

AGRICULTURAL HEALTH STUDY POLICY 2-4: GUIDELINES FOR COLLABORATION

AHS Executive Committee:

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Agricultural Health Study (AHS) investigators encourage collaborations involving outside researchers. The primary criteria for collaboration are the promotion of high quality science and protection/nurturing of the cohort. The following guidelines apply to any outside researchers interested in conducting targeted investigations on the cohort.

EVALUATION CRITERIA FOR POTENTIAL COLLABORATIVE STUDIES:

1. Proposed work shall be collaborative, involving one or more investigators from AHS principal institutions.
2. Prior to submitting the Data Request Form, external collaborators should have the AHS collaborator review the request to ensure that it is in the proper format and includes all needed information.
3. Proposed research must be deemed methodologically sound and scientifically valid by the AHS Executive Committee.
4. If the research topic overlaps with priority projects of AHS principal institutions, it may still be possible to carry out. However, this overlap should be discussed as early as possible with the AHS Executive Committee to determine whether the research activity can move forward.
5. The AHS Executive Committee must approve requests for data, samples, and/or add-on studies. The decision regarding collaboration will be communicated to the extramural investigator within 30 days of the application.
6. Primary analyses and authorship must be specified in the study proposal.
7. All data provided to collaborators will be stripped of identifying information. Collaborators conducting an add-on study should be aware that first contact with a potential participant shall be initiated by AHS study staff. If a participant provides consent to release identifying information to an add-on study, then the collaborator will have rights to that individual's identifying information. Collaborators shall provide the AHS with copies of the data collection instruments, forms, informed consent materials developed for the add-on study, and IRB approval letters, as well as data files linkable to the main AHS files.
8. Requests for new data collection or use of limited resources (e.g., buccal samples) require special consideration including the following:
 - Peer review
 - IRB approval
 - Scientific justification: question that is best (or only) addressed in the AHS cohort
 - Results of benefit to study participants
 - Respondent burden minimized
 - Confidentiality/data security maintained
 - Participation voluntary (new data collection)

DATA ACCESS AND PROPRIETY

1. The philosophy for collaborative projects is for data from the AHS and the collaborative project to be available to both AHS investigators and collaborators. Plans to accomplish this should be provided in the study protocol.
2. Access to AHS data is time limited and only for the approved purpose(s). The data will be provided for **18 months** for secondary analysis and for **five years** for add-on studies; this is expected to be sufficient time to complete the study analysis and draft a manuscript for AHS Executive Committee review. Collaborators shall destroy all data provided by the AHS at the end of the approved usage period, unless other arrangements are approved by the Executive Committee. Requests for extensions of the time limit should be addressed to the Executive Committee at least 60 days prior to the approved expiration date. NOTE: If the researcher needs access to a data file after it has been returned, he or she should inform the Executive Committee and a copy of the original data set will be made available for a defined period of time. New data collected by an add-on study will become the property of both the principal investigator of the add-on study and the AHS Project Officer. They will be jointly responsible for protecting the privacy of the subjects. Unless otherwise agreed upon in advance, all data that are generated by an add-on study shall be provided to the AHS at the end of the data collection period.
3. Data are nontransferable unless prior authorization by the Executive Committee has been granted.
4. No identifying information other than study IDs is to be provided in data sets.
5. Only AHS data required for the conduct of the study are provided to the extramural investigator and become part of the new study data set.
6. Any subset of AHS data may be requested by extramural investigators, but requests for all AHS data are not accepted at this time.
7. Secondary uses of combined data must be approved by a joint Steering Committee composed of the extramural Principal Investigator and the Executive Committee.
8. All required Federal reviews will be completed prior to submission for publication or abstract for presentation. The Executive Committee will meet to discuss issues related to a proposed publication when a member of the committee has any concerns with the paper.

REPORTING

1. The collaborator should provide a timeline of planned research activities that includes the length of time that the AHS data are needed, the standard time being 18 months for data analysis projects and five years for add-on studies.
2. The collaborator shall report semiannually on research progress to the Executive Committee. Collaborators will complete the AHS Project: Semiannual Progress Report Form when requested by the AHS STaRS. This report consists of a project summary, a timeline of study activities, a status report, and a list of investigators. In addition to the basic report, investigators shall indicate if they are experiencing any obstacles to completing the project or if they have plans to expand the activity in any way. It is expected that once a data set is obtained through an AHS data request, the investigator will complete analysis and produce a draft manuscript for the AHS Executive Committee to review within a period of 18 months for secondary analysis or five years for add-on studies. If it appears that this is not a reasonable assumption, this should be addressed in the report. A member of the Executive Committee may contact the investigator to discuss the matter further.
3. The collaborator must share plans for any expanded activity or analysis with the Executive Committee in the progress report and in advance of initiating the activity or analysis.

REQUIREMENTS FOR DATA GENERATED BY A COLLABORATION PROJECT

1. Collaborators collecting additional information from cohort members must provide the AHS with the data (pending IRB approval), unless other arrangements are made with approval of the Executive Committee.
2. Collaborators conducting secondary analysis shall provide the AHS with a copy of the analysis files used when reporting results. Once the AHS has acknowledged receipt of these files collaborators shall then destroy all AHS data files in their possession. Refer to Data Access and Propriety item 2.
3. Investigators conducting add-on studies shall provide the AHS with a copy of all data in a format approved by the AHS. This includes data generated by surveys, biological specimens, or environmental samples.
4. When reporting results, investigators shall indicate in the manuscript the version of the AHS dataset used in the analysis. Please see Appendix 1 for information on the AHS File Release Numbering system.
5. If biological samples are collected, the collaborator shall split the remaining sample upon completion of the study. One half of the sample is sent to the AHS biorepository. The Executive Committee may, at its discretion, waive the splitting of biological samples.
6. The specific laboratory used by the collaborator must be agreed upon by the Executive Committee.

FUNDING CONSIDERATIONS

1. Independent funding is required.
2. Costs incurred by AHS for collaborative study activities may be reimbursable by the extramural investigator.

AHS EXECUTIVE COMMITTEE PROCESS FOR REVIEWING DATA REQUESTS

The process by which the Executive Committee reviews data requests is outlined below:

1. The internal collaborator or external collaborator submits a data request via AHS STaRS.
2. AHS STaRS assigns a tracking number.
3. The AHS EC reviews proposals monthly with all proposals submitted by the first Monday of the month reviewed by the end of the month.
4. EC members provide public (for investigator) and private (for other EC members) comments on the data request. EC members have the option to approve, approve pending minor revisions, defer approval until revised, or reject a data request.
5. At the monthly EC calls, the proposals are discussed and final decisions are made. The investigator receives a notification from AHS STARS regarding the application.