James Madison University Office of Research Integrity & Compliance and Institutional Review Board Standard Operating Procedures			
TITLE: Post-approval Verification and Education			
SOP # 22	**Revision # 0**	**Effective Date: 9/9/2026**	**Page 1 of 4**

OBJECTIVE

To describe the policy and procedures for the Post-approval Verification and Education (PAVE) program by the Institutional Review Board (IRB).

GENERAL DESCRIPTION

The Office of Research Integrity & Compliance (ORIC) and the IRB must determine that approved and Exempt research is being ethically conducted in accordance with 45 CFR 46 and JMU Policy #1104. The PAVE program will provide education, guidance, and collaboration with human participant research teams as they pursue their research objectives. This Standard Operating Procedure (SOP) sets forth the process for review of research procedures, informed consent, and supporting documentation; submission requirements of PAVE program documents; and providing education and guidance for any knowledge gaps. Any issues of unanticipated problems, adverse events, or noncompliance will not be addressed by the PAVE program but rather referred to the IRB for review and resolution.

RESPONSIBILITY

Execution of SOP: ORIC Staff, Principal Investigator (PI)/Study Personnel, IRB Chairs, IRB Members

PROCEDURES

Protocol Selection
Protocols for routine PAVE reviews will be randomly selected from the human research protection program's electronic Research Administration (eRA) system, including active exempt, expedited, and full board review protocols. The IRB will request a for-cause PAVE evaluation when they receive a concern or complaint. (SOP No. 10)

Initial Contact with the Principal Investigator

After protocol selection, PAVE personnel will contact the PI to inform them that their research will undergo a PAVE review. The PAVE review process will be explained to the PI. The PI will receive a Self-Assessment Checklist (Appendix 1) to complete with a request to upload protocol documentation to a secure folder within a Teams site. If the PI does not want to upload their documentation to the Teams site, then a PAVE program visit will be conducted in person. The PI will have ten business days to provide the Self-Assessment Checklist and protocol

documentation. If the PI does not respond, the following courtesy reminder process will be followed:

1. PAVE personnel will send a courtesy reminder to the PI; they will be given three business days to respond.
2. If there is no response, an Urgent Notification email will be sent by PAVE Personnel copying in their academic unit head on the email. The PI has two business days to respond.
3. If there is still no response, an Urgent Notification email will be sent by PAVE Personnel copying in their academic unit head and the Institutional Official on the email. The PI has two business days to respond.

If the PI communicates that they need additional time, an extension may be granted on a case-by-case basis. PAVE personnel will conduct a review of all documentation and the self-assessment form, then schedule an exit interview with the PI to provide feedback, guidance, and education. The exit interview will be a one-on-one session with the PI and should take place within 30 days of receipt of the Self-Assessment Checklist and protocol documentation. PAVE personnel will then write a final report that will be shared with the IRB and the PI. PAVE personnel will also update the IRB of its activities during convened meetings.

Criteria for PAVE Review

PAVE personnel will conduct their review based on the following criteria:

1. Human subjects research is being conducted in alignment with the approved IRB protocol.
2. Supporting documentation (recruitment materials, informed consent, survey instruments, etc.) is current and consistent with the approved IRB protocol.
3. Research activities are in compliance with federal regulations, state laws, and institutional policies.

Follow-up Activities

PAVE personnel will complete a Digital Review Checklist (Appendix 2) within five business days and then schedule a one-on-one exit interview with the PI.
The one-on-one exit interview should take place within 30 days. The PI will have ten business days to schedule the exit interview. If the PI does not respond, the following courtesy reminder process will be followed:

1. PAVE personnel will send a courtesy reminder to the PI; they will be given three business days to respond.
2. If there is no response, an Urgent Notification email will be sent by PAVE Personnel copying in their academic unit head on the email.

3. If there is still no response, an Urgent Notification email will be sent by PAVE Personnel copying in their academic unit head and the Institutional Official on the email.

