

PUBLICATIONS AND PRESENTATIONS GUIDELINES

(Revised 4/21/00)

A. Goals

- 1. To encourage high quality publications and presentations produced in a timely fashion.
- 2. To encourage broad participation by Health ABC investigators in publications and presentations.

B. Scope of the guidelines

These guidelines cover papers (including methodology and validation papers), abstracts, oral and poster presentations, letters to the editor, meeting proceedings and extended abstracts that use data collected as part of the Health ABC study. These policies remain in force after funding for the study ends.

C. Publications and Data Analysis Committee

Leadership and membership in the Publications and Data Analysis Committee may be subject to approval by a majority of the Health ABC Steering Committee.

D. Types of publications

These guidelines deal with five different types of publications.

- 1. <u>Study-wide papers</u> 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 analyzed from the study-wide data base.
- 2. <u>Local papers</u> reporting data collected from locally initiated and separately funded ancillary studies that are unique to one site.
- 3. <u>Methodology/validation papers</u> that utilize data that has <u>not</u> yet been officially released for analysis by the UCSF Coordinating Center.
- 4. <u>Abstracts, meeting proceedings/extended abstracts, and presentations (oral and poster)</u> submitted to meetings.
- 5. <u>Letters to the editor</u> reporting Health ABC data collected from one or both of the field centers.

E. Authorship

- 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).
- 2. Authorship of study-wide papers and abstracts:
 - a. The Health ABC Executive Committee may assign first authorship of main papers.
 - b. Other study-wide papers may be proposed by Health ABC-paid investigators.
 - c. Fellows and non-Health ABC scientists may serve as first authors on study-wide papers and abstracts if:
 - d. 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 Health ABC of their intention to develop an analysis plan on a given topic, prior to submission, in order to identify potential conflicts.
 - e. Authorship of local papers and abstracts may be determined by the investigators from that field center.
- 3. Investigators will be limited to lead roles on <u>three</u> active analysis proposals ("active" defined as the manuscript not yet submitted for publication).
- 4. All study-wide papers, abstracts, and presentations (oral and poster) should include "for the Health ABC Study" in the authorship line.
- 5. First authors . . .
 - i. are <u>strongly encouraged</u> 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. <u>To encourage co-author participation</u>, the first author must 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.
 - ii. assemble the group of co-authors and determine the order of authorship. Authorship should be ordered by contribution to the conceptualization, analysis and writing of the paper. Disagreements that cannot be resolved by the writing group may be adjudicated by the Publications and Data Analysis Committee.
 - iii. are expected to distribute abstracts, manuscripts, presentations, letters to the editors, etc. to all co-authors for review <u>prior</u> to submission to the Publications and Data Analysis Committee.

iv. 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

- 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, please refer to it as the "Health, Aging, and Body Composition Study."
- 2. All study-wide papers, abstracts, and presentations (oral and poster) should list the NIA contract numbers (N01-AG-6-2106; N01-AG-6-2102; N01-AG-6-2103) in an "Acknowledgement."
- 3. Use of data from the DXA validation studies, Health ABC QDR 1500, AND whole body phantoms should acknowledge support from Hologic, Inc.
- 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

- 1. Proposals for analysis plans can only be submitted based on data that has officially been released for analysis by the UCSF Coordinating Center (See L.3, below, for an exception.)
- 2. In general, analyses will be performed at the institution of the first author.

H. Analysis Plans

- 1. Submitting Analysis Plans
 - a. Analysis plans must be submitted to the Publications and Data Analysis Committee for all reports utilizing Health ABC data, including study-wide and local papers, methodology/validation papers, abstracts, presentations (oral and poster), and letters to the editor.
 - b. Analysis plans should be submitted with a completed Health ABC Analysis Plan form. The analysis plan must include:
 - 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.
 - An initial list of potential co-authors.
 - Statement of the research question(s) or hypothesis.

- Brief background and rationale for addressing the research question or hypothesis in Health ABC.
- Variables to be used in the analysis; the main predictor and outcome variables should be identified.
- Between 1 and 3 mock tables.
- A timeline for completion and submission of the paper.
- Deadlines for submission of abstracts or dates of presentation (if applicable)
- The unit that will be responsible for analyzing the data.
- c. In general, each analysis plan should be designed to result in a single manuscript. When, in the course of the review process or analysis it becomes apparent that an analysis plan is too broad or will result in multiple manuscripts, an additional analysis plan should be submitted for each additional manuscript, or the original plan can be amended to narrow its scope.

