

## **Health ABC Analysis Proposal and Publications Guidelines (Revised 4/29/05)**

### **A. Goals**

A.1. To encourage high quality publications and presentations produced in a timely fashion.

A.2. To encourage broad participation by Health ABC investigators in publications and presentations.

### **B. Scope of the guidelines**

B.1. These guidelines apply to investigators affiliated with Health ABC and to those without an affiliation with Health ABC who are proposing any form of analysis, publication, or report that describes Health ABC methodology or utilizes core or ancillary study data collected in the course of the study.

B.2. These guidelines apply to papers (including methodology and validation papers), abstracts/extended abstracts, oral and poster presentations, letters to the editor, and meeting proceedings that use data collected as part of the core Health ABC study or ancillary study data (refer to Health ABC Ancillary Study Guidelines).

B.3. These policies remain in force after funding for the study ends.

### **C. Publications Committee**

C.1. Leadership and membership on the Health ABC Publications Committee may be subject to approval by a majority vote of the Health ABC Steering Committee.

### **D. Types of publications**

D.1. These guidelines broadly cover any form of analysis, publication, or report that describes Health ABC methodology or utilizes core or ancillary study data.

D.2. The guidelines encompass five different types of publications:

D.2.1. Study-wide papers reporting Health ABC data collected from both field centers. "Main papers" will be identified by the Executive Committee and, generally include results about the main outcomes of the study using the study-wide data base.

D.2.2. Local papers reporting data collected from locally initiated and separately funded ancillary studies that are unique to one site.

D.2.3. Methodology/validation papers.

D.2.4. Abstracts, meeting proceedings/extended abstracts, and presentations (oral and poster) submitted to meetings.

D.2.5. Letters to the editor reporting Health ABC data collected from one or both of the field centers.

## **E. Authorship**

E.1. Authors should participate in the writing of the paper in accordance with the International Committee of Medical Journal Editors guidelines (N Engl J Med 1991;324:424-8).

E.2. Authorship of papers and abstracts:

E.2.1. The Health ABC Executive Committee may assign first authorship of main papers.

E.2.2. Other study-wide papers may be proposed by Health ABC-paid investigators.

E.2.3. Fellows and non-Health ABC scientists may serve as first authors on study-wide papers and abstracts if at least one Health ABC investigator serves as a co-author and "sponsor" of the project and, no other Health ABC investigators have interest in first authorship. It is recommended that the proposer notify the Co-Chairs of the Publications Committee (Steve Kritchevsky, Michael Nevitt, or Susan Rubin) or the Publication Coordinator at the UCSF Coordinating Center of their intention to develop an analysis plan on a given topic, prior to submission, in order to identify potential conflicts.

E.2.4. Authorship of local papers and abstracts may be determined by the Health ABC investigators from that field center.

E.3. An individual investigator will be limited to lead author on three active analysis proposals ("active" defined as the manuscript not yet submitted for publication).

E.4. All study-wide papers, abstracts, and presentations (oral and poster) should include "for the Health ABC Study" in the authorship line.

E.5. Collaboration:

E.5.1. Publications resulting from study-wide analyses are expected to have at least one Health ABC investigator from each unit as a co-author. Lead authors are strongly encouraged to enlist the participation from appropriate investigators from other Health ABC units, including the field centers, Coordinating Center, NIA Project Office and the Reading Centers. To encourage co-author participation, the lead author should invite all co-authors to participate in at least one conference call or meeting to discuss a draft of the paper at a stage when co-authors may still contribute to methods of analysis and to writing of the manuscript.

E.5.2. Lead authors are responsible for assembling the group of co-authors and for determining the order of authorship. Authorship should be ordered by contribution to the conceptualization, analysis and writing of the paper. The Publications Committee may mediate disagreements that cannot be resolved by the writing group.

E.5.3. Lead authors are responsible for distributing all publication materials, including abstracts, manuscripts, presentations, letters to the editors, etc., to all co-authors for review prior to submission to the Publications Committee.

E.5.4. Lead authors are expected to delete names from the final list of authors if those individuals have not participated in the writing and/or analysis of the paper in accordance with the International Committee of Medical Journal Editors guidelines.

## **F. Official study name, required acknowledgements, and recommended terminology**

F.1. The official name of the study for scientific purposes is the “Health, Aging, and Body Composition Study.” When referring to the Health ABC Study in the text of an abstract or paper, refer to it as the “Health, Aging, and Body Composition Study.” If space is an issue, refer to the study as the “Health ABC Study.”

F.2. Papers, abstracts, and presentations (oral and poster) should list the NIA contract numbers of all participating centers (N01-AG-6-2101; N01-AG-6-2103; N01-AG-6-2106) in an “Acknowledgement.” In addition, Health ABC publications using ancillary study data should also list the grant or contract number of the ancillary study.

F.3. Use of data from the DXA validation studies, Health ABC QDR 4500, and whole body phantoms should acknowledge support from Hologic, Inc.

