Oklahoma State University Standard Operating Procedures		
Institutional Review Board: **Post Approval Monitoring Program**	SOP #	RR 412
	Effective Date	10/09/2024
	Revision Date	9/24/2024
	Version #	1
	Approval: IRB Committee	

1. PURPOSE

All researchers are expected to comply with the provisions of an approved Institutional Review Board (IRB) study protocol and to adhere to federal, state, and local regulations as well as OSU policies governing human subject research (45 CFR 46). The OSU IRB has the authority and responsibility for continuing oversight of approved protocols.

As part of the required review of approved study protocols, the Post Approval Monitoring Program will monitor research projects through onsite Post Approval Monitoring (PAM) visits. The goal of PAM visits is to work with, and provide support to, academic and research personnel and to confirm consistency and accuracy of approved protocols and practices. The PAM reviewer will confirm compliant performance through potential observations and document review, assuring the research is being performed in accordance with federal regulations and best research practices.

A PAM visit does not imply suspected wrongdoing within the conduct of the research study. PAM visits help the IRB to assess research compliance, as well as acting as an educational tool for the Principal Investigators (PIs), Research Team, and the IRB Office. It is an opportunity to discuss the protocol and its progress, and to review the procedures pertinent to the protection of human subjects.

Post Approval Monitoring Objectives:

- To confirm compliance by observation of the research study procedures and direct communication with the PI(s), Faculty Advisor, and Research Team, in an unobtrusive manner.
- To ensure the well-being of human subjects in research.
- To advise the PI(s) on best practices for conducting their human subject research study in compliance with their approved protocol, the OSU IRB policies and guidelines, and Federal/State regulations.

2. PROCESS and PROCEDURES

2.1 Criteria

All active human research studies are subject to PAM visits, except those determined to qualify for Exempt Status. The IRB selects protocols for visits by use of a random generator for the purpose of reviewing scientific, ethical, and regulatory research procedures and to ensure compliance with the IRB approved protocol (Appendix I).

Only <u>Expedited and Full Board</u> approved protocols will be randomly selected for PAM visits.

2.2 Notification

The PI(s) will be notified via email and with an official notification letter that their protocol has been randomly selected for a PAM visit (Appendix II). The email notification and the letter will specify which protocol has been selected. The availability and scheduling for the visit will be determined amongst the PI(s), Faculty Advisor, Research Team, and IRB Member, as well as the allocation of resources such as files, space, and/or access to electronic records. The email will also contain an attached IRB PAM Self-Assessment Report so that the Research Team may know what information will be reviewed at the time of the visit.

2.3 Conducting the Visit

I. The PI(s), Faculty Advisor, and any other Research Team Members involved in the study are expected to cooperate with the PAM visit conducted by the IRB.

II. The PI(s) should have all regulatory and participant documents available for review as requested. If the IRB Office requests files to be sent electronically, the PI(s) will need to make confidential documents encrypted and secured before sending by email.

III. During each monitoring visit, the IRB Member will compare procedures conducted with those listed in the IRB protocol. The IRB Member will use a checklist as a guide to review items such as personnel, recruitment methods, Informed Consent Process and Documentation, procedures, data storage, etc. (Appendix IV).

IV. The IRB Member(s) conducting the visit will provide guidance to the PI(s) and assist in addressing significant findings as appropriate. Upon completion of the visit, the PI(s) will be debriefed regarding any non-compliance issues, recommendations, and next steps. Research Teams must identify, evaluate, and respond to these deviations and unexpected events to protect the rights, safety, and welfare of participants and others and the integrity of the research data.

2.4 Follow Up

I. The IRB Member(s) shall send a written report of the monitoring results to the Principal Investigator (and Faculty Advisor, as applicable), describing any action items needed (Appendix III). When no concerns are noted during the site visit, a letter will be sent to the PI and study personnel commending them for their continued full compliance with the IRB.

II. All documents pertaining to the site visits will be stored electronically on a secure server. All documents will also be uploaded to the protocol's study site in the IRB OneAegis system.

III. A summary report of visits and any findings will be presented at the IRB meetings.

3. SCOPE

This procedure applies to all research approved by the OSU IRB.

4. RESPONSIBILITY

The IRB Office is responsible for notifying the PI(s) of the PAM visit, as well as any follow-up information from the visit.

The PI(s), Faculty Advisor, and any other Research Team Members involved in the study are expected to cooperate with the PAM visit conducted by the IRB.