2. Review and Approval of Analysis Plans

- a. 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.
- b. Analysis plans will initially be reviewed by the Publications Coordinator and/or Chair(s) of the Publications and Data Analysis 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 sent to the Publication and Data Analysis Committee for their approval.
- c. Members of the Publications and Data Analysis Committee 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.
- d. Analysis plans must be submitted to the Publications and Data Analysis Committee a minimum of 5 weeks prior to an abstract deadline to allow time for review and possible revision of the plan and/or abstract.
- e. If any member of the Publications and Data Analysis Committee disapproves 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.
- f. After approval by the Publications and Data Analysis Committee, analysis plans will be posted on the secure area of the Health ABC web site. Any investigator wishing to join the writing group should contact the first author. The UCSF Coordinating Center will be responsible for keeping this list up-to-date.

3. Changes to approved Analysis Plans.

- a. If the objectives of an approved analysis plan evolve and deviate substantially from the original plan, the first author should send a memo to the Publications and Data Analysis Committee briefly outlining the changes. In some cases, the committee may request an amended plan.
- b. A separate analysis plan should be submitted for additional papers that spin off from the approved plan.

4. Expiration of Analysis Plans

- a. Plans for study-wide papers remain current for 6 months from the date that "clean" data becomes available for the analysis or the date of approval of the analysis plan (which ever is later). If the Publications Chair has not received a draft of an abstract or manuscript within 6 months, the Chair may announce that the plan has expired and first authorship may be reassigned (for main papers) or claimed by other Health ABC-paid investigators.
- b. Plans will also expire and authorship reassigned if no additional drafts of manuscripts have been received by the Chair for a period of 3 months, or if a manuscript has not been submitted for publication within 18 months after the approval date.

I. Review and approval of study-wide papers

- 1. All study-wide papers must have an approved analysis plan before the paper is submitted to the Publications and Data Analysis Committee for review.
- 2. Papers must be reviewed by all co-authors prior to submission to the Publications and Data Analysis Committee.
- 3. Study-wide papers must be approved by the Publications and Data Analysis Committee prior to submission for publication.
- 4. The approval process will proceed as follows:
 - a. A final draft of the manuscript, including figures, must be submitted to the Publications and Data Analysis Committee for review and approval and to the NIA for clearance.
 - b. The Chair of the Publications and Data Analysis Committee will assign and notify two members of the Steering Committee to review the paper. The reviewers will come from at least 2 different units. They must indicate approval or disapproval and suggest revisions within 10 working days of notification. A reviewer may withhold approval pending revision. There will be no expedited review of papers.
 - c. The Publications Coordinator at the UCSF Coordinating Center will notify all Steering Committee members by fax about papers that have been submitted for review and approval. In addition to the "official" reviewers, other members of the Steering Committee may read and make suggestions to the authors.
 - d. If either reviewer, or any member of the Steering Committee disapproves of the submission of a paper after a good faith effort on the part of the authors to respond to concerns, then it will be reviewed by the Executive Committee. The Executive Committee may approve or withdraw submission of a paper by majority vote of all members.
 - e. A paper may be submitted for publication when all reviewers give approval and clearance is obtained from the NIA. A memo from the Chairs of the Publication and Data Analysis Committee noting the approval status will be faxed to the first author.

- f. The first author is responsible for sending both a paper copy and the electronic copy of the final, approved version of the paper to the Publications Coordinator at UCSF.
- g. Along with a copy of the final manuscript, the first author is also required to send to the Publications Coordinator at UCSF annotated copies of the tables indicating important derived variables and their names, a brief description of the derived variables, and the code used to create the variables. Only relevant code should be sent.

J. Review and approval of abstracts and presentations

- 1. All abstracts must have approved analysis plans before the abstract is submitted to the Publications and Data Analysis Committee for review.
- 2. Abstracts must be reviewed by all co-authors prior to submission to the Publications and Data Analysis Committee.
- 3. Abstracts must be approved by the Publications and Data Analysis Committee prior to submission to a meeting.
- 4. The approval process will proceed as follows:
 - a. A final draft of the abstract must be submitted to the Publications and Data Analysis

