UNIVERSITY of WASHINGTON
Human Subjects Division
Box 359470
Seattle, WA 98195-9470
Phone: 206-543-0098
Fax: 206-543-9218

Status Report Form

Version 1.99

For definitions, see Page 5. For instructions on how to complete this form, see Page 6.

For HSD Office Use Only

[ ] Master Copy	[ ] Approved	
[ ] IRB Working Copy	[ ] Conditional Approval	
[ ] Researcher Copy	[ ] Approval in Principle	
[ ] Full IRB Review Required	[ ] Denied	
[ ] Expedited Review	[ ] Withdrawn	

Date Received:

RECEIVED
Human Subjects Division
MAR 04 2010
UW

DORA CRR # 12

Approval period from:	MAR 09 2010	To:	MAR 08 2011
Date of IRB action:	MAR 09 2010	Printed name:	Blair E. Marrison
IRB Chair or Designee Signature:			
Notes:			

Research Study Information

Submission Reason	[X] RENEW IRB application	[ ] CLOSE IRB application	
Expiration date of IRB approval		**March 9, 2010**	
IRB Application #	**14122**	**IRB Committee**	**EG**
IRB Application Title	**Multi-Ethnic Study of Atherosclerosis**		

	Lead Researcher Name	**Contact Name**	
	Richard Kronmal		**Nick Yasinski**
Position and/or academic appointment	Professor	Position and/or academic appointment	Administrator
Department/Division	Biostatistics	Department/Division	Biostatistics
Phone #	206-685-7123	Phone #	206-897-1948
Fax #	206-616-4075	Fax #	206-616-4075
Box #	354922	Box #	354922
Street address, if applicable		Street address, if applicable	
Email	Kronmal@u	Email	Yasinski@u.

NOTE: Signature must be in ink.

Lead Researcher Signature: Richard A. Kronmal

Lead Researcher Printed Name: Richard A. Kronmal, PhD

Date Signed: 03/03/10

UNIVERSITY of WASHINGTON
Human Subjects Division
Box 359470
Seattle, WA 98195-9470
Phone: 206-543-0098
Fax: 206-543-9218

Status Report Form

Version 1.99

For definitions, see Page 5. For instructions on how to complete this form, see Page 6.

For HSD Office Use Only

[ ] Master Copy	[ ] Approved	
[ ] IRB Working Copy	[ ] Conditional Approval	
[ ] Researcher Copy	[ ] Approval in Principle	
[ ] Full IRB Review Required	[ ] Denied	
[ ] Expedited Review	[ ] Withdrawn	

Date Received:

RECEIVED
Human Subjects Division
MAR 04 2010
UW

DORA CRR # 12

Approval period from:	MAR 09 2010	To:	MAR 08 2011
Date of IRB action:	MAR 09 2010	Printed name:	Blair E. Marrison
IRB Chair or Designee Signature:			
Notes:			

Research Study Information

Submission Reason	[X] RENEW IRB application	[ ] CLOSE IRB application	
Expiration date of IRB approval		**March 9, 2010**	
IRB Application #	**14122**	**IRB Committee**	**EG**
IRB Application Title	**Multi-Ethnic Study of Atherosclerosis**		

	Lead Researcher Name	**Contact Name**	
	Richard Kronmal		**Nick Yasinski**
Position and/or academic appointment	Professor	Position and/or academic appointment	Administrator
Department/Division	Biostatistics	Department/Division	Biostatistics
Phone #	206-685-7123	Phone #	206-897-1948
Fax #	206-616-4075	Fax #	206-616-4075
Box #	354922	Box #	354922
Street address, if applicable		Street address, if applicable	
Email	Kronmal@u	Email	Yasinski@u.

NOTE: Signature must be in ink.

Lead Researcher Signature: Richard A. Kronmal

Lead Researcher Printed Name: Richard A. Kronmal, PhD

Date Signed: 03/03/10

UNIVERSITY of WASHINGTON
Human Subjects Division
Box 359470
Seattle, WA 98195-9470
Phone: 206-543-0098
Fax: 206-543-9218

Status Report Form

Version 1.99

For definitions, see Page 5. For instructions on how to complete this form, see Page 6.

For HSD Office Use Only				Date Received:
[ ] Master Copy	[ ] Approved			
[ ] IRB Working Copy	[ ] Conditional Approval			
[ ] Researcher Copy	[ ] Approval in Principle			
[ ] Full IRB Review Required	[ ] Denied			
[ ] Expedited Review	[ ] Withdrawn		DORA CRR #	

Approval period from:	To:
Date of IRB action:	Printed name:
IRB Chair or Designee Signature:	
Notes:	

Research Study Information			
Submission Reason	[X] RENEW IRB application	[ ] CLOSE IRB application	
Expiration date of IRB approval		March 9, 2010	
IRB Application #	14122	IRB Committee	EG
IRB Application Title	Multi-Ethnic Study of Atherosclerosis		
Lead Researcher Name	Richard Kronmal	Contact Name	Nick Yasinski
Position and/or academic appointment	Professor	Position and/or academic appointment	Administrator
Department/Division	Biostatistics	Department/Division	Biostatistics
Phone #	206-685-7123	Phone #	206-897-1948
Fax #	206-616-4075	Fax #	206-616-4075
Box #	354922	Box #	354922
Street address, if applicable		Street address, if applicable	
Email	Kronmal@u	Email	Yasinski@u.

NOTE: Signature must be in ink.

Lead Researcher Signature:

Lead Researcher Printed Name: Richard A. Kronmal, PhD

Date Signed:

Status Report Form

Version 1.99

A. Research Activity Status

1. RENEW IRB application because:
   [ ] New subject enrollment still in progress
   [X] Enrollment closed but subjects are still undergoing research procedures
   [ ] Enrollment closed, subjects have completed research procedures, but are still in follow-up
   [ ] Subject involvement completed, need approval for data analysis only
   [ ] Enrollment not yet begun
   [ ] Other, explain:

2. CLOSE IRB application because:
   [ ] Enrollment closed, research completed, & data analysis described in initial application completed
   [ ] Research never begun
   [ ] Other, explain:

B. Subject Numbers

Do NOT cut and paste from last year's Status Report.

	Normals (Controls)	Patients (Cases)
1. No. of subjects approved to complete the research		6,814
2. No. of subjects enrolled since initial IRB approval		6,814
3. No. of subjects enrolled since last IRB approval		0
4. No. of subjects undergoing research study intervention(s) or follow-up at this time		6,016
5. No. of additional subjects needed to complete research		0

- *DEFINITION: "Subjects" are people participating in your research, OR specimens from people that you use for your research, OR records from people that you use for research. Some research studies involve only specimens and/or records.*
- *NOTE: Add an explanation if you feel this table does not adequately address the way in which you have recorded the subject numbers in your research.*

C. Summaries

1. **Provide an abstract summarizing i) the purpose of this research activity, ii) the procedures subjects will undergo, and iii) a description of the subject populations.**

   i. The purpose of this study is unchanged since the last report. The Multi-Ethnic Study of Atherosclerosis (MESA) is an observational study of subclinical cardiovascular disease in a multi-ethnic population of men and women age 45-84 years. Five clinical exams are scheduled to take place, as well as 16 follow-up phone interviews to ascertain diagnoses and procedures (including records collection). We have completed Exam 4 and began Follow-up 10 in the fall of 2008. It is important to note that participants are not seen at, nor contacted by employees of, the University of Washington. The UW site functions as Data Management and Coordinating Center to the overall study. In August 2008, the NHLBI contract that funds MESA was extended to August 14, 2015, providing funding for the fifth exam (Exam 5) in 2010-11 and Follow-ups through 2014, as well as continuation of all data management, analytical, and administrative functions performed at the UW Coordinating Center.

   ii. Procedures

Exam 1 included:

- **Questionnaires**: standard questionnaires to collect information about demographics, socioeconomic and psychosocial status, medical and family history, medication use, dietary and alcohol intakes, smoking, and physical activity
- **Anthropometry**: height, weight, BMI
- **Blood pressure**: three readings using Dinamap
- **Ankel/Brachial blood pressure index**: systolic BP in both right and left brachial, posterior tibial, and dorsalis pedis arteries with Doppler instrument,
- **Electrocardiogram:** 12-lead ECG
- **Chest computed tomography scan**: electron beam or helical CT heart scans for coronary calcium deposits,
- **Carotid ultrasound**: ultrasound measurement of intima media thickness (IMT) of carotid arteries and plaque characterization
- **Aterial wave forms**: recorded by tonometry to measure compliance of arteries
- **Flow-dependent brachial artery vasodilation**: using B-mode ultrasound images
- **Cardiac magnetic resonance imaging**: to obtain measures of left ventricular mass, wall thickness, ejection fraction, cardiac output, aortic atherosclerosis, and aortic distensibility,
- **Blood draws/urinalysis**: to measure lipids, lipid oxidation markers, lipid metabolism parameters, cytokines, adhesion, molecules, nitric oxide, and Hemostasis/fibrinolysis markers. White cells to be cryopreserved for future generation of cell-lines and isolation of DNA needed for genetic studies.

Exam 2 included:

- Anthropometry
- Seated Blood pressure
- Phlebotomy
- Spot urine
- Carotid MRI, with and without contrast
- CT exam (subset of half of the cohort)
- Exam 1 questionnaires (except dietary intake, Health & Life questionnaire revised)
- Questionnaire on sleep history
- Questionnaire on family history

Procedures added to Exam 2 by ancillary studies include:

- Ultrasound IMT
- Retinal photography
- Ophthalmic autorefraction exam
- Questionnaire on vision history
- Questionnaire on socio-economic factors in neighborhoods

- Questionnaire on current and previous living addresses (to correlate pollution in these areas to cardiovascular disease)
- Aortic CT (subset of 850 participants)

Exam 3 included:

- Standard questionnaires to collect information about demographics, socioeconomic and psychosocial status, medical history, medication use, and alcohol intakes, smoking, and physical activity.
- Questionnaire on socio-economic factors in neighborhoods
- Anthropometry
- Seated Blood pressure
- Phlebotomy
- Spot urine
- CT exam
- Ultrasound IMT (only participants also selected for ancillary study)

Procedures added to Exam 3 by ancillary studies include:

- Questionnaire on current and previous living addresses (to correlate pollution in these areas to cardiovascular disease). Continued from Exam 2.
- Spirometry test (subset of 3800 participants)
- Maximal inspiratory pressure (subset of 3800 participants)
- Smoking history and habits questionnaire (subset of 3800 participants)
- Additional low-dose CT chest scan (subset of 50 participants)
- Additional blood draw of 20mL (subset of 1000 participants)
- Saliva sample (subset of 1000 participants)
- Additional urine sample (subset of 1000 participants)
- Additional blood draw of 10mL (subset of 1000 participants)
- Aortic CT (subset of 850 participants). Continued from Exam 2.

Exam 4 included:

- Questionnaires: standard questionnaires to collect information about demographics, socioeconomic and psychosocial status, medical history, medication use, alcohol intake, smoking, and sleep history (sleep history was part of Exam 2 but not Exam 3).
- Anthropometry: height, weight, BMI
- Seated blood pressure.
- Coronary CT scan (subset of 1400 participants)
- Phlebotomy

Procedures added to Exam 4 in the ancillary studies include:

- Blood draw of 20mL (subset of 1000 participants). Continued from Exam 3.
- Saliva sample (subset of 1000 participants). Continued from Exam 3.
- Additional urine sample (subset of 50 participants) . Continued from Exam 3.
- Spirometry test (subset of 3800 participants). Continued from Exam 3.
- Maximal inspiratory pressure (subset of 3800 participants). Continued from Exam 3.
- Smoking history and habits questionnaire (subset of 3800 participants). Continued from Exam 3.
- Aortic CT (subset of 2000 participants). Continued from Exam 3.
- MRI scan of heart (subset of 2300 participants). Renewal of ancillary study in Exam 2.
- MRI scan of heart (subset of 300 participants at Johns Hopkins site only).

Ongoing "Follow-up" interviews and record collection for "Events" Classification

- Phone interview with each participant (or proxy) every 9-12 months to ascertain health status and recent diagnoses and procedures, including deaths. We will begin Follow-up 9 in the spring of 2008.
- Collection of copies of records of participant hospital stays and physician visits.
- Select additional interviews and narratives from participants or proxies when necessary to supplement records.
- Review and classification of diagnoses and procedures by MESA Mortality and Morbidity Committee.

