



DATA AND RESEARCH SUPPORT SERVICES

Policies and Procedures

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I. Introduction

The AHEAD Institute provides professional scientific services at every stage of the research project life-cycle, including:

- Study design and protocol development
- Data collection (telephone, web-based and in-person interviewing; chart abstraction and database extraction)
- Database design and management
- Statistical programming and analysis
- Interpretation and reporting
- Communication of results

The AHEAD Institute also offers other customized technical services related to study design and implementation, such as sample-size calculations and secure data storage and warehousing.

The AHEAD Institute does not provide IRB support. Many data bases maintained by the Institute are de-identified and using them has been deemed non-human subjects research by the SLU IRB. Other databases require DUAs and special training (HCUP). Investigators seeking support to analyze their primary data, must provide proof of IRB approval before work can begin.

Our mission is to provide specialized technical assistance and management to investigators who share our commitment to improving the effectiveness, efficiency and equitability of the health care system.

II. Data and Research Support Request Process

The following steps are taken to request data and/or research support services:

A. Data and Research Support Request Process:

- a. The Data and Research Support Interest Form (Appendix A) is completed by the Primary Investigator (PI) and submitted through a REDCap application portal available on the AHEAD Institute website. <https://redcap.link/ahead-interest-form>
- b. The AHEAD Institute Director of Operations & Outreach schedules a meeting between the requesting PI, an AHEAD Core Faculty member, and Biostatistician as appropriate.
- c. The Biostatistician and PI determine the scope of the project, including anticipated timeline of deliverables and any necessary data requests. AHEAD Institute Core Faculty may be included in the scope of work depending on degree of methodological support needed. Funding source should be identified and established before any work is completed.
- d. For projects requiring access to AHEAD data resources, the PI or the Biostatistician assigned to the study completes and submits the final data access request to the Data Manager.

- a. The Data Manager grants access to the location of the requested data (either located in an on premises server or the AHEAD Institute Amazon Web Services account), accessible to the investigators and biostatistician.
- e. All projects are tracked by the assigned Biostatistician in the AHEAD Project Tracking system, located on the AHEAD Institute REDCap application.
- f. Upon completion of the research project, the secure folder will be zipped and stored for 2 years then permanently deleted (5 years for investigator-derived data).
 - a. The Data Manager will review open projects on a quarterly basis. Data sets with no activity for the prior 24 months will be considered inactive and the project will be closed and the project permanently deleted.
 - b. PI will be notified 3 months prior to data/project archival or destruction.
 - c. If the PI requires the project to be archived for longer than 24 months past project completion, the PI may be responsible for the cost of data storage. The PI is responsible for notifying the Data Manager of the need to store the project longer than 24 months after completion.

III. Request Timeline Policies

For AHEAD data requests, a period of 30 days from the formal resource-specific data request should be expected to fulfill the request.

For grant application requests, including power analysis, a period of 30 days from signing the SOW should be allowed to fulfill the request.

Other timelines related to project deliverables and outcomes will be outlined in the SOW by the assigned biostatistician. Anticipated timelines are subject to change, but will be discussed actively with the PI.

IV. Publication Policies

Any AHEAD Institute biostatisticians and faculty named in the scope of work must be included as co-authors of scholarly publications. All publications and presentations made using the AHEAD Institute's resources and name must be submitted to the Executive Director (or designee) prior to publication/dissemination. The AHEAD Institute reserves the right to have 10 business days to approve materials before submission to journals or scientific meetings. All publications using AHEAD scholarship resources must cite the following in acknowledgments, "This work is supported by a grant from the Saint Louis University Research Institute and resources from the AHEAD Institute."

Final published works (manuscripts, posters, presentations, etc.) are to be sent to ahead@health.slu.edu to be archived.

A. Optum® Data

Per the SLU Family Medicine & AHEAD Institute Internal DUA, the following publication policies will be strictly enforced for use of Optum® Data:

1. Investigators will not publish any information on an individual patient. Frequencies and percents in any cell in a summary data table with 1-4 patients must not be reported. These cells should be reported as “< 5” in tables.
2. Investigator may not publish any materials resulting in analysis of Optum® data without Optum’s prior, written approval.
3. Investigator must provide Optum with a copy of the final product to be submitted for publication at least 30 days prior to submission. This also applies to abstracts, posters or any form or dissemination using Optum data. Optum’s review is limited to ensuring that:
 - a) The name of the licensor of the Data Product and the name of the Data Product itself are accurate; and
 - b) No Data or Products themselves, or other Optum Confidential Information, are included as part of the proposed publication. Optum will review publication for use of data and Optum’s name and has the right to request data, confidential information, or Optum’s name to be deleted from materials.