Appendix I: Post Approval Monitoring-IRB selection procedure-Random generation

1) Access IRB Database and run an Ad-Hoc Report
2) Run report for Applications Received
3) Filter report for applications received that are of the expedited and full board review level with the open to enrollment status
4) Move report to Post-Approval Monitoring folder
5) Use random generator to identify an IRB protocol to be reviewed from the report for applicable semester

Appendix II: PAM Visit Notification Letter

University Research Compliance
Vice President for Research
Oklahoma State University
219 Scott Hall
Stillwater, Oklahoma 74078-1020
(405) 744-3377
www.research.okstate.edu

DATE: *Insert Date*

TO: *PI Name / Researchers*

FROM: *Name*
Role
Office of University Research Compliance

Dear Researcher,

Post-approval monitoring (PAM) of active Institutional Review Board (IRB) Human Research Protocols are performed to provide assurance to regulatory agencies and Oklahoma State University that research and academic programs doing research with living individuals is monitored for compliance with approved IRB protocols. As part of the PAM protocol review program, I would like to schedule a PAM visit, perhaps in the next week or two, to review this protocol with you and/or personnel listed on this IRB. Any other staff or students who might be interested in research compliance are also welcome. I am always open to fielding questions and offering guidance to those who might have an interest in research involving humans. The reviews usually only take about 30 minutes to an hour. This protocol was one that was randomly selected from all active IRB applications at OSU using a random number generator. At your earliest convenience, please work with the IRB Office to schedule this visit at a time that is convenient for you and any other research personnel needed. Conversely, if this protocol should be closed, or you have not started any work with human participants, please let me know as a PAM review would not be necessary at this time.

The purpose of this visit is to review records and perhaps visit lab spaces that are listed within the application. I have attached a checklist, which I will be using as a guide during the visit, so you and your personnel can anticipate what will be reviewed. Several of the items on the checklist may not apply to your IRB application as it is designed to cover all areas of research at the various colleges across the OSU campus.

At the completion of the site visit, I will provide an “Exit Briefing” to you and/or the personnel present during the PAM visit. The purpose of this briefing is to assure the accuracy of the observations and discuss IRB deviations or problematic conditions, if any, observed during the visit.

Within a few days of this visit, I will send you an email summarizing this visit and identify, again if any, items that may require corrective attention. The Office of University Research Compliance appreciates your willingness to ensure the integrity of the teaching activities and research with human participants at OSU.

Best regards,

Name
Role, University Research Compliance
218-219 Scott Hall
irb@okstate.edu
Phone

Appendix III: IRB PAM Follow Up Letter

University Research Compliance
Vice President for Research
Oklahoma State University
219 Scott Hall
Stillwater, Oklahoma 74078-1020
(405) 744-3377
www.research.okstate.edu

DATE: [INSERT DATE HERE]

TO: [INSERT RESEARCHER NAME HERE]

FROM: [INSERT NAME HERE]
[INSERT ROLE HERE]
Office of University Research Compliance

Dear [INSERT RESEARCHER NAME HERE]

This letter is to follow up on the post-approval monitoring (PAM) visit to your research study, "[INSERT STUDY TITLE HERE]", on [INSERT DATE HERE]

Overall, the PAM visit found that the study is being conducted in compliance with the approved protocol and applicable regulations. There were a few discussion items and/or findings we addressed during this visit that are listed below that I would like to bring to your attention:

[INSERT INFORMATION HERE]

Best regards,
Name
Role, University Research Compliance
218-219 Scott Hall
irb@okstate.edu
Phone

Appendix IV: IRB PAM_Self-Assessment Report

IRB Post-Approval Monitoring Self-Assessment Report

Institutional Review Board Office

219 Scott Hall | Tel: (405) 744-3377
Website: research.okstate.edu | Email: IRB@okstate.edu

IRB Post Approval Monitoring Report v. 1/23/ 2024

PAM Check List				
1. Approval and Record Keeping	**Yes**	**No**	**N/A**	**Notes**
Does the project have current IRB approval?	☐	☐	☐	
Are all IRB related records being retained in an accessible location? (Examples: approval letters, signed applications, approved consent forms, correspondence, protocol, etc.)	☐	☐	☐	
Are all research team members current in their Human Participants' Protections Training (CITI)?	☐	☐	☐	
Are all research team member training certificates on file?	☐	☐	☐	
Have all revisions to the project been reviewed and approved by the IRB prior to implementation?	☐	☐	☐	
2. Participant Recruitment and Screening	**Yes**	**No**	**N/A**	**Notes**
Were participants identified and recruited according to the procedures approved by the IRB?	☐	☐	☐	
Were the advertising and/or recruitment materials used approved by the IRB prior to use?	☐	☐	☐	
Were all inclusion and exclusion requirements followed as listed and approved by the IRB?	☐	☐	☐	
If **no**, were the deviations reported to the IRB?	☐	☐	☐	
For participants that did not meet eligibility requirements (failed screening), were IRB approved procedures followed?	☐	☐	☐	
How many participants have been enrolled to date?				
Is the number of participants enrolled greater than the IRB approved maximum participant enrollment?	☐	☐	☐	
3. Informed Consent Process and Documentation	**Yes**	**No**	**N/A**	**Notes**
Was the IRB approved version of the consent(s)/assent(s) used to enroll participants?	☐	☐	☐	
If using an oral or online consent, was the IRB approved script/text used to enroll participants?	☐	☐	☐	
Were all consent forms used to enroll participants approved by the IRB?	☐	☐	☐	
Did an appropriately trained research team member obtain consent from all participants?	☐	☐	☐	

