ARIC Ancillary Study Data and Tracking

The ARIC Study has a history of being very collaborative. In turn, ancillary studies are also expected to be collaborative, including being required to share data on ARIC participants generated by the ancillary study, while respecting the right of ancillary study investigators to be the first to publish using the data they generate. This document provides details of the requirements for sharing of ancillary study data.

1. Official ARIC Ancillary Study Policies on providing ancillary study data

The ARIC "Ancillary Studies Policy" at https://sites.cscc.unc.edu/aric/ancillary-studies-pfg states:

> *Data collected by the Ancillary Study, with thorough documentation (an archival copy of newly collected data with labels, and/or laboratory results as well as documentation on methods, visits and units used with specific instructions for using the data in analyses such as exclusions that were applied) is to be sent to the ARIC Coordinating Center one year after the conclusion of the data cleaning and closure or one year after acceptance of the primary publication, whichever comes first.*

and

> *The data from the ancillary study will be included in the ARIC Limited Access Data (LAD) set for distribution to outside researchers according to the established NHLBI procedures for distribution.*

2. Implementation of the policy on ancillary study data

Although the policy allows up to a year after data cleaning to provide the data to the Coordinating Center, earlier provision of the data is strongly encouraged. Doing so will not undermine the right of ancillary study investigators to first use of their data. The ARIC Publications Committee and Coordinating Center act as gatekeepers to study data. When a manuscript proposal includes use of data from an ongoing or recently-completed ancillary study, the Publications Committee typically requires inclusion of a relevant ancillary study investigator in the writing group before approving the proposal. Further, until the required exclusive use period has elapsed, the Coordinating Center will not distribute the ancillary study data except to an investigator with an approved manuscript proposal or if permission to distribute has been given by the ancillary study PI.

3. Providing raw data

The data to be supplied by the ancillary study include the underlying raw data, with "data" being defined in a broad sense to include images, recording, and other ways in which information is collected and stored. Exceptions may be made in instances where the raw datasets are very large or highly specialized, such as for the whole genome sequence data managed by the ARIC Genetics Laboratory at the University of Texas Health Science Center, Houston. Another exception is for Reading Centers, as described below.

4. Reading Centers

Reading Centers are expected to provide data they generate from the readings as close to real-time as practical. When reading is done on an ongoing basis, results should typically be sent on a regular schedule or, in some cases, data entered directly into the Coordinating Center's CDART data management system. When reading is done in batches, data should be sent after completion of cleaning of the data in a batch.

Reading Centers serving multiple studies and that expect to continue to function after their role on ARIC has been completed, are not required to send their raw data at that time. However, if a Reading Center anticipates closing, arrangements should be made with the Coordinating Center and/or NHLBI for transfer of the raw data. For example, when the Retinal Reading Center at the University of Wisconsin, Madison, closed, the hard-copies of the retinal photographs from ARIC visits 3 and 4 and the digital retinal photographs from visit 5 were transferred to the Coordinating Center.

If a Reading Center is established specifically for an ancillary study (or the main ARIC contract), with no intention of it serving in that role for other studies in the longer term, then the Reading Center should supply the raw data to the Coordinating Center or to NHLBI once its role has been completed.

5. Ancillary Study Tracking

The Coordinating Center is required to report progress on ancillary studies to the OSMB annually and to provide information to the Steering Committee on an ongoing basis. To that end, the Coordinating Center periodically requests updates from ancillary study PIs. When the status of an ancillary study changes, such as when funding is awarded, the PI should report that at the time rather than waiting for the next request for a progress report.