CRITERIA FOR AMENDMENT REVIEW

Protocol Review Committee (PRC) review is required if amendment to the protocol results in changes to the following:

- Drug (compound, dosage, or schedule)
- Eligibility (significant changes such as additional disease areas or updates reflecting a change in standard of care (SOC), etc.)
- Methods of response evaluation
- Study Objectives (primary and secondary)
- Statistical/analysis plan (study endpoints; statistical approach and methods; power analysis, including sample size)

The YCC PRC does not review the following amendment types:

- Amendments to National Clinical Trials Network studies, Experimental Therapeutics Clinical Trials Network studies, or externally peer reviewed studies
- Amendments to non-therapeutic or observational studies

SUBMISSION DOCUMENTS

All amendment submissions must include:

- Protocol (tracked version, if available)
- Protocol (clean version)
- Investigator’s Brochure (only if accompanying an amendment to the protocol)
- Summary of Changes document for protocol
- Summary of Changes document for the Investigator’s Brochure (if available)
- Sponsor correspondence (if amendment is initiated by an external sponsor)

SUBMISSION PROCESS

Amendments are submitted electronically through OnCore’s Electronic Protocol Review and Monitoring System (ePRMS) Console.

If the submitter does not have access to ePRMS, contact the PRC Regulatory Analyst at vcc.ycci.committees@yale.edu for instruction on gaining access to ePRMS.
The following significant amendments changes should be submitted for Full Committee review:

- Drug (compound)
- Eligibility (significant changes such as additional disease areas or updates reflecting a change in SOC, etc.)

All other amendment changes may be submitted for expedited review, if required. See Criteria for Amendment Review section above.

Changes involving only the statistical/analysis plan (study endpoints; statistical approach and methods; power analysis, including sample size) will be sent for expedited statistical review, while all other changes will be sent for expedited Chair or designee review.

**REVIEW**

Amendments reviewed by the full committee will be assigned to the next meeting agenda’s available slot.

Amendments requiring expedited review are reviewed by the PRC Chair, Vice Chair, or appropriate designee. If the assigned reviewer determines that further examination of the protocol is warranted, an additional scientific or biostatistical review may be requested prior to approval. Alternatively, the protocol may be placed on the PRC agenda for further discussion by the full committee per the reviewer’s request.

**REVIEW DECISION**

The PRC actions on full committee reviews are: approval, approval with recommendations, approval pending a required response, tabled, or disapproval. The actions on expedited reviews are: approval, approval with recommendations, approval pending a required response, schedule for full committee review or disapproval. A letter is provided to the PI which states the decision. Submissions approved pending a required response receive an additional letter once the required response is affirmed, and the study is then either approved or disapproved.

PRC review decisions are entered into ePRMS by PRC administrative staff, generating an automatic notification to the PI and study team.