NIH-AARP Diet and Health Study
Policies and Procedures for Data Access and Publications

1. Overview

The NIH-AARP Diet and Health Study (AARP study) has established polices to promote access to AARP study data by qualified investigators, allow for a transparent review process, and facilitate collaborative research in all areas. Investigators are encouraged to propose and develop publications and presentations. To protect the integrity of the AARP study, any research using AARP study data that is intended for publication or presentation must be reviewed and approved by either the AARP Management Team and/or the Steering Committee, as defined below. These policies will remain in force after funding for the study ends.

The goals of these policies and procedures are 1) Encourage high quality publications and presentations in a timely fashion; 2)Encourage multidisciplinary, collaborative and creative use of the AARP study data and resources; and 3) Ensure appropriate recognition of both AARP study investigators and the NCI for their role in the AARP Study

These guidelines deal with 1) Proposals for analyses that will be presented in manuscripts; 2) Manuscripts that report the findings of an approved project in a journal; 3) Abstracts submitted to national or international meetings; and 4) Presentations made to national or international meetings.

2. Review Process and Guidelines

2.1. Proposal evaluation criteria

Each proposal will be reviewed based on following criteria:

a. Scientific rational/justification
   - Is the hypothesis sound?
   - Is the study design appropriate?
   - What is the impact of the proposal?

b. Feasibility
   - Is the study using data available in the AARP study?
   - Does the scientific team (PI, collaborators, etc.) in the proposal have necessary expertise?
   - Is the project achievable within the timeline?

c. No duplication with ongoing or completed AARP study projects
   - Any significant overlap with ongoing or previously completed projects?

2.2 Analysis proposal

A proposal for each project/manuscript must be reviewed and approved by the AARP Steering Committee prior to accessing AARP data and to developing an associated manuscript. The Steering Committee generally does not approve broad proposals to analyze multiple risk factors and endpoints. It is recommended that authors focus on one particular risk factor or endpoint

per manuscript. An approved proposal should be developed into a single manuscript. If an investigator would like to draft more than one manuscript based on a single approved proposal, a formal request for the additional project must be sent to the Steering Committee. A new proposal ID number will be assigned if the request is approved.

A proposal must be submitted through the public website, NIH-AARP Diet & Health Study Tracking and Review System (STaRS, https://www.nihaarpstars.com). All proposals must contain information specified in the Proposal Form, including the research question, methods, proposed authorship list, timeline for submission of a manuscript/abstracts or dates of presentation (if any), and target date of completion of the project.

A list of all AARP study publications and approved proposals to date is available on the STaRS website. Before developing a proposal, prospective authors should review this list to avoid overlap with approved manuscript proposals that are already in progress as well as published manuscripts.

If overlap is identified, the prospective author may either drop the idea, contact the lead author of the proposal to determine if overlap can be avoided through selective data analysis and reporting, or discuss the possibility of joining the writing group should the lead author be in agreement.

In an effort to ensure timely completion of projects, it is expected that each analysis project will be completed (e.g., manuscript submitted) within 365 days of the date of approval, and investigators are generally discouraged from being the lead author of more than 2 papers at any one time.

Proposal Approval and Revisions

Analysis proposals submitted are reviewed during the Steering Committee meetings on a bi-monthly basis. At the time of review, the committee will decide on the recommended course of action. This includes: approval, approval based on modifications, revise and resubmit, disapproval. If the proposal receives either an approval status of 'approval based on modifications' or 'revise and resubmit', the investigator has 4 months to respond to the Steering Committee's recommendations. In some circumstances, the Steering Committee may recommend that a proposal be split into two projects; in such an event, two proposals will need to be re-submitted to the Steering Committee and should be done within 4 months.

When revisions are required, prospective authors should provide a point-by-point response to Steering Committee comments. A Word document using Track Changes should be prepared and emailed to ncinadhsproposals@mail.nih.gov.

2.3 Final manuscripts

All manuscripts must be reviewed and approved by the coauthors prior to submission for publication. Also, all papers involving a DCEG author need to be sent through DCEG clearance. A final copy of the all submitted manuscript should be loaded into the STaRS system for archival purposes.

All publications or manuscripts generated using data from NIH-AARP study are **required** to be sent to **Ashley Eure** (AshleyEure@westat.com) and **Linda Liao** (Linda.Liao@nih.gov) ***prior to publication*** for review by the Nevada State Cancer Registry. Investigators will be notified when the review is complete and the publication or manuscript can be submitted to a journal.

- Please also include the following information with your manuscript:
    1. Proposed journal name and
    2. Do you believe this manuscript will generate media interest? Yes / No (Select one)

Authors have 365 days after Steering Committee approval of a proposal to submit their manuscript to a journal. If the authors have not submitted a manuscript within this timeframe, the Steering Committee will review the progress and may offer the authorship to others. The investigator has the option of submitting a request for extension to the Steering Committee. If approved, the investigator will be given an additional 6 months to submit their manuscript to a journal.

NIH Public Access Policy

The manuscript accepted for publication in a peer-reviewed journal should be deposited in PubMed Central. The first or the senior author of the manuscript is responsible for complying with this policy. If a journal handles all aspects of the deposition, the author is automatically credited with being compliant for the manuscript. If a journal does not provide the service, the first/senior author must handle all aspects of the deposition. At the time the final manuscript is accepted for publication, the final accepted version of the manuscript should be submitted through the NIH Manuscript Submission System (http://nihms.nih.gov/).

2.4 Abstracts, Posters, and Presentations

All abstracts, posters and presentations must be based on an approved project proposal. Authors who plan to submit an abstract must seek approval from coauthors and, if a DCEG author is involved, DCEG clearance should also be obtained.

2.5 Collaborative projects

Collaborative projects are defined as proposals and papers developed to include AARP study data in combination with other datasets (e.g. pooled analyses). Proposals for collaborative projects are not required to be reviewed by the Steering Committee. However, proposals will be sent to the Steering Committee for informational purposes. Collaborative project proposals will be reviewed by the Study Management Team and the Study Management Team may recommend an AARP study liaison and AARP co-authors for the project. It is the responsibility

of the AARP study liaison to the consortium and AARP study coauthors of the manuscript to ensure the accuracy of AARP data analyses and the content of any resultant manuscripts.

3. Authorship and Acknowledgements

3.1. Authorship

Authors must contribute in a meaningful and identifiable way to the design, analysis, and reporting of the work and should meet the guidelines established by the International Committee of Medical Journal Editors, which have been adopted by many biomedical journals.

Investigators propose a list of coauthors when submitting a proposal. The Steering Committee will review the recommendations for authorship and may recommend additional co-authors. In general, authors should comprise those who can and will make the most substantial contributions to the manuscript. There also may be circumstances where the Steering Committee recommends that the NCI not be involved with a particular project.

In general, the investigators who first conceived the project and submitted a proposal for the manuscript to the Steering Committee should have the option of serving as first author, so long as they do not exceed the allowable limit of proposed or active projects, and so long as they submit the paper to DCEG clearance within a reasonable amount of time (365 calendar days). Conflicts in authorship will be resolved by the Steering Committee.

The order of authorship on a paper should be determined by the first author for that project (or the person who submits a proposal). In general, the authors will appear in order of contribution to the analyses and preparation of the manuscript. If conflicts regarding the order of authorship cannot be resolved by the group of people working on the project, the Steering Committee will adjudicate and may assign the order and/or the investigators to be included as co-authors.

3.2 Acknowledgement

All NIH-AARP study papers are required to include an "Acknowledgements" section, available on the study website.

The NIH-AARP study papers should include a paragraph describing the source of funding, including the NCI and fellowship program, if applicable. If required by the journal, each author's role in the analysis, writing and review of the paper may need to be noted.

4. Data access and quality control assurance

Investigators within DCEG will be given access to the data via the IMS (Information Management Service) server. For investigators outside of DCEG/NCI or for those investigators who work on AARP study projects after leaving DCEG, a Data Transfer Agreement should be executed before any data release, as required by NIH policy for the Transfer of Materials from the NIH Intramural Laboratories. Non-DCEG/NCI investigators will be charged a fee for data

preparation and access in accordance with IMS analyst hourly fees. If you need to change your data file (e.g., obtain additional variables), please consult with your IMS analyst about additional requirements and fees.

The first author of the manuscript should submit a Quality Control form in the study portal to the study programmer indicated in the QC form. Questions and comments from the review of the Quality Control form should be answered and corrections be made as needed.

5. Revisions of these guidelines

The Steering Committee will approve revisions of these guidelines by a unanimous vote.