

27. FHN Study Ancillary Studies

27.1 Definition

Ancillary studies are defined as research studies employing participants, biological specimens or the database from the main study which have relevance to the overall objectives of the main study, but are not part of the mainstream protocol for all centers.

27.2 Funding of ancillary studies

Ancillary studies will not be funded by the main study, but will require an independent source of funding.

27.3 Approval procedures

1. Proposals may be generated by a participating clinical center or by other interested investigators providing at least one center is included as a co-investigator. These applications are submitted to the Data Coordinating Center for review by the Publications and Ancillary Studies Committee.

2. There will be a two-step review by the Publications and Ancillary Studies Committee. The first step is to have the proposal reviewed for its concept and general acceptability. This will be done in 2-4 weeks. A short description of the study including the following information should be submitted.

- a. Hypothesis to be tested.
Specific outcome variables that will be assessed.
Need for data from the DCC.
- b. Significance of the proposed ancillary study.
- c. How will performance of this ancillary study affect the main Study? Specifically:
 - i. Will there be any deviations from the main Study protocol? If so, what will they be?
 - ii. How much additional participant, staff and DCC time will be required to complete this ancillary study?
 - iii. Will additional funds be requested for the study and what will their source be?

3. If this proposal is acceptable in concept to the Publications and Ancillary Studies Committee, a more detailed proposal should be written and submitted for review. This proposal should include detailed information on:

- a. Hypothesis to be tested.
- b. Significance of the study.
- c. Conduct and performance of the study including specifying the study population and the data to be collected.
- d. Sample size justification.
- e. Quality control of the data.
- f. Data analysis methods.

4. The Publications and Ancillary Studies Committee will make its recommendation within 2-4 weeks and submit it to the Steering Committee. The proposal will be discussed and voted upon at the next Steering Committee meeting. At that time, the applicant has the option to discuss his or her proposal before the Steering Committee.

27.4 Publication of ancillary study results

The policies regarding publications and presentations of the result of ancillary studies are the same as those governing the publications and presentations of results of the main study (see Section 26). These policies are designed to:

1. Assure timely publication of the results to the appropriate professional audiences.
2. Avoid premature publications of results that might compromise the performance of the main study or that might compromise the ability to publish the results in high quality peer reviewed journals.
3. Maintain high standards of the published material.
4. To guard against duplicate publication of results.
5. Assure equitable attribution of credit to all of the professionals participating in the ancillary study and the Study.