

IRB-HSR Post-Approval Monitoring Summary

Jan-Dec 2023

Reasons for Review:

- Random selection
- Follow-up of previous audit findings or misc. IRB request
- Requested for assistance with FDA or sponsor audit preparation
- New CRC or PI assessment
- Cancer Center DSMC request
- For cause
- Focus on non-UVA IRB of record

93 Post-Approval Monitoring Reviews Completed in 2023

- **67 Studies** were approved by IRB-HSR Full Committee Review
- **15 studies** were approved by IRB-HSR Expedited Review
- **11 studies** were approved by non-UVA IRB of record Full Board

68 audits were completed remotely, 25 audits were completed in person

Most studies reviewed had only minor deviations

- **Minor deviations were without significant problems or continuing non-compliance.**
- **Studies where there were significant problems identified, the PI completed required education and follow-up.**

PAM Working Group

The PAM Working Group meets on the second Wednesday of each month and reviews all PAM audits completed the previous month. The group may make additional recommendations for the IRB PAM Advisory Committee to consider.

- Research Compliance Monitors
- SOM CTU Educators, Director and Assistant Director
- Associate VP for Research Operations, Compliance & Policy
- IRB Compliance Training Specialist
- IRB-HSR Director

IRB PAM Advisory Committee

The IRB PAM Advisory Committee meets at the end of each month. They review all PAM audits completed the previous month and recommendations from the PAM Working Group. The Committee may make final determinations or refer studies to the IRB-HSR Full Committee if needed.

- Research Compliance Monitors
- IRB Chair
- IRB Director and IRB Associate Director
- IRB non-scientist or unaffiliated member
- IRB member Study Coordinator