Exam 5

The components of MESA Exams 1-4, and the role of the MESA Coordinating Center at UW, have been outlined in MESA's past annual status reports and in modifications submitted to the UW HSD (MESA #14122 (formerly 98-6582-EA). The Exam 5 components and the Coordinating Center's role will vary little from the past. ***On 1/5/2010, HSD (Tanya Matthews) returned to the Coordinating Center the modification submitted regarding Exam 5 procedure data, noting that review by modification was not necessary since the activities were within the scope of the existing approval.***

Exam 5 will start in April 2010 and will be completed in a minimum of 18 months, or up to 24 months if supported by ancillary studies. All participants will undergo the following procedures. Data from these procedures will be sent to the MESA Coordinating Center at UW.

- **Questionnaires**: Standard questionnaires will be used to collect information about demographics, socioeconomic and psychosocial status, medical and family history, medication use, dietary and alcohol intakes, smoking, and physical activity.

- **Anthropometry:** Height and weight will be measured to the nearest 0.1 cm and 0.5 kg respectively. Body mass index (kg/m^2) will be used a measure of overall obesity. Girths (waist at the umbilicus and hips at the maximal circumference of buttocks) will be measured to the nearest 0.1 cm using a steel measuring tape (standard 4 oz. tension). Total body fat and fat free mass will be measured using a body composition scale.

- **Blood Pressure:** Resting blood pressure will be measured in the right arm after five minutes in the seated position. An automated oscillometric method (Dinamap) and appropriate cuff size will be used. Three readings will be taken; the second and third readings will be averaged to obtain the blood pressure levels used in analyses.

- **Oximetry:** Resting oxygen saturation will be measured in the seated position. A pulse oximeter with a finger probe will be used. Nail-polish will be removed, if necessary. Oximetry will be measured off supplement oxygen, if used. For participants who use supplement oxygen, supplement oxygen will be restarted immediately if they are short of breath or their oxygen saturation drops below 82%.

- **Cognitive Function:** Participants will be tested for cognitive function using the validated CASI, Digit Symbol Substitution Test, and Digit Span Test instruments. Testing will be administered and evaluated by certified interviewers and results will be entered into the data collection system.

- **Ankle/Brachial Blood Pressure Index:** Systolic blood pressure will be measured in both the right and left brachial, posterior tibial, and dorsalis pedis arteries with a Doppler instrument. The average of the measures will be used to calculate ankle arm ratio for each side, which will be used as measure of peripheral vascular disease.

- **Electrocardiogram (ECG):** A 12-lead ECG will be obtained and transmitted to the ECG Reading Center via telephone lines for Minnesota coding.

- **Fundus Photographs:** Retinal photographs of both eyes of the MESA participants will be obtained and graded at the Ocular Epidemiology Reading Center (OERC) at the University of Wisconsin-Madison for retinal microvascular characteristics.

- **Eye Refraction:** Objective refraction will be measured to look at the distribution of visual acuity and extent of visual impairment in the MESA

study population and to examine associations between visual impairment, retinal changes and markers of cardiovascular disease.

- **Cardiac Magnetic Resonance Imaging:** Cardiac MRI will use used to obtain measures of left ventricular mass, wall thickness, ejection fraction, cardiac output, and aortic atherosclerosis. For eligible participants, the protocol will include tagged MRI of the heart to measure regional myocardial strain. These participants will have creatinine measured in a clinical chemistry lab at the sites to ascertain eligibility for this procedure, and will then receive a gadolinium injection if eligible.

- **Laboratory Measurements**: These will include a lipid profile, glucose, creatinine, insulin, and HgA1C. White cells may also be cryo-preserved for future generation of cell-lines and isolation of DNA needed for genetic studies.

Participants who are enrolled in the MESA Air Pollution ancillary study subclinical cohort will undergo the following, also shown in Table 12:

- **Coronary Calcium Determination:** Coronary calcium will be determined with helical CT. An experienced and trained technologist will scan the heart in order to obtain an accurate and reproducible assessment of coronary calcium deposits. The technologist will transmit the scans over the Internet to the Reading Center.

- **Carotid Ultrasound:** High-resolution B-mode ultrasonography will be used for noninvasive measurement of intima-media thickness (IMT) of the carotid arteries and assessment of plaque.

Participants who are enrolled in the MESA Lung ancillary study and participants with lung disease and controls who are selected for the MESA COPD ancillary study will undergo the following, also shown in Table 12:

- **Spirometry:** Spirometry consists of participants inhaling and exhaling as hard and as fast as they can through the mouth. Participants will also be asked to breathe in and out slowly through the mouth. These actions will be repeated at least three times to ensure valid readings. A SensorMedics model 1022 rolling-barrel spirometer will be used for all readings, and the procedure will follow American Thoracic Society guidelines. A new mouthpiece will be used for each volunteer. Participants in this substudy will be asked to complete a brief questionnaire prior to spirometry to ensure that it is safe for them to perform spirometry and, if selected, receive albuterol.

- **Post-bronchodilator Spirometry:** The subset of participants who have airflow limitation on spirometry, defined as an FEV_1/FVC ratio < 0.70 or FEV1/FVC ratio < lower limit of normal, and controls for the MESA COPD

study will complete post-bronchodilator spirometry. After review of safety exclusions, two puffs of albuterol (total 180 mcg) will be administered via a spacer. Spirometry maneuvers will then be repeated 15 minutes to 2 hours later.

- **Emphysema Determination:** Pulmonary emphysema will be determined with CT scan. Experienced and trained technologists will scan the lungs of each consenting subject in order to obtain an accurate and reproducible assessment of pulmonary emphysema. The technologist will transmit the scans over the Internet to the Reading Center.

In addition, participants selected for the MESA COPD ancillary study will undergo the following, also shown in Table 12:

- **Six Minute Walk Test:** The Six Minute Walk Test consists of walk for 6 minutes on a level surface to see how far the participant can go. If the participant uses supplemental oxygen, it will be used during the test.

Other procedures added to Exam 5 in the ancillary studies include:

- **Arterial Pulse Wave:** The Arterial Pulse Wave form is measured by placement of a tonometer over the radial artery of the arm and is captured by the HDI/PulseWave CR2000 device in order to evaluate functional changes in the arterial system

Ongoing "Follow-up" interviews and record collection for "Events" classification

As outlined in MESA's annual status reports and in modifications submitted to the UW HSD, participants have been undergoing the following follow-up procedures and will continue to do so; the follow-up interviews conducted during and after the Exam 5 period may include new interview questions related to areas of research represented by the Exam 5 procedures. The Follow-up and Events process entails the following:

- Phone interview with each participant (or proxy) every 9-12 months to ascertain health status and recent diagnoses and procedures, including deaths.
- Collection of copies of records of participant hospital stays and physician visits.
- Select additional interviews and narratives from participants or proxies when necessary to supplement records.
- The MESA Coordinating Center at UW receives de-identified data and blinded medical records from Follow-ups and Events via encrypted email transmission from the field centers. Updates to personal identifiers are also sent via encrypted email when participants provide such information to field centers.

- The MESA Coordinating Center at UW distributes de-identified data and blinded copies of medical records to the members of the MESA Mortality and Morbidity Committee who record classification results for storage at the Coordinating Center and re-distribution in data sets.

Participating Centers Organization, Roles and Responsibilities, as of Exam 5

Center	Site	Principal Investigator
Project Office	National Heart, Lung, and Blood Institute (NIH)	Diane Bild, PhD, Project Officer
Coordinating Center	University of Washington	Richard Kronmal, PhD Robyn McClelland, PhD
Field Center	Columbia University	Steven Shea, MD
Field Center	Johns Hopkins University	Wendy Post, MD, MS
Field Center	Northwestern University	Kiang Liu, PhD
Field Center	University of Minnesota	Aaron Folsom, MD, MPH
Field Center	University of California at Los Angeles	Karol Watson, MD, PhD
Field Center	Wake Forest University	Gregory Burke, MD, MS
Central Laboratory	University of Vermont	Russell Tracy, PhD
Magnetic Resonance Imaging Reading Center	Johns Hopkins University	David Bluemke, MD, PhD Joao Lima, MD, PhD
ECG Reading Center	Wake Forest University	Elsayed Soliman, MD, MSc
Cardiac CT Reading Center*	University of California at Los Angeles (UCLA)	Matthew Budoff, MD, PhD
Ultrasound Reading Center*	University of Wisconsin	James Stein, MD
Lung CT Reading Center†	University of Iowa	Eric Hoffman, PhD
Spirometry Rdg Ctr†	Columbia University	R Graham Barr, MD DrPH John Hankinson, PhD Paul Enright, MD

**Supported by the MESA Air Pollution ancillary study.*
†Supported by the MESA Lung and MESA COPD ancillary studies.

iii. The cohort was recruited at 6 Field Centers (Wake Forest U., Columbia U., Johns Hopkins U., U. of Minnesota, Northwestern U., and UCLA) and the actively enrolled cohort is comprised of 39.2% Caucasian, 27.0% African American, 21.8% Hispanic, and 12.0% Chinese American.

2. **Provide a summary of the research progress to date.**
   - **Do NOT cut and paste from last year's status report.**
   - **If you have not yet enrolled subjects, please explain why.**
   - **Send one copy of each manuscript based on the data from this research, written since the last approval.**
   - **If you are closing your IRB application, explain what you will do with identifiable data and/or the link to the subjects' identities.**

Recruitment was completed by Sept. 2002. Exam 4 was completed by early 2007. Follow-up 10 is currently underway.

Manuscripts based on the data from this study that have been published to date: 282 (including articles in press), 92 of which have been published since the last HS Status Report. Citations and links for all publications can be found at http://www.mesa-nhlbi.org/Publications.aspx

3. **List all modifications you have made during the last period of approval by IRB approval date. Include a summary of each modification. If you have pending modifications, please list them as "pending."**

- DORA MOD #84, Approved 10/1/09, submitted 9/21/09: Ancillary Study (procedures and add funding), "Genome-wide and Linkage Study of Quantitative Emphysema Phenotypes" (Graham Barr, PI, Columbia University).
- DORA MOD #83, Approved 9/18/09, submitted 9/10/09: Ancillary Study (funding), "Vitamin K and the progression of coronary artery calcium" (Dr. Kyla Shea, PI, Wake Forest University).
- DORA MOD # 82, Approved 9/11/09, submitted 9/10/09: Ancillary Study (funding), "Ventricular Size and Valve Calcification Measures by CT" (Dr. Matthew Budoff, PI, UCLA).
- DORA MOD # 81, Approved 8/7/09, submitted 7/24/09: Ancillary Study (funding), "Fetuin-A: A Novel Biomarker of Vascular Calcification and Diabetes Mellitus" (Dr. Joachim Ix, PI, UC-San Diego)
- DORA MOD # 80, Approved 3/5/09, submitted 01/08/08: Participation in data sharing through the revised protocol for NHLBI's GWAS project titled "SNP (Single Nucleotide Polymorphism) Health Association Resource" (SHARe).

- DORA MOD # 87, Approved 12/29/09, submitted 12/2/09: Ancillary Study (procedures and funding), "Human Exome Sequencing in Six Well-Phenotyped NHLBI Cohorts" (Stephen Rich, PhD, PI, University of Virginia).

Modification forms submitted but returned by HSD because activities are allowable under existing approval without additional review:

- DORA MOD # 86, Activity already approved under existing approval, submitted 11/20/09: Ancillary Study (procedures), "PALM – Predictive Algorithm using Longitudinal data from MESA" (Ted McCluskey, MD/PhD, PI, Aviir, Inc.).
- DORA MOD # 85, Activity already approved under existing approval, submitted 11/20/09: Ancillary Study (funding), "Cost Implications of Atherosclerosis Imaging" (Leslie Shaw, PhD, PI, NHLBI).
- DORA MOD # 89, Activity already approved under existing approval, submitted 12/15/09: Ancillary Study (procedures), "PALM – Predictive Algorithm using Longitudinal data from MESA" (Ted McCluskey, MD/PhD, PI, Aviir, Inc.).
- DORA MOD # 88, Activity already approved under existing approval, submitted 12/11/09: MESA Exam 5 (procedures), "MESA," "MESA Air Pollution ancillary study," and "MESA Lung and MESA COPD ancillary studies" (multiple PIs at various participating universities).

