FAQs on the Technical Review Process

Q: Why are you doing this?

A: We were conducting “technical reviews” several years ago before workload prevented us from continuing. The “technical review” helps the Investigator prepare an IRB that the Board spends less time on minor or compliance issues, and more on Risk/Benefit analysis and other criteria for approval. What should happen is a review letter with fewer minor change requests.

Q: What exactly is a “technical review”?

A: The IRB Administrator will conduct what is essentially a first read of the IRB and identify any inconsistencies, incompleteness or compliance issues. The IRB will be returned to you with these comments so that you can make revisions prior to the study going on the next IRB meeting agenda.

Q: Why do you need an extra two weeks from the 1st of each month?

A: The agenda for studies goes out a week before the IRB meeting. The extra three weeks is to allow time for the “technical review” to be complete and you can return the revised study in time for the agenda. Most of the time, the 1st of the month only allows us a week to conduct this process before the agenda.

![Diagram of the Technical Review Process]

Q: What will the IRB review for?

A: The IRB conducts a review against certain criteria established in the regulations for human subjects research. They will primarily examine the risks of the study and weigh them against prospective benefits. They look at the population, procedures, consent process, protecting data, and the overall safety of the research. The technical review is not designed to replace the IRB review, but to remove minor issues that could prevent the IRB from being able to determine whether the study can be approved because of many unaddressed issues.

Q: Does this affect renewal or modification requests?

A: Our focus on this process is for new studies, unless your modification is significantly changing elements of your study. Try to send in renewal requests and modifications before the first of each month to be added to the IRB agenda for that month. If you have questions about whether you need a technical review for modification, contact the IRB Office.