

SOP: Post Approval Compliance Monitoring			
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**1 PURPOSE**

1.1 This SOP implements the Florida State University post approval monitoring requirement in accordance with FSU Policy 7-IRB-0 (University Human Subjects Policy: Human Research Protection Program Plan), applicable federal law, and the terms of the FSU Federalwide Assurance, and outlines the Post Approval Compliance Monitoring function and procedures.

**2 REVISIONS FROM PREVIOUS VERSION**

2.1 None

**3 POLICY**

3.1 All studies approved by the Florida State University (FSU) Institutional Review Board (IRB) or otherwise cleared pursuant to human research regulatory review are subject to post approval compliance monitoring to ensure the integrity of continuing protection of the rights and welfare of subjects in human research, as well as to ensure that these studies comply with applicable requirements for the conduct and oversight of human research. Studies will undergo post approval compliance monitoring based upon the procedures listed below.

**4 AUTHORITY AND SCOPE**

4.1 The post approval compliance monitoring (PACM) functions and procedures are under the direction of the FSU Office for Human Subjects Protection (OHSP) Director. The scope of PACM includes the following:

- 4.1.1 **Routine Reviews:** PACM review based upon a randomly selected study's regulatory classification, risk or study population, which may for example include:
  - Studies involving FDA-regulated products, including Investigational New Drug (IND) and Investigational Device Exemption (IDE) studies;
  - Studies sponsored or funded in whole or in part by a federal department or agency;
  - Clinical trials;
  - Studies involving vulnerable, at-risk or unhealthy human subjects; and/or,
  - Other studies involving greater than minimal risks to human subjects or others or the collection and use of sensitive, confidential information.
- 4.1.2 **Directed or For-Cause Reviews:** PACM review performed at the request of the IRB, IRB Chair, OHSP Director, Vice President for Research/Other FSU official or designee, or study sponsor. Circumstances under which a directed or for-cause review may be requested include:
  - Studies where there is concern about serious non-compliance, a documented history of non-compliance and recidivism, or as a follow-up to previous non-compliance
  - Studies where there is a documented history of serious adverse events, protocol deviations, and/or unanticipated problems involving risks to human subjects or others;
  - Studies involving a new or inexperienced Principal Investigator (PI) or research staff) or concerns about PI or faculty advisor supervision;
  - As part of an ongoing corrective action;
  - To support a review associated with Reportable New Information (RNI);
  - When there are concerns about the validity or integrity of the data collected; and/or,
  - Any other circumstances meriting directed or for-cause review, including when there are concerns regarding whether the rights and welfare of human subjects are adequately protected.
- 4.1.3 **Voluntary Reviews:** Conducted upon request of the PI to support self-assessment and improvement efforts by the PI and study team.
  - The PI may also use an applicable HRP-430 - CHECKLIST – PI Quality Improvement

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Assessment to conduct a voluntary self-assessment.

- 4.1.4 **IRB Minutes Review:** Conducted semi-annually to assure compliance and support the operations of the IRB.
- 4.1.5 **Human Research Protection Program Quality Assurance:** Conducted at least annually to track and improve institutional compliance with human research protection program requirements.

## 5 RESPONSIBILITIES

- 5.1 Members of the OHSP staff, led by the OHSP Director, PACM Manager or designee, are responsible for ensuring that the following procedures are executed.

## 6 PROCEDURE

### 6.1 Routine Review:

#### 6.1.1 **Selection and Scheduling:**

6.1.1.1 Studies are selected as follows:

- 6.1.1.1.1 Quarterly, consisting of a targeted sample of active studies that at fiscal year-end will accumulatively represent 2% of a cross-section of studies listed in section 4.1.1.
- 6.1.1.1.2 That have not been selected for routine review in any prior 2-year period.

6.1.1.2 The PACM Manager contacts the PI and study coordinator in writing (email) to:

- 6.1.1.2.1 Schedule the review in a timely manner, but no later than in the quarter for which the study was selected for review;
- 6.1.1.2.2 Identify the study staff that will participate in the review visit;
- 6.1.1.2.3 Provide an (including a copy of or link to this SOP) overview of the scope, process, method and required workspace needed for the review; and,
- 6.1.1.2.4 Provide a copy of the applicable HRP - 430 - CHECKLIST - PI Quality Improvement Assessment that will be used as a general guide for review.

