HEALTH ABC ANCILLARY STUDY GUIDELINES
(Revised April 28, 2005)

A. Definition of an ancillary study

A.1. An ancillary study is a study that requires access to Health ABC participants, whether from a single clinical center or from the entire cohort, to collect measurements or data directly from Health ABC participants using procedures or instruments that are not included in the already funded core protocol.

A.2. An ancillary study is a study that requires access to archived biologic specimens (e.g., blood, urine, DNA).

A.3. All proposals for ancillary studies are reviewed and approved by the Executive Committee, with feedback from the Steering Committee, as needed.

A.4. Studies that generate new data from existing measurements (such as the reading of x-rays or CT scans) are not ancillary studies for purposes of these guidelines.

B. Who may submit a proposal?

B.1. Investigators are encouraged to conduct ancillary studies with the stipulation that such studies be scientifically sound and have little or no adverse impact on the main study or on Health ABC participants.

B.2. Investigators affiliated with Health ABC and those without an affiliation with Health ABC may propose ancillary studies.

B.2.1. Proposals must have at least one paid Health ABC investigator as a sponsor and include a Health ABC investigator from each of the 2 Health ABC clinical centers undertaking the study and from the NIA Project Office; ancillary studies that involve only one of the two Health ABC clinical centers are not required to have a Health ABC investigator from each site.

B.2.2. The UCSF Coordinating Center should be involved with every ancillary study proposal.

C. Proposal format

C.1. An investigator who wishes to conduct an ancillary study submits a written proposal to the Health ABC Executive Committee (via the designated person at the UCSF Coordinating Center). The proposal, generally 4-5 pages in length, should include the following elements:

1) Name of principal investigator and contact information
2) Health ABC investigator sponsoring the proposal
3) List of other participating investigators
4) Working title of proposal
5) Research question with clearly stated hypothesis
6) Background and rationale for the study
7) A detailed description of the methods and procedures
8) An estimate of the sample size required to test the primary hypothesis (including the assumptions underlying the estimate)
9) A detailed estimate of the impact of the study on the main study: cost (including data collection and administration, data management, and data analysis), staff and participant time, risks to participants, Coordinating Center costs, radiation exposure, and/or quantity of any biological specimen(s) to be consumed per participant.
10) A discussion of human subject issues and risks related to the ancillary study measurements and procedures
11) Plans and timeline for submitting the ancillary study data to the UCSF Coordinating Center for inclusion in the main study database
12) Biological Specimen Request Form (if applicable)

D. Approval process

D.1. The Executive Committee will review each application, considering:

1) its scientific merit,
2) quality of the design and methods, and
3) the potential impact (both positive and negative, including participant burden) on the main study.

D.2. The Executive Committee will discuss each proposal during the monthly Executive Committee conference call and make a formal decision about approval or disapproval, along with any comments, at that time. The Committee may ask the investigator to revise and resubmit the proposal before voting.

D.3. Ancillary studies must be approved by a 2/3 majority of members who participate in the vote.

E. Priorities

E.1. Priority will be given to proposals that are scientifically important and consistent with the overall goal of Health ABC.

E.2. In general, proposals that augment or complement the main scientific aims of Health ABC will be favored over those that take advantage of Health ABC for more tangential purposes.

F. IRB approval

F.1. The appropriate institutional review boards must eventually approve all ancillary studies before they are performed, but IRB approval is not required to submit a proposal to the Executive Committee.

F.2. Ancillary studies may have separate consent forms from the main study.

G. Funding

G.1. Proposals for funding ancillary studies must be approved by the Executive Committee before they are submitted to the funding agencies. Proposers should allow at least 8 weeks between the submission of the ancillary study proposal to the Executive Committee and the funding application deadline.

G.2. Proposals for funding must include coverage of all the relevant costs, including clinical center investigators, coordinators and staff for data collection, procedure-related costs, equipment and supplies needed at the clinic, UCSF Coordinating Center and data management costs, training and quality assurance costs, etc.

H. Changes after approval

H.1. If substantial changes in the design of the protocol or in the potential impact of the protocol on the main study occur after Executive Committee approval, then the investigators must submit a revised protocol to the Executive Committee for review.

H.2. The Executive Committee may, by majority vote, terminate an ancillary study if it judges that a study has become too burdensome or its scientific value has diminished, or it has failed to make substantial progress toward the completion of its goals.

I. Data disposition

I.1. All data collected in ancillary studies will be included in the Health ABC database. This database will be made available to all Health ABC investigators. A timeline for sending the data to the UCSF Coordinating Center should be included in the ancillary study proposal.

I.2. The main Health ABC Investigator named in the proposal will arrange for analysis of the data by one of the Health ABC study units.

J. Analysis proposals using ancillary study data

J.1. The Principal Investigator of the ancillary study will have priority for first authorship on the first three analysis plans that use data generated from the ancillary study.

J.2. The Principal Investigator of the ancillary study will have the option of joining the writing group for other analysis proposals that use the data from their ancillary study and serving as a co-author on these publications (in accord with the Health ABC Publication Guidelines).

J.3. An analysis proposal can be submitted by the Principal Investigator to the Publications Committee for review and approval so that the investigator can start the analyses. However, publications (refer to Section C of Health ABC Publication Guidelines for definition of Publications) cannot be submitted to the Publications Committee for approval until the ancillary study data is officially released by the UCSF Coordinating Center.

J.4. The Principal Investigator (or their designate) can submit up to three analysis plans using data that has not been officially released. However, publications resulting from these plans may not be submitted for approval until the data has been officially released.