

**HEALTH ABC ANCILLARY STUDY GUIDELINES  
(Revised 1-21-09)**

**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. Studies that generate new data from existing measurements (such as the reading of x-rays or CT scans) are ancillary studies for purposes of these guidelines.

A.4. All proposals for ancillary studies are reviewed and approved by the Executive Committee, with feedback from the Steering Committee, as needed.

**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, the NIA Project Office and the San Francisco Coordinating Center. 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 should submit a written proposal to the Health ABC Executive Committee (E-mail: [HABCPublications@psg.ucsf.edu](mailto:HABCPublications@psg.ucsf.edu)). 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) Detailed description of the methods and procedures
- 8) Estimate of the sample size required to test the primary hypothesis (including the assumptions underlying the estimate)
- 9) Detailed estimate of the impact of the study on the main study: cost (including data collection, management, and analysis), staff and participant time, risks to participants
- 10) 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 Health ABC Coordinating Center for inclusion in the main study database
- 12) Plans for obtaining funds to pay for the study, including RFA or RFP identifier (where applicable), application submission dates, amount of funds available, or letters from funding agencies committing funds to the project
- 13) 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 review and discuss ancillary study proposals 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.2.1. Ancillary study proposals will be reviewed by the Health ABC Executive Committee three times per year (April, August, and December). The timeline for the review cycle is as follows:

<b>Ancillary Study Due Date</b>	<b>Executive Committee Review Date</b>
April 1st	mid-April
August 1st	mid-August
December 1st	mid-December

D.2.2. Investigators who wish to submit genetics proposals with a deadline that falls outside of the Health ABC review cycle should contact the Health ABC Publications Coordinator (E-mail: [HABCPublications@psg.ucsf](mailto:HABCPublications@psg.ucsf)).

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

D.3.1. Ancillary study proposals that need to be "revised and resubmitted" will need to go through a formal review again at a subsequent review session; investigators should closely note the deadlines for each review cycle, since proposals cannot be submitted to a funding agency for review until they have been approved by the Health ABC Executive Committee.

## **E. Priorities**

E.1. Priority will be given to proposals that are scientifically important and consistent with the overall goals 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. All ancillary studies must be approved by the appropriate Institutional Review Boards of the participating centers before they are performed. However, 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 10 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, San Francisco 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 Health ABC and other investigators. A timeline for sending the data to the Health ABC Coordinating Center should be included in the ancillary study proposal.

I.2. All data must be transferred to the Health ABC Coordinating Center via the Health ABC secure gateway (data should NEVER be e-mailed). Please contact

the Health ABC Help Desk ([HABCHelp@psg.ucsf.edu](mailto:HABCHelp@psg.ucsf.edu)) for access to the secure gateway.

## **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 proposals 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. The Principal Investigator (or their designate) can submit up to three analysis proposals using data that has not been officially released for review and approval by the Publications Committee so that the investigator can start the analyses. However, publications (refer to Health ABC Analysis Proposal and Publication Guidelines) resulting from these analysis proposals may not be submitted to the Publications Committee for approval until the ancillary study data is officially released by the Health ABC Coordinating Center.