

Grant Development

Procedure Overview

To define guidelines for the preparation of a grant submission when collaborating with the NETT. This guideline is for proposals that have been approved according to SOP #, *Approval of NETT Studies*, and are planned to be submitted to NIH or other potential funding agency.

Responsible Individuals

Study Principal Investigator, NETT CCC, NETT SDMC.

Procedure

1. Tasks:

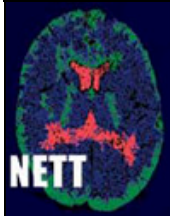
- I. Establish a grant writing working group and roles of each member. Members should include the Study PI, main editor (as designated by the PI), representative(s) from the NETT CCC and SDMC.
- II. Assign writing assignments according to the workscope (i.e., PI draft research plan, CCC draft project management, SDMC draft data management plan and, if appropriate, statistical sections).
- III. Schedule periodic conference calls and /or meetings with working group members.

2. Task Timeline:

Each member of the working group must have adequate time to review the research plan section of the grant and provide comments. Discrepancies in the research plan should be addressed in the working group's periodic meetings. If resolution cannot be met, the discrepancy will be brought to the NETT Operations Committee. The following are suggested timelines for the working group.

- I. ≥ 6 months prior to submission date
 - a. NETT approval per the NETT Process for Solicitation and Review of Clinical Trials for NETT SOP.
 - b. Proposal completion timeline provided to the PI by the NETT CCC.
- II. ≥ 5 months prior to submission date
 - a. Working group established.
 - b. PI circulates a rough draft of the research plan (some sections may be left blank to be completed by the appropriate working group expertise in the subsequent period). Draft needs to include

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a details on the primary outcome including anticipated effect sizes (to allow preliminary sample size calculations), and a proposed schedule of assessments.

- III. ≥ 3 months prior to submission date
 - a. 1st draft of writing sections to be circulated among the working group.
 - b. Main editor compiles research section of the grant proposal.
 - c. Budget estimates and justification of SDMC and CCC submitted to Study PI.
 - IV. ≥ 6 weeks prior to submission date
 - a. Resources section for the SDMC and CCC submitted to Study PI.
 - b. Penultimate budget.
 - c. Final draft of research section and relevant appendices circulated for final review.
 - V. ≥ 5 weeks prior to submission date
 - a. Final comments given to main editor at >5 weeks
 - b. Final budget from PI, CCC and SDMC begin routing.
 - VI. ≥ 3 weeks prior to submission date
 - a. Penultimate version of the grant provided by PI.
 - VII. ≥ 2 weeks prior to submission date
 - a. NETT provides letters of support to accompany final grant. However, support letters will not be provided until all parties consent to the final grant version.
 - b. Institutional signed forms sent to Study PI.
3. Consequences of deviation:
- The ability to support a submission in any given funding cycle is dependent upon meeting the timeline as described above. Deviation from these guidelines will generally require submission delay to the next funding cycle.

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