UCLA Research Administration
Human Research Protection Program

Guidance and Procedure: Post Approval Monitoring of Human Research Studies

Version Date: October 19, 2020

General Overview

The OHRPP Quality Improvement Unit (QIU) has the authority and responsibility for continuing oversight of approved human research protocols based on federal regulations, University policy and UCLA's Federal Wide Assurance (FWA) with the federal Office for Human Research Protections (OHRP).

Post Approval Monitoring of Human Research Studies

The Post Approval Monitoring program is a core component of the UCLA OHRPP and is performed to promote quality and integrity in the conduct and methodology of human subject research. The Post Approval Monitoring program may be either routine or for-cause. The purpose of the monitoring is to ensure regulatory compliance and to provide tools for researchers to maintain compliance. This monitoring also enables the OHRPP to identify common pitfalls in the implementation of human research and tailor ongoing education activities accordingly.

Coordination with Other QI/QA Units

The OHRPP QIU coordinates activities with other UCLA Quality Assurance/Improvement Units (including Health Compliance, Campus Compliance, Clinical and Translational Science Institute (CTSI), and Jonsson Comprehensive Cancer Center (JCCC)) on campus to reduce duplication of effort and ensure expertise for compliance is available to the study team.

Policy

All researchers are expected to comply with the provisions of an IRB-approved protocol and to adhere to all federal and state regulations and UC/UCLA policies governing human subject research. The Institution supports and maintains compliance with applicable federal regulations and state laws related to the protection of the safety, rights and welfare of human subjects in research under the terms of UCLA's Federal Wide Assurance (FWA).

How Studies are Selected for Monitoring

Routine Monitoring

IRB approved studies will be randomly selected for monitoring within a risk-based stratification. Study selection will prioritize investigator-initiated IND and IDE studies, emergency research with consent waivers, and greater than minimal risk studies that have minimal or no external monitoring.

- Protocols will not be selected for routine monitoring more than once a year.

Studies where the reviewing IRB is not a UCLA IRB may be subject to monitoring by the OHRPP QIU (depending on the reliance agreement).

For-Cause Monitoring

For-cause monitoring is conducted when concerns regarding research compliance, protocol adherence, or subject safety are brought to the attention of the reviewing IRB and may be initiated by the UCLA IRB or other internal or external stakeholders.

Monitoring Procedures

The Post Approval Monitoring program includes 3 steps of review. All routine reviews will start with the Self-Assessment. For-cause reviews may start at any step.

Step 1 - Self-Assessment:

The UCLA PI will be informed that their study has been selected for Self-Assessment and will receive a copy of the Self-Assessment Form. The focus of the review is subject safety and compliance with the IRB policies and federal regulations.

The study team will complete and return the Self-Assessment form. The deadline will be indicated in the notification letter. Findings that meet the threshold for Post Approval Monitoring should also be reported to the IRB according to the OHRPP Guidance and Procedure: Post-Approval Reporting (PAR).

The review will provide an opportunity for the researchers to ask any particular questions about the safe conduct of their research and for the QIU staff to provide individualized training and education as needed. UCLA investigators are welcome to complete the Self-Assessment at any time whether or not they are selected for Self-Assessment by the OHRPP.

Upon receipt of the Self-Assessment form, the OHRPP QIU will review the form to identify areas where additional information is needed. Depending on the outcome of the self-assessment review, studies may be selected for targeted or extended review.

Step 2 – Targeted Review:

Targeted review is limited to specific areas of compliance of IRB requirements. For example, if the Self-Assessment form indicates a discrepancy between the number of participants enrolled and the number of consent documents in the participant files, then the OHRPP QIU may do a targeted review of enrollment related documents. The PI will be notified in advance of the review to ensure the PI and research team's awareness of the extent of the review and the documents that will need to be available.

Step 3 - Extended Review:

If indicated, a review of all areas of IRB interest will be conducted.

Results of Monitoring

A monitoring report will be prepared by the OHRPP QIU with the results of the limited or extended review.

- The report will be available within five working days after completion of the review.
- The report will include an assessment of the study's compliance with federal regulations, state and local laws, university policies, and the IRB-approved protocol requirements.
- If any significant findings are revealed, the report will recommend a corrective action plan and identify any additional education that may be needed for the research team.

The QIU will share the report with the PI and any research staff the PI designates.

If the monitoring is for-cause, the report will also be shared with the stakeholder (UCLA IRB, reviewing IRB, Department Chair, etc...) that requested the review.

Principal Investigator Responsibilities

Investigators and all research personnel involved in the study are expected to cooperate with any routine or for-cause monitoring conducted by the QIU.

Investigators should have all regulatory and participant documents available for review as requested. If the review is done remotely, the investigator shall make the documents available through a secure/compliant file transfer system.

OHRPP Responsibilities

Monitoring will be focused on applicable laws, institutional policies, human subjects regulations, and IRB requirements/determinations. The OHRPP QIU will provide guidance and education to investigators and assist in addressing significant findings as appropriate.

Regulations and References

Food and Drug Administration

- Information Sheet - Continuing Review after Study Approval
- 21 CFR 56.109(f)

- 21 CFR 56.108(b)

Department of Health and Human Services

- 45 CFR 46.108(a)(3)(iii)
- 45 CFR 46.109(e)

Office of Human Research Protection

- Guidance on Written IRB Procedures
- Guidance for IRBs, Clinical Investigators, and Sponsors; IRB Continuing Review after Clinical Investigation Approval

UCLA

- Policy 991

UCLA Office of Human Research Protection Program

- OHRPP Guidance and Procedure: Post-Approval Reporting (PAR)

AAHRPP Elements

- Element 1.5.A.
- Element II.3.E.
- Element II.3.F.
- Element III.2.C.

Change history:

10/19/2020: Change the frequency of selection of studies for routine monitoring from no more than once in the life of the study to no more than once a year. Remove limit (by Investigator) on selection of protocols for routing monitoring.