

Clinical Research Budget Advisory Working Group

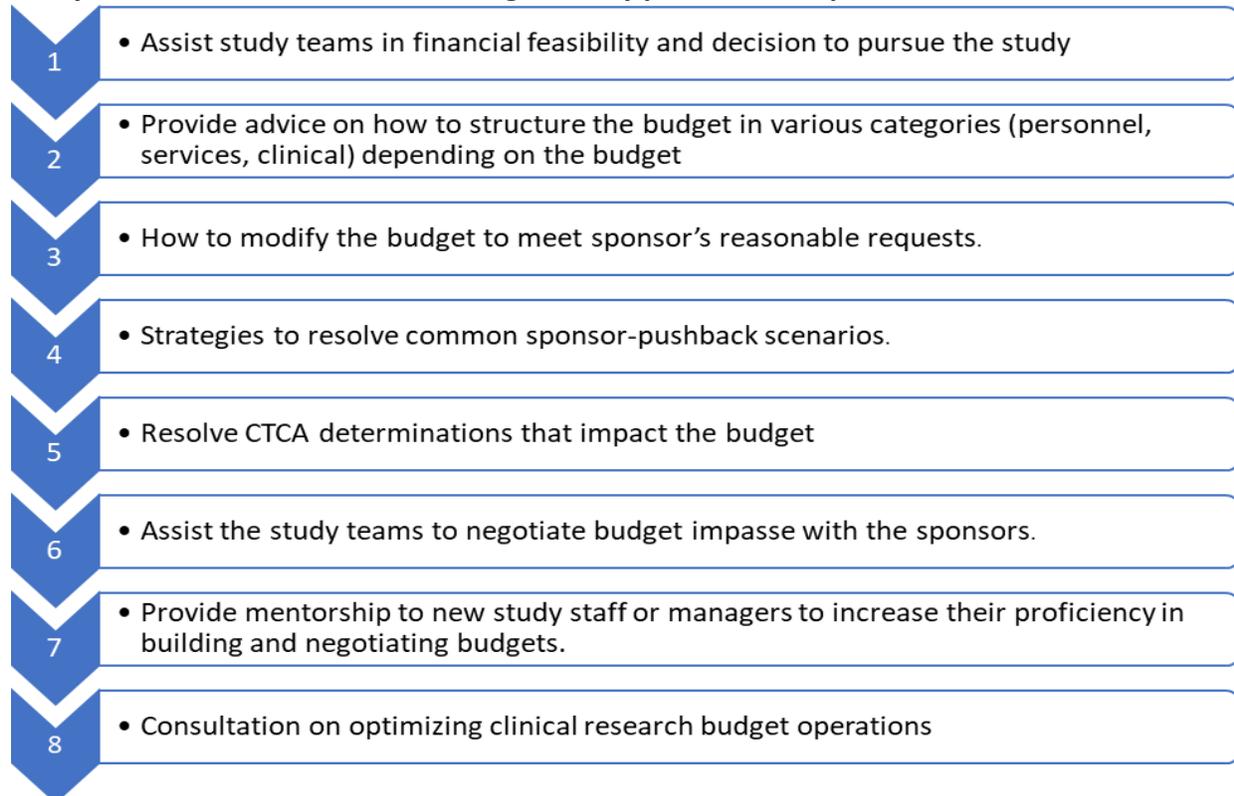
Scope:

In our efforts to decrease the TTA time < 90 days, we have found that Budget negotiations are the key reason for the delay in the contract execution. As a result, this group is formed with representatives from OCR, SPA, and clinical research teams (experienced coordinators or regulatory who have experience in budgets) to meet twice a month and *advise (offer suggestions about the best course of action)* to research teams on budget preparation and negotiations. This group is not intended to teach the study teams how to make a budget from scratch since we have various resources made available through SPA for that purpose.

Key Goals of this Group:

- Assisting study teams in financial feasibility and decision to pursue the study.
- Provide advice on how to structure the budget in various categories (personnel, services, clinical) depending on the budget.
- How to modify the budget to meet sponsor's reasonable requests.
- Strategies to resolve common sponsor-pushback scenarios.
- Resolve CTCA determinations that impact the budget.
- To assist the study teams to negotiate budget impasse with the sponsors.
- Provide Mentorship to new study staff or managers to increase their proficiency in building and negotiating budgets.
- Consultation on optimizing clinical research budget operations.

Study teams can receive advice throughout any part of the sequence below:



Research Budget Advisory Working Group Participants:

- OCR – (Aaron Brunson, Saumya Sunny, Kate Esselink (optional), Julie Long (optional) Lucy Palmer (optional), Bhanu Pappu (optional),
- SPA – Lance Holmes, Sue Liao, Nataliya Samadov, Julia Spesivtseva, Megan Mark (optional)
- Coordinators – Deb Town (Children's),
- Surgery CRU - Jarett Hubbard (Primary), Himabindu Pappu (Backup)
- SCCC CRO – Jennifer Knight, Kelly Kyle
- Pediatrics - Amanda Iannon

Intake Process:

- Eligible study teams are teams that need advice on budget preparation for feasibility and/or delayed (>30 days) on budget negotiations; need advice on finetuning the budget, estimate personnel cost and other services.
- The Research Budget Advisory Working Group will meet the 1st and 3rd Tuesday of the month.
- The study team will submit their budget draft and issues they need the group to address one week (5 business days) prior to the groups meeting dates using the attached Redcap form [here](#).

Review Meeting:

- Aaron Brunson will review and submit the intake forms from the study team to the advisory team three business days prior to the scheduled Budget Advisory Group meeting. The working group will review the issues, formulate, and provide their responses in writing (via Redcap).
- Budget Advisory Working Group meetings will be conducted within 1 hour on the 1st and 3rd Tuesday of the month, starting Tuesday March 5th 2024.
- If no review requests are submitted from study teams to Redcap by the deadline date, the meeting will be cancelled until the next meeting date. Aaron Brunson will send out a meeting cancellation notification to all participants.