
Sponsor-Investigators (SI): Planning for Monitoring Services on your IND/IDE studies

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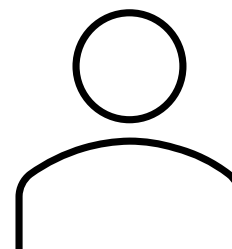
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Sponsor-Investigator (SI) Monitoring Services: Purpose

Purpose

- Ensure rights and well-being of all human subjects are protected
- Ensure reported trial data are accurate, complete, and verifiable from source documents

HRPP QAM staff serving as monitors:

- Periodic on-site and/or remote monitoring
- Monitoring Reports and Action Item (Queries) Log generated after each visit
- Monitor will work with study team to address and resolve queries as generated

Relatively New Initiative

- Currently, 3 studies at UTSW are receiving ongoing SI Monitoring services

Sponsor-Investigator (SI) Monitoring Services: Which studies are eligible?

Eligibility:

- IND/IDE studies
- PI is the IND-holder / IDE-holder
- Phase 1, 2 and 3 studies

Other Considerations:

- Phase 0, 1, 2 and 3 studies
- First in-human studies
- Continuous oversight by an independent monitoring team

Sponsor-Investigator (SI) Monitoring Services: Monitoring Focus



Sponsor-Investigator (SI) Monitoring Services: Type of Visits



Sponsor-Investigator (SI) Monitoring Services: HRPP QAM Monitoring Fee Structure



Sponsor-Investigator (SI) Monitoring Services: HRPP QAM Monitoring Fee Structure (contd.)

Factors that affect the overall monitoring fee structure*

Project Management Fee

- One-time fee of \$1500
- Each additional site where review is needed (for example, Children's, Parkland): \$500
- Coverage: Includes development of monitoring plan, study monitor's familiarization with protocol, creation of study-specific monitoring worksheets, other administrative tasks, correspondence.
- Factors: Study Complexity, Number of sites involved, duration of study (in years), targeted enrollment

Interim Monitoring Visits

- Depends on type of study protocol/design – **Standard / Complex IMV visits**
- **Standard:** \$500 per visit, **Complex:** \$1000 per visit
- **Standard** is loosely defined as simple study design, occasional monitoring needed (6 months, annual), greater than minimal risk study interventions. For example - Long term follow-up IND/IDE studies.
- **Complex** is loosely defined as complex study design, frequent monitoring needed (biweekly, monthly, quarterly), multiple greater than minimal risk study interventions, complex review of study documentation

Study Close-Out Visit Procedures

- Depends on type of study protocol/design – **Standard / Complex Close-Out visit**
- **Standard:** \$500 per visit, **Complex:** \$1000 per visit
- Close-Out Visit includes complete review of regulatory and subject study documentation, review of retention policies, IP accountability, IP return/destruction policies, and all other study close-out activities.

Create Monitoring Plan Only

- Monitoring Plan Only: \$750
- For studies that only need services for creation of a Monitoring Plan
- No IMV/Close-Out visits conducted by HRPP QAM
- Study team is responsible for implementation and conduct of monitoring activities outlined in monitoring plan

*Final estimated fee structure will be provided after development of monitoring plan

Sponsor-Investigator (SI) Monitoring Services: Recommended timeline to contact HRPP QAM

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When the study is -

- Under IRB initial submission review process -OR-
 - Ongoing Coverage Analysis / Budgeting process -OR-
 - Before study enrollment begins
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- Ensure sufficient time is available for developing & finalizing monitoring plan
 - Schedule initial consultation or send us an email inquiry
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- For studies currently active and enrolling, send us an email inquiry

Sponsor-Investigator (SI) Monitoring Services: HRPP QAM Contact Information

For inquiries -OR- to schedule first consultation:

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Sponsor-Investigator (SI) Monitoring Services: Conclusion

Thank you!