event reporting log, enrollment log, informed consent checklists) as needed.
3. If a reportable event or other unanticipated problem is discovered, the PI will be instructed to submit an Event Form as applicable.
4. If other compliance issues are identified, the OIRB will consult with the IRB Chair to determine appropriate action.