UNIVERSITY of VIRGINIA | Vice President for Research

## 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
- For cause
- Focus on non-UVA IRB of record

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# IRB-HSR Post-Approval Monitoring Summary

## Jan-Dec 2023

## 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