

Primary Reviewer – Notes for Review

- The primary reviewer's goal is to review the study in reasonable detail and present highlights to the board.
- The primary reviewer should do their best to answer any questions the board may have about the study.

Review the study through the lens of human subject protection although study feasibility and scientific merit may warrant discussion.

Keep in mind that many of the new studies coming to us are multi-site and have been well vetted already by the respective sponsor and study teams and sometimes by the FDA. Most are scientifically sound and feasible.

We may need to look at the scientific feasibility more with investigator-initiated studies that have not been as thoroughly vetted.

Reviewing the Informed Consent Form is a key piece of the review to make sure that the study is well explained to the participant and that regulatory requirements are met.

Time estimate: as an average it normally takes between 4 to 6 hours of time to prepare for meetings with much of that time dedicated to the new study reviews and any complex modifications or RNIs.