# REGARDS Ancillary Study Proposal Form

**A. Title:**

**B. Investigators:**

**C. Date:**

**D. Study Goals:**

1. **General Aim.**

2. **Specific Aims / Hypotheses.**

3. **Rationale and Background.**

**E. Methods:**

**F. Ancillary Study Questions:**

If a question is already answered elsewhere in the proposal, summarize the answer here and direct the reader to the appropriate section.

1. What is the expected burden to participants, and what, if any, REGARDS core data are needed for the ancillary study?

2. Describe materials to be used. If blood samples, DNA or urine is requested, please review the section 3.E of the REGARDS Ancillary Study Policies and Procedures in consideration of your description, and respond to the required questions here.

   2a. If blood samples, DNA or urine is requested, please review the section 3.E of the REGARDS Ancillary Study Policies and Procedures in consideration of your description, and respond to the required questions here.

   **Will DNA be used? If DNA use is planned**:

   a) Name the gene variant(s) to be investigated.

   b) Will genetic information be used to study a Primary REGARDS aim (stroke and vascular disease) or a secondary aim (other diseases)?

   c) Specify amount of DNA requested. Minimization of amount is required.

   d) Discuss plans for addressing any relevant clinical or other (ethical, legal, or social) implications of the findings. Should genetic results be reported to participants or their physicians? If reporting may be needed, how will this be accomplished?

   e) Are the investigators aware of the elements of informed consent of REGARDS participants in relation to DNA use?

f) Do the investigators agree to abide by the informed consent of REGARDS participants in relation to DNA consent (exclusion of non-consenting participants needs to be considered in planning at the Ancillary Study proposal stage).

2b. Will blood or urine be used?

a) Name the analytes to be investigated and method (eg. kit name).

b) Sample type (e.g. serum or EDTA).

c) Requirement for frozen vs. previously thawed samples, and if the latter, what is the maximum number of freeze-thaw cycles acceptable.

d) Sample volumes (list by sample type; REGARDS has a limited repository; efforts to minimize volumes must be demonstrated)

e) Efforts to integrate sample needs with those of other studies to conserve sample and/or limit freeze-thaw cycles. If investigators are aware of related projects that would allow this, please mention here.

f) Are you requesting that the REGARDS lab analyze samples? If so, communicate with Dr. Cushman or Ms. Boyle at the lab before preparing your proposal.

g) Provide your projected timeline with dates for:

1. pulling samples and shipping, if applicable;
2. sample analysis, if applicable;
3. return of samples to REGARDS lab, if applicable.

3. What collaboration with REGARDS investigators is planned? With whom? Have the collaborating investigators approved the proposal?

4. What, if any, follow-up is needed? Specify length of time and events to be ascertained.

5. How many participants are required?

6. When will data be collected?

7. How will the ancillary study be funded? Un-reimbursed work or personnel time of REGARDS investigators or staff cannot be offered. If applying for a grant, what is the application deadline?

8. How will the confidentiality and other aspects of protection of human subjects be maintained?

9. Will the findings have clinical implications? If so, describe the plan for reporting results to participants and providing recommendations for follow-up.

10. Where will the data analyses be conducted? The ancillary study's PI should provide evidence that adequate support for carrying out data analysis is available at his/her institution; if not, the REGARDS coordinating center will conduct the analyses using resources provided by the ancillary study.
11. Does this study involve industry support or collaboration? If yes, please describe.
12. Do you anticipate using the data to file an application for a patent, to the FDA, or for other similar purposes?
13. Why will the data be collected in the REGARDS study? Why not use other populations? What is the relevance of this study to REGARDS? What is the unique advantage of using the REGARDS cohort?

**Provide the following assurances (check each):**

| **Y** | **N** | |
|---|---|---|
| ☐ | ☐ | The Ancillary Study PI will adhere to the Ancillary Study Policy. |
| ☐ | ☐ | The Ancillary Study PI will report the progress of the study as requested. |
| ☐ | ☐ | Confidentiality of REGARDS participants will be maintained. |
| ☐ | ☐ | REGARDS informed consent directives will be followed. |
| ☐ | ☐ | Data collected by the Ancillary Study, with documentation, will be provided to the REGARDS Coordinating Center for integration into the main database. |
| ☐ | ☐ | Papers resulting from the Ancillary Study will follow the Publications Policies of the REGARDS Steering Committee. |

For GWAS studies only:

| **Y** | **N** | |
|---|---|---|
| ☐ | ☐ | NIH-GWAS policies will be followed. |