UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

2500 North State Street
Jackson, Mississippi 39216-4505

Institutional Review Board
Telephone (601) 984-2815
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DHHS FWA # 00003630

Approval Notice
Amendment

May 31, 2006

Thomas H. Mosley, M.D.
Medicine
University of Mississippi Medical Center
2500 North State Street
Jackson, MS 39216-4505

RE: IRB File # 1985-0122
Atherosclerosis Risk in Communities (ARIC) Study

Dear Dr. Mosley:

Your Amendment was reviewed and approved by the Expedited review process on May 31, 2006. You may implement the amendment. **The expansion of long-term follow-up being done with currently enrolled participants is approved. If new participants are going to be enrolled, please let us know.**

Please note the following information about your approved research protocol:

- Protocol Approval period: May 31, 2006 - January 30, 2007
- Approved Enrollment #: 100000
- Performance Sites: UMC
- Amendment Description: Revised protocol

Amendment Review History:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
05/26/2006	Amendment	Expedited	05/31/2006	Approved

Please remember to:

→ Use **the IRB file number** (1985-0122) on all documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the enclosure, UMC Investigator Responsibilities, Protection of Human Research Participants.

Please note that the UMC IRB has the prerogative and authority to ask additional questions, request further information, require additional revisions, and monitor the conduct of your research and the consent process.

As a condition for publication of study results, the International Committee of Medical Journal Editors (ICMJE) requires all clinical research studies that begin enrolling participants on or after July 1, 2005 to be entered in a public registry before enrollment begins. For additional information please go to http://dor.umc.edu/proposalprep/policies/RegisteringClinicalTrialinPublicRegistry.doc.

We wish you the best as you conduct your research. If you have questions or need additional information, please contact the IRB office at (601) 984-2815.

Sincerely,

Gailen D. Marshall, Jr., M.D., Ph.D.
Chairman, Institutional Review Board 2

GDM/kc

Enclosure: (1) UMC Investigator Responsibilities, Protection of Human Research Participants

UMMC Investigator Responsibilities
Protection of Human Research Participants

The IRB reviews research to ensure that the federal regulations for protecting human research participants outlined in UMMC policy, the Department of Health and Human Services (DHHS) regulations (45 CFR 46) and the Food and Drug Administration (FDA) regulations (21 CFR Parts 50 & 56), as well as other requirements, are met. The University of Mississippi Medical Center's Federalwide Assurance (FWA), FWA# 00003630, awarded by the Office for Human Research Protections (OHRP) at DHHS, is a written pledge to follow federal guidelines for protecting human research participants in accordance with the principles of the Belmont Report. **All investigators must read both the Belmont Report and the UMMC FWA to understand their responsibilities in conducting research involving human participants**. Both documents are available on the IRB webpage, http://irb.umc.edu/, and in hard copy by request from the IRB office. Some of the responsibilities investigators have when conducting research involving human participants are listed below.

1. Conducting the Research: You are responsible for making sure that the research is conducted according to the IRB approved research protocol. **You are also responsible for the actions of the study's co-investigators and research staff**.

2. Participant Enrollment: You may not recruit or enroll participants prior to the IRB approval date or after the expiration date of IRB approval. All recruitment materials for any form of distribution or media use must be approved by the IRB prior to their use. If you need to recruit more participants than was noted in your IRB approval letter, you must submit an amendment requesting an increase in the number of participants.

3. Informed Consent: Informed consent is a process that begins with the initial contact and ends at some point after the study is complete. You are responsible for the conduct of the consent process, ensuring that effective informed consent is obtained and documented using **only** the IRB-approved consent documents, and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Whoever is presenting the consent document to the potential participant and conducting the consent process must have all pertinent information at hand, be knowledgeable about the study and the disease or condition involved, if any, and have the ability and experience to answer questions regarding the study and any treatment involved. Please give all participants a signed copy of each informed consent or assent document they sign, and keep the originals in your secured research files for at least six (6) years. When appropriate, you should place a copy of the informed consent document in the participant's medical record.

4. Continuing Review: The IRB must review and approve all IRB-approved research protocols at intervals appropriate to the degree of risk, but not less than once per year. **There is no grace period.** Prior to the date on which IRB approval of the

research expires, the IRB will send you a reminder to submit a Renewal Application. Although the IRB sends reminders, **it is ultimately your responsibility to submit the renewal in a timely fashion to ensure that a lapse in IRB approval does not occur.** If IRB approval of your research lapses, you must stop new participant enrollment, and contact the IRB immediately.

5. Amendments and Revisions: If you wish to amend or change any aspect of your research, including research design, interventions or procedures, number of participants, participant population, informed consent document, instruments, surveys or recruiting material, you must submit the amendment or revisions to the IRB for review using the UMC Amendment Application. You **may not initiate** any amendments or changes to your research without first obtaining IRB review and written approval. The **only exception** is when the change is necessary to eliminate apparent immediate hazard to participants. In that case the IRB should be immediately informed of this necessity, but the change may be implemented before obtaining IRB approval.

6. Adverse or Unanticipated Events: Any **serious and unexpected** adverse event, participant complaint, and all unanticipated problems that involve risks to participants or others, as well as any research related injury occurring at a UMMC performance site, must be reported to the IRB **within fourteen (14) days** of discovery of the incident. You must also report any instances of serious or continuing problems, or non-compliance with the IRB's requirements for protecting human research participants. The only exception to this policy is death - **the death of a UMMC research participant must be reported within 48 hours.** All reportable events should be submitted to the IRB using the Adverse Event/Unanticipated Problem Report form available on the IRB webpage, http://irb.umc.edu/.

7. Research Record Keeping: At a minimum, you must keep the following research related records in a secure location for at least six years: the IRB approved research protocol and all amendments; all versions of the investigator's brochure; all informed consent documents; all recruiting materials; all renewal applications; all adverse or unanticipated event reports; all correspondence to and from the IRB; and all raw data.

8. Reports to FDA and Sponsor: When you submit the required annual report to the FDA or you submit required reports to your sponsor, you **must** provide a copy of that report to the IRB. You may submit the report with your IRB continuing review application.

9. Provision of Emergency Medical Care: When a physician provides emergency medical care to a participant without prior IRB review and approval, to the extent permitted by law, such activities will not be recognized as research and the data cannot be used in support of the research.

10. Final Reports: When you have completed the study, (no further participant enrollment, interactions, interventions or data analysis) or stopped work on it, you

must submit a Final Report to the IRB using the Final Report form found on our web page, http://irb.umc.edu/.

11. On-Site Evaluations, FDA Inspections, or Audits: If you are notified that your research will be reviewed or audited by the FDA, OHRP, the sponsor, any other external agency, or any internal group, you **must** inform the IRB immediately and submit all audit reports received as a result of the audit to the IRB.

If you have questions or need assistance, please contact the IRB office at 601 984-2815.