Written approval for publication from Optum should be sent to Alyce Kuklinski at alyce.kuklinski@optum.com and CC’d to AHEAD@health.slu.edu.

V. Funding Policies

Research support services are offered at a rate of \$150/hr. To remove barriers to accessing our services, there are several mechanisms available to secure funding for research projects:

A. Financial relationships with individual units

Departments within SLU or SSM Health can establish financial relationships with the AHEAD Institute to cover costs associated with analytic support for research projects.

B. Washington University in St. Louis’s (WashU) Institute of Clinical and Translational Sciences (ICTS) Just-In-Time (JIT) funding

The AHEAD Institute is a JIT CORE in the Institute of Clinical and Translational Sciences – Washington University. The JIT Core Usage Funding Program is designed to provide quick access to funding to use any of the JIT Cores for research advancing medical knowledge that can improve human health. This designation for the AHEAD Institute enables SLU researchers to apply for up to \$5,000 in funding to utilize AHEAD Institute data and research support services. <https://icts.wustl.edu/funding/just-in-time-jit/>

The JIT Core Usage Funding Program is supported by the ICTS, Mallinckrodt Institute of Radiology, Foundation for Barnes-Jewish Hospital, St. Louis Children’s Hospital, Hope Center, and Siteman Cancer Center.

Projects that utilize this funding mechanism must be approved by the AHEAD Institute prior to application.

C. [Internal SLU grants](#)

- SLU Spark Microgrant
- Applied Health Sciences Research Grant

D. [External grants](#)

As per the AHEAD Institute By-Laws, budgets for research project proposals are reviewed by the Senior Director for Research or an appropriate staff designee prior to submission. Funded budgets are administered by individual principal investigators. Projects using AHEAD Institute data are expected to build in data use fees and costs of statistical support into the project budget. Grant funded projects should include 15% of total direct costs for use of AHEAD data and costs for analytic support should be budgeted at a rate of \$150 per hour.

VI. Appendices

A. Appendix A – Data and Research Services Interest Form

Confidential

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AHEAD Data and Research Support Interest Form

The Advanced HEALTH Data (AHEAD) Institute provides data warehousing and research support services to the Saint Louis University community.

This statement of interest form provides the AHEAD Institute with a record of your request and enables the AHEAD Institute to ensure your needs are met.

Once the AHEAD Institute receives your completed request, the following actions will occur:

The AHEAD Program Coordinator processes all requests and will schedule a 30-60 minute research consultation meeting, which will include necessary AHEAD faculty and staff (i.e. data manager, biostatistician, AHEAD core faculty) as applicable. A scope of work (SOW) will be developed during the initial research consultation meeting and approved by all parties following the meeting. The SOW will include: Summary of the work request, Data domains required for project (if using AHEAD databases), Forms that need to be signed and completed (see below), *Estimated delivery date(s), Location of data on restricted access shared drive (if conducting own analysis), Associated compensation, if applicable. Forms that need to be signed and completed before data delivery and/or work begins need to be signed by the Primary Investigator, sponsoring faculty mentor (if applicable), biostatistician, and any other individual with direct access to AHEAD data:

Scope of Work Agreement, Data Use Agreements, AHEAD Institute Acknowledgement Statement. Please allow three business days for your request to be processed and a member of the AHEAD Institute to contact you. For questions, please e-mail ahead@health.slu.edu

General Information

Is the Primary Investigator an AHEAD Institute Member?

Yes
 No

AHEAD Members are those faculty that actively use AHEAD data resources and have a current CV on file with the AHEAD Institute. Clinicians participating in the Clinical Research Scholars Program (CRSP) are automatically designated as members of the Institute.

Students and collaborators need not be approved as members of the AHEAD Institute but must be working with sanctioned AHEAD Institute members when using the Institute resources or logo.

If the PI is not currently an AHEAD Institute Member, please include a current CV if there is interest in becoming a member.

Primary Investigator's First Name

Primary Investigator's Last Name
