



ARIC Ancillary Studies Committee

Review Protocol

Last updated: **July 29, 2024**

ARIC ANCILLARY STUDY REVIEW PROCESS

1) Ancillary Study Proposal is received by ARIC-AS@unc.edu and forwarded to Ancillary Study Committee Chair (eselvin@jhu.edu)

2) Chair reviews and determines participant burden classification:

- 1) Data analysis only
- 2) Laboratory/biospecimen use only
- 3) Participant contact but NO laboratory/biospecimen collection or use
- 4) Participant contact with laboratory/biospecimen collection or use

CATEGORY 1 PROPOSAL – Data analysis only

- Chair sends Ancillary Study Proposal to Coordinating Center PI for review with cc to ARIC Steering Committee (comments optional; no vote)
- Chair reviews comments (if any) and makes decision (approved, deferred, not approved) in consultation with Coordinating Center PI within ~1 week
- Ancillary Study number is assigned (if approved) and letter is sent by Chair (with comments if applicable) to Ancillary Study PI and ARIC Sponsor(s), with cc to ARIC-AS and NHLBI PO
- Duration of approval: 3 years from the date in approval letter. If funding is not received within 3 years of approval, the PI should re-apply to the ARIC Study.

CATEGORY 2 PROPOSAL – Laboratory/biospecimen use only

- Chair sends Ancillary Study Proposal to ARIC Laboratory Committee Chair (Eric.Boerwinkle@uth.tmc.edu; cc Camille.J.Breaux@uth.tmc.edu) with cc to Steering Committee
- Dr. Boerwinkle will triage the Proposal based on the biospecimen request and forward to the appropriate ARIC laboratory contact for review of volume amount, availability of specimen type and comments
- Laboratory Committee reviews at scheduled monthly meeting and Laboratory Committee Chair sends comments and vote to Ancillary Study Chair
- Ancillary Chair and Laboratory Committee make final decision (approved, deferred, not approved)
- Ancillary Study number is assigned (if approved) and letter is sent by Chair (with comments if applicable) to Ancillary Study PI and ARIC Sponsor(s), with cc to ARIC-AS and NHLBI PO
- Duration of approval: 2 years from the date in approval letter. If funding is not received within 2 years of approval, the PI should re-apply to the ARIC Study.

CATEGORY 3 PROPOSAL – Participant contact but NO laboratory/biospecimen collection or use

- Chair sends Proposal for review (assigns reviewer and sends email with attached Ancillary Study Proposal and review form)
- Review is returned within 2 weeks

- Chair forwards Ancillary Study Proposal along with the completed review form to ARIC Steering Committee for review and Coordinating Center adds Proposal to next Steering Committee Agenda
- Vote is conducted at ARIC Steering Committee meeting (approved, deferred, not approved); at least 4 votes are needed, must be unanimous
- Ancillary Study number is assigned (if approved) and letter is sent by Chair (with comments if applicable) to Ancillary Study PI and ARIC Sponsor(s), with cc to ARIC-AS
- Final version of approved Ancillary Study is forwarded by PI to NHLBI PO for review by OSMB. The NHLBI PO will forward to OSMB Executive Secretary and Executive Secretary will send OSMB comments and decision directly to PI
- Duration of approval: 2 years from the date in approval letter. If funding is not received within 2 years of approval, the PI should re-apply to the ARIC Study.

CATEGORY 4 PROPOSAL - Participant contact with laboratory/biospecimen collection or use

- Chair sends Proposal for review (assigns reviewer and sends email with attached Ancillary Study Proposal and review form)
- Review is returned within 2 weeks
- Chair sends Ancillary Study Proposal to ARIC Laboratory Committee Chair (Eric.Boerwinkle@uth.tmc.edu; cc Camille.J.Breaux@uth.tmc.edu)
- Dr. Boerwinkle will triage the Proposal based on the biospecimen request and forward to the appropriate ARIC laboratory contact for review of volume amount, availability of specimen type and comments
- Laboratory Committee reviews at scheduled monthly meeting and Laboratory Committee Chair sends comments and vote to Ancillary Study Chair
- Chair forwards Ancillary Study Proposal, review, and summary of comments from Laboratory Committee to ARIC Steering Committee for review and Coordinating Center adds Proposal to next Steering Committee Agenda
- Vote is conducted at ARIC Steering Committee meeting (approved, deferred, not approved); at least 4 votes are needed, must be unanimous
- Ancillary Study number is assigned (if approved) and letter is sent by Chair (with comments if applicable) to Ancillary Study PI and ARIC Sponsor(s), with cc to ARIC-AS.
- Final version of approved Ancillary Study is forwarded by PI to NHLBI PO for review by OSMB. The NHLBI PO will forward to OSMB Executive Secretary and Executive Secretary will send OSMB comments and decision directly to PI
- Duration of approval: 2 years from the date in approval letter. If funding is not received within 2 years of approval, the PI should re-apply to the ARIC Study.

List of approved ARIC Ancillary Studies (with Ancillary Study Numbers):

<https://sites.csc.unc.edu/aric/appr-ancill-stud-email>

Initial Intake and Proposal Classification

Ancillary Study Proposal is submitted to ARIC-AS@unc.edu

Ancillary Study Proposal is forwarded to Ancillary Study Chair for classification

Category 1
Data Analysis Only

Category 2
Lab Specimens and Data Use Only

Category 3
Participant Burden without Lab Specimens

Category 4
Participant Burden and Lab Specimens

Review Process

Chair sends Ancillary Study Proposal to ARIC Steering Committee for comments

Chair sends Ancillary Study Proposal to Laboratory Committee Chair and ARIC Steering Committee for comments

Chair assigns reviewer to Ancillary Study Proposal

Chair sends Ancillary Study Proposal to Laboratory Committee Chair

Chair assigns reviewer to Ancillary Study Proposal

Laboratory Committee reviews Proposal and Lab Chair sends comments and vote to AS Chair

Review returned to Chair within ~2 weeks

Laboratory Committee reviews Proposal and Lab Chair sends comments and vote to AS Chair

Review returned to Chair within 2 weeks

Chair forwards Proposal and Review to ARIC Steering Committee
Coordinating Center adds Proposal to next Steering Committee Agenda

Chair forwards Proposal and Review to ARIC Steering Committee
Coordinating Center adds Proposal to next Steering Committee Agenda

Decision

Ancillary Study Chair and Coordinating Center PI

Ancillary Study Chair and Laboratory Committee

Vote of ARIC Steering Committee
Must be unanimous decision of at least 4 Committee members

Vote of ARIC Steering Committee
Must be unanimous decision of at least 4 Committee members

Approval Next Steps

Ancillary Study Proposals with participant burden need to be approved by ARIC OSMB

If Approved, Ancillary Study Number is assigned and letter is sent by Ancillary Study Chair to Ancillary Study PI and ARIC Sponsor(s) with CC: ARIC-AS and NHLBI Project Officer