

CARDIA ANCILLARY STUDY INSTRUCTIONS TO APPLICANTS

1. Applicants must complete and include the following as part of their study proposal application:
 - a. Cover memo from CARDIA Investigator participating in the study; include email addresses for both the Ancillary Study Principal Investigator and CARDIA Investigator.
 - b. Table of Projected Burden; this should include a brief statement about what tasks are expected of each entity, general estimates of costs and how they will be covered and any pertinent additional information (e.g., incentives to be paid to participants, who will pay for shipping of materials).
 - c. Request for Use of Stored Materials (if applicable, or mark as NA)

2. The proposal must include:
 - a. Names of the approved CARDIA Investigator(s) serving as co-investigator
 - b. Study title and PI
 - c. Planned start date and funding plans
 - d. Abstract describing the study (limited to 300 words)
 - e. Description of the study, including
 - i. Rationale and brief background
 - ii. Specific aims
 - iii. Design and Methods, including sample size, justification, analyses and quality control plans
 - iv. Data and/or biological materials requested or to be collected
 - v. Impact on main study, including burden on participant.
 - vi. Specific statements addressing:
 1. Industry funding
 2. Confidentiality of individually identifiable data
 3. Submission of manuscripts and presentations
 4. Changes to the study after approval
 5. Specific Center approvals
 6. Planned funding to Coordinating Center and Field Centers
 - f. Proposed funding source

3. The completed application must be submitted to the Chairman of the CARDIA Executive Committee:

O. Dale Williams, PhD
University of Alabama at Birmingham
Division of Preventive Medicine
1717 11th Avenue South
Medical Towers Building, STE 401
Birmingham, AL 35205
E-mail: odalew@dopm.uab.edu
Fax: 205-934-0777

4. If the study is approved and funded, additional documents will be required:

1. Proof of PI's HIPAA and IRB Human Subjects training completion
2. CARDIA Confidentially Agreement
3. CARDIA Materials Distribution Agreement (if study materials are required)
4. Study IRB approval (if specimens requested)