Is there a signed and dated consent form on file for every participant enrolled in the project?	☐	☐	☐	
Did the research team member sign and date each consent form?	☐	☐	☐	
Do the participant and researcher consent dates match?	☐	☐	☐	
If changes were made to the consent form, were the changes submitted and approved by the IRB prior to use?	☐	☐	☐	
Did every participant receive a copy of the consent form?	☐	☐	☐	
4. Research Protocol	**Yes**	**No**	**N/A**	**Notes**
Was the research conducted consistent with the description and procedures as approved by the IRB?	☐	☐	☐	
Were the data collection tools (e.g. surveys, interview questions, etc.) used approved by the IRB, prior to use?	☐	☐	☐	
For each participant, was consent obtained prior to any project procedures?	☐	☐	☐	
Are all participant compensation records being documented and stored appropriately?	☐	☐	☐	
If changes were made to the protocol, were the changes submitted and approved by the IRB prior to implementation?	☐	☐	☐	
Have all reportable events been addressed as required by the IRB?	☐	☐	☐	
5. Privacy, Data Storage, and Confidentiality	**Yes**	**No**	**N/A**	**Notes**
Were privacy standards and procedures implemented as approved by the IRB?	☐	☐	☐	
If you collected data anonymously, has anonymity been maintained in the physical/electronic records?	☐	☐	☐	
Are signed consent forms and coded research data stored separately?	☐	☐	☐	
Are signed consent forms secured as approved by the IRB? Provide location:	☐	☐	☐	
Are research data secured as approved by the IRB? Provide location(s):	☐	☐	☐	
If electronic data are being stored on a desktop, is it secured as approved by the IRB? Provide computer location:	☐	☐	☐	
Are electronic data secured (e.g. password protected, encrypted, etc.) as approved by the IRB?	☐	☐	☐	
Are you aware of the security on your computer and server?	☐	☐	☐	
Is access to computer, electronic files, and physical files limited to appropriate research personnel?	☐	☐	☐	
Was/are identifiers stored/disposed of as approved by the IRB?	☐	☐	☐	

Was/is the research data (raw) stored/disposed of as approved by the IRB?	☐	☐	☐	

6. Biospecimen Collection & Storage	Yes	No	N/A	Notes
Are biospecimens being collected in accordance with IRB approved procedures?	☐	☐	☐	
Are the biospecimens being properly stored/disposed of as approved by the IRB?	☐	☐	☐	
Are there appropriate biohazard disposal containers placed where the biospecimens are being collected?	☐	☐	☐	
Are the biospecimen collection areas being properly sanitized in accordance with IRB approved procedures?	☐	☐	☐	
Do all members of the research team have the BBP training on file and up to date?	☐	☐	☐	

7. Continuing Review	Yes	No	N/A	Notes
Are you aware of when the IRB approval for this project expires? Expiration date:	☐	☐	☐	
Have you placed a reminder on your schedule to submit continuing review documents 30 days prior to expiration?	☐	☐	☐	
Has IRB approval for this project ever expired?	☐	☐		
If **yes**, did you report any research activity that was done while IRB approval was expired?	☐	☐		
Have there been any adverse events, unanticipated problems, or complaints while conducting this research?	☐	☐		
If **yes**, have all details been reported to the IRB?	☐	☐	☐	
Has the researcher become aware of new information that changes the risk benefit ratio of this project?	☐	☐		
Does the enrollment number reported in the continuing review application include all individuals who signed an informed consent document?	☐	☐	☐	

8. Project Completion	Yes	No	N/A	Notes
Is data collection complete for this project?	☐	☐	☐	
If data collection is ongoing**, what is your anticipated end date for data collection?** Anticipated end date.				
Have all identifiers been destroyed in accordance with IRB approved procedures?	☐	☐	☐	

If **yes to both questions above**, submit a Closure Application (and supporting documentation) to the IRB Office.