#### 6.1.2 **Review Procedures:**

6.1.2.1 In advance of the review visit, the PACM Manager reviews the sampled study's documentation on file with the IRB;

6.1.2.2 On the day of the review visit, the PACM Manager will meet (in-person or virtually) with the PI and designated study staff at the open and close of the review if possible. When necessary, the PI will arrange for a private work area for the conduct of the review. At a minimum, designated study staff should make themselves available for study documentation retrieval, answer questions or provide clarification as may be needed;

6.1.2.3 The PI must provide the following study files (as applicable depending upon the scope of review) for the PACM review:

- 6.1.2.3.1 All study related regulatory documents (e.g., IRB-approved protocol, consent- and recruitment-related forms, measures and instruments, etc.);
- 6.1.2.3.2 Subject screening/enrollment log;
- 6.1.2.3.3 Case report forms;
- 6.1.2.3.4 Source documents;
- 6.1.2.3.5 Signed Informed consents, assents and HIPAA for all enrolled and screened participants;
- 6.1.2.3.6 Study drug/product accountability logs, as applicable;

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- 6.1.2.3.7 Device accountability logs, as applicable;
- 6.1.2.3.8 Lab logs as applicable; and,
- 6.1.2.3.9 Any other documents/files as requested that support the study administration.
- 6.1.2.4 Research records are expected to be maintained by study team in a review-ready state at all times. The study team will have an opportunity to locate and provide materials or documentation not present in the files at time of review, but the initial absence of material or documentation will be noted in the findings.

**6.1.3 Findings**

- 6.1.3.1 Assessment findings may include, but are not limited to:
  - 6.1.3.1.1 No further action is necessary;
  - 6.1.3.1.2 Minor administrative issue(s) with best practice or additional recommendations for corrective action;
  - 6.1.3.1.3 Findings that meets the definition of Reportable New Information (RNI) with best practice, additional recommendations or requirements for corrective action; and,
  - 6.1.3.1.4 Major finding indicating potential harm, imminent risk of harm or actual harm to human subjects' rights and welfare. These findings will be promptly reported to the OHSP Director and IRB Chair; further reporting may be required pursuant to applicable law and FSU policy.
- 6.1.3.2 Potential research misconduct will be reported to the Designated Officer in accordance with FSU Policy 7A-2 (Misconduct in Research, Creative Activity, and Scholarship).

**6.1.4 Documentation and Distribution of Findings**

- 6.1.4.1 The PACM Manager will document observations, findings and any concerns.
- 6.1.4.2 At the conclusion of the review, the PACM Manager verbally debriefs the PI and/or designated study team members regarding findings, applicable recommendations and next steps.
- 6.1.4.3 The PACM Manager generates a written report of findings and recommendations. The written report of findings is shared with the PI, OHSP Director, IRB Chair and IRB.
- 6.1.4.4 The PACM Manager submits a copy of the written report into the electronic protocol management system (RAMP IRB) through the Reportable New Information activity.
- 6.1.4.5 The PI is asked to review the written report and provide a response and a corrective action when necessary.
- 6.1.4.6 In the event the PI disagrees with the findings of fact or wishes to provide clarification, the PI may provide the rebuttal and/or clarifications, in writing. The provided information and any corrective action plan will be submitted into the electronic protocol management system (RAMP IRB).
- 6.1.4.7 The PI is also asked to submit each incident of Reportable New Information found through the review that has not already been reported by the PACM Manager to the IRB.
- 6.1.4.8 Follow-up reviews may be scheduled to confirm ongoing adherence to corrective action recommendation and continued compliance.

**6.2 Directed or For Cause Review**

**6.2.1 Selection and Scheduling**

- 6.2.1.1 The IRB, IRB Chair, OHSP Director, Vice President for Research/Other FSU

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official or designee, or study sponsor (“Requestor”) may request a directed or for-cause review, to assess specific compliance issues or general compliance with regulatory and institutional requirements.

