JOHNS HOPKINS
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SCHOOL of PUBLIC HEALTH

FWA #00000287

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CONTINUING REVIEW APPROVAL NOTICE

Date: April 20, 2009

To: Josef Coresh, MD, PhD
Department of Epidemiology

From: Elizabeth A. Skinner, MSW
Chair, IRB-X

Re: **Study Title**: "Atherosclerosis Risk in Communities (ARIC) Study - Morbidity/Mortality Follow-up Field Center"
IRB No: H.34.99.07.02.A1
Study Expiration Date: April 15, 2010

Review Category:	**45 CFR 46.110 (5 & 7)**
Waiver of Consent:	**45 CFR 46.117(c)(2)**
	45 CFR 46.116(d)

The JHSPH IRB-X reviewed and approved the Progress Report submitted for the above referenced study on **April 16, 2009**. Approval of the study is for the period of **April 16, 2009** to **April 15, 2010**.

As principal investigator of the study, 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) Submit an Amendment Request Form for any changes in research. These changes in research are required to be reviewed and approved prior to the activation of the changes, with the following exception: changes made to eliminate an apparent immediate hazard to the research participant may be instituted immediately and the JHSPH IRB should be informed of such changes promptly.
3) Unanticipated problems involving risks to participants or others must be reported to the JHSPH IRB in accordance with the **JHSPH IRB Organizational Policy on Reports of Unanticipated Problems Involving Risks to Participants or Others.** An Adverse Event Form must be submitted to the IRB immediately.
4) Only consent forms with a valid approval stamp may be presented to participants. All consent forms signed by participants enrolled in the study should be retained on file. The Office of Graduate Education and Research conducts periodic compliance monitoring of protocol records, and consent documentation is part of such monitoring.

5) Federal regulations require review of approved research not less than once per year. **Therefore, a Progress Report for continuing review must be submitted to the IRB Office no later than <u>six weeks</u> prior to the study expiration date of April 15, 2010**. This will allow sufficient time for review of the Progress Report to be completed prior to the expiration date. Failure to submit a Progress Report for continuing review 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. All ongoing research activities must stop immediately, including data analysis.

EAS/sro