UT Southwestern Medical Center™

CTSA Program

Quality Assurance & Monitoring (QAM) Office

Human Research Protection Program

Quality Assurance & Monitoring (QAM) Office

- The Quality Assurance and Monitoring (QAM) Office is vital in promoting and maintaining ethical research that is compliant with institutional policies, state and federal regulations, and best practices for protecting human subjects by reviewing and monitoring human research studies as well as conducting QA reviews of the activities of the IRB and HRPP Department.
- **Team Responsibilities:**
    1. Study Monitoring:
        1. Research studies (routine and for-cause)
        2. Institutional Review Board (IRB) records
        3. HRPP activities and records
    2. Provide routine monitoring for sponsor-investigator studies as required by FDA
    3. FDA audit support
- **Investigators/Study Teams should contact the QAM Office when:**
    - They are notified of an external audit (FDA or any other external entity) by completing the Audit Notification to HRPP intake form via REDCap: Audit Notification to HRPP (swmed.edu) to request support for the audit ***and***
    - To report allegations of noncompliance or subject complaints
    - To request the services of the QAM program in fulfilling their responsibilities of monitoring as a Sponsor-Investigator holding the IND/IDE
    - To request a not-for-cause review and/or training upon study start-up or prior to study close-out

      ~ by emailing the QAM program manager, Kimberly Mapes

Quality Assurance & Monitoring (QAM) Office

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To obtain more information about the QAM Office:

Visit Quality Assurance and Monitoring Office: Human Research Protection Program (HRPP) - UT Southwestern, Dallas, TX 

Other helpful links:

PI Self Assessment Checklists: Reportable Events: Human Research Protection Program (HRPP) - UT Southwestern, Dallas, TX – SiteName 

UTSW HRPP Policies and Procedures: HRPP Complete P&P Manual (utsouthwestern.edu)