4. **Describe the changes in the risks and/or benefits to subjects over the last period of approval. If there are no changes in the risks or benefits, provide an explanation of why not.**

None. Research goals remain the same. Risks remain minimal.

D. Adverse Events and Other Problems:

- *Provide this information about adverse events and/or other problems for the approval period since your last status report by answering the questions below.*
- *If there were no adverse events or other problems, write **"None."***
- *If you are reporting events in questions #1 and #2, and you have not submitted a Serious Adverse Event Report Form to HSD, complete the SAE Report form and submit it under separate cover.*
- *Use the definitions at the end of this form for guidance.*
- *NOTE: If you have an outside monitoring body (DSMB/DSMC), you are responsible for reporting the events to that body.*

1. **Number of adverse events that were related to research procedures, serious, and unexpected : 0**

2. **Number of adverse events that were related to research procedures and expected, but more severe or occurred at a greater frequency than expected : 0**

Complaints, if any, go directly to the clinics at the local institutions. As the off-site Coordinating Center, we have not been notified of any specific complaints relevant to our protocols or our management of data, including protected personal information.

3. **List the adverse events that were related, non-serious, but unexpected in the table below:**

Event type/description	Number of events	Number of subjects affected
N/A		

4. **Does the occurrence of any of the adverse events listed above suggest that the risk(s) to subjects are greater than described in your initial IRB application?** [ ] Yes [ ] No **[X] Not applicable**
   - If yes, provide an explanation:

5. **Number of other problems (unanticipated problems, protocol violations, protocol deviations) 0**

   If you answered 1 or more to the above question and have not already submitted the *Modification Form* with accompanying *Supplemental Form: Report of Other Problems* to report an Unanticipated Problem, complete *both* forms and submit separately from this status report.

6. **Number of complaints: 0**
   Describe each complaint, and explain how you handled each one.

   Complaints, if any, go directly to the clinics at the local institutions. As the off-site Coordinating Center, we have not been notified of any specific complaints relevant to our protocols or our management of data, including protected personal information.

7. **Number of subject withdrawals: 330**
   For each withdrawal, explain:
   - **why the subject chose to withdraw, or**
   - **why you withdrew the subject from the research, and/or**
   - **how the withdrawal affects your subject enrollment numbers for the past year as well as your overall enrollment totals.**

   Of the 6,814 participants originally enrolled, 468 have died of natural causes. (Some natural deaths are to be expected in a cohort of 45–84 years at enrollment.) Of the 6346 remaining participants, 330 have withdrawn since the beginning of the study, leaving 6016 actively enrolled. Of the 330 withdrawals, most were no longer interested in participating in the study, were too ill to continue, or gave no reason for withdrawing.

E. Conflict of Interest: Have there been any changes since your last approval in the financial conflict of interest for any members of the research team? [ ] Yes [X] No

- If yes, provide a copy of the letter you received from the Office of Research about how this conflict should be managed.

F. Department of Defense involvement: Does your research involve any component (people, office, institution, agency) of the Department of Defense (DoD), as defined below? [ ] Yes [X] No

- Funding from a component of DoD (example: Office of Naval Research)
- Cooperation, collaboration, or other type of agreement with a component of DoD
- Use of property, facilities, or assets of a component of DoD
- Intentional enrollment of subjects who are personnel (military and/or civilian) from a component of DoD

If YES: please confirm that the DoD requirement to obtain annual "refresher" education in human subjects research has been fulfilled for you and all co-investigators and staff who interact with subjects or identifiable data/specimens. ***Your IRB approval cannot be renewed until the IRB has verified the fulfillment of this requirement.***

[ ] Confirmed

G. Funding:

1. Please fill out the grant and contract information on the following page(s). Include all current and IRB-approved funding for the research, even if you think the IRB already has this information.
   NOTE:
   - *For Center or Program grants, list the Lead Researcher (Principal Investigator) and the Title for each separate project or core.*
   - *If there is new funding for the research, complete the (K-325) Modification Form on the HSD Forms Page and submit the form with complete copy of the grant proposal under separate cover.*
   - *Copy and paste the table below if you have multiple sources of funding.*

CURRENT FUNDING

Funding Type:
☐ Research Grant ☐ Fellowship ☐ Training Grant ☒ Contract ☐ Other, specify:

Funding Agency: **NIH/NHLBI**

Principal Investigator (on proposal): **Richard Kronmal, PhD**

Note: Competing renewal was successful. Modification No. 18 extended the contract to 8/14/15.

Agency Number (if known): **N01 HC95159**

Proposal Title: **Multi-Ethnic Study of Atherosclerosis (MESA)**
(Formerly: Subclinical Cardiovascular Disease Study, Coordinating Center)

Status: ☐ New ☐ Competing ☒ Non-Competing

Start Date: **01/15/99** End Date: **08/14/15** Funded? ☒ Yes ☐ No

Submitted through GCS? ☒ Yes ☐ No If NO, explain

Funding Type:
☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Status Report Form

Version 1.99

Funding Agency: **NIH**

Principal Investigator (on proposal): **Ana Diez-Roux, MD, PhD**
(Richard Kronmal, PhD – Subcontract to UW)

Agency Number (if known): **R01 HL071759**

Proposal Title: **Neighborhoods and Cardiovascular Risk in a Multi-Ethnic Cohort**

Status: ☐ New ☐ Competing ☒ Non-Competing

Start Date: **06/02/03** End Date: **05/31/14** Funded? ☒ Yes ☐ No

Submitted through GCS? ☒ Yes ☐ No If NO, explain

☒ American Recovery and Reinvestment Act (ARRA) - also known as the Stimulus

If you checked this box, please attach the ARRA cover sheet to your submission.

Funding Type:

☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Funding Agency: **NIH**

Principal Investigator (on proposal): **Matthew Budoff, MD (Ronit Katz, DPhil–Subcontract to UW)**

Agency Number (if known): **R01 HL071739**

Proposal Title: **Ventricular Size and Valve Calcification Measure by CT**

Status: ☐ New ☒ Competing ☐ Non-Competing

Start Date: **04/01/03** End Date: **07/31/11** Funded? ☒ Yes ☐ No

Submitted through GCS? ☒ Yes ☐ No If NO, explain

☒ American Recovery and Reinvestment Act (ARRA) - also known as the Stimulus

If you checked this box, please attach the ARRA cover sheet to your submission.

Funding Type:

☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Funding Agency: **NIH**

Principal Investigator (on proposal): **R. Graham Barr, MD (Karen Hinckley Stukovsky – Subcontract to UW)**

Agency Number (if known): **R01 HL077612**

Proposal Title: **Endothelial Dysfunction, Biomarkers, and Lung Function**

Status: ☐ New ☐ Competing Renewal ☒ Non-competing

Start Date: **08/02/04** End Date: **07/31/10** Funded? ☒ Yes ☐ No

Submitted through GCS? ☒ Yes ☐ No. If No, explain

Funding Type:

☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Principal Investigator (on grant proposal): **Joan Bathon, MD (Richard Kronmal, PhD--Subcontract to UW)**

Proposal Title: **Inflammation and Subclinical Cardiovascular Disease in Rheumatoid Arthritis**

Status Report Form

Version 1.99

Funding Agency: **NIH**

Agency Number (if known): **R01 AR050026**

Status: ☐ New ☐ Competing Renewal ☒ Non-competing Renewal

Start Date: **05/01/04** End Date: **04/30/10**

Submitted through GCS? ☒ Yes ☐ No. If No, explain

Funding Type:

☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Principal Investigator: **Ana Diez Roux, MD, PhD (Richard Kronmal, PhD–Subcontract to UW)**

Proposal Title: **Socioeconomic Patterning of Inflammation and Hemostasis**

Funding Agency: **NIH**

Agency Number (if known): **R01 HL076831**

Status : ☐ New ☒ Competing Renewal ☐ Non-competing Renewal

Start Date: **09/01/04** End Date: **06/30/10**

Submitted through GCS? ☒ Yes ☐ No. If No, explain

Funding Type:

☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Funding Agency: **NIH**

Principal Investigator (on proposal): **Jerry Rotter, MD (Richard Kronmal, PhD-Subcontract to UW)**
MESA Family Study, UW IRB approval 03-0353 E/G 03

Agency Number (if known): **R01 HL071205**

Proposal Title: **Multi-Ethnic Study of Atherosclerosis (MESA Family Study)**

Status: ☐ New ☐ Competing ☒ Non-Competing

Start Date: **08/01/03** End Date: **06/30/10** Funded? ☒ Yes ☐ No

Submitted through GCS? ☒ Yes ☐ No If NO, explain

Funding Type:

☒ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☐ Other, specify:

Funding Agency: **EPA**

Principal Investigator (on proposal): **Joel Kaufman, MD, MPH**
UW IRB approval 04-4050 E/G 03

Agency Number (if known): **RD83169701**

Proposal Title: **MESA Air Pollution**

Status: ☐ New ☐ Competing ☒ Non-Competing

Start Date: **08/01/04** End Date: **07/31/14** Funded? ☒ Yes ☐ No

Submitted through GCS? ☒ Yes ☐ No If NO, explain

Funding Type:

☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Principal Investigator: **David Herrington, MD, MHS (Richard Kronmal, PhD-PI of subcontract to UW)**

Status Report Form

Version 1.99

Proposal Title: **SNPs and Extent of Atherosclerosis Study (SEA Study)**

Funding Agency: **NIH** Agency Number (if known): **R01 HL080443**

Status: ☒ New Start Date: **03/15/06** End Date: **02/28/11**
☐ Competing Renewal
☐ Non-competing Renewal Submitted through GCS? ☒ Yes ☐ No. If No, explain

Funding Type:

☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Principal Investigator: **João AC Lima, MD (Richard Kronmal, PhD-PI of subcontract to UW)**

Proposal Title: **Regional Dysfunction by MRI in Incident Heart Failure**

Funding Agency: **NIH** Agency Number (if known): **R01 HL066075**

Status: ☒ New ☐ Competing Renewal ☐ Non-competing Renewal

Start Date: **3/15/06** End Date: **1/31/10**

Submitted through OSP? ☒ Yes ☐ No. If No, explain

Funding Type:

☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Principal Investigator (on grant proposal): **Matthew Allison, U of California, San Diego (Robyn McClelland, UW subcontract PI)**

Proposal Title: **Abdominal Body Composition, Inflammation and Cardiovascular Disease**

Funding Agency: **NHLBI** Agency Number (if known): **R01HL088451**

Status: ☒ New ☐ Competing Renewal ☐ Non-competing Renewal

Start Date: **09/01/07** End Date: **06/30/12** Submitted through OSP? ☒ Yes ☐ No. If No, explain

Funding Type:

☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Principal Investigator (on grant proposal): **Darcy Majka, Northwestern University (Robyn McClelland, UW subcontract PI)**

Proposal Title: **The Multi-Ethnic Study of Autoimmunity and Atherosclerosis**

Funding Agency: **NIH** Agency Number (if known): **K23 AI064397**

Status: ☒ New ☐ Competing Renewal ☐ Non-competing Renewal

Start Date: **9/1/07** End Date: **7/31/10** Submitted through OSP? ☒ Yes ☐ No. If No, explain

Funding Type:

Status Report Form

Version 1.99

☐ Research Grant ☐ Fellowship ☐ Training Grant ☒ Contract ☒ Other, specify: **Industry Sponsor**

Principal Investigator (on grant proposal): **Mary Cushman (U of Vermont) and Robyn McClelland (UW), Co-PIs**

Proposal Title: **Associations of Lipoprotein-Associated Phospholipase A2 Mass and Activity with Subclinical Cardiovascular Disease in the Multi-Ethnic Study of Atherosclerosis**

Funding Agency: **GlaxoSmithKline** Agency Number (if known):

Status: ☒ New ☐ Competing Renewal ☐ Non-competing Renewal

Start Date: **08/01/07** End Date: **07/31/10** Submitted through OSP? ☒ Yes ☐ No. If No, explain

Funding Type:

☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Principal Investigator (on grant proposal): **Joachim Ix, UC San Francisco (Ronit Katz, UW subcontract PI)**

Proposal Title: **Fetuin-A: A Novel Biomarker of Vascular Calcification and Diabetes Mellitus**

Funding Agency: **NIH**

Agency Number (if known): **R21 HL091217**

Status: ☒ New ☐ Competing Renewal ☐ Non-competing Renewal

Start Date: **05/01/09** End Date: **04/30/11** Submitted through OSP? ☒ Yes ☐ No. If No, explain

Funding Type:

☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Principal Investigator (on grant proposal): **Matthew Allison, U of California, San Diego (Robyn McClelland, UW subcontract PI)**

Proposal Title: **Subclinical Renal Artery Atherosclerosis, Kidney Function and Hypertension**

Funding Agency: **NIH**

Agency Number (if known): **R01 DK080015**

Status: ☒ New ☐ Competing Renewal ☐ Non-competing Renewal

Start Date: **09/25/09** End Date: **08/31/12** Submitted through OSP? ☒ Yes ☐ No. If No, explain

☒ American Recovery and Reinvestment Act (ARRA) - also known as the Stimulus

If you checked this box, please attach the ARRA cover sheet to your submission.

A. Type of proposal: ☐ Research ☐ Contract ☐ Fellowship ☐ Training grant ☒ Subcontract ☐ Other, specify

B. Name of principal investigator: **Leslee J. Shaw, PhD (Richard Kronmal PhD – UW Subcontract)**

C. Name of funding agency: **NIH**

Status Report Form
Version 1.99

D. Agency's number (if assigned): **RC1 HL100915**

E. Title of proposal: **Economic Consequences of Advanced Testing for Subclinical Cardiovascular Disease**

F. Inclusive dates: from **09/30/09** through **07/31/11**

G. Status: ☒ New ☐ Competing ☐ Non-competing renewal

H. Submitted through UW Office of Sponsored Programs? ☒ Yes ☐ No, (attach explanation)

☒ American Recovery and Reinvestment Act (ARRA) - also known as the Stimulus
If you checked this box, please attach the ARRA cover sheet to your submission.

A. Type of proposal: ☐ Research ☐ Contract ☐ Fellowship ☐ Training grant ☒ Subcontract ☐ Other, specify

B. Name of principal investigator: **Stephen Rich, PhD (Richard Kronmal PhD – UW Subcontract)**

C. Name of funding agency: **NIH**

D. Agency's number (if assigned): **RC2 HL103010**

E. Title of proposal: **Human Exome Sequencing in Six Well-Phenotyped NHLBI Cohorts**

F. Inclusive dates: from **09/30/09** through **06/30/11**

G. Status: ☒ New ☐ Competing ☐ Non-competing renewal

H. Submitted through UW Office of Sponsored Programs? ☒ Yes ☐ No, (attach explanation)

A. Type of proposal: ☐ Research ☐ Contract ☐ Fellowship ☐ Training grant ☒ Subcontract ☐ Other, specify

B. Name of principal investigator: **R. Graham Barr, MD**

C. Name of funding agency: **NIH**

D. Agency's number (if assigned): **R01 HL093081**

E. Title of proposal: **Pulmonary Vascular Changes in Early Chronic Obstructive Pulmonary Disease (COPD)**

F. Inclusive dates: from **08/28/08** through **07/31/12**

G. Status: ☒ New ☐ Competing ☐ Non-competing renewal

H. Submitted through UW Office of Sponsored Programs? ☒ Yes ☐ No, (attach explanation)

A. Type of proposal: ☐ Research ☐ Contract ☐ Fellowship ☐ Training grant ☒ Subcontract ☐ Other, specify

B. Name of principal investigator: **Kyla Shea, PhD**

C. Name of funding agency: **American Heart Association**

D. Agency's number (if assigned): **09CRP2070013**

Status Report Form
Version 1.99

E. Title of proposal: **Vitamin K and the Progression of Coronary Artery Calcification**

F. Inclusive dates: from **07/01/09** through **06/30/11**

G. Status: ☒ New ☐ Competing ☐ Non-competing renewal

H. Submitted through UW Office of Sponsored Programs? ☒ Yes ☐ No, (attach explanation)

CURRENTLY PENDING (Just in Time) PROPOSALS:

A. Type of proposal: ☐ Research ☐ Contract ☐ Fellowship ☐ Training grant ☒ Subcontract ☐ Other, specify

B. Name of principal investigator: **David Jacobs, PhD and Daniel Duprez, MD, PHD**

C. Name of funding agency: **NIH**

D. Agency's number (if assigned): **R01 HL098382**

E. Title of proposal: **Arterial Elasticity, Subclinical, and Clinical CVD in MESA**

F. Inclusive dates: from **07/01/10** through **06/30/14**

G. Status: ☒ New ☐ Competing ☐ Non-competing renewal

H. Submitted through UW Office of Sponsored Programs? ☒ Yes ☐ No, (attach explanation)

Funding Type: ☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **SUBCONTRACT**

Principal Investigator (on grant proposal): **R. Graham Barr, Columbia University (Martin Schmitz, UW subcontract PI)**

Proposal Title: **Subpopulations and Intermediate Outcome Measure in COPD Study (SPIROMICS)**

Funding Agency: **NIH** Agency Number (if known):

Status: ☒ New ☐ Competing Renewal ☐ Non-competing Renewal

Start Date: **7/31/2012** End Date: **7/30/2015** Submitted through OSP? ☒ Yes ☐ No. If No, explain

Funding Type: ☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **SUBCONTRACT**

Principal Investigator (on grant proposal): **Andrew Levey, Tufts-New England Medical Center (Norma Dermond, UW subcontract PI)**

Proposal Title: **Kidney Measurement and Estimation: Beyond Inulin and Creatinine**

Funding Agency: **NIH** Agency Number (if known):

Status: ☒ New ☐ Competing Renewal ☐ Non-competing Renewal

Start Date: **12/1/2008** End Date **11/30/2012** Submitted through OSP? ☒ Yes ☐ No. If No, explain

POSTPONED FUNDING

Funding Type: ☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **subcontr.**

Status Report Form

Version 1.99

Funding Type:
☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Funding Agency: **NIH**

Principal Investigator (on proposal): **Joseph Polak, MD, MPH (Richard Kronmal, PhD–Subcontract to UW)**

Agency Number (if known): **R01 HL069003**

Proposal Title: **Epidemiology of Carotid Intima-MedialThickness (IMT) in Atherosclerosis**

Status: ☐ New ☐ Competing ☒ Non-Competing Start Date: **06/15/03** End Date: **05/31/09** Funded? ☒ Yes ☐ No

Submitted through GCS? ☒ Yes ☐ No If NO, explain

Funding Type:
☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify:**Subcontract**

Principal Investigator (on grant proposal): **Russell Tracy, PhD (Richard Kronmal, PhD–Subcontract to UW)**

Proposal Title: **Epidemiology of Vascular Inflammation and Atherosclerosis**

Funding Agency: **NIH**

Agency Number (if known): **R01 HL077449**

Status: ☐ New ☐ Competing Renewal ☒ Non-competing Renewal Start Date: **07/01/04** End Date: **06/30/09 NCE**

Submitted through GCS? ☒ Yes ☐ No. If No, explain

Funding Type:
☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Funding Agency: **NIH**

Principal Investigator (on proposal): **Michael Criqui, MD (Richard Kronmal, PhD – Subcontract to UW**

Agency Number (if known): **R01 HK72403**

Proposal Title: **Aortic Calcium: Epidemiology and Progression**

Status: ☐ New ☐ Competing ☒ Non-Competing Start Date: **03/10/03** End Date: **02/28/09** Funded? ☒ Yes ☐ No

Submitted through GCS? ☒ Yes ☐ No If NO, explain

Funding Type: ☒ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☐ Other, specify:

Principal Investigator (on grant proposal): **Annette Fitzpatrick, PhD**

Proposal Title: **Use of Herbs and Dietary Supplements in Four Ethnicities**

Funding Agency: **NIH/NCCAM**

Agency Number (if known): **1 R21 AT002152**

Status: ☐ New ☐ Competing Renewal ☒ Non-competing Renewal Start Date: **04/15/04** End Date: **3/31/08 (No Cost Extension)**

Submitted through GCS? ☒ Yes ☐ No. If No, explain

Status Report Form
Version 1.99

PREVIOUSLY PENDING PROPOSALS THAT WERE NOT FUNDED

Funding Type: ☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **SUBCONTRACT**

Principal Investigator (on grant proposal): **Darcy Majka, Northwestern University (Robyn McClelland, UW subcontract PI)**

Proposal Title: **The Multi-Ethnic Study of Autoimmunity and Atherosclerosis**

Funding Agency: **American Heart Association** Agency Number (if known): **Grant-in-Aid**

Status: ☒ New ☐ Competing Renewal ☐ Non-competing Renewal

Start Date: **7/1/2007** End Date: **06/30/2010** Submitted through OSP? ☒ Yes ☐ No. If No, explain

---

Funding Type: ☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **SUBCONTRACT**

Principal Investigator (on grant proposal): **Inmaculada del Rincon, U of TX Health Science Ctr, San Antonio (Aruna Kamineni, UW subcontract PI)**

Proposal Title: **Effect of Chronic Inflammation on Atherosclerosis Outcomes in Rheumatoid Arthritis**

Funding Agency: **NHLBI** Agency Number (if known): **1R01HL085742-01A2**

Status: ☒ New ☐ Competing Renewal ☐ Non-competing Renewal

Start Date: **07/01/10** End Date: **06/30/12**

Submitted through OSP? ☒ Yes ☐ No. If No, explain

Period for entire grant is 07/01/07 – 06/30/12, but UW subcontract is only for FY04-05, which is 07/01/10 06/30/12

Funding Type:

☐ Research Grant ☐ Fellowship ☐ Training Grant ☐ Contract ☒ Other, specify: **Subcontract**

Principal Investigator: **Kathy Klos, U of Texas Health Science Center, Houston (Aruna Kamineni, UW subcontract PI)**

Proposal Title: **Oxidative Stress Genes and Atherosclerotic Complications of Hypertension**

Funding Agency: **NIH**

Agency Number (if known):

Status: ☒ New ☐ Competing Renewal ☐ Non-competing Renewal

Start Date: **07/01/10** End Date: **06/30/12** Submitted through OSP? ☒ Yes ☐ No. If No, explain

Period for entire grant is 07/01/07 – 06/30/12, but UW subcontract is only for FY04-05, which is 07/01/10 – 06/30/12

THE UNIVERSITY of WISCONSIN MADISON

Minimal Risk IRB
NOTICE OF ACTION
Approval
Date of Correspondence: 1/12/2010

Principal Investigator:	James H Stein, M.D. Mail Code #3248-Cardiovascular Medicine-Rm.G7/341 CSC 600 Highland Ave., Madison, WI 53792
Point of Contact:	Claudia E Korcarz Cardiovascular Medicine, H6/377 CSC, Mail Code 3248 600 Highland Ave., Madison, WI 53792
Protocol:	**M-2009-1385** "Prospective Study of Atherosclerosis, Clinical Cardiovascular Disease, and Long-term Exposure to Ambient Particulate Matter and Other Air Pollutants in a Multi-Ethnic Cohort (MESA Air)"
Review Period:	12 months
Approval Expires:	1/10/2011
IRB Staff Contact:	Staci T Lowe, 608-262-4501, slowe@wisc.edu

---

Your Initial Review Application, including the supporting materials you submitted with your application, was reviewed and approved by the full Minimal Risk IRB at its 1/11/2010 meeting. You may now begin your research. The review period and expiration date of your approval are listed above.

*****Please note: The protocol and model consent form currently under review by the University of Washington must be submitted to the MR IRB once they are approved. Please submit these documents using the *Provision of Supplemental Approvals* form, which can be found on the HS IRBs website. *****

Please be sure to do the following:

- Use your Minimal Risk IRB protocol number (listed above) on any documents or correspondence with us concerning your protocol.
- Keep a copy of this approval letter with your files.
- Comply with all requirements described in the **Investigator Responsibilities Related to the Protection of Human Subjects** attachment.

Sincerely,

Staci T Lowe
Staff Reviewer, Health Sciences IRB Office

Enclosure(s):
Investigator Responsibilities Related to the Protection of Human Subjects

WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Yongmei Liu, M.D., Ph.D.
PHS - Epidemiology

From: Chair, Institutional Review Board

Date: 3/17/2010

Subject: Expedited Review: IRB00010058
Epigenome-Wide Association Study of DNA Methylation and Atherosclerosis in the Multi-Ethnics Study of Atherosclerosis (MESA)

This research study qualifies for expedited review under the Federal Regulations [45CFR46.110]. These regulations allow an IRB to approve certain kinds of research involving no more than minimal risk to human subjects. The risks of harm anticipated in the proposed research are not greater than those ordinarily encountered by the general population in daily life or during the performance of routine physical, laboratory, or psychological exams or tests. [45CFR46.102(i)]. Upon review of the research, the IRB finds that this study meets the following expedited review category(s):

Category 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

HHS regulations [45CFR46.116(d)] allow an IRB to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or to waive the requirements to obtain informed consent. The IRB approves the waiver or alteration in the requirement for informed consent for this study.

