RSC Submission Guide

Review process recap

Committee Determinations

Approve:
An approval form is issued to the submitter and the project is ready for IRB/GCO submission.

Conditionally Approve:
The project must be edited and then resubmitted for review by the committee. This project is not ready for IRB/GCO submission.

Deny:
The committee has denied the project. A decision letter detailing reasons for the committee's decision is sent to the submitter. If these issues are corrected, the project can be resubmitted for committee review.

Submission Guide: Research Question and Endpoints

Research Question and Study Significance:

- The research question should be well-defined.
  - Ex.) Terms like "good recovery" are very broad. What indicators will be used to determine a good recovery?
- Study significance: Discuss the gap in knowledge that this study aims to address and how this study will address this gap. How will this benefit the field and/or those that this condition affects?

Primary and Secondary Endpoints

- These are usually presented in bullets and are directly linked to the outcomes of statistical analysis
- Ex.) Primary Endpoint:
  - The proportion of subjects with good clinical outcome defined as Modified Rankin Score (mRS) of ≤2 as assessed by a blinded assessor at 90 days (± 15 days)

Submission Guide: Stats and Enrollment

Statistical Plans

- How do these meet primary and secondary endpoints? Are plans appropriate for the sample size/study goals?
- Plan on who will conduct statistical analyses before data is collected. Be sure that this person is qualified to do so and assess any costs associated with outsourced analyses.

Enrollment Goal

- Make sure this number is realistic and appropriate. Bigger estimations are not always better, especially if more complex statistical plans call for a larger sample size than is feasible ex.) rare diseases.
- Conflicting studies that draw from the same patient pool should be considered when defining the enrollment goal
- Is this goal feasible for the size of the study team? Will someone be able to cover recruitment and enrollment outside of business hours?

Submission Guide: Recruitment and Consent

Subject Population

- Inclusion and exclusion criteria should be specific and clear.

Recruitment Plan

- Walk reviewers through how potential participants will be identified and approached.
- Keep in mind that the treating team must grant the study team permission to approach the patient for research purposes.

Consent Process

- Include plans related to consent, assent, where documents will be stored and whether teleconsent will be sought.
- For retrospective studies (most commonly): will a waiver of consent be sought?

Submission Guide: Study Team and COI

Risks

- Loss of data/confidentiality is almost always a risk. Include this in your submission.
- Be sure to not only include risks, but specify how these risks will be mitigate or managed
  - Ex.) "De-identified data will be stored on a HIPAA compliant database and will only be accessible by the research team"

Database Considerations

- If PHI will be stored for research purposes, it must be stored in a HIPAA compliant database.
- All databases must be assessed and approved by IT security. If the database has not been authorized, it must be submitted for approval. This process may take a few weeks.

Submission Guide: Study Team and COI

Study Team and Required Effort

- The workload must be manageable for the size of the study team.
  - Please note that the department only provides CRC assistance for funded studies
- How long will data entry take per patient? Who will enter data, conduct follow-up procedures, be responsible for consent and randomization procedures? Are there multiple sites where these procedures will occur?

Conflicts of Interest

- This applies to PI's and Sub-I's. If your faculty mentor has a conflict of interest, the committee may suggest selecting another mentor for this project.