



# APPROVAL NOTICE

OFFICE FOR PROTECTION OF RESEARCH SUBJECTS  
11000 Kinross Avenue, Suite 102  
169407  
www.oprs.ucla.edu

DATE: August 22, 2007

TO: Karol E. Watson, M.D.  
Principal Investigator

FROM: Lawrence E. Wolinsky, DMD, PhD  
Chair, Medical Institutional Review Board 1

RE: UCLA IRB #99-11-057-21  
**Approved by Full Committee Review**  
**(Approval Period from 08/22/2007 through 08/21/2008)**  
Multi-Ethnic Study of Atherosclerosis [MESA]

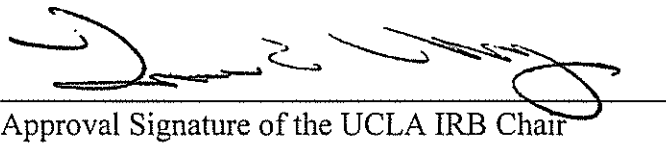
Please be notified that the UCLA Institutional Review Board (UCLA IRB) has approved the above referenced research project involving human subjects in research. The UCLA's Federalwide Assurance (FWA) with the Department of Health and Human Services, Office for Human Research Protections is FWA00004642.

**PLEASE COMPLY WITH THE FOLLOWING CODICIL(S) IMPOSED BY THE IRB:**

- 1. The UCLA IRB acknowledges receipt of the Approval Notice for the research from the University of Washington IRB (expiration date March 8, 2008.)**
- 2. Study closed to subject accrual. No new subjects may be contacted, recruited, or enrolled. Participants in this study may be contacted for follow-up. No consent form(s) are attached.**
- 3. The UCLA IRB acknowledges receipt of the IRB Authorization Agreement signed by Neil Rosenfield, C.O.O., Heart Check Los Angeles, on July 31, 2006. The UCLA IRB agrees to act as the designated IRB for Heart Check Los Angeles [FWA00010466].**
- 4. Appropriate translation(s) of the study materials must be forwarded to the M-IRB for review and approval prior to implementation.**
- 5. The M-IRB acknowledges receipt of the attached translated copies of the approved English version of the follow-up up phone call 8 script. The M-IRB accepts the translated copies of the currently approved English script based upon the Principal**

**Investigator's assurance that the documents are complete and the content is accurate. The attached copies have been stamped with the expiration date only and can be used with Spanish and Chinese speaking subjects when needed.**

- 6. The M-IRB acknowledges receipt of the attached translated copies of the approved English version of the follow-up up phone call 7 script. The M-IRB accepts the translated copies of the currently approved English script based upon the Principal Investigator's assurance that the documents are complete and the content is accurate. The attached copies have been stamped with the expiration date only and can be used with Spanish and Chinese speaking subjects when needed.**



A handwritten signature in black ink, appearing to be 'D. ...', is written over a horizontal line.

Approval Signature of the UCLA IRB Chair

#### **PRINCIPLES TO BE FOLLOWED BY PRINCIPAL INVESTIGATORS:**

As the Principal Investigator, you have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the UCLA IRB. You must abide by the following principles when conducting your research:

1. Perform the project by qualified personnel according to the approved protocol.
2. Do not implement changes in the approved protocol or consent form without prior UCLA IRB approval (except in a life-threatening emergency, if necessary to safeguard the well-being of human subjects.)
3. If written consent is required, obtain the legally effective written informed consent from human subjects or their legally responsible representative using only the currently approved UCLA-IRB stamped consent form.
4. Promptly report all undesirable and unintended, although not necessarily unexpected adverse reactions or events, that are the result of therapy or other intervention, within ten working days of occurrence. All fatal or life-threatening events must be reported to the UCLA IRB in writing within 2 working days after discovery.
5. In clinical medical research, any physician(s) caring for your research subjects must be fully aware of the protocol in which the subject is participating.
6. No subjects may be identified, contacted, recruited, or enrolled until the contract with the sponsor is finalized by the University.
7. Ensure that all individuals who will interact with subjects and/or have access to identifiable research data have completed the UCLA Protection of Human Research Subjects Certification.

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8. Ensure that all individuals who will access subjects' medical records have completed the UCLA HIPAA Research Training Certification.
9. If non-UCLA sites or personnel are involved, follow all study-specific requirements and consent processes approved by the UCLA IRB.

**FUNDING SOURCE(S):**

According to the information provided in your application, the funding source(s) for this research project may include the following: extramural.

PI of Contract/Grant: Karol Watson  
Funding Source: National Heart, Lung, and Blood Institute  
Contract/Grant No: N01-HC-95160  
Contract/Grant Title: Subclinical Cardiovascular Disease Study

PI of Contract/Grant: Adrian Casillas  
Funding Source: University of Washington  
Contract/Grant No: RD83169701  
Contract/Grant Title: Prospective Study Atherosclerosis, Clinical Cardiovascular Disease, and Long Term Exposure to Ambient Particulate Matter and Other Air Pollutants in a Multi-Ethnic Cohort

PI of Contract/Grant: Michael Criqui  
Funding Source: National Heart, Lung, and Blood Institute  
Contract/Grant No: R01HL72403  
Contract/Grant Title: Aortic Calcium Epidemiology and Progression

PI of Contract/Grant: Graham Barr  
Funding Source: National Heart, Lung, and Blood Institute  
Contract/Grant No: Pending  
Contract/Grant Title: Pulmonary Vascular Changes in Early COPD

PI of Contract/Grant: Karol Watson  
Funding Source: Centers for Disease Control and Prevention  
Contract/Grant No: 20063135  
Contract/Grant Title: MESA Occupational Coding Substudy-UCLA