HHS regulations [45CFR164.512(i)] allow an IRB to approve the alteration or waiver, in whole or in part, of the requirement for individual Authorization for the use or disclosure of protected health information. The IRB approves the waiver or alteration in the requirement for individual authorization because certain conditions have been met or because the requirement for authorization does not apply.

Medical Center Boulevard, Winston-Salem, NC 27157-1023 (336) 716-4542 / fax (336) 716-4480

IRB approval is for a period of 12 months from 3/16/2010**.** Please notify the Office of Research when the project is complete.

Thomas Pranikoff, M.D.

WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Gregory Burke, M.D.
Public Health Sciences

From: Chair, IRB # 1
Institutional Review Board

Date: 2/3/2010

Subject: Human Protocol: BG00-035
Multi-Ethnic Study of Atherosclerosis
Amendment 18 for IRB Study #BG00-035

Study Documents:
Protocol Version: Cardiac Atlas Project , CT MOP exam 5, CueCards.pdf, F8-Air Questionniare - All.pdf, F8-Medical Conditions MESA 12102007.pdf, Follow Up 10 Air Questionnaire, revised, 06152009, Follow Up 10 General Health, revised, 06152009, Follow Up 9 Air Questionnaire - Revised Version, Follow Up 9 General Health - Revised Version, Follow Up 9 General Health Death - Revised Version, FU10 English 02092009.pdf, FU8 MESA Form Packet_03282007.pdf, FU9Forms_02072008.pdf, MESA Exam 5 Protocol, MESA RNA Phlebotomy Processing Protocol v.4.9.07.doc, MESA RNA phone script 4-5-07.doc, MESAGene.exp.prot.version 4.9.07, mesaprot000225-updated.doc; Informed Consent Version: MESA Exam 5 Consent Form (approved), WFU MARRS Consent Version 4.9.07.doc (approved), WFU MESA consent, Exam 4, 021406, eirb.doc (approved); Advertisements: Information Session Invitation, mesabrochure.pdf, recruit lettergbversion.doc, Save the Date Postcard

The Institutional Review Board voted approval of the amendments listed below at its meeting of 2/2/2010. This action of the full Board does not extend the term of approval for this protocol.

The amendment includes the following:

- This amendment covers the changes to the GCRC plan, the study protocol and the consent that are necessary in order to conduct the upcoming MESA fifth exam, which is scheduled to begin in April.

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.

Richard Weinberg, M.D.

Medical Center Boulevard, Winston-Salem, NC 27157-1023 (336) 716-4542 / fax (336) 716-4480

WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Gregory Burke, M.D.
Public Health Sciences

From: Chair, IRB # 2
Institutional Review Board

Date: 3/10/2010

Subject: Human Protocol: BG00-035
Multi-Ethnic Study of Atherosclerosis
Amendment 20 for IRB Study #BG00-035

Study Documents:
Protocol Version: Cardiac Atlas Project , CT MOP exam 5, CueCards.pdf, Exam 5 Forms, F8-Air Questionniare - All.pdf, F8-Medical Conditions MESA 12102007.pdf, Follow Up 10 Air Questionnaire, revised, 06152009, Follow Up 10 General Health, revised, 06152009, Follow Up 9 Air Questionnaire - Revised Version, Follow Up 9 General Health - Revised Version, Follow Up 9 General Health Death - Revised Version, FU10 English 02092009.pdf, FU11 Forms Packet, FU8 MESA Form Packet_03282007.pdf, FU9Forms_02072008.pdf, MESA Exam 5 Protocol, MESA RNA Phlebotomy Processing Protocol v.4.9.07.doc, MESA RNA phone script 4-5-07.doc, MESAGene.exp.prot.version 4.9.07, mesaprot000225-updated.doc; Informed Consent Version: MESA Exam 5 Consent Form 03052010 (approved), MESA Exam 5 Pilot Study Consent Form 03052010 (approved), WFU MARRS Consent Version 4.9.07.doc (approved), WFU MESA consent, Exam 4, 021406, eirb.doc (approved); Advertisements: Information Session Invitation, mesabrochure.pdf, recruit lettergbversion.doc, Save the Date Postcard

The Institutional Review Board voted approval of the amendments listed below at its meeting of 3/9/2010. This action of the full Board does not extend the term of approval for this protocol.

The amendment includes the following:

- A pilot study of all of the previously approved Exam 5 interviews, procedures and scans is scheduled to be conducted in March 2010. Eight to ten age-appropriate, healthy volunteers will be examined. In preparation for this pilot study a consent form for the pilot volunteers and a modified protocol are being submitted for approval.
- The forms to be used during the pilot study, Exam 5 and Follow Up 11 are also being submitted for approval.
- The main study consent form has been modified to include a statement about audiorecording of participant interviews.

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.

Gregory Hawkins, Ph.D.

Columbia University Medical Center

Institutional Review Board

Protocol Number: #IRB-AAAA7791
Principal Investigator: Steven J Shea
Originating Department: MEDICINE - 527
IRB Approval Date: 12/09/2009
Expiration Date: 12/08/2010
Title: Multi-Ethnic Study of Atherosclerosis

This is to certify that the above noted protocol has been approved by the Columbia University Medical Center IRB and is valid through 12/08/2010.

Columbia University IRB
Approved for
use until: **12/08/2010**

Office of Human Subjects Research
Institutional Review Boards

1620 McElderry Street, Reed Hall, Suite B-130
Baltimore, Maryland 21205-1911
410-955-3008
410-955-4367 Fax
e-mail: jhmirb@jhmi.edu

Date: March 24, 2010

CHANGE IN RESEARCH APPROVAL

Review Type:	Convened
PI Name:	WENDY POST
Study #:	NA_00030361_AM00004951
Study Name:	Multi-Ethnic Study of Atherosclerosis (MESA)
Committee Chair:	RICHARD MOORE
Committee:	JHM-IRB 3

Date of approval: March 9, 2010

The JHM IRB approved the above-referenced Change In Research.

Approval Includes:

1. The addition of the following study team members: Diana Hakakin, Charles Simpson, Elena Blasco Colmenares, Darshan Dalal, Cheryl Dennison, Bennette Drummond Watts, Eliseo Guallar, Khurram Nasir, Ana Navas Acien, Laura Samuel, Gordon Tomaselli, Monica Vladut Talor, and Yiyi Zhang
2. MESA exam 5 protocol , consent form, and exam forms
3. A letter for participants

Study Team Members:
JOAN BATHON, ERIN MICHOS, HOCHANG LEE, CATHERINE CAMPBELL, DAN ARKING, CAROL CHRISTMAN, DARSHAN DALAL, Diana Hakakian, Theodore Wies, REBECCA GOTTESMAN, NARESH PUNJABI, ROGER BLUMENTHAL, Raimond Winslow, SUZANNE JAN DE BEUR, CHERYL DENNISON, BRAD ASTOR, BENNETTE DRUMMOND WATTS, Laura Samuel, PAMELA OUYANG, Yiyi Zhang, ANN MARTZ, LAURENCE MAGDER, KHURRAM NASIR, Monica Vladut Talor, Tammy Crunkleton, Sheila Odum, Albert Sharrett, BRUCE WASSERMAN, Catherine Morales, DHANANJAY VAIDYA, ANA NAVAS ACIEN, DANIEL JUDGE, Joao Lima, Manuel Franco, JON GILES, Youfa Wang, HARRY SILBER, GERALD BLOOMFIELD, GORDON TOMASELLI, Charles Simpson, ELISEO GUALLAR, ELENA BLASCO COLMENARES, ADRIAN DOBS, ANNABELLE RODRIGUEZ, ANTONIO PAZIN-FILHO, SONIA WATKINS, MEGAN COYLEWRIGHT, MOYSES SZKLO

JOHNS HOPKINS
MEDICINE

Office of Human Subjects Research
Institutional Review Boards

1620 McElderry Street, Reed Hall, Suite B-130
Baltimore, Maryland 21205-1911
410-955-3008
410-955-4367 Fax
e-mail: jhmirb@jhmi.edu

Date: November 24, 2009

NEW APPLICATION APPROVAL

Review Type:	Expedited
PI Name:	Joao Lima
Study #:	NA_00031350
Study Name:	Multi-Ethnic Study of Atherosclerosis (MESA): MRI Reading Center
Committee Chair:	LAURA ROCCO
Committee:	JHM-IRB X

Date of approval: November 21, 2009

Date of expiration: November 20, 2010

The JHM IRB approved the above-referenced New Application.

IRB approval includes the following:

A waiver of consent. The waiver was granted under 45 CFR 46 based on the following criteria: 1) the research involves no more than minimal risk to subjects; 2) the waiver will not adversely affect the rights and welfare of the subjects; 3) the research could not be practicably carried out without the waiver; and 4) in this case it is not appropriate to provide participants with additional pertinent information after participation.

Date of Approval and Expiration Date: The approval and expiration date for this research are listed above. If the approval lapses, the research must stop and you must submit a request to the IRB to determine whether it is in the best interests of individual participants to continue with treatment interventions.

Changes in Research: All proposed changes to the research must be submitted using an eIRB Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately, and promptly reported to the JHM IRB.

Continuing Review: Continuing Review Applications should be submitted at least 6 weeks prior to the study expiration date. Failure to allow sufficient time for review may result in a lapse of approval. If the Continuing Review Application is not submitted prior to the expiration date, your study will be terminated and a New Application must be submitted to reinitiate the research.

Unanticipated Problems: You must inform the IRB of any unanticipated problems involving risks to participants or others.

Study documents:

HIPAA Form 4:
HIPAA Form 4 - revised

Study Team Members:
Ellen Stengel, Chia-Ying Liu, Siamak Ardekani, JOHN ENG, ELZBIETA CHAMERA, Evrim Bengi Turkbey, MONDA SHEHATA, Cuilian Miao, Erin Ricketts, DAVID BLUEMKE, Raimond Winslow, Aditya Jain

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/

02/15/2010

Aaron R Folsom
Epidemiology
Room 300 WBOB
1300 S 2nd St
Minneapolis, MN 55454

RE: "Multi-Ethnic Study of Atherosclerosis (MESA)"
"Subclinical Cardiovascular Disease Study: Field Center"
"Prospective Study of Atherosclerosis, Clinical Cardiovascular Disease, and Long-Term Exposure to Ambient Particulate Matter and Other Air Pollutants in a Multi-Ethnic Cohort (MESA-Air)"
"Cardiopulmonary Structure and Function in the Multi-Ethnic Study of Atherosclerosis"
"Epigenomics of Human Health and Disease"
IRB Code Number: **9805M00034**

Dear Dr. Folsom:

The Institutional Review Board (IRB) has received your response to its stipulations of February 11, 2010. Since this information satisfies the requirement set by the IRB, final approval for the change in protocol dated November 23, 2009 is noted in our files.

The consent form for exam 5 is also approved.

For your records and for grant certification purposes, the approval date for the referenced project is November 18, 2009 and the Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003).

As Principal Investigator for this study, you are required by federal regulations to inform the IRB of any proposed changes to your research that will affect human subjects. Changes should be reviewed and approved before they are initiated. Unanticipated problems and adverse events should be reported to the IRB as they occur. Research projects are subject to continuing review and approval.

Upon receipt of this letter you may institute the changes. If you have any questions, please call the IRB office at 612-626-5654.

