
HRPP Quality Assurance: Remote to Onsite Visit Reviews (ROVRs)

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Remote to Onsite Visits Reviews (ROVRs): Purpose

Purpose

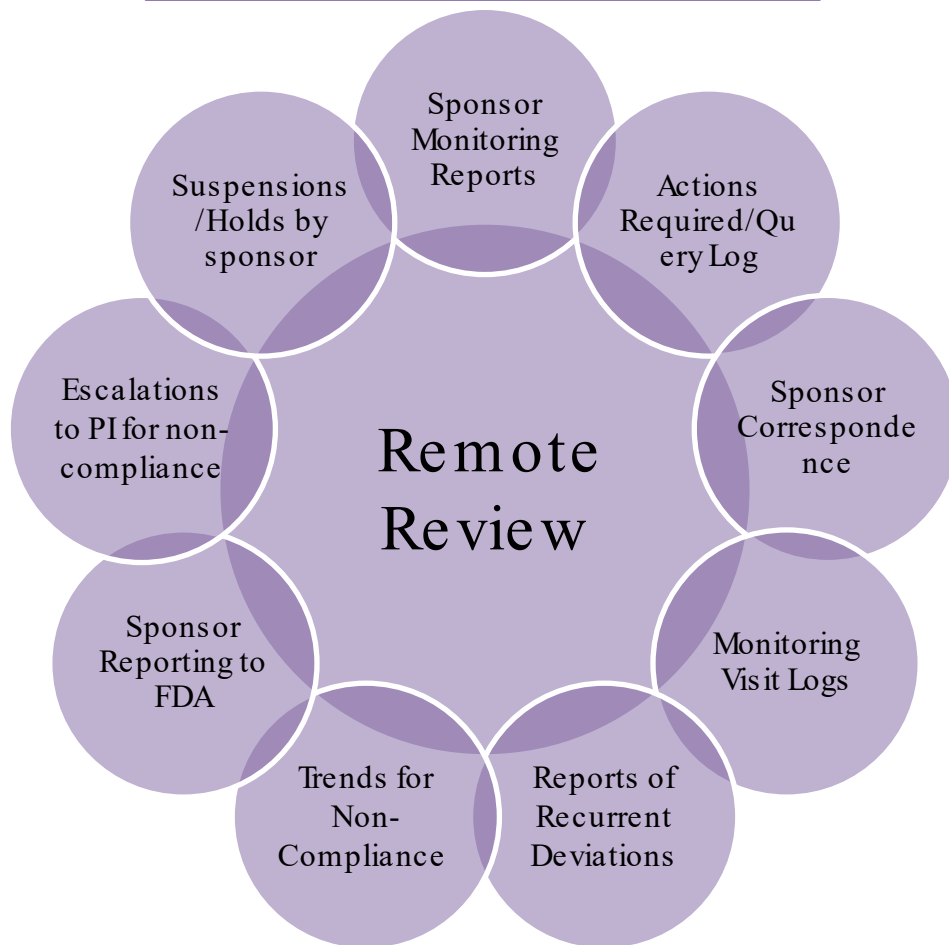
- Provide guidance and oversight for studies that have external monitoring from sponsor/CRO.
- Check for any recurring deviations, trends of non-compliance and sponsor/CRO complaints
- Provide tools/resources to help study teams resolve action items.
- Serve as a preventive measure

