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### Ancillary Study Proposal Form

**Atherosclerosis Risk in Communities (ARIC)**

**Part A: Basic Study Information and Projected Impact on ARIC**

**1.** **Title of study:**

**2.** **Principal investigator(s)** (name, institution, address, phone, e-mail address):

**3.** **List collaborators with email addresses** (must include the name of at least one ARIC investigator who will serve as the sponsor and has reviewed and approved this proposal):

 Name of ARIC sponsor:

 Date of approval of this proposal by ARIC sponsor:

 Funding source (institute and grant mechanism) and date of grant submission (if applicable):

 Proposed starting and ending dates:

**4.** **Participant Burden Classification** (select one)

 a. Data analysis only (including pooling projects/meta-analysis) [ ]

 b. Laboratory/biospecimen use only [ ]

 c. Participant contact but NO laboratory/biospecimen collection or use [ ]

 d. Participant contact with laboratory/biospecimen collection or use [ ]

If you selected (b), please briefly summarize biospecimen type, location, and availability. If you are uncertain about sample availability, please work with your sponsor and/or contact ARIC investigators before proceeding:

**5.** **Coordinating Center Involvement**  [ ]  Yes [ ]  No

**6.** **Brief Summary of Proposed Research and Projected Impact on the ARIC Study** (<100 words)

1. **Summary of ARIC centers and tasks involved** – Leave cell blank if Not Applicable

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Center** | **Enroll or examine participants (N)** | **Assay samples****(N participants)** | **Provide samples (N participants)** | **Provide data files (yes/no)** | **Analyze data (yes/no)** |
| Forsyth Co. Field Center  |  |  |  |  |  |
| Jackson Field Center  |  |  |  |  |  |
| Minnesota Field Center  |  |  |  |  |  |
| Washington Co. Field Center  |  |  |  |  |  |
| DNA Central Lab |  |  |  |  |  |
| MN Chem Lab |  |  |  |  |  |
| Lipid Central Lab |  |  |  |  |  |
| ECG Reading Center |  |  |  |  |  |
| Coordinating Center (UNC) |  |  |  |  |  |
| Other (specify) |  |  |  |  |  |

**8.** **IRB**

Select the IRB plan for this ancillary study (either sIRB or Local IRB) and the reason(s) for selection:

sIRB **[ ]**

a. new data collection at more than one center either directly with ARIC participants or using medical records **[ ]**

b. lab analysis of ARIC stored samples that use identifiers or require reporting data back to participants **[ ]**

c. more than one center will see PHI for the study **[ ]**

d. there eventually may be an FDA application **[ ]**

or

Local IRB **[ ]**

1. proposals that only use only existing ARIC deidentified data (e.g., most student projects, career development projects) will qualify as exempt or non-human subjects research **[ ]**
2. exclusively single center proposals (this can include some investigators at other sites who are only coauthors or provide services but never see participants or PHI **[ ]**
3. lab studies where the ARIC component is already approved in the sIRB parent protocol **[ ]**

**9.** **ARIC participant and staff involvement**

 a. ARIC Field Centers:

 Describe effort (and estimated time) required of ARIC staff at each participating center. Include consent, collection of samples, etc.

 b. Describe participant involvement.

 Describe number of subjects needed; special characteristics of study population; age and sex distribution. Will participants be contacted, interviewed, examined, or asked to provide specimens? Will this contact be embedded into an existing clinic visit or involve a separate (de novo) visit? Will the study involve radiation or administration of a drug or contrast?

 c. Estimate time required of each participant.

d. Describe any human subject protections issues including level of risk to participants and protections against risk.

**10. Describe ARIC Coordinating Center involvement**

\* *Unless you provide strong justification, the Coordinating Center must be included, and its costs budgeted.*

If activities will be performed at the Coordinating Center, support for these activities should be included in the grant application. Guidelines for reimbursement are provided on the ARIC website.

Describe effort (and estimated time) required of ARIC Coordinating Center staff. Specifically:

1. Will the Coordinating Center be involved in data collection, tracking, or preparation of forms or software? or will these tasks be completed locally by the Ancillary Study, and a data file sent to the Coordinating Center?
2. If a Reading Center or laboratory is involved, will data be sent directly from the Reading Center or laboratory to the Coordinating Center for processing, or will processing be done locally (either by the Ancillary Study or at the Reading Center/Laboratory)?

1. Will analyses be done locally by the Ancillary Study or by analysts at the Coordinating Center? If analyses will be done locally, should Coordinating Center verify the analyses?

**11. Stored ARIC specimens**

If stored specimens will be requested from the ARIC Laboratories, support for these activities should be included in the grant application. If the Ancillary Study is approved, please contact the appropriate lab for estimates and budgeting requirements.

