# University of Idaho Institutional Review Board Standard Operating Procedures Manual

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| **Procedure and Guideline** | **Last Revised: July 5, 2022** |
| **Post Approval Monitoring** | **Effective Date: August 2, 2022** |

# IRB Procedures: Post Approval Monitoring

## Purpose

**To ensure that approved or certified research protocols are ethically protecting human research participants, compliant with policy, procedures, and regulations, and as a means of providing education to researchers:**

The Post Approval Monitoring (PAM) program will provide additional oversight, quality assurance, and education during human subjects’ research projects. Designated ORA staff intends to conduct PAM reviews of no less than three protocols per year, usually from the categories of 3(a), (b), and (c), below. Protocols from category 3(d) below will be selected at random. Category 3(e) will be conducted as directed by the Board.

## Procedures

## Upon selection, the IRB will notify the Primary Investigator (PI) of the selection of their protocol for Post Approval Monitoring, provide a timeline for completion of the activities, and as needed, request access to documents, staff, research records, or other relevant information to be provided in a reasonable times and manner. If there is no response by the PI, this would be considered non-compliance and can result in closure of the protocol, a full assessment, a processing hold on future submissions, or escalation.

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## 3 Methods

1. **Continuing Review**

Continuing Review is conducted annually (or earlier as directed by the Board) for Full Board protocols and Expedited protocols approved prior to January 20, 2019. The PI is required to submit an annual report. Failure to do so results in automatic closure of the protocol.

1. **Status Check**

Status Checks are conducted annually for Expedited protocols approved after January 20, 2019. The PI is requested to send an annual report.

1. **Self-Assessment requested by IRB**

Self-Assessments that are requested are conducted by random selection from Exempt, Expedited, and Full Board protocols. These will consist of a worksheet and request for the most recent consent documents.

1. **Informed Consent Process Assessment/Observation**

Informed consent document assessments are conducted by random selection from Exempt, Expedited, and Full Board protocols. These will consist of a request for documents and a re-review of the documents to ensure the most recently approved versions are being used. ORA staff will also observe the consent process with one or more research participants and may check all consent documents for completion. A worksheet may also be used.

1. **Full Assessment**

Full assessments are conducted for cause by selection from Exempt, Expedited, and Full Board protocols upon direction from a quorum of the Institutional Review Board. These assessments will consist of a request for documents and a re-review of the documents to ensure the most recently approved versions are being used. ORA staff will also observe the consent process with one or more research participants and may check all consent and research documents and records for completion. Lab or site visits may be included. A worksheet may also be used.

1. **Results**
2. **Corrective Action**

If reportable events or unanticipated problems are discovered, the PI will be required to submit a report to the IRB. If compliance issues are identified, the ORA staff will consult with the IRB Chair and Director to determine appropriate action.

1. **Education**

If an educational opportunity is identified, the ORA staff will provide education to the PI regarding needed improvements. This can include recommendations, tools, or other guidance as to policy and regulations. ORA staff will document the outcome of PAM activities and provide a written report of the results to the IRB.