

ARIC ancillary study review

The ARIC Steering Committee chair will triage Ancillary Study proposals into four categories-- those with:

- (1) data analysis only, including career development awards and pooled/meta analyses;
- (2) lab/specimen and data use only;
- (3) participant burden but no lab specimens; and
- (4) both lab/specimen use and participant burden.

Reviewer Role

The Steering Committee chair will identify and assign one Steering Committee or Ancillary Committee member to thoroughly review each submitted ancillary proposal. This assigned reviewer's task includes completing a summary and the Ancillary Study evaluation form and sharing it with the Steering Committee.

Lab Committee Role

The Lab Committee will review proposals in categories 2 and 4 and comment to Steering Committee on acceptability of specimen resource usage, lab methods, etc.

Steering Committee Role

For categories 1 and 2, Steering Committee members will consider the assigned Reviewer's evaluation and any Lab Committee feedback and will email to the Steering Committee chair their vote to approve or disapprove (no response is considered approval), attaching any additional comments they may have. For categories 3 and 4, Steering Committee members are encouraged not just to rely on others' summaries, but also to thoroughly review the full proposals with regard to burden and acceptability. If an approval/disapproval decision cannot be made by email, the Steering Committee will discuss at a conference call.

OSMB Role

OSMB review is required for categories 3 and 4. The ancillary investigators must send the revised proposal (or an email indicating no revision required) to the NHLBI Project Officer.