UT Southwestern
Medical Center
Human Research Protection Program

HRPP Quality Assurance and Monitoring
Consent Observation

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Consent Observation: Background and Purpose

- The Division of Quality Assurance and Monitoring (QAM) in the UTSW Human Research Protection Program Office (HRPPO) conducts periodic Quality Assurance reviews of IRB-approved research to ensure it is being conducted in compliance with the IRB-approved protocol; UTSW HRPP and institutional policies and procedures; federal, state, and local regulatory requirements; and good clinical practices (GCPs), as applicable.
    a. Not for Cause Reviews
    b. For Cause Reviews
    c. Study Initiation Reviews

- The purpose of observing the consent process is to determine whether the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally authorized representative, and that informed consent was freely given by the subject or the legally authorized representative.

Consent Observation: Selection

- When multiple deficiencies with consent or the consent process are observed during a quality assurance review.
- High risks to subjects.
- Particularly complicated procedures or intervention.
- Vulnerable populations.
- Study staff with minimal experience in administering consent to potential subjects.
- Other situation where there are concerns that the consent process might not be proceeding well.

Consent Observation: Procedures

- The Research Monitoring Analyst and the PI/Coordinator will work out a mutually agreeable date and time for the observation.

- Before beginning the observation process, the Regulatory Monitoring Analyst will:
  a. Introduce himself/herself to the potential study participant.
  b. Explain the reason for his/her presence .
  c. Obtain the study participant's verbal permission to observe the consent process.

- The Regulatory Monitoring Analyst will use a checklist to document any observations.

- During consenting, should any issues or questions arise concerning the reason for the observation, the observer may contribute to the discussion (with the consenter present).

Consent Observation: Conclusion

- The Regulatory Monitoring Analyst may debrief the person that obtained consent, once the consent process has concluded. This discussion may be deferred if no substantive issues arose, or if the consenter is unable to meet at that time.

- Any observed issues or deficiencies will be included in the Actions Required Report for the quality assurance review.

- The Regulatory Monitoring Analyst may schedule a second consent observation to determine if observed “issues/deficiencies” have been addressed (if applicable).