If the PI communicates that they need additional time, an extension may be granted on a case-by-case basis. PAVE personnel will compile an Exit Interview Report (Appendix 3) and will share its review findings with the PI and provide education and guidance on any knowledge gaps. The PI will have the opportunity to respond to the PAVE program's findings and to ask questions. Next steps, needed follow-up actions, and timeframe to complete follow-up actions will be discussed.

Final Reporting

PAVE personnel will compile a Final Report (Appendix 4) and share it with the PI and the IRB. PAVE personnel will also provide a PAVE update at each IRB convened meeting.

Potential Corrective Actions

The IRB makes the determination that corrective actions are required and the timeframe required for addressing any findings. The timeframe for corrective action resolution will be on a case-by-case basis. PAVE personnel will follow up with research teams to confirm that they have resolved all issues found in the PAVE review. Corrective actions may include the following:

- No action required (no concerns or findings)
- Additional education and training for the research team
- A Modification to the protocol
- An Incident Report to address protocol deviations, adverse events, new or increased risks of participation, or written reports from government agencies. (SOP No. 5)
- Whether or not protocol violations or serious non-compliance occurred. (SOP No. 7) and (SOP No. 15)
- Study suspension or termination (SOP No. 6)

Revision History

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	9/9/2026

Signature History

Name and Title	Signature	Date

References

45 CFR 46
JMU Policy # 1104

PI Self-Assessment Checklist for IRB Protocols

This checklist is provided to help principal investigators (PI's):

- **Evaluate** their study's compliance with regulatory, institutional, and ethical standards.
- **Prepare** for the post-approval verification and education process.
- **Identify** and submit the IRB protocol documents for digital review prior to the exit interview.

I. PROTOCOL INFORMATION

Study Title:_____

Protocol Number:_____

Study Enrollment Status: Open ☐ Closed ☐

Funding: External ☐ Internal ☐ N/A ☐ Source:_____

Study Population: # approved_____ # enrolled_____ # withdrawn_____

Study Expiration Date:_____

II. IRB APPROVAL AND COMPLIANCE

Please respond to the areas below that apply to your IRB protocol, or indicate, "N/A." Explanations and clarifications can be provided in the "Notes" section below.

Completed	N/A	
		IRB approval was received prior to initiating any research activities.
		Deviations, adverse events, and unanticipated problems have been reported.
		Protocol Renewal was submitted prior to the expiration date.

Notes:

III. STUDY RECORDS AND DATA STORAGE

Please respond to the areas below that apply to your IRB protocol, or indicate, "N/A."
Explanations and clarifications can be provided in the "Notes" section below.

Completed	N/A	
		Physical study data is securely stored in a locked, restricted access area.
		Electronic data is password protected and encrypted (if required).
		Signed consent forms are securely stored separately from data.
		Participant logs, sign-in sheets, are securely stored.
		Data storage and destruction plans follow the approved IRB protocol.

Notes:

IV. TRAINING AND PERSONNEL

Please respond to the areas below that apply to your IRB protocol, or indicate, "N/A."
Explanations and clarifications can be provided in the "Notes" section below.

Completed	N/A	
		All study personnel have taken the required CITI trainings within the last 3 years.
		All personnel changes were submitted to the IRB.

Notes:

V. INFORMED CONSENT PROCESS

Please respond to the areas below that apply to your IRB protocol, or indicate, "N/A."
Explanations and clarifications can be provided in the "Notes" section below.

Completed	N/A	
		Consent was obtained using the correct, IRB-approved version.
		Waivers of consent are documented.
		Signed, dated copies of consent forms are on file for all participants.
		Participants received a signed copy of the informed consent.
		PI or a study team member conducted and documented the informed consent process in a private setting.

Notes:

VI. PARTICIPANT MANAGEMENT & ELIGIBILITY

Please respond to the areas below that apply to your IRB protocol, or indicate, "N/A."
Explanations and clarifications can be provided in the "Notes" section below.

Completed	N/A	
		Enrollment logs match the number of consented and active participants.
		Inclusion and exclusion criteria were followed and documented.
		Participant withdrawals are documented with reasons.

Notes:

VII. REQUIRED DIGITAL DOCUMENTATION FOR POST-APPROVAL EVALUATION

Please respond to the areas below that apply to your IRB protocol, or indicate, "N/A."
Explanations and clarifications can be provided in the "Notes" section below.

