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
Federalwide Assurance (FWA) #4801

**To**: David Couper
Biostatistics

**From**: Non-Biomedical IRB

**Approval Date**: 7/18/2013
**Expiration Date of Approval:** 7/17/2014

**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) Analysis

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

**Study Description:**

The Collaborative Studies Coordinating Center (CSCC) provides support with preparation of datasets, conducting analysis, and submitting mauscripts for the Atherosclerosis Risk in Communities (ARIC) study. ARIC is a multicenter study involving ARIC field centers, where all participant contact is conducted with IRB approval through collaborating institutions.

**Submission Description:**

The following personnel have been added to the study:

Silvana Lawvere, Eunsil Yim, Sheila Burgard and Allison McGee

The following personnel have been removed from the study:

Carter Church, Ashley Buchanan, Viet Nguyen, Gary Wolgast, and Lie Liu

**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.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. 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 http://irbis.unc.edu.

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
Nancy Cohn, Biostatistics
Kimberly Ring, Biostatistics
Silvana Lawvere, Biostatistics

JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

FWA #00000287

**Institutional Review Board Office**

615 N. Wolfe Street / Suite E1100
Baltimore, Maryland 21205
Office Phone: (410) 955-3193
Toll Free: 1-888-262-3242
Fax Number: (410) 502-0584
E-mail Address: irboffice@jhsph.edu
Website: www.jhsph.edu/irb

# CONTINUING REVIEW APPROVAL NOTICE

**Date**: January 10, 2013

**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: December 19, 2013**

The JHSPH IRB-X reviewed and approved the Progress Report submitted for the above referenced study at its meeting on **December 20, 2012**. Approval of the study is valid for the period of **December 20, 2012** to **December 19, 2013**.

**This approval is inclusive of all previously approved documents. If you are actively enrolling, or if participants are in follow-up, you may only use previously approved consent forms and other study documents.**

| | | | |
|---|---|---|---|
| **Single Reviewer** ☐ **Convened** ☒<br><br>DHHS 46.110 . . ☐ DHHS..... ☒<br>FDA 56.110 . . . ☐ FDA..... ☐<br><br>Category: 5 & 7<br><br>**GWAS** ..... ☐ | **Consent/Parental Permission Required From:**<br>Adult Participant ..... ☒<br>LAR ..... ☐<br>One Parent ..... ☐<br>Two Parents..... ☐<br>Legal Guardian ..... ☐<br>(Foster Care Children) | **Form of Consent/Permission:**<br>Written Consent..... ☒<br>Waiver of Signature..... ☒<br>(Oral Script)<br>Waiver of Informed Consent.... ☒<br>HIPAA Authorization..... ☐<br>HIPAA Waiver..... ☐<br>No Longer Enrolling..... ☐ | **Study Site(s):**<br><br>U.S. ☒ International ☐<br><br>**List Country(ies):** |
| **Vulnerable Populations:**<br><br>Children ..... ☐<br>Foster Care Children ..... ☐<br><br>**DHHS** **FDA**<br>46.404 . . . . ☐ 50.51 ..... ☐<br>46.405. . . . ☐ 50.52 ..... ☐<br>46.406 . . . . ☐ 50.53 ..... ☐ | **Assent Required From:**<br>No children (waived) . ... ☐<br>Children aged:_____ ☐<br><br>**Form of Assent:**<br>Written ..... ☐<br>Oral..... ☐<br>Assent Statement in Parent Permission..... ☐ | **Pregnant Women/Fetuses**<br>46.204 ..... ☐<br><br>**Neonates**<br>46.205 ..... ☐<br><br>**Prisoners**<br>46.305 ..... ☐<br>46.306 ..... ☐<br>Epidemiological Research.... ☐ | **Sample Size:**<br>(screened plus enrolled)<br><br>4,020<br>**Final Enrollment=**<br><br>**Secondary Data Analysis**:<br>(# specimens/participants)<br>50,000 |

And is inclusive of the following documentation:

