UTSouthwestern Medical Center

FAQs – ORRA Quality Assurance Reviews

The Quality Assurance and Monitoring (QAM) Office of the UTSW Office of Research Regulatory Affairs (ORRA) regularly conducts QA reviews of IRB-approved research studies conducted at UTSW. Below are some of the most frequently asked questions (FAQs) about ORRA QA reviews:

1. Is a QA review the same as an audit?
QA reviews are similar to an audit in that the reviews are systematic, and their purpose is to determine if the conduct complies with regulatory and policy standards. QA reviews are intended to provide a quick "snapshot" overview of the study's compliance with the research documents (e.g., protocol, consent document), investigational plan (e.g., eIRB Smartform), regulations/laws, institutional and ORRA/IRB policies, and good clinical practices (GCPs), as applicable.

2. How are studies selected?
Studies are chosen from the list of IRB-approved studies conducted at UTSW. Priority is given to studies that involve direct interventions or interactions with research participants. The ORRA aims to review all studies at least once every 5 years.

3. My study has an outside sponsor who sends a monitor to do this kind of activity…. do I really need another review?
Yes. The ORRA QA monitor is independent from the project team and offers a "fresh set of eyes" to ascertain whether the monitoring was adequate; systems and processes are working; any problematic patterns or trends are identified and rectified; and institution-specific requirements are followed. Most importantly, the ORRA has an obligation to ensure that human research conducted at UTSW (and its affiliates) adheres to applicable regulations, institutional policies, and best practices to ensure human research subjects are protected and the study data are reliable and valid.

4. What is the purpose of this review?
QA reviews are performed to ensure IRB-approved studies are conducted in compliance with applicable policies, regulations, and guidance, and to ensure that the rights and welfare of study participants are protected. The reviews are intended to be educational and consultative in nature. The goal is to identify patterns and help correct potential problems in study conduct, documentation, or processes before they affect the safety of participants or data integrity.

5. What does the QA review entail?
Unless otherwise specified, the study team is expected to provide (or provide access to) **all** study related documents (both hardcopy and electronic), including regulatory documents, source documents, subject files, case report forms (CFRs), and data files. This includes, but is not limited to, screening and enrollment logs, subject eligibility assessments, randomization records, signed informed consent documents (ICDs) and HIPAA authorization forms, study visit activities, delegation of authority (DOA) logs, drug/device/product accountability records, and subject payment records. ORRA monitors will also verify staff who have been delegated study tasks by the PI are qualified by education, training, and experience; noncompliance and unanticipated problems have been reported and addressed properly; subjects are registered in Velos and records are current; any conflict of interest (COI) management plans are being followed; subjects are being paid appropriately (if applicable); and the IRB-approved confidentiality, recruitment, and data safety monitoring plans are being conducted as specified in the eIRB Smartform. Other aspects of the study may also be reviewed as needed.

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6. How much time will be required? Does the PI need to attend?
Most onsite reviews are completed in 6-8 hours during a single visit. However, additional visits are also sometimes needed. A member of the study team must be available for the entirety of the monitoring visit to answer questions, escort the monitor(s) around the site, and provide access to and photocopies of the necessary documents. Unless otherwise specified, the PI is not required to be present during the QA review; however, it is preferable that the monitor meet with the PI and SC near the conclusion of the visit to review findings. If the PI is not available, the debriefing may be scheduled for a later date.

7. What do I need to do to get ready for the review?
You should make sure that **all** study-related documents (subject records and regulatory documents, both hardcopy and electronic) are accurate, complete, and readily available to the QA reviewer. This includes completing all necessary CRFs and obtaining (or being able to provide access to) source documentation to verify study data. You may also perform a self-assessment prior to the visit to identify and rectify issues before the visit, but this is not required. Self-assessment checklists are located on the HRPP website. If possible, a private work area for the monitor(s) to conduct the review (preferably with Wi-Fi connection and access to a copier) should be provided.

8. Will I find out the results of the review?
A monitoring report, which will include the ORRA's observations and findings, will be sent to study teams by email. If the review identifies any events that have not already been addressed or reported to the ORRA/IRB, these will be noted in the "Actions Required" section of the report.

9. Are the review findings shared with any other offices/departments?
The PI, SC, and ORRA Director are provided copies of the reports. The reports may also be sent to other UTSW offices or officials, which includes, but is not limited to, the Department Chair, Office of Compliance, Associate Dean of Clinical Research, Institutional Official, and Research Administration at affiliate sites, as applicable.

If you have additional questions, you may contact a member of the ORRA QA and monitoring team at 214-648-3060 or HRPPMonitoring@utsouthwestern.edu.