JOHNS HOPKINS
MEDICINE
SCHOOL OF MEDICINE
Website: http://irb.jhmi.edu

Office of Human Subjects Research
Institutional Review Boards

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JHM-IRB 3

CONTINUING REVIEW with Change APPROVAL NOTICE
With Revised Consent Form
CONVENED REVIEW

TO : Moyses Szklo, MD
Professor, Epidemiology and Medicine
6009 Hygiene
Bloomberg School of Public Health

FROM: Richard Moore, M.D.
Chairman - JHM-IRB 3

DATE: October 25, 2006

RE : **Application Number: 99-11-10-06, entitled, Multi-Ethnic Study of Atherosclerosis (MESA) (with Joao Lima, Roger Blumenthal, Pamela Ouyang, Wendy Post, Harry Silber, Joel Hill, Javier Nieto, Bruce Wasserman, Naresh Punjabi, Brad Astor, Hochang Benjamin Li, Adrian Dobs, Erin Michos, Antonio Pazin)**
Request to revise forms for follow-up #7

I am pleased to inform you that **JHM-IRB 3** voted to approve the continuing review application for the above-referenced application on **10/17/2006.** Approval of the research is for the period of **10/17/2006 to 10/16/2007.** The JHM IRB revised and approved the consent form. A clean and track change copy of the consent form is enclosed. As principal investigator of the research, you are responsible for fulfilling the following requirements of approval:

1) The co-investigators listed on the application should be kept informed of the status of the research.
2) Additional changes to the research must be submitted on a **"Changes in Research Application"** to the JHM IRB for review and approval prior to the activation of the changes, with the following exception: changes made to eliminate apparent immediate hazards to the research participant may be instituted immediately and the JHM IRB should be informed of such changes promptly.
3) Reports of unanticipated problems involving risks to participants or others must be submitted to the JHM IRB in accord with the **JHM IRB Organization Policy on Reports of Unanticipated Problems Involving Risks to Participants or Others (Policy No. 103.6(b)**, using the Problem/Event Report Form (on the JHM IRB Website)
4) Only consent forms with a valid approval stamp may be presented to participants. All consent forms signed by participants enrolled in the research should be retained on file. The Office of Human Subjects Research conducts periodic compliance monitoring of approved research and consent documentation review is part of such monitoring.
5) Federal regulations require review of approved research not less than once per year. **Therefore, a continuing review application must be submitted to the JHM IRB office six weeks prior to the expiration date of 10/16/2007. This will allow sufficient time for review of the application to be completed prior to the expiration date.** Failure to submit a continuing review application prior to the expiration date will result in termination of the research, at which point new participants may not be enrolled and currently enrolled participants must discontinue participation in the study.

RM:bscherer
Enclosures