

NETT Ancillary Study/Substudy Approval Process

Procedure Overview

To define the standard procedures for proposing, reviewing, and approving ancillary/substudies conducted within the NETT Network.

Responsible Individuals

NETT Executive and Steering Committee members, PIs of the parent and ancillary/substudies, and members of the Data and Safety Monitoring Board (DSMB) or Observational Study Monitoring Board (OSMB) for the trial.

Definitions

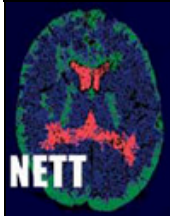
1. Ancillary study or substudy: A research activity undertaken to address a scientific question that requires access to data or records from the parent study and/or involves collection of additional data, specimens, or records from patients enrolled in the parent study.
2. Parent study: The primary study funded through a grant mechanism or other form of support

Procedure

All ancillary/substudy concepts must be reviewed and approved by the NETT Steering Committee and by the Data and Safety Monitoring Board/Observational Study Monitoring Board before ancillary/substudy initiation. The NINDS ancillary study policy can be found at http://www.ninds.nih.gov/funding/research/clinical_research/policies/ancillary.htm

1. Any ancillary study investigator must complete a NETT Ancillary Clinical Trial Protocol Summary form. The form, along with the study protocol must be submitted to the NETT Executive Committee (EC) for Review.
2. After review, the NETT EC will forward the summary form for NETT-appropriate studies to the NETT Steering Committee (SC) and Data and Safety Monitoring Board/Observational Study Monitoring Board for the parent study for their review and comment.

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3. After review of submitted materials and comments, the SC will vote on proposed trial. The vote can take place at a face-to-face meeting or conference call with all members present; if this is not feasible, e/mail review and voting may be substituted. Criteria for Steering Committee approval of ancillary study include:
 - a. The proposed study addresses a question of importance.
 - b. The proposed study should not compete with any previously approved ancillary study.
 - c. Conduct of the study must not adversely affect the parent study.
 - d. Funding for the study will be obtained by the PI and will be independent of the parent study funding.
 - e. Procedures for accessing necessary data and records from the parent study are explicit and acceptable.
 - f. The proposing PI has the appropriate expertise and facilities to conduct the study.
 - g. Plans for publication and authorship of study results are appropriate, including review and approval of manuscripts per the NETT publication policy.
 - h. SC members will be given adequate time to review the proposal before a vote is taken.
4. Once approved by the SC, protocols will be forwarded to the DSMB/OSMB; results of DSMB/OSMB vote will be communicated to the SC.
5. The ancillary study PI will be notified of the outcome of the Steering Committee and the DSMB votes.
6. A list of all proposed and approved ancillary studies will be maintained by the coordinating center.

Procedure Author

NETT Executive Committee

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