Completed	N/A	
		Waivers of consent documentation.
		Signed consent forms for all participants.
		Documentation of verbal consent.
		Signed parental consent forms.
		Signed child or youth assent forms.
		Translated consent/assent forms.
		Consent process documentation (e.g., progress notes, consent logs.)
		Adverse events and serious adverse events reports.
		Unanticipated problem reports.
		Screening logs.
		Enrollment logs.
		Withdrawal documentation.
		Compensation records.
		Data storage location description (physical and electronic).
		Data retention schedule.

Notes:

VIII. DIGITAL DOCUMENTATION SUBMISSION ACKNOWLEDGEMENT

PI Signature:_____

Date of Digital Upload:_____

Digital Review Checklist for IRB Protocols

This checklist is provided to help principal investigators (PI's):

- **Confirm** that all required documentation has been submitted and is complete.
- **Ensure** records adhere to the approved protocol and to institutional and regulatory requirements.
- **Identify** missing, unclear, or incomplete information that requires clarification or follow-up.

I. PROTOCOL INFORMATION

Study Title:_____

Protocol Number:_____

Study Enrollment Status: Open ☐ Closed ☐

Funding: External ☐ Internal ☐ N/A ☐ Source:_____

Study Population: # approved_____ # enrolled_____ # withdrawn_____

Study Expiration Date:_____

II. PI SELF-ASSESSMENT CHECKLIST VERIFICATION

☐ PI Self-Assessment Checklist was completed, submitted, and signed.

☐ Checklist was submitted within the required timeframe.

III. DIGITAL REVIEW – PROTOCOL ADHERENCE AND STUDY ALIGNMENT

Verification that all uploaded documentation aligns with the approved IRB protocol and supports compliance.

Documentation	Uploaded	Reviewed	Congruent
IRB-approved Protocol			
Approval letters: Initial, Modifications, Renewals			
IRB correspondence (Exempt determinations, clarifications, etc.)			
IRB-approved recruitment & screening materials			
Signed consent forms			
Documentation of consent process (logs, notes, scripts)			
Parental consent forms & Child/youth assent forms (if applicable)			
Translated consent materials (if applicable)			
Subject tracking logs (screening, enrollment, visits)			
Documentation of withdrawals			
Documentation of deviations, incidents, or adverse events			
Compensation documentation			
Required training for PI and study team			
Data storage description			
Data retention and destruction plan			

IV. FOLLOW UP ON MISSING OR INCOMPLETE DOCUMENTATION

Has a follow-up been sent to the PI?___Yes ☐ No ☐ N/A☐ Date Sent:_____

If there is missing documentation, what is the reason?

☐ No Response ☐ Unable to Provide ☐ Other

Date of escalation to REDI leadership:_____

V. SUMMARY OF FINDINGS

☐ Missing documentation or information: _____

☐ Incomplete documentation or information:_____

☐ Unapproved protocol modifications:_____

☐ Inconsistencies in personnel or training documentation:_____

☐Other digital document review concerns:_____

VI. DIGITAL EVALUATION ACKNOWLEDGEMENT

PAVE Representative Signature:_____

Date of Completion:_____

Exit Interview Form for IRB Protocols

PURPOSE

This checklist is used during the final review meeting to:

- **Verify** the information assessed during the digital review.
- **Clarify** outstanding questions or discrepancies.
- **Discuss** preliminary findings and identify any areas of improvement.

START OF INTERVIEW

Monitor: *"Thank you for meeting with me today. This exit interview concludes our post-approval evaluation for your IRB protocol. We'll confirm a few key details, review items noted during the digital review, and discuss your study team's practices in managing human subjects research."*

I. PROTOCOL INFORMATION

"Let's begin with a quick confirmation of your protocol details."