 Describe materials to be used (e.g., stored plasma, urine, DNA). If blood samples are requested, please review the Criteria for Approval section of the Ancillary Study Policy (<https://sites.cscc.unc.edu/aric/ancillary-studies-pfg>) in consideration of your description of the following:

Study participants and material requested:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Yes/No | Cohort | Total Number of Specimens | Full Cohort(or ) | Number of Cases | Number of Controls |
|  | All parent study participants (or )  |  |  |  |  |
|  | Specify sample and specimens in each sample/stratum |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of Specimen | N | Volume Requested | Time point (e.g. visit\*) | Specify proposed lab and analytes to be assayed at catch lab (be specific) |
| Serum |  | ul |  |  |
| EDTA plasma |  | ul |  |  |
| Citrate plasma |  | ul |  |  |
| DNA |  | ug/ng |  |  |
| Urine |  | ul |  |  |
| Other (specify) |  |  |  |  |

\* Please contact ARIC in advance and indicate here how many tubes of each visit and type you are requesting:

1. Is the proposed work consistent with the stipulations in the ARIC informed consent form? [ ]  Yes [ ]  No (The informed consent forms can be obtained from the collaborating ARIC investigator).
2. Are thawed/re-frozen acceptable? [ ]  Yes [ ]  No

If No, specify reasons for specific assays:

1. Describe efforts to integrate sample needs with those of other studies to conserve sample and/or limit freeze-thaw cycles.
2. If approved, when will samples be requested for retrieval?

**12. Genomic information** (defined as any data from a participant’s DNA):

1. Does your proposal include any genomic materials? (please check one)

 [ ]  No (go to question 13) [ ]  Yes

b. Name the gene(s), genotypes, SNPs to be investigated:

c. Is genetic information used to address a primary aim or secondary aim of ARIC? (please check one or both)

 [ ]  Primary aim (heart/vascular disease)

 [ ]  Secondary aim (other health conditions)

 List the conditions addressed:

d. Should DNA-based results be reported to patients’ physicians? Base your response on your knowledge of existing literature and current practice regarding increased risk and availability of treatment for adverse outcomes associated with the gene mutations to be studied.

**13. Does this study involve the support or collaboration of a for-profit corporation, or do you intend to use the data to patent any process, aspect or outcome of the analysis?**

**14. What is the advantage, both to ARIC and yourself, of conducting the study within the ARIC cohort versus another population?**

**15. Discuss impact on and coordination with ongoing ARIC studies (main study or other Ancillary Studies):**

**16. Provide the following** **assurances** (answer each):

1. Who (name and position) will report progress of the study in the fall of each year? (Ancillary Study PI or designate preferred)
2. How will confidentiality of ARIC participants be maintained?

1. Data collected by the Ancillary Study, will be provided to the ARIC Coordinating Center for integration into the main database. This will include documentation of newly collected data with labels, and/or laboratory results as well as documentation on methods, visits and units used with specific instructions for using the data in analyses. such as exclusions that were applied. After that has been done the Ancillary Study investigators will receive the integrated file containing data from the main study.

The Ancillary Study PI will be given the first and exclusive opportunity to analyze, present and publish data collected under the auspices of the Ancillary Study. After a reasonable time (in general, 12 months after data cleaning is complete or 12 months after acceptance of primary manuscript, whichever is earlier), Ancillary Study data will be made available for additional uses by other ARIC investigators. It is the responsibility of the Ancillary Study PI to state in writing to the ARIC Steering Committee any special circumstances that would warrant an exception to these guidelines for data sharing. In the spirit of encouraging collaboration, reasonable and justified requests for limiting Steering Committee access to the data will be honored, or a compromise will be worked out.

1. Will the Coordinating Center be receiving data from your ancillary study?
2. How many papers do you estimate will be written from the Ancillary Study?
3. Variables/measurements from the ARIC main study database to be analyzed:

**17. If the study will have clinical implications, explain and describe the plan for reporting results to participants and providing recommendations for follow up:**

# Part B Abbreviated Ancillary Study Proposal

Please provide a brief (2 to 4 page) description of the proposed study. Include the following:

**Purpose/Aims:**

**Background:**

**Hypotheses:**

# Experimental Design (include sample size justification):

**Methods, including:**

 **Participant involvement (if any):**

**Data to be collected by the ancillary study (attach questionnaires and forms):**

 **Analysis Methods:**

**Literature References**

**Please send the completed form to** **ARIC-AS@unc.edu** **and use ‘ARIC ancillary proposal’ in the subject line**