We have created a short survey that will only take a couple of minutes to complete. The questions are basic, but will give us guidance on what areas are showing improvement and what areas we need to focus on:

https://umsurvey.umn.edu/index.php?sid=36122&lang=um

Sincerely,

Andrew Allen
Research Compliance Supervisor
AA/ks

CC: Alvaro Alonso, Charlotte Flipp, David Jacobs Jr, Pamela Schreiner

Office for the Protection
of Research Subjects

Northwestern University
750 North Lake Shore Drive
Suite 700
Chicago, Illinois 60611

irb@northwestern.edu
Phone 312-503-9338
Fax 312-503-0555

NORTHWESTERN
UNIVERSITY

3/2/2010

Dr. Kiang Liu
Professor
Department of Preventive Medicine
Feinberg School of Medicine
680 N. Lake Shore Drive, Suite 1400
Chicago, IL 60611

kiangliu@northwestern.edu

IRB Project Number: STU00021057
Project Title: Multi-Ethnic Study of Atherosclerosis (MESA)
Project Expiration Date: 9/1/2010
Project Sites: Northwestern University

Sponsor Information (Grant #, if applicable):

[View] Environmental Protection Agency	RD 83169701
[View] National Institute of Health	R01 HL093081
[View] National Heart, Lung, and Blood Institute	R01 HL077612
[View] National Heart, Lung, and Blood Institute	N01-HC-95164

Submission Considered: REVISION **Submission Number:** Rev2_STU00021057
Submission Description: 1. Request to incorporate MESA Air and MESA Lung study under this project as the same consent form is used for MESA, MESA COPD, MESA Air and MESA Lung. The grants and contracts funding these studies have been added to the study.

2. Minor Changes to the MESA 5 consent form:
3. Submission of a consent form for pilot particiants.
4. Request for a Waiver of Documentation of Consent for the fasting and withholding of medications prior to the clinic visit. submission of a verbal consent scipt.
5. Submission of a Participant reminder letter, Clinic Exam result form, and Exit interview form
6. Addition of Shane Holmes as authorized personnel

Review Type: Expedited
Review Date (for Expedited review): 3/2/2010

Status: APPROVED

Dear Dr. Liu,
The IRB considered and approved your revision referenced above. The documents approved as part of this revision are listed below:

Written Consent Form/Consent Form and Authorization for Research:

Name	Version
MESA Exam 5 Consent clean copy	0.01
STU21057 MESA Exam 5 Consent Chicago Center 02-26-10 - Pilot Version.doc	0.01

Waiver of Documentation of Informed Consent:

Name	Version
Exam 5 Consent Verbal Script	0.01

Recruitment Materials:
MESA Exam 5 Clinic Result form
MESA Exam 5 exit form

Survey/Questionnaires:
Exam 5_forms packet

For more information regarding OPRS submissions and guidelines, please consult http://www.northwestern.edu/research/OPRS/irb.
This Institution has an approved Federalwide Assurance with the Department of Health and Human Services: FWA00001549.

APPROVAL NOTICE

OFFICE OF THE HUMAN RESEARCH PROTECTION PROGRAM
11000 Kinross Avenue, Suite 102
Campus Mail Code: 169407
www.research.ucla.edu/ohrpp

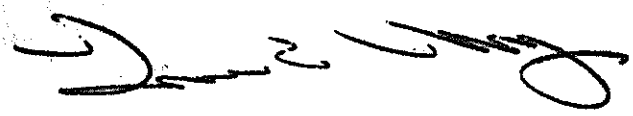
DATE: March 17, 2010

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

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

RE: UCLA IRB #99-11-057-23B
Approved by Expedited Review
(**Approval Period from** 03/17/2010 **through** 09/13/2010)
Multi-Ethnic Study of Atherosclerosis [MESA][MESA Exam 5 Pilot Study Exam 5 and Follow up 11]

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.



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. Ensure that the personnel **performing the study are qualified and appropriately trained,** key personnel have completed the CITI training program and will adhere to the provisions of the approved protocol.

2. Implement **no changes** in the approved protocol or consent process or documents without prior UCLA IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects and then notify the IRB as soon as possible afterwards.)
3. Obtain the **legally effective informed consent** from human subjects or their legally authorized representative (when approved), and use only the currently approved consent process and stamped consent documents, as required by the IRB.
4. **Report unanticipated problems** related to the protocol to the IRB in writing within the appropriate time period (2 days to 10 working days).
5. Assure that **adequate resources** to protect research subjects (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if such resources become unavailable.
6. **Arrange for a co-investigator** to assume direct responsibility of the study if at any time you will be unavailable to direct this research personally, for example, when on sabbatical leave or vacation or other absences. Either this person is named as a co-investigator on this application, or you will advise the IRB by letter in advance of such arrangements.

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: Pilmonary Vascular Changes in Early COPD

PI of Contract/Grant: Karol Watson

APPROVAL NOTICE
IRB #99-11-057-23B

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

PI of Contract/Grant:	Joao Lima
Funding Source:	National Heart, Lung, and Blood Institute
Contract/Grant No:	pending
Contract/Grant Title:	**Regional Dysfunction by MRI in Incident Heart Failure**

PI of Contract/Grant:	Ana Diaz Roux
Funding Source:	National Heart, Lung, and Blood Institute
Contract/Grant No:	HL087831
Contract/Grant Title:	Socioeconomic Patterning of Inflammation and Hemostasis

Multi-Ethnic Study of Atherosclerosis (MESA) — Fifth Exam (Pilot)

CONSENT TO PARTICIPATE IN RESEARCH

• INTRODUCTION

You are invited to participate in a pilot study of the Multi-Ethnic Study of Atherosclerosis (MESA) fifth examination, a research study sponsored by the National Heart, Lung, and Blood Institute and conducted by Karol Watson, MD, Christine Darwin, MD, Arleen Brown, MD, Deborah Kado, MD, and Preethi Srikanthan, MD, from the Department of Medicine and Antoinette Gomes, MD, from the Department of Radiology at the University of California, Los Angeles. The National Eye Institute and the US Environmental Protection Agency are also supporting certain study components.

MESA is a multi-center study which includes approximately 6,800 participants and is being conducted at six centers across the country. The UCLA center enrolled approximately 1,300 participants belonging to four ethnic groups (Whites, African-Americans, Hispanics, and Chinese Americans). The first MESA examination took place in the period July 2000 – August 2002. The second examination was performed in the period September 2002 – December 2003, the third examination took place March 2004 – August 2005. The fourth examination took place in the period September 2005 – May 2007. You are invited to participate in a pilot for the fifth examination that will take place in the period Marchl 2010.

Your participation in this pilot is entirely voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

• PURPOSE OF THE STUDY

The main purpose of MESA is to study heart disease and diseases of the blood vessels beginning in the early stages. People who may have early heart disease, known as "sub-clinical" heart disease, may not know it because they feel well. MESA is studying why some people develop clinical conditions such as heart attack, heart failure, and stroke. In order to learn this information, the people in the study are being followed for many years. Over time, MESA has studied other conditions, such as lung disease and rheumatoid arthritis, and will likely include other conditions in the future.

The purpose of the pilot study is to help study investigators assess preparedness for the actual fifth examination.

- **PROCEDURES**

If you decide to participate in the pilot study, you will be asked to undergo an examination which will require 6 – 9 hours and will be performed over one or two days. All the procedures described below will be performed at the UCLA Research Center in Alhambra, except the electron beam computed tomography (EBCT) and the magnetic resonance imaging (MRI) which will be performed in the Department of Radiology at UCLA's main campus.

If you volunteer to participate in this pilot study, we will ask you to do the following things:

1. **Physical Examination**: You will undergo a limited physical exam in which your blood pressure, height, weight, and body size will be measured. A small sensor device will be placed on your finger to measure the amount of oxygen in your blood (this brief test will done without using supplementary oxygen if you use that).

2. **Health Interviews**: You will be asked questions concerning previous illnesses, hospitalizations, diet, physical activity, social issues, and use of tobacco, alcohol, and medications.

3. **Ankle-Arm Blood Pressure**: This test involves measuring blood pressure in both arms and legs.

4. **Fasting blood samples** will be collected to measure blood sugar, blood fats (including cholesterol) and other substances related to the risk of disease. You may have up to 90 mL (3 ounces or 6 tablespoons) of blood drawn for these tests. Samples will also be frozen and stored indefinitely for future analysis. Samples may also be frozen and stored for additional assessment of pilot sample and testing quality assurance.

5. **Urine will be collected for analysis**. Approximately one cup will be collected, and may be frozen and stored for additional assessment of pilot sample and testing quality assurance.

6. **Electrocardiogram (ECG or EKG)**: This is a recording of the electrical activity of your heart. Electrodes will be placed on the skin of your chest, arms, and legs for this test.

7. **Eye Exam**: The purpose of this test is to find out how well you see at a distance and to take photographs of the back of your eyes to look at the blood vessels. We will ask you some questions about how well you see. We will then measure your vision. If you use glasses, we will ask you to take them off for the test and the prescription of your glasses will be measured. If you wear contact lenses, we will not ask you to take them out. We will then darken the room and place a special camera close to your eyes

to photograph the back (retina) of both of your eyes. No eye drops will be used and the camera will not touch your eyes. There will be a flash of light when the pictures are taken.

In addition, you are asked to undergo the procedures next to the checked boxes:

☐ **Magnetic Resonance Imaging (MRI)**: Pilot participants may be asked to undergo an MRI scan of the heart. The MRI exam will evaluate the size and function of your heart and nearby blood vessels. For this exam, you will need to lie still on a table and will be moved into a large device that takes pictures of your heart using magnetic fields. The exam takes 45-60 minutes. **If you are a woman of childbearing age, you will have a pregnancy test to make sure that you are not pregnant before having the MRI.**

☐ **MRI with Gadolinium**: All participants who have the MRI exam and who have good kidney function will be asked to receive gadolinium as part of the test. Gadolinium is an FDA approved contrast agent that allows us to see the heart and blood vessels better. It is given via a regular intravenous (IV) line, which will be placed in your arm before the test. If you agree to receive gadolinium, we will test your kidney function before the MRI to check that it is safe for you.

☐ **Computed Tomography (CT) of the Arteries of the Heart**: Pilot participants may be asked to undergo a CT scan. The CT scan is a special type of x-ray examination that is done to measure the amount of calcium in the arteries of your heart. You will be asked to lie on a table with just the upper part of your body inside the CT scanner. You will need to remain still and hold your breath for about 10-20 seconds during the test. **If you are a woman of childbearing age, you will have a pregnancy test to make sure that you are not pregnant before having the CT scan.**

☐ **Carotid Ultrasound**: Pilot participants may be asked to undergo an ultrasound scan of the arteries in the neck. Ultrasound will be used to measure the size and function of the carotid arteries, which are the large arteries in the neck. You will be asked to lie on a table for this test. Gel will be applied to the skin on your neck and a small hand-held probe will be used to examine the carotid arteries on both sides of the neck.

☐ **Spirometry**: Pilot participants may be asked to participate in spirometry testing. Spirometry measures your lung function. It involves breathing into and out of a tube as hard and as fast as you can, three or more times. A new, clean mouthpiece is used for each participant. Pilot participants selected for this test will be administered an inhaled bronchodilator medication (albuterol), which opens up the air passages, and repeated spirometry testing. You will be asked some questions to assure your safety for spirometry and albuterol. Spirometry takes approximately 20 minutes.

☐ **Computed Tomography (CT) of the Lungs**: Pilot participants who have spirometry and undergo a CT of the heart may also be asked to undergo CT of the lung. The CT

scan is a special type of x-ray examination that is done to measure any amount of emphysema in your lungs. You will be asked to lie on a table with just the upper part of your body inside the CT scanner. You will need to remain still and hold your breath for about 10-20 seconds during the test. **If you are a woman of childbearing age, you will have a pregnancy test to make sure that you are not pregnant before having the CT scan.**

☐ Six minute walk: Two hundred participants in the MESA Lung Study or who have lung disease will be asked to perform this test. You will be asked to walk for 6 minutes on a level surface to see how far you can go. If you use oxygen when you walk, you will use it for this test.

☐

If you have one of the imaging tests listed above, you will receive a report listing the main finding (for example, amount of calcium in the arteries of the heart). The scan will be reviewed in case there are other findings that may have a major and significant impact on your health. In the unusual case of such a finding being present, it will be reported to you and, if you wish, your physician.

Sharing of Data and Samples

Use of data and samples:

- Samples and data sent to other laboratories will be labeled only with a code number. No standard information that identifies you, such as your name, date of birth, address, etc., will be available to other researchers.

Potential Risks and Discomforts

- **Clinic Exam**: The procedures used in this study are considered to be safe. The risks associated with the clinic exam are minimal.

- **Blood Draw**: Risks of drawing of a blood sample are discomfort at the site of needle insertion, bruising (black and blue discoloration) or inflammation at the site, and rarely, faintness. The bruise is usually painless and disappears within a few days.

- **EKG**: Minor skin irritation may occur where the EKG leads are placed on the skin.