Study Title:_____ **IRB Protocol #:** _____

Study Enrollment Status: Open ☐ Closed ☐ Funding Source: External☐ Internal☐

Study Population: # approved_____ # enrolled_____ # withdrawn_____ Source:_____

Study Expiration Date:_____

II. CLARIFYING DIGITAL AND ON-SITE REVIEW FINDINGS- *If Applicable*

"During the digital review, we noted a few items we'd like to revisit — not as findings, but to confirm our understanding and ensure we're accurately representing your study's practices. Our goal is to maintain clarity and alignment in how your research is documented."

Notes:

_____

_____

_____

	Notes:
Are there any items from the digital review you'd like to clarify or provide additional context on?	

III. IRB APPROVAL & PROTOCOL COMPLIANCE

"Let's talk about your protocol and how updates or changes are managed."

	Notes:
➢ Can you confirm the current approved version of your protocol and consent form(s)?	
➢ How do you verify your team is using the most recent IRB-approved versions?	
➢ What steps are taken when new IRB documents are approved—how do you communicate and implement updates?	
➢ Have any study activities occurred outside of IRB approval periods?	
➢ How do you ensure amendments and continuing reviews are submitted on time?	
➢ Are there any pending IRB submissions or anticipated amendments?	
➢ Have there been any protocol deviations or unanticipated problems? How were these reported and resolved?	

IV. INFORMED CONSENT

"Now, let's discuss your informed consent process and participant interactions."

	Notes:
➢ How do you ensure participants receive the most current IRB-approved consent form version?	
➢ Who conducts the consent process, and what training have they completed?	
➢ How do you verify participant understanding before consent?	
➢ How are signed consent forms stored, and who has access?	
➢ How do you handle re-consent when a form or protocol is modified?	
➢ Are participants provided with a copy of their signed consent form?	

V. PARTICIPANT MANAGEMENT

"Let's review how you manage participant eligibility, safety, and confidentiality."

	Notes:
➢ How do you confirm participant eligibility and document screening?	
➢ Have recruitment materials changed since approval? If yes, how was that managed?	
➢ How do you track enrollment, screen failures, withdrawals, and visits?	
➢ How do you monitor participant safety and report adverse events?	
➢ What measures protect participant confidentiality during recruitment and data collection?	

VI. STUDY PERSONNEL & TRAINING

"Let's go over how personnel training and oversight is managed."

	Notes:
➢ How do you verify all active study personnel are IRB-approved before starting work?	
➢ What is your process for onboarding new staff?	
➢ How are CITI training completions tracked?	
➢ How are study responsibilities delegated and documented?	
➢ How do you maintain ongoing training compliance throughout the study?	

VII. STUDY RECORDS & DOCUMENTATION

"Good recordkeeping is key for compliance. Let's review how your documentation is managed."

	Notes:
➢ How are IRB-approved versions of study documents organized and maintained?	
➢ How do you ensure that all staff are using the current versions?	

➢ How are participant source documents and regulatory files managed?	
➢ How are deviations, adverse events, and amendments documented?	
➢ Who oversees record maintenance and version control?	
➢ What happens to documentation when staff leave or roles change?	

VIII. DATA SECURITY & CONFIDENTIALITY

"Let's discuss your data handling and protection practices."

	Notes:
➢ Where is your study data stored (physical and electronic)?	
➢ How is access restricted to authorized team members?	
➢ Are identifiers stored separately from research data?	
➢ What systems are used (e.g., Qualtrics, Excel, sponsor database)?	
➢ How is data de-identified or anonymized?	
➢ What is your retention and destruction plan after study closure?	
➢ Have there been any data breaches or security concerns?	

IX. PI REFLECTION & FEEDBACK

"As we wrap up, we'd appreciate your feedback."

	Notes:
➢ What aspects of post-approval verification have been most helpful?	
➢ Are there any resources or training opportunities that would support your compliance efforts?	

X. CLOSING THE INTERVIEW

"Thanks again for your time today. We'll compile everything into a summary report, and you'll have a chance to review and respond before anything is finalized. Do you have any questions before we conclude?"

PAVE Representative: _____ Date of Exit Interview: _____

Post Approval Evaluation Final Report for IRB Protocols

PURPOSE

This final report form is designed to:

- **Document** observations made during the post-approval monitoring of an active IRB protocol.
- **Support** the IRB in its oversight responsibilities by identifying areas requiring clarification or attention.
- **Provide** feedback on best practices and institutional expectations.

I. PROTOCOL INFORMATION

Study Title:_____ **IRB Protocol #:** _____

Study Enrollment Status: Open ☐ Closed ☐ Funding Source: External☐ Internal☐

Study Population: # approved_____ # enrolled_____ # withdrawn_____ Source:_____

Study Expiration Date:_____

II. SUMMARY OF EVALUATION COMPONENTS

Protocol & IRC Documentation

- Current, full IRB-approved protocol on file
- IRB approval letters (initial, amendments, renewals)
- IRB correspondence available
- Amendments submitted and approved prior to implementation
- Deviations, incidents or adverse events reported
- SOP's reflect IRB-approved practices

☐ Consistent with approved protocol
☐ Inconsistent with approved protocol

Research Personnel & Training

- All study personnel completed required CITI training
- Delegation of duties documented
- Personnel changes submitted to IRB as needed

☐ Consistent with approved protocol
☐ Inconsistent with approved protocol

Informed Consent

- IRB-approved versions of consent forms used
- Signed, dated consent forms on file for all participants
- Participants received copy of signed consent
- Documentation of consent process (logs, notes, scripts)
- HIPAA Authorization completed when applicable

☐ Consistent with approved protocol
☐ Inconsistent with approved protocol

Participant Management

- Enrollment logs consistent with consent logs
- Inclusion/exclusion criteria documented and followed
- Screen failures and withdrawals logged with rationale
- IRB-approved recruitment materials used
- Participant compensation disbursed per protocol

☐ Consistent with approved protocol
☐ Inconsistent with approved protocol

Data Security, Confidentiality & Storage

- Electronic data access is restricted and encrypted as required
- Physical records stored in secure, access-controlled locations
- Data de-identification and coding schema documented

☐ Consistent with approved protocol
☐ Inconsistent with approved protocol

- Data retention and destruction plans followed
- Any data breaches reported per IRB/institutional policy

Documentation & Recordkeeping

- Current IRB-approved protocol and amendments available
- IRB approval letters and stamped documents present
- Enrollment, screening, and compensation logs are complete
- Organized with version control and date stamps
- Study status documentation maintained (open, closed, data analysis, etc.)

☐ Consistent with approved protocol
☐ Inconsistent with approved protocol

III. OBSERVATIONS AND FINDINGS

Evaluation Overview:

Detailed description of timeline, interactions, and monitoring activities.

_____
_____
_____
_____
_____

Findings:

List of incongruencies, missing documentation, or practices that need the committee's review.

_____
_____
_____
_____
_____

PI Clarifications Provided:

Summarize any clarifications or additional documentation provided by the PI during or after the evaluation.

_____
_____
_____
_____
_____

IV. EDUCATION & SUPPORT

The following areas were identified during the evaluation process as opportunities for additional review, training, or clarification.

☐ IRB Documentation & Recordkeeping
☐ Informed Consent & HIPAA Authorization
☐ Study Personnel Responsibilities & Training
☐ Subject Management & Tracking
☐ Protocol Amendments & IRB Communication
☐ Data Privacy, Storage, and Retention
☐ Adverse Events, Incidents and Protocol Deviations
☐ Other: _____

Additional Notes from the PAVE Unit: *Click or tap here to enter text.*

V. PAVE PROGRAM DISCLAIMER

The Post-Approval Verification and Education (PAVE) program provides this report to document all observations and findings from the monitoring evaluation. The PAVE Program does not make compliance determinations. While the program promotes best practices through monitoring and education, this report does not confirm full compliance nor account for matters not observable during the visit or that may arise thereafter.

This report is made available to both the James Madison University Institutional Review Board (IRB) and the Principal Investigator for review. The IRB retains sole authority for compliance determinations and any follow-up actions it deems appropriate.

VI. ACKNOWLEDGEMENT

The PAVE Program acknowledges completion and the closing of this monitoring evaluation.

PAVE Monitor Signature : _____ Date: _____