



ARIC Ancillary Studies Committee

Review Protocol

Last updated: **April 3, 2025**

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)
- Outlook invite is added to Chair's calendar for the date of the review deadline
- 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 and NHLBI PO. In this email, the NHLBI PO is notified that the study involves contact with participants and should be forwarded to the OSMB for their review and approval.
- The NHLBI PO will forward the approved Ancillary Study 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)
- Outlook invite is added to Chair's calendar for the date of the review deadline
- 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 and NHLBI PO. In this email, the NHLBI PO is notified that the study involves contact with participants and should be forwarded to the OSMB for their review and approval.
- The NHLBI PO will forward the approved Ancillary Study 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>

