THE CITY OF NEW YORK

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Michael R. Bloomberg
Mayor

Thomas R. Frieden, M.D., M.P.H.
Commissioner

INSTITUTIONAL REVIEW BOARD
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New York, NY 10013
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January 17, 2007

Re: IRB# 00-041 "Multi-Ethnic Subclinical Atherosclerosis MESA Study"
Principal Investigator: Steven Shea, MD MS
This Action: Approval of Continuation, Expedited by Chair
Expiration Date: January 29, 2008

Steven Shea, MD MS
Professor of Medicine
Columbia University College of Physicians & Surgeons
622 West 168th Street, PH-9 East, Room 105
New York, NY 10032

Dear Dr. Shea:

Your application to continue the study "Multi-Ethnic Subclinical Atherosclerosis MESA Study" has been approved by the Chair under 45 CFR §46.110(b)(1)(category F9), as "continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified".

As principal investigator, you are responsible for ensuring that the study continues to be conducted according to the protocol approved by the IRB and your data use agreement with the Bureau of Vital Statistics. You may submit written requests to modify the protocol to the IRB, but you may not implement any modifications until you have received written approval from the IRB. If modifications affect your confidentiality, data security or original records destruction protocol, or any other portion of your data use agreement, you must also obtain the approval of the Bureau of Vital Statistics. Adherence to all provisions of your data use agreement is essential and will be evaluated as part of your continuation review. Please advise the IRB immediately of changes in sponsorship, funding, key personnel, or suspension of approval by another IRB. **Your study is subject to random or for-cause audit at any time.**

Any adverse physical or psychological event affecting a study participant, violation of your data security protocol, or breach of confidentiality, must be reported in writing to the IRB within 5 days of occurrence. Serious adverse events must be reported in writing within 24 hours.

This approval expires on **January 29, 2008.** If at that time you have completed your study, please submit a final report. If you wish to continue the study, please submit a progress report. In either case, the IRB requests that these reports be received **not less than four weeks prior to expiration date.**

Sincerely,

Olivette Burton, MSW, Mbe
Chair, Institutional Review Board

CC: Richard Genovese, Office of Vital Statistics
OR/ir