- **Eye Exam**: There are no known risks associated with taking a photograph of the eye. People who are light sensitive may experience some minor discomfort from the camera flash. After the pictures are taken, you may see a blue or red spot which will disappear within 5 to 7 minutes and which causes no damage to the eye.

- **Data Sharing**: MESA takes extensive efforts to protect your identity and privacy. Yet, because of the large amount of information collected about you, we cannot absolutely guarantee that information about you will never become known. **However, researchers are strictly prohibited from attempting to identify you.**

☐ **MRI**: The MRI machine does not use ionizing radiation (like x-rays). Instead, it uses a strong magnet and radio waves to generate pictures of the body. The procedure is associated with minimal risk. You will need to wear earplugs or earphones since the machine can produce high noise levels, which may be uncomfortable. With earplugs, the risk to hearing is insignificant. Some people may experience psychological discomfort in the scanner if they are uncomfortable in tight places (known as claustrophobia). You will be able to speak directly to the MRI technologist at all times, and the examination will be stopped at any time upon your request.

☐ **MRI with gadolinium**: This contrast agent is generally safe. There is a small risk of allergic reaction after the gadolinium injection, with less than a one in 300,000 chance that this will be severe. There is also a smaller risk of nephrogenic systemic fibrosis, a potentially serious and rare skin condition that can occur in patients with kidney problems. We will guard against this risk by checking your kidney function prior to the MRI and will not give gadolinium if you have low kidney function. Metallic taste in the mouth, tingling in the arm, nausea, or headache occurs in less the 1% (less than 1 in 100) people. Insertion of the needle may also cause minor pain, bruising and/or infection at the injection site.

☐ **Computed Tomography of the heart**: The CT scan uses x-rays to make pictures. The amount of radiation you will be exposed to during the CT scanning is less than 3 mSev, which is 6% of the yearly on-the-job exposure allowed radiation workers. Another way of understanding this is to compare the exposure from the CT to the radiation exposure you receive on average from natural sources. The radiation exposure from the CT scanning is approximately the amount of natural background radiation that the average person in the United States receives each year. The radiation in this study is not expected to measurably increase your risk of cancer. The potential lifetime cancer risk associated with the above estimated radiation is less than 3 per 10,000.

☐ **Computed Tomography of the lung**: The CT scan uses x-rays to make pictures. The amount of radiation you will be exposed to during the CT scanning is less than 6.5 mSev, which is 12% of the yearly on-the-job exposure allowed radiation workers. Another way of understanding this is to compare the exposure from the CT to the radiation exposure you receive on average from natural sources. The radiation exposure from the CT scanning is approximately the amount of natural background radiation that the average person in the United States receives in two years. The radiation in this study is not expected to measurably increase your risk of cancer. The potential lifetime cancer risk associated with the above estimated radiation is less than

6 per 10,000. If you are also receiving a CT scan of the heart, the lung scan will be one minute or less of additional scanning time.

☐ **Spirometry**. Minimal or no risk. Occasionally after receiving the albuterol inhaler, a temporary sensation of "heart racing" and shakiness may develop. This will resolve quickly.

☐ **Discomfort of Interviews:** It is possible that some of the questions asked during the interviews may cause you to feel uncomfortable or embarrassed. You do not have to answer any questions that you do not wish to answer.

All of the tests, particularly imaging studies (MRI and CT), may identify abnormalities for which you may be recommended to have additional testing. You will be referred to your own doctor for follow-up of all medical information obtained by the study and you, or your insurance company, will be responsible for those costs. MESA will not pay for these tests.

- **ANTICIPATED BENEFITS TO SUBJECTS**

This study is not designed to benefit you directly. Nonetheless, one benefit of participating in this study is that a free evaluation of your health will be performed. Information from the tests will be available to you and to your doctor. If a health condition is detected during this evaluation, your doctor or clinic will be notified, if you authorize the study staff to do so. However, please keep in mind that these tests are being performed for research purposes and are not intended to diagnose any specific medical condition. Additionally, MESA is not intended to provide medical care or interfere with your relationship with your own doctor. You will be referred to your own doctor for follow-up of all medical information obtained by the study. If you do not have a local doctor, you can be referred to one.

- **ANTICIPATED BENEFITS TO SOCIETY**

This study may help increase scientific knowledge about the characteristics and factors associated with subclinical atherosclerosis and its progression.

- **ALTERNATIVES TO PARTICIPATION**

The alternative is not to participate.

- **INFORMATION ABOUT YOUR SAMPLE**

On the checklist at the end of this consent form you are asked to let us know if you would like to receive general information about the results of this study. There is also a checklist for you to indicate whether you wish to release the results of the research tests to your personal doctor. You may also choose not to receive any information about the

results of this study and not to release study results to your personal doctor. Obtaining general information from a project may take years.

- **FINANCIAL OBLIGATION**

Neither you nor your insurance company will be billed for your participation in this research.

- **PAYMENT FOR PARTICIPATION**

You will be reimbursed $50 at the end of each visit. The total reimbursement will be up to $100.

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

If you are injured as a direct result of research procedures not done primarily for your own benefit, you will receive treatment at no cost. The University of California does not provide any other form of compensation for injury.

- **PRIVACY AND CONFIDENTIALITY**

The only people who will know that you are a research subject are individuals involved in the research and, if you authorize, your personal doctor and nurses. You may be asked for your personal information . This information, along with your name, will be sent to the MESA Coordinating Center at the University of Washington, where it will be stored in a secure database and who will use the information to send you lab results and to help us to reach you if we lose touch.

No information about you or provided by you during the research will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care).

This research is covered by a Certificate of Confidentiality issued by the Department of Health and Human Services (DHHS). This Certificate will protect the investigators from being forced to release any research data in which you are identified, even under a court order or subpoena. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

This protection, however, is not absolute. A Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns abut your participation and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this research is VOLUNTARY. If you choose not to participate, that will not affect your relationship with UCLA (or UCLA Medical Center), or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at UCLA.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If you become ill during the research, you may have to drop out, even if you would like to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

- **IDENTIFICATION OF INVESTIGATORS**

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact Dr. Karol Watson, Dr. Christine Darwin, Dr. Arleen Brown, Dr. Deborah Kado or Dr. Preethi Srikanthan during office hours at 626-979-4920, 330 S. Garfield Ave., Suite 308, Alhambra, CA 91801.

After office hours or if you have an emergency, you can page the study doctors by calling the UCLA Page Operator at 310-825-6301 and ask them to page one of the study doctors.

- **RIGHTS OF RESEARCH SUBJECTS**

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the Office for Protection of Research Subjects, 11000 Kinross Ave Suite 102, UCLA Box 951694, Los Angeles, CA 90095-1694, (310) 825-8714.

SIGNATURE OF RESEARCH SUBJECT

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____
Name of Subject

_____ _____
Signature of Subject Date

PERMISSION TO RELEASE RESULTS TO YOUR PERSONAL DOCTOR

Please indicate by checking and initialing the category below whether you want the results of your tests sent to your personal doctor:

❑ _____I want to have the results sent to my doctor.

❑ _____I do not want the results sent to my doctor

Consent for Use of Gadolinium for the MRI of the Heart

I agree to have the gadolinium injection as part of the MRI scan of my heart

☐ Yes, I consent to the gadolinium injection
☐ No, I do not wish to have the gadolinium injection

Consent for Lung Substudy

I agree to participate in the Lung Substudy to study lung structure and function and their impact on the heart. I understand that the results of spirometry and the CT scan of the lung will be sent to me and, if I so indicated above, to my physician. I also understand that information and samples that I have previously provided or may subsequently provide to MESA (for example, responses to questionnaires, data from CT scans, and genetic materials) may be analyzed for studies of lung disease in MESA.

☐ Yes, I consent to participant in the Lung Substudy
☐ No, I do not wish to participant in the Lung Substudy

Consent for MESA COPD Substudy

I agree to participate in the COPD Substudy, which includes the breathing test, six minute walking test, CT scan of the lung and the gadolinium injection as part of the MRI scan of my heart. The purpose of this substudy is to study the blood vessels in the lung. I understand that the breathing test will help determine my eligibility for this substudy, and that the results of spirometry and the CT scan of the lung will be sent to me and, if I so indicated above, to my physician. I also understand that information and samples that I have provided or may in the future provide to MESA (for example, responses to

questionnaires, data from CT scans, and genetic materials) may be analyzed for studies of lung disease in MESA.

☐ Yes, I consent to participant in the MESA COPD Substudy
☐ No, I do not wish to participant in the MESA COPD Substudy

With my signature I also am giving permission for my hospital and/or health clinic to release any of my health records that MESA needs and requests. This permission has no expiration date.

INFORMATION REGARDING FUTURE STUDIES

Please indicate by checking and initialing the category below whether you permit us to contact you regarding future studies:

☐ _____ I agree to be contacted about future studies.

☐ _____ I do not want to be contacted about future studies.

SIGNATURE OF INVESTIGATOR

I have explained the research to the subject and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____
Name of Investigator

_____ _____
Signature of Investigator Date (must be the same as subject's)

UNIVERSITY OF CALIFORNIA LOS ANGELES

RESEARCH PARTICIPANT'S

BILL OF RIGHTS

These rights are the rights of every person who is asked to be in a medical research study. As a research participant, I have the following rights:

1. I have the right to be told what the research is trying to find out.
2. I have the right to be told about all research procedures, drugs, and/or devices and whether any of these are different from what would be used in standard practice.
3. I have the right to be told about any risks, discomforts or side effects that might reasonably occur as a result of the research.
4. I have the right to be told about the benefits, if any, I can reasonably expect from participating.
5. I have the right to be told about other choices I have and how they may be better or worse than being in the research. These choices may include other procedures, drugs or devices.
6. I have the right to be told what kind of treatment will be available if the research causes any complications.
7. I have the right to have a chance to ask any questions about the research or the procedure. I can ask these questions before the research begins or at any time during the research.
8. I have the right to refuse to be part of the research or to stop at any time. This decision will not affect my care or my relationship with my doctor or this institution in any other way.
9. I have the right to receive a copy of the signed and dated written consent form for the research.
10. I have the right to be free of any pressure as I decide whether I want to be in the research study.

If I have any questions or concerns I can ask the researcher or the research assistant. I can also contact the UCLA Office of the Human Research Protection Program (OHRPP) which helps protect research study participants. I can reach the OHRPP by calling 310-825-8714 from 8:00 AM to 5:00 PM, Monday to Friday. If I call this office and do not speak English or Spanish, I should have someone available who can interpret for me. I may also write OHRPP, 11000 Kinross Avenue, Suite 102, Box 951694, Los Angeles, CA 90095-1694.

University of California, Los Angeles

Multi-Ethnic Study of Atherosclerosis (MESA) — Fifth Exam

CONSENT TO PARTICIPATE IN RESEARCH

• INTRODUCTION

You are invited to continue to participate in the Multi-Ethnic Study of Atherosclerosis (MESA), a research study sponsored by the National Heart, Lung, and Blood Institute and conducted by Karol Watson, MD, Christine Darwin, MD, Arleen Brown, MD, Deborah Kado, MD and Preethi Srikanthan, MD, from the Department of Medicine and Antoinette Gomes, MD, from the Department of Radiology at the University of California, Los Angeles. The National Eye Institute and the US Environmental Protection Agency are also supporting certain study components.

MESA is a multi-center study which includes approximately 6,800 participants and is being conducted at six centers across the country. The UCLA center enrolled approximately 1,300 participants belonging to four ethnic groups (Whites, African-Americans, Hispanics, and Chinese Americans). You participated in the first MESA examination in the period July 2000 – August 2002. The second examination was performed in the period September 2002 – December 2003, the third examination took place March 2004 – August 2005. The fourth examination took place in the period September 2005 – May 2007. Now you are invited to participate in the fifth examination that will take place in the period April 2010 – April 2012.

Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

• PURPOSE OF THE STUDY

The main purpose of MESA is to study heart disease and diseases of the blood vessels beginning in the early stages. People who may have early heart disease, known as "sub-clinical" heart disease, may not know it because they feel well. MESA is studying why some people develop clinical conditions such as heart attack, heart failure, and stroke. In order to learn this information, the people in the study are being followed for many years. Over time, MESA has studied other conditions, such as lung disease and rheumatoid arthritis, and will likely include other conditions in the future.

• PROCEDURES

If you decided to continue your participation in the study, you will be asked to undergo an examination which will require 6 – 9 hours and will be performed over one or two days.

