UT Southwestern
Medical Center
Human Research Protection Program

HRPP Quality Assurance Study Initiation Review (SIR)

Study Initiation Review (SIR): Study Selection

- All recently IRB approved will be eligible for an SIR. A review emphasis will be given, but not limited to the following category of studies:
  - Full board reviewed
  - Non-Industry Sponsored
  - Enrolled at least 1 participant
  - Although we will focus on the above criteria, all studies including minimal risk, industry sponsored, and studies that haven't begun enrollment may be eligible for selection.

- An SIR may also be conducted by request.
  - Any study, regardless of sponsorship, risk level, or enrollment status is eligible for this service.
  - Study teams may request either a complete study initiation review, or a virtual consultation on Teams.
  - A request form will be available on the HRPP QA/Monitoring Webpage and via a barcode at the end of this presentation.

Study Initiation Review (SIR): Review Process

- Expect the SIR to last approximately 2 hours, but this may change depending on the discussion or complexity of the study.
- Depending on the complexity of the study, a remote or in-person regulatory document review may be done prior to enrollment with a follow-up expected after the first subject is enrolled.
- Regulatory documentation and participant files, if enrollment has begun, will be subject to review.
- The SIR will emphasize education and discussion.
    - All study team members are welcome and encouraged to attend
    - Ask questions
    - Work together to develop documentation practices or correct errors
- The study team will be encouraged to complete a "Study Team Self-Assessment" checklist prior to the new study review.
- An SIR may be chosen to include a consent observation. This may also be requested by the study team.

Study Initiation Review (SIR): Review Process

- Upon arrival, the regulatory monitoring analyst will conduct a preliminary consultation with the study team discuss the study, PI Self-Assessment checklist(s) (if completed) and go over any preliminary questions the attendees have.
- Study materials will be reviewed with the study team, including any subject files. When possible, the regulatory monitoring analyst will work with study team onsite to address any issues or areas for improvement.
- After the review, the study team will be debriefed and given an opportunity to discuss observations and ask questions.
- A summary and report for the SIR will be sent to the study team after the review.
- Study teams will have two weeks to respond to any requested changes in the report.

Study Initiation Review (SIR): Conclusion

- The study initiation review is new quality assurance initiative
- The first 6 studies were reviewed Q4 FY23
- This initiative evolving
- Your feedback is valuable!
- You may request an SIR using this bar code: