CHR Form B (12/2001)

CHR Use Only
Type of Review:_____

Johns Hopkins Bloomberg School of Public Health
Committee on Human Research
Progress Report

CHR Expiration Date: August 9, 2006 ✓

CHR #: H 34 99 07 02 A1 **Principal Investigator:** Josef Coresh, MD, PhD

Address: 2024 E Monument St, Ste 2-600 Phone #: 410-955-0495 Email: coresh@jhu edu

Co-Investigator(s): See Attachment I

Student Investigator(s): See Attachment I

Project Title: Atherosclerosis Risk in Communities (ARIC) Study - Morbidity/Mortality Follow-up

RECEIVED
JUN 0 3 2006
Office for Research Subjects

A. Project Status: *(Since last approval, check one category only.)*

___1. Enrollment Has Not Begun*
___2. Actively Enrolling Subjects*
✓ 3. Enrollment Completed, Contact with Subjects Ongoing
___4. Contact with Subjects Completed, Analyzing Identifiable Data Analysis Only
___5. Analyzing Identifiable Data (Samples or Data) Only
___6. Analyzing Unidentifiable Data; Data Do Not Contain Identifiers or Linkage to the Data

If this is a Program Project, check here ___, complete Section E., sign the Progress Report and attach a completed List of Associated Projects (CHR Form F).

If enrollment has not begun or you are actively enrolling subjects, attach an unvalidated copy of the consent document used or to be used.

B. Number of Subjects Studied, Records Reviewed or Samples Analyzed:

Since last renewal: 0

# of males 0 # of females 0 # of adults 0 # of children 0

Since original approval: 4020

# of males 1884 # of females 2136 # of adults 4020 # of children 0

C. ***(Answer Questions 1 through 7 based on information since last review. Attach a memo explaining "Yes" answers to questions 1 through 6.)***

Yes	No	N/A		
✓			1.	Have any subjects withdrawn voluntarily or been withdrawn from the study?
	✓		2.	Have any unexpected side effects, complications, or findings been noted that have not been reported to the Committee?
	✓		3.	Have there been any changes to the protocol (subject population, recruitment, study procedures, sample size or consent process) that have not been reviewed and approved by the Committee?
	✓		4.	Are you requesting any changes to the project (change in investigators, subject population, recruitment, study procedures, sample size or consent process)?
	✓		5.	Have there been any significant new findings which may relate to the subjects' willingness to continue participation in the study?
	✓		6.	Has any new information appeared in the literature or been discovered from the study results that would affect the risk-benefit assessment of the project?
	✓		7.	Has a Data Safety and Monitoring Board been established for this project? If yes, provide a status report from the DSMB. *(See the adverse event reporting policy on the CHR website.)*
	✓		8.	Do any of the participating faculty (or their immediate family, staff or students) have a financial interest (royalty, equity or consulting) in the sponsor and/or products used in this project? Has this been reported to the CHR previously? ___Yes ___No *If no, attach a ememo explaining the conflict.*

D. In the space below, provide a brief summary of the progress and results obtained to date.

See Attachment III.

E. Funding Status: *(select one)*

✓ Awarded ___ Pending ___ Project **not** Funded

If awarded or pending, provide the following information:

Name of Sponsor: NHLBI Proposal/Award Number: RFP-NIH-99-09

Title of Grant/Contract: _____

_____

Signature of Principal Investigator — 6/8/06 Date

RETURN THIS FORM AND SUPPORTING DOCUMENT(S) TO:
Committee on Human Research, Room E1100, Bloomberg School of Public Health

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CHR USE ONLY: 45 CFR 46.110(8)

✓ Project Re-approved for Period August 2, 2006 to August 1, 2007**

___ Project Reclassified as Exempt Status; Continuing Review No Longer Required

Co-Chair, Committee on Human Research — 8/2/06 Date

SEE REVERSE SIDE FOR INVESTIGATOR RESPONSIBILITIES

Investigator Responsibilities

1. Changes, amendments, or addenda made to the protocol or the informed consent process must be submitted to the CHR for review and approval prior to initiating the change. This includes changes in investigator(s), sample size, population, research site, subject compensation, etc.

2. Incarcerated individuals may not be included in the study unless the study has been approved by the CHR for inclusion of prisoners. (http://www.jhsph.edu/chr)

3. The CHR protocol number should be cited in all correspondence.

4. Adverse events should be reported promptly to the CHR. (http://www.jhsph.edu/chr/).

5. Significant new information that may affect the risk:benefit ratio must be submitted promptly to the CHR.

6. Only consent/assent documents with a valid approval date may be presented to the subjects.

7. Signed consent forms for all subjects enrolled in the study must be retained on file.

8. All active research projects must be reviewed and re-approved by the CHR prior to the project's expiration date.

9. The Principal Investigator is responsible for submitting progress reports by the project's current submission date.

10. The Principal Investigator is responsible for keeping the Co-Investigator(s) and Student Investigator(s) informed of the status of the project.