F.4. All papers, abstracts, and presentations should use the following terminology conventions: race (instead of ethnicity, since ethnicity was not measured in Health ABC) and Black/White when referring to race.

## **G. Availability and analysis of data**

G.1. Proposals for analysis plans can only be submitted using data that has officially been released for analysis by the UCSF Coordinating Center (See section G.2. below for possible exceptions.)

G.2. Analyses and publications based on unreleased data may be permissible in certain specified circumstances and must be approved by the Executive Committee. Approved analysis plans are required for these possible exceptions. Exception may include the following:

- Technical reports
- Methodology reports/studies
- Validation and pilot studies
- Letters to the editor

G.3. In general, analyses will be performed at the institution of the lead author.

## **H. Analysis Plans**

### H.1. Submitting Analysis Plans

H.1.1. All investigators planning projects or publications (including study-wide and local papers, methodology/validation papers, abstracts, presentations [oral and poster], letters to the editor) utilizing Health ABC core or ancillary study data must submit an analysis plan to the Publications Committee for approval.

H.1.2. Analysis plans should be submitted via e-mail to the Health ABC Publications Committee Coordinator at the UCSF Coordinating Center. The analysis plan must include:

- a. The name of the first author. If the first author is not a Health ABC-paid investigator, then the sponsoring Health ABC investigator must also be listed.
- b. The name of the senior co-author (Health ABC investigator) who will serve as the internal manuscript reviewer.
- c. A provisional list of potential co-authors.
- d. Statement of the research question(s) or hypothesis.
- e. Brief background and rationale for addressing the research question or hypothesis in Health ABC.
- f. Variables to be used in the analysis; the main predictor and outcome variables should be identified.
- e. A mock-up of key tables.
- f. A timeline for completion and submission of the paper.
- g. Deadlines for submission of abstracts or dates of presentation and meeting (if applicable)
- h. The unit that will be responsible for analyzing the data.

H.1.3. In general, each analysis plan should be designed to result in a single manuscript. The Publications Committee may determine that an analysis plan is too broad or will result in multiple manuscripts, and request that the scope be narrowed to correspond to a single publication.

H.1.4. If the objectives of an analysis plan evolve and deviate substantially from the original plan, the first author is responsible for submitting an amended analysis plan.

H.2. Review and Approval of Analysis Plans. The process is as follows:

H.2.1. Once an analysis plan is received by the UCSF Publications Coordinator, the analysis plan will be listed on the Health ABC web site within 48 hours of receipt, with a status of “under review.”

H.2.2. Analysis plans will initially be reviewed by the Publications Coordinator and/or Chair(s) of the Publications Committee to check for potential overlap with other plans. If there is no overlap and the analysis plan packet is complete, then the plan will be transmitted electronically to the Publication Committee for their review and approval. Any member of the Publications Committee and the Steering Committee can also submit comments and a recommendation to accept or revise. All other Health ABC investigators may submit comments on the proposal.

H.2.3. Reviewers will have 10 working days to review a submitted analysis plan and forward comments to the Publications Coordinator at the UCSF Coordinating Center. There will be no expedited reviews of analysis plans.

H.2.4. Analysis plans must be submitted to the Publications Committee a minimum of 6 weeks prior to an abstract deadline to allow time for review and possible revision of the plan and/or abstract.

H.2.5. If an assigned reviewer or member of the Publications Committee does not approve the plan, the first author must consider revisions and then resubmit the plan. If necessary, final approval of an analysis plan will require a majority vote of the Executive Committee.

H.2.6. After approval by the Publications Committee, an outside manuscript reviewer(s) will be designated by the Publications Coordinator. The name, institutional affiliation, and e-mail address of the reviewer will be provided in the approval memo.

H.2.7. After approval by the Publications Committee, analysis plans will be posted on the secure area of the Health ABC web site.

H.2.8. Any investigator wishing to join the writing group should contact the first author. The Publications Coordinator will depend on the first author to provide updates regarding members of writing group.

### H.3. Expiration of Analysis Plans

H.3.1. Analysis plans remain current for 9 months from the date of approval of the analysis plan. If the Publications Coordinator has not received a draft of an abstract or manuscript within 9 months, the Publications Coordinator may announce that the plan has expired and first authorship may be reassigned or claimed by other Health ABC-paid investigators.

H.3.2. Plans may also expire and authorship potentially reassigned if a manuscript has not been submitted for publication within 18 months from the date of approval of the analysis plan.

## I. Review and approval of abstracts and presentations

I.1. Abstracts must have approved analysis plans before the abstract is submitted to the Publications Committee for review. Analysis plans must be submitted to the Publications Committee a minimum of 6 weeks prior to an abstract deadline to allow time for review and possible revision of the plan and/or abstract.

I.2. Abstracts must be reviewed and approved by all co-authors prior to submission to the Publications Committee.

I.3. Abstracts must be approved by the Publications Committee prior to submission to a meeting.