**Informant Interview for Surveillance-Introductory Statement (12-20-12)**

**Annual Follow-Up Form (Version #1.0, 4-20-11)**

**Heart Failure Survey (Version #1.0, 5-2-11)**

**First Letter to Participant to Request Medical Records Release (12-20-12)**

**Second Letter to Participant to Request Medical Records Release (12-20-12)**

**Letter to Legal Representative to Request Medical Records Release (12-20-12)**

**First Letter to Informant to Request Interview (12-20-12)**

**Second Letter to Informant to Request Interview (12-20-12)**

**Thank You Letter/Request for Medical Records Release to Informant (12-20-12)**

**Letter to Vital Statistics to Request Death Certificate (12-20-12)**

**Letter to Vital Statistics to Request Death Certificate (12-20-12)**

**First Letter to Request Medical Records at Hospital (12-20-12)**

**Second Letter to Request Medical Records at Hospital (12-20-12)**

**First Letter to Request Medical Records at Hospital with Waiver of Authorization (12-20-12)**

**Second Letter to Request Medical Records at Hospital with Waiver of Authorization (12-20-12)**

**Reply Letter from Informant (12-20-12)**

**Letter to Power of Attorney to Request Copy of Power of Attorney Form (12-20-12)**

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 JHSPH IRB approval stamp may be presented to participants, unless otherwise approved by the IRB. 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 six weeks prior to the study expiration date of December 19, 2013**. 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.

6) If your research involves international travel, please don't forget to register with the International Travel Registry https://apps4.jhsph.edu/ITR/Default.aspx so that the School may locate you in the event of an emergency.

EAS/sro

# UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

2500 North State Street
**Jackson, Mississippi 39216-4505**

**Institutional Review Board**
Telephone (601) 984-2815
Facsimile (601) 984-2961

**DHHS FWA #00003630**
IORG #0000043
IRB 1 Registration #00000061
IRB 2 Registration #00005033

## Approval Notice
## Continuing Review

10/23/2013

Thomas Mosley, PhD
Medicine - Division of Geriatrics
University of Mississippi Medical Center
2500 North State Street
Jackson, MS 392164505

RE: IRB File #1985-0122
Atherosclerosis Risk in Communities (ARIC) Study

Your Continuing Review was reviewed and approved by the Convened Review process on 10/22/2013. You may continue this research.

Please note the following information about your approved research protocol:

| | |
|---|---|
| Protocol Approval Period: | 10/22/2013 - 10/21/2014 |
| Sponsor: | National Heart, Lung, and Blood Institute (NHLBI) |
| Approved Enrollment #: | 100000 |
| Participant Population: | Adults - Healthy |
| Performance Sites: | UMMC |

Documents / Materials:

| Type | Description | Version # | Date |
|---|---|---|---|
| Recruitment Letters | 90337-ARIC Recruitment Letter.pdf | 1 | 10/03/2011 |
| Other Consent/Assent Document | Home Visit Consent 05 20 11 Changes Cleared.pdf | 1 | 10/29/2012 |
| Other Consent/Assent Document | 90332-ARIC Informant Consent 03 08 11.pdf | 1 | 10/29/2012 |
| Consent Document | Clinic Visit Consent 05 20 11 Changes Cleared.pdf | 1 | 11/13/2012 |
| Recruitment Letters | ARIC Participant Recruitment Letter 19 Feb 2013 | 1 | 02/19/2013 |
| Recruitment Letters | ARIC Proxy Recruitment Letter 19 Feb 2013 | 1 | 02/19/2013 |

| | | | |
|---|---|---|---|
| Recruitment Letters | ARIC Proxy Letter 2nd Mailing | 1 | 06/10/2013 |
| Recruitment Letters | ARIC Proxy Letter Other Field Center | 1 | 06/10/2013 |
| Recruitment Letters | ARIC Participant Letter Other Field Center | 1 | 06/10/2013 |
| Recruitment Letters | Participant Recruitment Letter 2nd Mailing | 1 | 06/10/2013 |
| Recruitment Letters | MRI Recruitment Letter | 1 | 09/10/2013 |
| Related Publication | 1.pdf | 1 | 10/08/2013 |
| Related Publication | 2.pdf | 1 | 10/08/2013 |
| Related Publication | 3.pdf | 1 | 10/08/2013 |
| Related Publication | 4.pdf | 1 | 10/08/2013 |

Review History:

| Date | Type | Decision |
|---|---|---|
| 10/22/2013 | Convened Review | Approved |

Please remember to:

- Use the IRB file number (1985-0122) on all documents or correspondence with the IRB concerning your research protocol.

- Review and comply with all requirements on the enclosure, UMMC Investigator Responsibilities, Protection of Human Research Participants.

The IRB has the prerogative and authority to ask additional questions, request further information, require additional revisions, and monitor the conduct of your research and the consent process.

Please note, if this study involves an intervention (whether or not it involves a drug or device) you (or the "responsible party") must register the study before enrollment begins and report results within 12 months of study closure through Clinicaltrials.gov http://www.clinicaltrials.gov/. Penalties for responsible parties who fail to register applicable clinical studies are significant and include civil monetary penalties and, for federally-funded studies, withholding or recovery of grant funds. For additional information please go to http://irb.umc.edu/GuidanceInfo/ClinTrialRegistry.htm.

We wish you the best as you conduct your research. If you have questions or need additional information, please contact the Human Research Office at (601) 984-2815.

IRB 2

Enclosure(s): (1) Investigator Responsibilities, Protection of Human Research Participants

# UMMC Investigator Responsibilities
# Protection of Human Research Participants

The IRB reviews research to ensure that the federal regulations for protecting human research participants outlined in UMMC policy, the Department of Health and Human Services (DHHS) regulations (45 CFR 46) and the Food and Drug Administration (FDA) regulations (21 CFR Parts 50 & 56), as well as other requirements, are met. The University of Mississippi Medical Center's Federalwide Assurance (FWA), FWA# 00003630, awarded by the Office for Human Research Protections (OHRP) at DHHS, is a written pledge to follow federal guidelines for protecting human research participants in accordance with the principles of the Belmont Report. **All investigators must read both the Belmont Report and the UMMC FWA to understand their responsibilities in conducting research involving human participants**. Both documents are available on the Human Research Office webpage, http://irb.umc.edu/ , and in hard copy by request from the Human Research Office. Some of the responsibilities investigators have when conducting research involving human participants are listed below.

1. Conducting the Research: You are responsible for making sure that the research is conducted according to the IRB approved research protocol. **You are also responsible for the actions of the study's co-investigators and research staff**.

2. Participant Enrollment: You may not recruit or enroll participants prior to the IRB approval date or after the expiration date of IRB approval. All recruitment materials for any form of distribution or media use must be approved by the IRB prior to their use. If you need to recruit more participants than was noted in your IRB approval letter, you must submit an amendment requesting an increase in the number of participants.

3. Informed Consent: Informed consent is a process that begins with the initial contact and ends at some point after the study is complete. You are responsible for the conduct of the consent process, ensuring that effective informed consent is obtained and documented using **only** the IRB-approved and stamped consent document(s), and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Whoever is presenting the consent document to the potential participant and conducting the consent discussion must have all pertinent information at hand, be knowledgeable about the study and the disease or condition involved, if any, and have the ability and experience to answer questions regarding the study and any treatment involved. Please give all participants a signed copy of each consent or assent document they sign, and keep the originals in your secured research files for at least six (6) years. When appropriate, you should place a copy of the consent document in the participant's medical record.

4. Continuing Review: The IRB must review and approve all IRB-approved research protocols at intervals appropriate to the degree of risk, but not less than once per year. **There is no grace period.** Prior to the date on which IRB approval of the research expires, the IRB will send you three reminders to submit a Continuing Review, 90, 60 and 30 days prior to expiration. Although reminders are sent, **it is ultimately your responsibility to submit the renewal in**

**a timely fashion to ensure that a lapse in IRB approval does not occur.** If IRB approval of your research lapses, you must stop new participant enrollment, and contact the IRB immediately.

5. Amendments and Revisions: If you wish to amend or change any aspect of your research, including research design, interventions or procedures, number of participants, participant population, consent document, instruments, surveys or recruitment and retention material, you must submit the amendment or revisions to the IRB for review with a Request for Change. You **may not initiate** any amendments or changes to your research without first obtaining IRB review and written approval. The **only exception** is when the change is necessary to eliminate apparent immediate hazard to participants. In that case the IRB should be immediately informed of this necessity, but the change may be implemented before obtaining IRB approval.