 Committee for review and approval at least 7 working days before the deadline for
 submission to a meeting.
 - b. The Chair of the Publications and Data Analysis Committee will assign and notify up to two members of the Steering Committee to review the abstract. They must indicate approval or disapproval and suggest revisions within 4 working days of notification. A reviewer may withhold approval pending revision. If a reviewer fails to respond, this will be taken as approval.
 - c. Co-authors who are members of the executive or publications committee can indicate their approval at the time the abstract is sent to the Publications Coordinator for review. The co-author must state in writing that they have read and approved the abstract for submission.
 - d. Expedited Review: When an abstract is submitted without sufficient time for review, the Chair may approve or disapprove the abstract within 2 working days of receipt of the abstract. The Publications Coordinator at the UCSF Coordinating Center (Alan Camardo) must be notified 3 working days in advance regarding the need for an expedited review. Exceptions to deadlines for first authors may be made only one time.
 - e. Analysis plans must be submitted to the Publications and Data Analysis Committee a minimum of 5 weeks prior to an abstract deadline to allow time for review and possible revision of the plan and/or abstract.
 - f. An abstract may be submitted to a meeting when both reviewers give approval and clearance is obtained from the NIA. A memo from the Chairs of the Publication and Data Analysis Committee noting the approval status will be faxed to the first author.

- 5. The Publications Coordinator at the UCSF Coordinating Center will post the final version of the abstract on the Health ABC web site.
- 6. The first author is responsible for sending to the Publications Coordinator both a paper copy (on the "abstract reproduction form" for the meeting) and the electronic copy of the final version of the abstract.
- 7. Final versions of abstracts will be posted on the secure area of the Health ABC web site.
- 8. Presentations to national or international meetings that contain results of Health ABC data must have approval for the slides or printed material. This approval will be handled in the same manner as for abstracts.

K. Review and approval of local papers and abstracts

- 1. Local papers should be based on unique data collected by that field center in a locally-initiated, separately funded and approved ancillary study; they should not be based only on one field center's portion of study-wide data.
- 2. <u>Authorship of local papers</u> will be decided by the Principal Investigator of the field center. Local papers should acknowledge the Health ABC study in the title or the text.
- 3. All local papers must have an approved analysis plan before the paper is submitted to the Publications and Data Analysis Committee for review.
- 4. Papers must be reviewed by all co-authors prior to submission to the Publications and Data Analysis Committee.
- 5. The approval process will proceed as for study-wide papers (see I.4.).
- 6. The first author is responsible for sending to the Publications Coordinator both a paper copy and the electronic copy of the final version of the paper.

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L. Miscellaneous (Letters to the Editor, Meeting Proceedings, Extended Abstracts, Methodology / Validation Papers)

1. Letters to the Editor

- a. All Letters to the Editor <u>that use unpublished Health ABC</u> data must have approved analysis plans (utilizing data that has been officially released by the UCSF Coordinating Center) before the Letter to the Editor is submitted to the Publications and Data Analysis Committee for review.
- b. Letters to the Editors must be submitted to the Publications and Data Analysis Committee for review prior to submission for publication. They must be reviewed by all co-authors prior to submission to the Publications and Data Analysis Committee.
- c. The approval process will be handled in the same manner as for abstracts.
- d. The first author is responsible for sending to the Publications Coordinator both a paper copy and the electronic copy of the final version of the Letter to the Editor.

2. Meeting Proceedings and Extended Abstracts

- a. All Meeting Proceedings and Extended Abstracts must be based on approved analysis plans.
- b. Meeting Proceedings and Extended Abstracts that are nearly identical to or minimally expand on an approved abstract do <u>not</u> need to be submitted to the Publications and Data Analysis Committee for review prior to submission for publication. These should be reviewed by all co-authors prior to submission.
- c. Meeting Proceedings and Extended Abstracts that significantly expand an approved abstract <u>must be</u> submitted to the Publications and Data Analysis 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.
- d. 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.
- e. The first author is responsible for sending to the Publications Coordinator both a paper copy and the electronic copy of the final version of the Meeting Proceedings and Short Communications.

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3. Methodology / Validation Papers

- a. All methodology / validation papers must have an approved analysis plan before the paper is submitted to the Publications and Data Analysis Committee for review.
- b. The Publications and Data Analysis Committee will consider analysis plans for methodology and validation papers that utilize data that has <u>not</u> yet been officially released for analysis by the UCSF Coordinating Center.
- c. The approval process will be handled in the same manner as for manuscripts.

M. 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. An electronic copy of the final draft and a paper copy of the published paper will be posted on the web site or sent to the UCSF Coordinating Center for posting before the scheduled date of publication.

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