ADVANCE Ancillary Study
INSTRUCTIONS TO APPLICANTS

1. Applicants must complete and include the following as part of their study proposal application:
   a. Cover memo to the ADVANCE Study Steering Committee including e-mail and address of the Ancillary Study Principal Investigator and the name and e-mail of the ADVANCE Investigator participating in the ancillary study.
   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)(it is the general policy of the ADVANCE study that transfer of stored biological materials will only be done under extraordinary circumstances).

2. The proposal must include:
   a. Study title and PI
   b. Names of the ADVANCE Investigator(s) serving as co-investigator(s)
   c. Planned start and end dates 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 (limit to 3 single-spaced pages), including sample size calculations, analysis plan, quality control plans.
      iv. Data and/or biological materials requested or to be collected
      v. Impact on main study, including potential burden on participants.
      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 ADVANCE Coordinating Center
   f. Proposed funding source

3. The completed application must be submitted to the Chairperson of the ADVANCE Steering Committee:
   Thomas Quertermous, MD
   Stanford Cardiovascular Medicine, Falk CVRC
   300 Pasteur Drive
   Stanford, CA 94305
   E-mail: tomq1@stanford.edu
   Fax: 650-725-2178

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. ADVANCE Confidentially Agreement
   3. ADVANCE Materials Distribution Agreement (if study materials are required)
   4. Study IRB approval (if specimens requested)