6. Unanticipated Events: All adverse events that are unanticipated **(unanticipated means that the event is serious,unexpected, related or possibly related to participation in the study and places participants at greater risk of harm than previously recognized)** and serious protocol deviations, must be reported to the IRB **within ten (10) business days** of discovery. The only exception to this policy is death - **the death of a UMMC research participant must be reported within 48 hours of discovery.** Reportable events should be submitted to the IRB with the Adverse Event/Unanticipated Problem Report form.

   Events that do not meet the definition of an unanticipated problem involving risk to participants or others, including research related injury occurring at a UMMC performance site or to a UMMC study participant, participant complaints, problems, minor protocol deviations and non-compliance with the IRB's requirements for protecting human research participants should be reported as follows: Minor deviations and problems should be submitted at the time of continuing review, as instructed on the form. All other events should be reported in writing via letter or email to the IRB with sufficient detail to allow the reviewer to understand the problem and any actions taken to prevent it from happening again.

7. Research Record Keeping: At a minimum, you must keep the following research related records in a secure location for at least six years: the IRB approved research protocol and all amendments; all versions of the investigator's brochure; all informed consent documents; all recruiting materials; all renewal applications; all adverse or unanticipated event reports; all correspondence to and from the IRB; and all raw data.

8. Reports to FDA and Sponsor: When you submit the required annual report to the FDA or you submit required reports to your sponsor, you **must** provide a copy of that report to the IRB. You may submit the report with your IRB continuing review application.

9. Provision of Emergency Medical Care: When a physician provides emergency medical care to a participant without prior IRB review and approval, to the extent permitted by law, such activities will not be recognized as research and the data cannot be used in support of the research.

10. Final Reports: When you have completed the study, (no further participant enrollment, interactions, interventions or data analysis) or stopped work on it, you must submit a Final Report to the IRB using the Final Report form.

11. On-Site Evaluations, FDA Inspections, or Audits: If you are notified that your research will be reviewed or audited by the FDA, OHRP, the sponsor, any other external agency, or any internal group, you **must** inform the IRB immediately and submit all audit reports received as a result of the audit to the IRB.

*If you have questions or need assistance, please contact the Human Research Office at 601 984-2815.*

**To**: Gerardo Heiss
Epidemiology

**From**: Non-Biomedical IRB

**Approval Date**: 10/15/2013
**Expiration Date of Approval:** 10/14/2014
**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

This submission has been approved by the 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.

The cohort inducted by the Forsyth Co. Field Center during 1987-89 and followed since then numbers 4035.

**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.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. 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 http://irbis.unc.edu.

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.

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

WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD

**MEMORANDUM**

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To: Lynne Wagenknecht, Dr.P.H.
Public Health Sciences

From: Assistant Director, Institutional Review Board

Date: 11/18/2013

Subject: Human Protocol: BG86-0155
Atherosclerosis Risk in Communities
Amendment 26 for IRB Study #BG86-0155 (Personnel Change Request)

Study Documents:
Protocol Version: ARIC Protocol revised 8-5-2013.docx, ARIC Surveillance Coronary Heart Disease Protocol update, ARIC Surveillance Heart Failure Protocol update, AVID PROTOCOL AV-45-A14 1 Amendment 3.pdf, AVID PROTOCOL LIST OF CHANGES Amendment 3.pdf, Study Protocol for ARIC Holter, WFU ARIC PET Protocol Mar 2013.docx; Informed Consent Version: Clinic Visit Consent May 2011.docx (approved), Holter Monitor Addendum Consent August 23. 2013.docx (approved), Home Visit Consent May 2011.docx (approved), Informant Consent April 2011.docx (approved), MRI Addendum Consent Jan 2013.docx (approved), PET Addendum Consent Jan 2013.docx (approved); Investigator's Brochure: AV-45 IB version 8 0 USPI Ref - FINAL approved with sig pdf.pdf; Advertisements: WFU ARIC PET Study Brochure Dec 2012.pdf; Other Documents: 6 item screener_1 11.doc, ARIC Forms.docx.doc, ARIC large scale genetic memo to IRB July 2012.docx, ARIC NCS Forms docx.doc.2.doc, Correspondence-Case Physician Letter, Correspondence-Informational Flyer, Correspondence-NOK Case Physician Letter , Correspondence-NOK Letter, Correspondence-NOK Refusal Script, Correspondence-Refusal Script, Cover Letter Explanation of Consent Forms for WFU IRB 12.23.10.docx, Data Collection Case Letter, Data Collection-NOK PHI Release, Data Collection-NOK Telephone Screener Script, Data Collection-PHI release, Data Collection-Physician Form, Data Collection-Telephone Screener Script, Dementia Ascertainment Scripts.pdf, Dementia Rating Interview-Deceased Participants_highlighted 7-22-13.pdf, Dementia Rating Interview-Living Participants_highlighted 7-22-13.pdf, Documentation of INFORMANT Consent.docx, Forsyth Co Participant Newsletter.pdf, Holter Recruitment Ltr., Holter telephone Questionnaire, Participant Results Letter - Depression.docx, Participant Results Letter - Echocardiogram.docx, Physician Results Letters - Echocardiography and AAA.docx, Prototype Recruitment Letter.docx

