



Procedure for Ancillary Study Proposal

The preliminary concept proposal should be **3 pages** and contain:

1. Investigators and collaborators name, role, and institutional affiliation. Include NIH biosketches for investigators and key personnel.
2. Planned start and end dates.
3. Estimated costs and plans for funding, including the anticipated source of funding.
4. Design and methods:
 - Statement of primary and secondary goals and objectives.
 - Brief background, significance, and rationale.
 - Description of additional methods and procedures to be carried out on a study participant.
 - Data needed (a) from the GRADE study central database and (b) from additional tests, surveys, etc.
 - Plans for analysis.
 - Sample size and justification (including power calculation).
 - Burden on participants.
 - Impact on GRADE study (clinical centers and central units).
 - Measures to be taken to ensure participant safety and confidentiality.
 - Payment or incentives to participants.
5. Declare whether the application is for an ancillary study or a sub-study (see the Policy for explanations). If a substudy, describe the Coordinating Center and other study resources to be requested. If an ancillary study, describe the source of the statistical support to be provided, and whether additional support is needed from the Coordinating Center (see the Policy).

In addition to the 3 page proposal, the collaborating investigators should each provide a statement that they have reviewed and approved the application, are committed to participate and that they approve the funding arrangements and level of funding proposed.