Relatively New Initiative

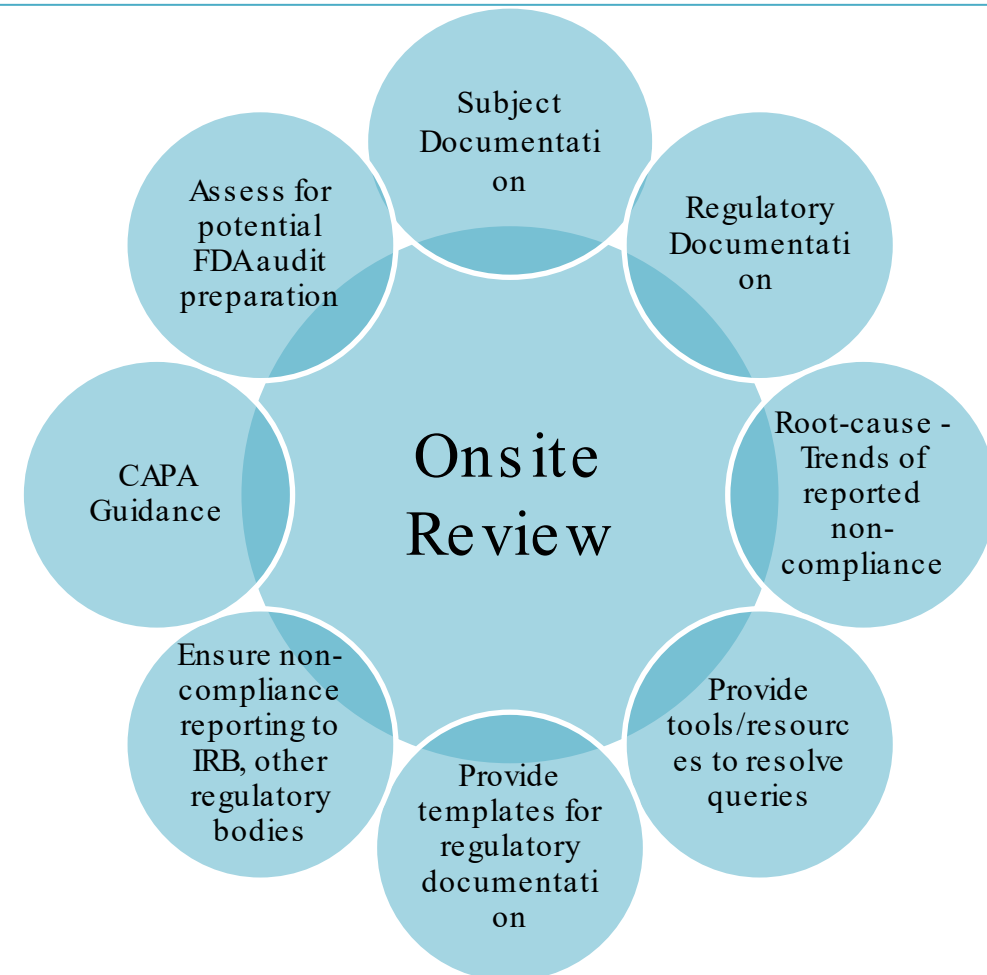
- Started September 2023.
- Currently, 4 studies at UTSW have completed ROVR reviews.
- 6 studies will have ROVR reviews in FY24 Q3 (March-May)

Remote to Onsite Visit Reviews (ROVRs): Scope of Review

Sponsor Documentation Review



(If needed) Complete Study Documentation Review



Remote to Onsite Visit Reviews (ROVRs): Which studies are eligible?

Eligibility:

- FDA regulated
- Ongoing monitoring oversight by sponsor/CRO

Selection Criteria

- IND/IDE studies
- Phase 1, 2 and 3 studies
- Interventional research procedures
- Multiple deviations/non-compliance reported in past 5 years
- Requested by PI/study teams

Remote to Onsite Visit Reviews (ROVRs): Review Process

- **Remote Review:**
 - Duration: 5-6 hours
 - Provide RMA with electronic access to sponsor monitoring documentation. You may choose to share Florence or OneDrive folder access or scan in the monitoring reports/documents via email.
 - De-briefing meeting with CRC: Discuss issues if any, RMA to assess IF an onsite complete study documentation review is needed or not.
 - Final HRPP Monitoring Report sent to study team

- **Onsite Review (if needed):**
 - Duration: 5-6 hours
 - RMA will need allocated space for review
 - Provide RMA with regulatory and subject documentation.
 - Debriefing meeting with PI and CRC: Discuss observations, and receive guidance, tools/templates, and resources to help study teams resolve queries or meet reporting requirements.
 - Final HRPP Monitoring Report sent to study team

Remote to Onsite Visit Reviews (ROVRs): Conclusion

- ROVR reviews are a new quality assurance initiative
- This initiative is evolving, your feedback is valuable!

Thank you!