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:

Beverly Belle, Mary Brewer, Becky Clutts, Heather Duncan, Barabara Lasater, Robert Mortis, Susan Moxley, Holly Smith, Kathryn Stewart, Carol Thomas, and Pradeep Garg removed from the study team.

Lorrie Caldwell added to the study team.

Changed the study coordinator to a different project manager who is currently on the study and keeping the current study coordinator as a team member.

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.

Brian Moore

The IRB: Human Subjects Committee renewed its approval of the referenced study listed below:

*Study Number:* 8412M01053

*Principal Investigator:* Aaron Folsom

*Expiration Date:* 05/28/2014

*Approval Date:* 05/29/2013

*Title(s):*

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

Identifying Epidemiological Risk Factors for Abdominal Aortic Aneurysm

ARIC Neurocognitive Study (ARIC-NCS) IRB #1005M81992

Atherosclerosis Risk in Communities - Parkinson's Disease Olfactory Testing

Longitudinal Study of Predictors and Consequences of Chronic Kidney Disease

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This e-mail confirmation is your official University of Minnesota HRPP notification of continuing review approval. You will not receive a hard copy or letter. This secure electronic notification between password protected authentications has been deemed by the University of Minnesota to constitute a legal signature.

You may go to the View Completed section of http://eresearch.umn.edu/ to view or print your continuing review submission.

For grant certification purposes you will need this date and the Assurance of Compliance number, which is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Childrens Specialty Healthcare FWA00004003). Approval will expire one year from that date. You will receive a report form two months before the expiration date.

In the event that you submitted a consent document with the continuing review form, it has also been reviewed and approved. If you provided a summary of subjects' experience to include non-UPIRTSO events, these are hereby acknowledged.

As Principal Investigator of this project, you are required by federal regulations to inform the IRB of any proposed changes in your research that will affect human subjects. Changes should not be initiated until written IRB approval is received. Unanticipated problems and adverse events should be reported to the IRB as they occur. Results of inspections by any external regulatory agency (i.e. FDA) must be reported immediately to the IRB. Research projects are subject to continuing review.

If you have any questions, please call the IRB office at (612) 626-5654.

The IRB wishes you continuing success with your research.

To: Sally Stearns

Health Policy and Management

From: Non-Biomedical IRB

Approval Date: 10/30/2013

Expiration Date of Approval: 10/29/2014

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)

Submission Type: Renewal

Expedited Category: 7.Surveys/interviews/focus groups,5.Existing or non-research data

Study #: 10-2064

Study Title: Cardiovascular Outcomes Research Center for the Atherosclerosis in Communities (ARIC) Study

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

Study Description:

Purpose: This project (CORC) will examine the comparative effectiveness of treatments related to heart failure for participants in the Atherosclerosis Risk in Communities (ARIC) Study. This IRB application is ONLY for CORC activities, as the main ARIC Study has its own IRB approval (IRB #96-0484). Participants: The CORC will use secondary data for members of ARIC study cohort. Procedures (methods): The CORC will suggest additional questions to be included in ARIC study questionnaires (to be reviewed under the ARIC IRB) and will also use CMS Medicare data linked to ARIC data to examine the relationship between health service utilization and outcomes.

