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: Gerardo Heiss
Epidemiology
CB# 8050 Bank Of America Suite

From: Public Health-Nursing IRB

Authorized signature on behalf of IRB

Approval Date: 11/10/2010
Expiration Date of Approval: 11/09/2011

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Renewal
Expedited Category: 7.Surveys/interviews/focus groups
Study #: 96-0484 (Former IRB Number 96-156)
Study Title: Atherosclerosis Risk in Communities (ARIC) Study (Post-Visit 4 Follow-up)

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

Study Description:

The ARIC study is a multi-center, bi-ethnic cohort study of 15,800 men and women. The goals of the study are to monitor the secular trends of cardiovascular risk factors and morbidity and mortality rates, as well as to study novel risk factors for non-invasively determined atherosclerosis and the clinical sequelae of atherosclerosis in the coronary and the cerebral arteries. In the current phase of the study the only activity which includes continued participant contact involves an annual telephone interview of all surviving ARIC participants, as has been done since the inception of the ARIC study.

Study Specific Details:

This approval does not cover any study activities for the 5th examination visit for the ARIC cohort.

Regulatory and other findings:

Direct interaction with subjects is complete but subsequent monitoring or follow up continues.

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). Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at https://irbis.unc.edu/irb.

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.

Diane Catellier - IRB Notice

From: IRB <irb_no_reply@mailserv.grad.unc.edu>
To: <diane_catellier@unc.edu>
Date: 12/17/2010 11:27 AM
Subject: IRB Notice
CC: <gina.andrews@mail.cscc.unc.edu>, <chris.anderson@mail.cscc.unc.edu>

A paper copy of the approval memo and any relevant documents are being mailed today.

To: Diane Catellier
Biostatistics
CB: 8030

From: Public Health-Nursing IRB

_____
Authorized signature on behalf of IRB

Approval Date: 12/17/2010
Expiration Date of Approval: 12/16/2011

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.

Submission Description:

This renewal includes an amendment, dated 12/13/2010, to change the PI from Lloyd Chambless to Diane Catellier. Max He has been removed from the list of study personnel.

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). Any unanticipated problem involving risks to subjects or others (including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at https://irbis.unc.edu/irb.

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:
Gina Andrews, Biostatistics
Christopher Anderson, Biostatistics

IRB Informational Message—please do not use email REPLY to this address

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER
2500 North State Street
Jackson, Mississippi 39216-4505
Institutional Review Board DHHS FWA #00003630
Telephone (601) 984-2815 IORG #0000043
Facsimile (601) 984-2961 IRB 1 Registration #00000061
IRB 2 Registration #00005033

Approval for Development Only

September 3, 2010

Thomas H. Mosley, PhD
Medicine - Division of Geriatrics
University of Mississippi Medical Center
2500 North State Street
Jackson, MS 39216-4505

RE: IRB File # 2010-0205
Atherosclerosis Risk in Communities (ARIC) Study - Field Centers

Dear Dr. Mosley:

Your research proposal was reviewed on September 3, 2010 and found to meet the criteria of 45 CFR 46.118, a proposal that lacks definite plans for the involvement of human participants. While human participants may be involved at some point during the period covered by the research grant, agreement or contract, definite plans have not been described within the proposal.

The proposal might be an institutional grant where UMC will select the specific projects; a research training grant in which the activities involving human participants are not yet selected; or a project in which the involvement of human participants will depend on the completion of instruments, prior animal studies, or purification of compounds. Please note, human participants cannot be involved in any research project supported by these awards until the project has been reviewed and approved by the Institutional Review Board (IRB).

If you have questions or need additional information, please contact the Human Research Office at (601) 984-2815. Please include the IRB protocol number identified above on all correspondence.

Sincerely,

Gailen D. Marshall, Jr., M.D., Ph.D.
Chairman, Institutional Review Board 2
GDM/kc
cc: Shirley Schlessinger, M.D., Medicine - Division of Geriatrics

WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

MEMORANDUM

–

To: Lynne Wagenknecht, Dr.P.H.

Public Health Sciences

From: Vice Chair, Institutional Review Board

Date: 5/6/2010

Subject: Human Protocol: BG86-0155

Atherosclerosis Risk in Communities

Amendment 3 for IRB Study #BG86-0155

Study Documents:

Protocol Version: ARIC IRB update April 2010.doc, ARIC Protocol, Participant_Follow-up_(Visit_5_Manual_2).5_2.pdf, STAMPEED Proposal.pdf

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

- This amendment to enable the award of NHLBI funding for study protocol development leading to a re-examination of the ARIC cohort.

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.

Scott Rhodes, Ph.D.

JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Institutional Review Board Office

615 N. Wolfe Street / Suite E1100
Baltimore, Maryland 21205
Office Phone: (410) 955-3193
Toll Free: 1-888-262-0245
Fax Number: (410) 502-0588
E-mail Address: irboffice@jhsph.edu
Website: www.jhsph.edu/irb

FWA #00000287

PLANNING PHASE REVIEW

Date: March 8, 2010

To: Josef Coresh, MD, PhD
Department of Epidemiology

From: Elizabeth Skinner, MSW
Chair, IRB-X

Re: **Study Title:** "Planning Phase-Atherosclerosis Risk in Communities (ARIC) Study - Field Center Exam 5"
IRB No: 00002760

The JHSPH IRB reviewed your request for the Planning Phase for the above referenced study in accordance with 45 CFR 46.118. This regulation acknowledges certain types of applications for grants, cooperative agreements or contracts submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but at the time of proposal submission, specific details of human subject involvement are not set forth in the proposal. This regulation further allows for the development of instruments and design of the study up to initiation of contact with human subjects.

Prior to initiation of contact with human subjects, you must submit a new application for review, referencing the IRB number stated above, and withdraw the Planning Phase application by submitting a memo to the IRB Office.

If you have not submitted a new application by **March 7, 2011** we will contact you to request an update on the progress of your Planning Phase. Should you require an extension of the Planning Phase period, please submit a memo to the IRB Office for this request.

If you have any questions regarding this action, please contact the JHSPH IRB Office at (410) 955-3193 or via email at irboffice@jhsph.edu.

EAS: ts

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

D528 Mayo Memorial Building
420 Delaware Street S.E.
MMC 820
Minneapolis, MN 55455

Office: 612-626-5654
Fax: 612-626-6061
E-mail: irb@umn.edu or ibc@umn.edu
Website: http://research.umn.edu/subjects/

09/17/2010
Aaron R Folsom
Epidemiology
Room 300 WBOB
1300 S 2nd St
Minneapolis, MN 55454
RE: "Atherosclerosis Risk in Communities Study"
"Atherosclerosis Risk in Communities (ARIC) Study"
"Atherosclerosis Risk in Communities (ARIC) Study--Field Center"
"Parkinson's disease case validation in the ARIC Study"
IRB Code Number: **8412M01053**
Dear Dr. Folsom
The Institutional Review Board (IRB) reviewed the referenced proposed study and granted PROVISIONAL APPROVAL because the plans as described meet the requirements found at 45CFR46.118. This provisional approval is granted with the understanding that the final protocol and plan will be submitted to the IRB for review prior to implementation.
The IRB reminds the researcher that final approval for this change in protocol has NOT been granted for this study. Rather, provisional approval has been granted since the submitted proposal is strictly planning purposes only. At this time human subjects may not be involved in this new proposal until the proposed project has been reviewed and approved by the University of Minnesota IRB. WHEN RESEARCH DETAILS ARE FINALIZED DEVELOP AND SUBMIT A REVISED CHANGE IN PROTOCOL FOR IRB REVIEW.
We cannot record approval for this change in protocol and the study may not be initiated until the details of the study have been returned to the IRB and reviewed and approved. This provisional approval is valid for six months. If the study has not been reviewed at the end of six months provisional approval for this code number will lapse, the study will be filed inactive and a new application required for further consideration.

If you have questions, please call 612-626-5654.
Sincerely,
Andrew Allen
Research Compliance Supervisor
CC: Alvaro Alonso, Ellen Demerath, Charlotte Flipp, Rachel Huxley, Pamela Lutsey, James Pankow, Lyn Steffen, Weihong Tang