THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
Medical School Building 52
Mason Farm Road
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
https://my.research.unc.edu for IRB status
Federalwide Assurance (FWA) #4801

To: Lloyd Chambless
Biostatistics
CB# 8030 137 E Franklin St St

From: Public Health-Nursing IRB

Ruth Humphrey JSS
Authorized signature on behalf of IRB

Approval Date: 2/05/2009
Expiration Date of Approval: 2/04/2010

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Renewal
Expedited Category: 5.Existing or non-research data
Study #: 96-0467 (Former IRB Number 96-090)
Study Title: Atherosclerosis Risk in Communities (ARIC)

This submission has been approved by the above IRB for the period indicated.

Study Description:

The Collaborative Studies Coordinating Center (CSCC) provides support for the Atherosclerosis Risk in Communities (ARIC) study. It coordinates activities and archives data from the ARIC field centers, where all participant contact is conducted with IRB approval through collaborating institutions (for which documentation is provided). UNC serves as the coordinating center for the ARIC study, which is carried out at several engaged sites outside of UNC. This study also includes the data collection activities for the ARIC Relationship of Lipoprotein-associated Phospholipase A2 to Incident Stroke in Middle-aged Men and Women.

Regulatory and other findings:

This research meets criteria for waiver of research consent [45 CFR 46.116(d)] and waiver of HIPAA authorization [45 CFR 164.512(i)(2)(ii)].

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

When applicable, enclosed are stamped copies of approved consent documents and other

recruitment materials. You must copy the stamped consent forms for use with subjects unless you have approval to do otherwise.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented (use the modification form at ohre.unc.edu/forms). Should any adverse event or unanticipated problem involving risks to subjects or others occur it must be reported immediately to the IRB using the adverse event form at the same web site.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40CFR 26 (EPA), where applicable.

CC:
Sandra Irving, Biostatistics
Christopher Anderson, Biostatistics