Submission Description:

The following personnel have been added to the study: Hadi Beyhaghi, Lei Zhou, Samuel Savitz. The following personnel have been removed from the study: Shrikant Bangdiwala, Michael Pignone.

Regulatory and other findings:

Please note that no human subjects may be involved in any project supported by this award until the project has been reviewed and approved by the IRB.

This research is for data analysis only.

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.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. 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 http://irbis.unc.edu.

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:

Carla Dupree, Medicine

Anna Kucharska-Newton, Epidemiology

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

PARTNERS HEALTHCARE
FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL AND MASSACHUSETTS GENERAL HOSPITAL

Partners Human Research Committee
116 Huntington Avenue, Suite 1002
Boston, MA 02116
Tel: (617) 424-4100
Fax: (617) 424-4199

# Continuing Review: Notification of IRB Approval/Activation
# Protocol #: 2005P000100/BWH

Date: September 11, 2013

To: Scott D Solomon, MD
BWH
Medicine / Cardiology

From: Partners Human Research Committee
116 Huntington Avenue, Suite 1002
Boston, MA 02116

| | |
|---|---|
| Title of Protocol: | Cardiac Imaging Lab (CIL) |
| Version Date: | 1/12/2005 |
| IRB Continuing Review #: | 9 |
| IRB Review Type: | Expedited |
| Risk: | Minimal Risk |
| Expedited Category/ies: | (5) |
| IRB Approval Date: | 9/11/2013 |
| Approval Activation Date: | 9/11/2013 |
| IRB Expiration Date: | 9/11/2014 |

This project has been reviewed by BWH IRB . During the review of this project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for obtaining and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

Please note that if an IRB member had a conflict of interest with regard to the review of this project, consistent with IRB policies and procedures, the member was required to leave the room during the discussion and vote on this project except to provide information requested by the IRB.

Approved for Ongoing Data Collection for Repository.

As Principal Investigator, you are responsible for ensuring that this project is conducted in compliance with all applicable federal, state and local laws and regulations, institutional policies, and requirements of the IRB, which include, but are not limited to, the following:

1. Submission of any and all proposed changes to this project (e.g., protocol, recruitment materials, consent form, status of the study, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB as an unanticipated

Partners Human Research Committee
116 Huntington Avenue, Suite 1002
Boston, MA 02116
Tel: (617) 424-4100
Fax: (617) 424-4199

problem.

2. Submission of continuing review submissions for re-approval of the project prior to expiration of IRB approval and a final continuing review submission when the project has been completed.
3. Submission of any and all unanticipated problems, including adverse event(s) in accordance with the IRB's policy on reporting unanticipated problems including adverse events.
4. Obtaining informed consent from subjects or their legally authorized representative prior to initiation of research procedures when and as required by the IRB and, when applicable, documenting informed consent using the current IRB approved consent form(s).
5. Informing all investigators and study staff listed on the project of changes and unanticipated problems, including adverse events, involving risks to subjects or others.
6. When investigator financial disclosure forms are required, submitting updated financial disclosure forms for yourself and for informing all site responsible investigators, co-investigators and any other members of the study staff identified by you as being responsible for the design, conduct, or reporting of this research study of their obligation to submit updated Investigator Financial Disclosure Forms for this protocol to the IRB if (a) they have acquired new financial interests related to the study and/or (b) any of their previously reported financial interests related to the study have changed.

**The IRB has the authority to terminate projects that are not in compliance with these requirements.**

Questions related to this project may be directed to Fausta M Figueroa, FFIGUEROA@PARTNERS.ORG, 617-424-4119.

CC: Chau Duong, BS, BWH - Medicine - Cardiology, Data Coordinator/Manager

October 10, 2013

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CHRISTIE MITCHELL BALLANTYNE
BAYLOR COLLEGE OF MEDICINE
MEDICINE: ATHERO & LIPO

H-7492 - ATHEROSCLEROSIS RISK IN COMMUNITIES (ARIC) STUDY - MORBIDITY/MORTALITY FOLLOW-UP - CENTRAL LIPID LABORATORY

APPROVAL VALID FROM 10/10/2013 TO 9/30/2014

Dear Dr. BALLANTYNE

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol named above was approved.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

GABRIEL HABIB, M.D.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals