



TITLE: IRB POST APPROVAL MONITORING	SOP NO.: 900
EFFECTIVE DATE: 3/24/2025	REVISION NO.: 01

1. PURPOSE

- 1.1. The purpose of post-approval monitoring (PAM) is to enhance the protection of human subjects and the oversight of approved research. PAM can occur through reviews of ongoing research projects and completed research projects whose IRB protocol has been closed for fewer than three years. The reviews will be completed to verify that IRB approved procedures are being followed. In addition, the IRB will use the results to develop researcher education and improve IRB processes/procedures/guidance.
- 1.2. UMBC Office of Research Protections and Compliance [ORPC] and its committee are responsible for the approval and implementation of this SOP.
- 1.3. SCOPE: This policy applies to non-exempt human subject research conducted at UMBC.

2. DEFINITIONS

- 2.1. IRB – Institutional Review Board
- 2.2. IRB Admin. – IRB administrators are in staff positions within the Office of Research Protections & Compliance (ORPC) and include IRB general associates, compliance specialists, senior compliance specialists, managers, and (in some cases) the Director(s) of ORPC.
- 2.3. PI – Principal Investigator
- 2.4. PAM – Post approval monitoring is the routine auditing of non-exempt protocols by ORPC.

3. PROCEDURE



- 3.1. Any active full board or expedited study involving human subjects may be selected for review. Studies may be selected for review for any of the following reasons:
 1. Randomly Selected Studies
 2. Studies that involve more than minimal risk
 3. Studies eligible for closure (e.g., PI-requested closure)
- 3.2. The IRB office will contact the PI via email. The email will include:
 1. A letter describing what a PAM review is
 2. How or why the study was selected for PAM review
 3. A PAM checklist describing all of the study-related items that will be reviewed by IRB Admin. or the IRB Chair.
 4. A due date of when the checklist is to be returned to the PAM IRB Admin. in ORPC.
- 3.3. PAM IRB Admin. will review the completed checklist, alongside the respective IRB protocol, within two weeks of its receipt. If the PI has not shared their completed checklist by the due date noted, the PAM IRB Admin. will send a reminder email.

Presence of Minor or No Errors

- 3.4. Any comments/questions generated by the PAM IRB Admin.'s review of the completed checklist will be emailed to the PI. The PI will be given a due date of two (2) weeks to answer questions, address comments, and update their PAM checklist, as requested.
 - 3.4.1. If the checklist is not completed by the communicated due date, an in person audit review will be scheduled at our convenience.
 - 3.4.2. If the PAM IRB Admin.'s review detects no errors in the checklist or respective protocol, then no further action is requested of the PI at the time.
- 3.5. Once the PAM checklist is sufficiently completed by the PI and approved by the PAM IRB Admin., a PAM compliance letter will be issued to the PI by email.
- 3.6. The approved PAM checklist and PAM compliance letter will be uploaded in the Admin Notes & Files section of the respective Kual protocol.



Presence of Major Errors

- 3.7. If the PAM IRB Admin. detects one or more major errors during PAM review, a Reportable Event action may be warranted.
- 3.8. The PAM IRB Admin. will email the IRB Chair to request if the respective protocol requires formal Reportable Event action.
- 3.9. The IRB Chair will read the PAM request, checklist, and the respective protocol. If the IRB Chair determines that a Reportable Event is needed, they notify the PAM IRB Admin. by email.
- 3.10. The PAM IRB Admin. emails the PI (and copies the IRB Chair and IRB Manager) to formally request that the PI submit a Reportable Event through their Kuali protocol.
- 3.11. Once the PI submits the Reportable Event through Kuali, the PAM IRB Admin. notifies and assigns the Reportable Event to the IRB Chair. The IRB Chair and PAM IRB Admin. review the Reportable Event simultaneously.
- 3.12. The IRB Chair's approval is required to Resolve the event in the Kuali protocol. If the IRB Chair does not approve the PI's explanation and/or corrected course of action as documented in the Reportable Event, then the Chair informs the PI of the necessary next steps (e.g., Require Follow-Up function in Kuali, prompting additional action by the PI).
- 3.13. Once the IRB Chair approves a Reportable event, they Resolve it in the Kuali protocol and inform the PAM IRB Admin. of the decision.
- 3.14. The PAM IRB Admin. sends a PAM compliance letter to the PI by email. If the Reportable Event has been resolved by the IRB Chair, this result is included in the PAM compliance letter.
- 3.15. The approved PAM checklist, Reportable Event output, PAM compliance letter, and any supporting correspondence will be uploaded in the Admin Notes & Files section of the respective Kuali protocol.