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.

   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.

   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.

**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.

List of approved ARIC Ancillary Studies (with AS Numbers):
https://sites.cscc.unc.edu/aric/appr-ancill-stud-email
Ancillary Study Proposal is submitted to ARIC-AS@unc.edu

Ancillary Study Proposal is forwarded to Ancillary Study Chair for classification

**Initial Intake and Proposal Classification**

- **Category 1**
  - Data Analysis Only
  - Chair sends Ancillary Study Proposal to ARIC Steering Committee for comments

- **Category 2**
  - Lab Specimens and Data Use Only
  - Chair sends Ancillary Study Proposal to Laboratory Committee Chair and ARIC Steering Committee for comments
  - Laboratory Committee reviews Proposal and Lab Chair sends comments and vote to AS Chair

- **Category 3**
  - Participant Burden without Lab Specimens
  - Chair assigns reviewer to Ancillary Study Proposal
  - 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

- **Category 4**
  - Participant Burden and Lab Specimens
  - Chair assigns reviewer to Ancillary Study Proposal
  - 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

**Review Process**

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

**Decision**

- **Ancillary Study Chair and Laboratory Committee**
  - Vote of ARIC Steering Committee
  - Decision of at least 4 Committee members

- **Vote of ARIC Steering Committee**
  - Decision of at least 4 Committee members

**Approval Next Steps**

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