6.2.1.2 The Requestor will notify the OHSP Director, PACM Manager or OHSP staff of the PI and the study that should be subject to a directed or for-cause review. The PACM Manager will send an official notification to the PI with a copy to their department head. This notice will include the scope, timing, scheduling process and next steps.

6.2.1.3 Unless directed to contact the PI sooner, the PACM Manager will contact the PI by the next business day following receipt of the review request to schedule the review and will work with PI and study team to schedule the review within the timeline established by the requestor.

6.2.1.4 If scheduling and/or completion of review will not be possible within the established timeframe due to circumstances beyond the PI’s control, the PACM Manager will notify the Requestor and request additional guidance.

6.2.1.5 As research records are expected to be maintained in an audit-ready state at all times, time needed for record preparation is not an acceptable reason to request delay.

**6.2.2 Review Procedures and Findings**

6.2.2.1 Review procedures and findings will follow those outlined in 6.1.2 and 6.1.3 above.

6.2.2.2 An abbreviated assessment may be conducted when the review involves only a specific compliance issue and the PI has a record of satisfactory compliance. An abbreviated assessment may include a document-only (i.e., no visit) review and one or more of the study files listed in section 6.1.2.3.

**6.2.3 Documentation and Distribution of Findings**

6.2.3.1 The report and associated findings are shared with the Requestor, OHSP Director, IRB Chair, the VPR and others as needed. The findings are also provided to the PI and their department head.

6.2.3.2 The Documentation and Distribution of Findings procedures will follow those as outlined in 6.1.4 above.

**6.3 Voluntary Review**

6.3.1 The OHSP staff makes the applicable HRP - 430 - CHECKLIST - PI Quality Improvement Assessment available to PIs and study team members.

6.3.2 The PI, or study team member with PI’s support, may conduct a self-assessment or ask for a voluntary review/assisted review, time and effort permitting, by the PACM Manager.

6.3.2 The review procedures will follow those outlined in 6.1.2 and 6.1.3 above.

**6.4 IRB Minutes Reviews**

6.4.1 The PACM Manager reviews the IRB minutes for compliance with HRP-043 - SOP - IRB Meeting Minutes; review should be conducted at least quarterly for all IRB minutes for the immediate preceding or current quarter.

6.4.2 The PACM Manager uses the HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment to guide and document the review.

6.4.3 The PACM Manager prepares a report of findings, if any, and forwards to the OHSP Director, OHSP staff and IRB Chair.

6.4.4 The OHSP Director or designee develops a corrective action plan if necessary, and communicates the plan to OHSP staff and the IRB Chair.

**6.5 Human Research Protection Program Quality Improvement**

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**6.5.1 Routine Monitoring Trends Assessment**

- 6.5.1.1 On an annual basis or more often if requested by the OSHP Director, the PACM Manager will provide a report of general trends and findings from the audits and reviews to the OSHP Director or others as may be directed.
- 6.5.1.2 The PACM Manager and the OHSP Director will review the findings with the IRB Chair, IRB and OHSP staff, and develop corrective and education action plans as may be deemed necessary.
- 6.5.1.3 The PACM Manager will monitor the impact of the corrective and education plans on findings and will report outcomes to the individuals listed in 6.1.5.2.

**7 MATERIALS**

- 7.1 HRP-430 - BIOMED - CHECKLIST - PI Quality Improvement Assessment
- 7.2 HRP-430 - SBER - CHECKLIST - PI Quality Improvement Assessment
- 7.3 HRP-430 - IND/IDE - CHECKLIST - PI Quality Improvement Assessment for FDA Regulated Products
- 7.4 HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment
- 7.5 HRP-043 - SOP - IRB Meeting Minutes

**8 REFERENCES**

- 8.1 FSU Policy 7-IRB-0 (University Human Subjects Policy: Human Research Protection Program Plan)
- 8.2 FSU Policy 7A-2 (Misconduct in Research, Creative Activity, and Scholarship)
- 8.3 OHRP 45 CFR 46.108(a)(3),(4); 45 CFR 46.109(e)
- 8.4 FDA 21 CFR 56.108(a),(b); 21 CFR 56.109(f)
- 8.5 Federalwide Assurance (FWA00000168, Florida State University)