I.4. The approval process is as follows:

I.4.1. A draft of the abstract must be submitted to the Publications Committee, through the UCSF Publications Committee Coordinator, for review and approval at least 7 working days before the deadline for submission to a meeting. The abstract will be distributed to the Publications Committee for approval. Responses should be returned to the Publications Coordinator within 5 working days.

I.4.2. Co-authors who are members of either the Executive or Publications Committee can indicate their approval at the time the abstract is sent to the Publications Coordinator for review. The first author is responsible for having the co-author complete the Abstract/Presentations Approval Form (available on the Health ABC website) and for faxing or e-mailing the form to the Publications Coordinator prior to the submission deadline for the abstract.

I.4.3. A memo from the Chairs of the Publication Committee noting the approval status will be sent electronically to the first author.

I.5. The Publications Coordinator at the UCSF Coordinating Center will post the final version of the abstract on the Health ABC web site.

I.6. The first author is responsible for sending to the Publications Coordinator an electronic copy of the final version (on the “abstract reproduction form”) of the abstract.

I.7. No formal review will be required for presentations (oral or poster) to national or international meetings if:

- a. The oral or poster presentation was generated by an approved abstract, AND
- b. The first author and presenter is a paid Health ABC investigator
- c. Presenters who are not paid Health ABC investigators must have their presentations reviewed. The review process will be handled in the same manner as for abstracts.
- d. The first author is responsible for sending to the Publications Coordinator an electronic copy of the slides and/or poster presentation.

## **J. Review and approval of papers**

J.1. Papers must have an approved analysis plan and use data that has been officially released by the UCSF Coordinating Center before the paper is submitted to the Publications Committee for review.

J.2. Papers must be reviewed by all co-authors prior to submission to the Publications Committee.

J.3. Papers must be approved by an interval reviewer, an assigned outside reviewer, with final approval by the Publications Committee prior to submission for publication.

J.4. Papers must also receive clearance from the NIA prior to submission for publication.

J.5. The approval process is as follows:

J.5.1. The first author will be responsible for sending the manuscript to all co-authors and to both the senior co-author reviewer (“internal” reviewer) and the assigned outside reviewer for detailed comments.

J.5.2. The first author must carefully consider the comments and revise the manuscript incorporating the co-authors and reviewers’ suggestions.

J.5.3. The first author must complete a Manuscript Approval Form (available on the Health ABC website) confirming that all co-authors have had the opportunity to review the manuscript and provide comments. In addition, the senior co-author reviewer and the assigned outside reviewer must sign confirming that they approve the manuscript for submission to the Publications Committee. A reviewer may withhold approval pending revision. There will be no expedited review of papers.

J.5.4. If a reviewer disapproves of the submission of a paper to the Publications Committee after a good faith effort on the part of the authors to respond to concerns, then the Executive Committee will approve or withdraw submission of a paper by majority vote of all members.

J.5.5. Once the required signatures are obtained, the Manuscript Approval Form should be faxed and a copy of the manuscript sent electronically to the Publications Coordinator.

J.5.6. The Publications Coordinator and/or the Project Director will review the submitted paperwork. A memo from the Chairs of the Publications Committee noting the approval status will be e-mailed to the first author.

J.5.7. The Publications Coordinator will submit an approved paper to the NIA for clearance.

J.5.8. A paper may be submitted for publication when the first author receives an approval memo from the Chairs of the Publications Committee AND has been notified that the NIA has cleared it for publication.

J.5.9. The first author is responsible for sending an electronic copy of the final version of the manuscript to the Publications Coordinator, and when accepted, for sending a PDF of the published article (or a paper copy if no PDF file is available from the Journal) to the Coordinator.

J.5.10. The first author is responsible for sending any programming code for derived (calculated variables) constructed specifically for the analysis in the paper to the Publications Coordinator.

## **K. Miscellaneous**

K.1. Meeting Proceedings and Extended Abstracts that are nearly identical to or minimally expand on an approved abstract do not need to be submitted to the Publications Committee for review prior to submission for publication. These should be reviewed by all co-authors prior to submission.

K.2. Meeting Proceedings and Extended Abstracts that significantly expand an approved abstract must be submitted to the Publications Committee for review

prior to submission for publication. New analyses and results not included in the abstract and substantial additional detail about methods are examples of significant expansion. The approval process will be handled in the same manner as for abstracts.

K.3. In order not to jeopardize the publication of the complete manuscript in a peer-reviewed journal, Health ABC investigators are encouraged to take a “minimalist” approach when drafting Meeting Proceedings and Expanded Abstracts. The content should closely mirror the abstract; the analyses and results should be presented with the same level of detail as the abstract. Expanding the background and discussion sections is a good alternative to expanding the methods and results section. Authors should feel free to provide half as much text as requested for the Meeting Proceedings and Expanded Abstract.

#### **L. Archives**

The UCSF Coordinating Center will maintain an electronic archive of all Health ABC publications. Electronic copies of the final version of all papers and abstracts, including local papers, will be posted on the secure area of the Health ABC web site.