## Jackson Heart Study Ancillary Study Proposal Procedure

Contact Ancillary Study Coordinator @ (601) 815-5778 or jhsanc@umc.edu

## A. Pre-Approval Procedures

- 1. PI notifies the JHS Chief Science Officer (CSO), Dr. Adolfo Correa (<a href="mailto:acorrea@umc.edu">acorrea@umc.edu</a>) or the Ancillary Study Subcommittee (ASSC) Chairperson, Dr. Mario Sims (<a href="mailto:msims2@umc.edu">msims2@umc.edu</a>) of their intent to submit and ancillary study prior to completing the Concept Form.
- 2. PI submits an Ancillary Study Proposal via the JHS website:
  - a. Ancillary Study (AS) Proposal
  - b. Ancillary study narrative describing the study, including:
    - i. Relevance
    - ii. Specific aims
    - iii. Research strategy, including significance, innovation, and approach
    - iv. Summary
    - v. References
  - c. Signed Signature Sheet/or e-mail verification from all co-investigators
  - d. Lab Application (if biospecimen requested)

## **B.** Approval Procedures

- 1. All ancillary studies are reviewed and approved by JHS in the following order:
  - a. Lab Subcommittee (if applicable)
  - b. Ancillary Study Subcommittee (ASSC)
  - c. Steering Committee (SC)
  - d. NHLBI/OSMB
- 2. The ancillary study is approved once the PI has received all levels of approval

For information on resubmission, see <u>Ancillary Study Guidelines</u>.

## C. Post-Approval Procedures

- 1. PI submits proposal to funding agency(ies)
- 2. PI submits IRB application to home institution and verifies HIPAA Certification by home institution
- 3. PI submits DMDA application to JHS
- 4. PI submits IRB approval letter to JHS
- 5. PI notifies JHS of funding approval(s)
- 6. JHS notifies UMMC IRB to add AS to the list of JHS approved studies; once added, PI is notified that he/she may implement the study (e.g., submit request for JHS data and/or bio-specimen)
- 7. PI is required to submit <u>Progress Reports</u> semi-annually to JHS after approval regardless of funding status

For information on manuscript proposals, abstracts, manuscripts and slide presentations emanating from ancillary studies, see <u>Publications & Presentations Procedure</u>