All the procedures described below will be performed at the UCLA Research Center in Alhambra, except the electron beam computed tomography (EBCT) and the magnetic resonance imaging (MRI) which will be performed in the Department of Radiology at UCLA's main campus.

If you volunteer to participate in this study, we will ask you to do the following things:

1. **Physical Examination**: You will undergo a limited physical exam in which your blood pressure, height, weight, and body size will be measured. A small sensor device will be placed on your finger to measure the amount of oxygen in your blood (this brief test will done without using supplementary oxygen if you use that).

2. **Health Interviews**: You will be asked questions concerning previous illnesses, hospitalizations, diet, physical activity, social issues, and use of tobacco, alcohol, and medications.

3. **Ankle-Arm Blood Pressure**: This test involves measuring blood pressure in both arms and legs.

4. **Fasting blood samples** will be collected to measure blood sugar, blood fats (including cholesterol) and other substances related to the risk of disease You may have up to 90 mL (3 ounces or 6 tablespoons) of blood drawn for these tests. Samples will also be frozen and stored indefinitely for future analysis.

5.

6. **Urine will be collected for analysis**. Approximately one cup will be collected, and will be frozen and stored for future analyses.

7. **Electrocardiogram (ECG or EKG)**: This is a recording of the electrical activity of your heart. Electrodes will be placed on the skin of your chest, arms, and legs for this test.

8. **Eye Exam**: The purpose of this test is to find out how well you see at a distance and to take photographs of the back of your eyes to look at the blood vessels. We will ask you some questions about how well you see. We will then measure your vision. If you use glasses, we will ask you to take them off for the test and the prescription of your glasses will be measured. If you wear contact lenses, we will not ask you to take them out. We will then darken the room and place a special camera close to your eyes to photograph the back (retina) of both of your eyes. No eye drops will be used and the camera will not touch your eyes. There will be a flash of light when the pictures are taken.

In addition, you are asked to undergo the procedures next to the checked boxes:

☐ **Magnetic Resonance Imaging (MRI)**: All participants who had this test during the first MESA exam will be asked to repeat the MRI during the present exam. The MRI

exam will evaluate the size and function of your heart and nearby blood vessels. For this exam, you will need to lie still on a table and will be moved into a large device that takes pictures of your heart using magnetic fields. The exam takes 45-60 minutes. **If you are a woman of childbearing age, you will have a pregnancy test to make sure that you are not pregnant before having the MRI.**

☐ **MRI with Gadolinium**: All participants who have the MRI exam and who have good kidney function will be asked to receive gadolinium as part of the test. Gadolinium is an FDA approved contrast agent that allows us to see the heart and blood vessels better. It is given via a regular intravenous (IV) line, which will be placed in your arm before the test. If you agree to receive gadolinium, we will test your kidney function before the MRI to check that it is safe for you. **If you are a woman of childbearing age, you will have a pregnancy test to make sure that you are not pregnant before having the MRI.**

☐ **Computed Tomography (CT) of the Arteries of the Heart**: Approximately half of MESA participants will have this test. The CT scan is a special type of x-ray examination that is done to measure the amount of calcium in the arteries of your heart. You will be asked to lie on a table with just the upper part of your body inside the CT scanner. You will need to remain still and hold your breath for about 10-20 seconds during the test. **If you are a woman of childbearing age, you will have a pregnancy test to make sure that you are not pregnant before having the CT scan.**

☐ **Carotid Ultrasound**: Approximately one half of MESA participants will have this test. Ultrasound will be used to measure the size and function of the carotid arteries, which are the large arteries in the neck. You will be asked to lie on a table for this test. Gel will be applied to the skin on your neck and a small hand-held probe will be used to examine the carotid arteries on both sides of the neck.

☐ **Spirometry**: Participants who previously participated in the MESA Lung Study will be selected to participate in spirometry testing. Spirometry measures your lung function. It involves breathing into and out of a tube as hard and as fast as you can, three or more times. A new, clean mouthpiece is used for each participant. About one in five participants will be selected on the basis of the spirometry results for an inhaled bronchodilator (albuterol), which opens up the air passages, and repeated spirometry testing. You will be asked some questions to assure your safety for spirometry and albuterol. Spirometry takes approximately 20 minutes.

☐ **Computed Tomography (CT) of the Lungs**: Participants who previously participated in the MESA Lung Study will have this test, many of whom will also get the CT of the heart. The CT scan is a special type of x-ray examination that is done to measure any amount of emphysema in your lungs. You will be asked to lie on a table with just the upper part of your body inside the CT scanner. You will need to remain still and hold your breath for about 10-20 seconds during the test. ~~If you are a~~

woman of childbearing age, you will have a pregnancy test to make sure that you are not pregnant before having the CT scan.

☐ Six minute walk: Two hundred participants in the MESA Lung Study or who have lung disease will be asked to perform this test. You will be asked to walk for 6 minutes on a level surface to see how far you can go. If you use oxygen when you walk, you will use it for this test.

If you have one of the imaging tests listed above, you will receive a report listing the main finding (for example, amount of calcium in the arteries of the heart). The scan will be reviewed in case there are other findings that may have a major and significant impact on your health. In the unusual case of such a finding being present, it will be reported to you and, if you wish, your physician.

Follow-Up Information (Phone and Mail contact)

We will continue to contact you by phone every 6-9 months and ask you about your health since the last contact. If you are unable to answer questions yourself, we may contact a person you have named who could answer questions for you. If you are hospitalized or admitted to a convalescent or nursing home, we will ask that institution for your records. We will review the records to determine the reason for your admission and your diagnosis. We may request records from your doctor for certain office or clinic visits to determine if you have been diagnosed with one of the diseases that MESA is studying. We may also request Medicare records.

DNA Testing

Genetics, or the study of genes and gene products, has progressed rapidly since MESA began. If you gave your permission at an earlier exam, MESA collected DNA, the material that contains the genes, from your blood samples and stored it at that time. Your DNA is used to try to learn who is at increased (or decreased) risk of heart disease, stroke, or other diseases. MESA is looking at specific genes and also at a wide sampling of participants' DNA. MESA is also looking at a substance called RNA, which is closely related to DNA and may help to understand how genes work. If you agree, MESA will collect more DNA and prepare cell lines from your blood sample in this examination and allow researchers to potentially read almost all of people's genetic code. Cell lines are blood cells that have been treated so they will live for long periods of time.

Researchers will read your genetic code looking for genes for heart disease and related conditions. They may also occasionally read genes that have variations known to cause other rare but serious diseases. Most people have versions of these genes that are safe and cause no disease; however, a small number of people may have a version that suggests a greater risk for these other diseases. If you were to have such a DNA finding, there would be a chance that your family members would have the same DNA finding.

Some people do not want to be told if they have such a rare but important DNA finding, especially if there is little that can be done to prevent the related disease from occurring. Other people do want this information. We will ask you your preference now in case we examine for and find such a DNA finding in the future. MESA will consult with experts to make decisions on what DNA findings to report and how this should be done. People who do want this genetic (DNA) information will need to be tested in a second laboratory to make sure the first test was correct. They may also be advised to talk with a trained professional (a genetic counselor) about their own and their family members' risks of disease. This counseling could be important because the genetic information may be complicated and its impact on individual and family member risk can be difficult to interpret. The genetic counselor can explain the results and answer questions. MESA will pay for the additional genetic testing and counseling if we examine for and find such a DNA finding.

Sharing of Data and Samples

Use of data and samples:

- Portions of samples of your blood, urine and DNA, in addition to study information and genetic data, will be stored for use by researchers indefinitely.

- The National Institutes of Health will allow researchers who qualify to analyze your data and samples. Researchers can qualify by proposing a research study approved by National Institutes of Health and by agreeing to protect your identity.

- Samples and data sent to other laboratories will be labeled only with a code number. No standard information that identifies you, such as your name, date of birth, address, etc., will be available to other researchers.

Commercial use of data and samples:

- Researchers from private companies that develop diagnostic lab tests or treatments for diseases may request access to your study information or samples. However, these researchers will not have access to personal information that identifies you, such as your name, date of birth, address, etc.

- Your samples will not be sold to any person, institution, or company and will not be used for cloning (creating body organs or tissues or fluids from your genetic material).

- Neither you nor your family would benefit financially from discoveries made using the information and/or specimens that you provide.

Genetic research:

- Very detailed information about your DNA will be stored centrally at the National Institutes of Health, where it will be shared with other investigators for research. This information and all of your other data will be used by researchers to look for genes that affect the risk of developing diseases and may lead to better methods for prevention and treatment. The stored information is de-identified, which means that identifying information such as your name, date of birth, address, etc., is removed. Access to this stored information will be controlled by the National Institutes of Health. The National Institutes of Health is committed to protecting the confidentiality of all the information it receives, but will also comply with relevant laws which might include Freedom of Information Act (FOIA) requests for de-identified information.

Potential Risks and Discomforts

- **Clinic Exam**: The procedures used in this study are considered to be safe. The risks associated with the clinic exam are minimal.

- **Blood Draw**: Risks of drawing of a blood sample are discomfort at the site of needle insertion, bruising (black and blue discoloration) or inflammation at the site, and rarely, faintness. The bruise is usually painless and disappears within a few days.

- **EKG**: Minor skin irritation may occur where the EKG leads are placed on the skin.

- **Eye Exam**: There are no known risks associated with taking a photograph of the eye. People who are light sensitive may experience some minor discomfort from the camera flash. After the pictures are taken, you may see a blue or red spot which will disappear within 5 to 7 minutes and which causes no damage to the eye.

- **DNA information**: Receiving DNA information may cause anxiety. Also, some people have been worried that genetic information could be used to discriminate against them. A law was passed in 2008 by the Federal Government ("GINA" or Genetic Information Nondiscrimination Act) that prevents many forms of discrimination based on genetic information.

- **Data Sharing**: MESA takes extensive efforts to protect your identity and privacy. Yet, because of the large amount of information collected about you, we cannot absolutely guarantee that information about you or your blood relatives will never become known. This is partly because of the possibility of matching your DNA sample with other DNA collections (such as those kept by law enforcement agencies). **However, researchers are strictly prohibited from attempting to identify you.**

☐ **MRI**: The MRI machine does not use ionizing radiation (like x-rays). Instead, it uses a strong magnet and radio waves to generate pictures of the body. The procedure is associated with minimal risk. You will need to wear earplugs or earphones since the machine can produce high noise levels, which may be uncomfortable. With earplugs, the risk to hearing is insignificant. Some people may experience psychological discomfort in the scanner if they are uncomfortable in tight places (known as claustrophobia). You will be able to speak directly to the MRI technologist at all times, and the examination will be stopped at any time upon your request.

☐ **MRI with gadolinium**: This contrast agent is generally safe. There is a small risk of allergic reaction after the gadolinium injection, with less than a one in 300,000 chance that this will be severe. There is also a smaller risk of nephrogenic systemic fibrosis, a potentially serious and rare skin condition that can occur in patients with kidney problems. We will guard against this risk by checking your kidney function prior to the MRI and will not give gadolinium if you have low kidney function. Metallic taste in the mouth, tingling in the arm, nausea, or headache occurs in less the 1% (less than 1 in 100) people. Insertion of the needle may also cause minor pain, bruising and/or infection at the injection site.

☐ **Computed Tomography of the heart**: The CT scan uses x-rays to make pictures. The amount of radiation you will be exposed to during the CT scanning is less than 3 mSev, which is 6% of the yearly on-the-job exposure allowed radiation workers. Another way of understanding this is to compare the exposure from the CT to the radiation exposure you receive on average from natural sources. The radiation exposure from the CT scanning is approximately the amount of natural background radiation that the average person in the United States receives each year. The radiation in this study is not expected to measurably increase your risk of cancer. The potential lifetime cancer risk associated with the above estimated radiation is less than 3 per 10,000.

☐ **Computed Tomography of the lung**: The CT scan uses x-rays to make pictures. The amount of radiation you will be exposed to during the CT scanning is less than 6.5 mSev, which is 12% of the yearly on-the-job exposure allowed radiation workers. Another way of understanding this is to compare the exposure from the CT to the radiation exposure you receive on average from natural sources. The radiation exposure from the CT scanning is approximately the amount of natural background radiation that the average person in the United States receives in two years. The radiation in this study is not expected to measurably increase your risk of cancer. The potential lifetime cancer risk associated with the above estimated radiation is less than 6 per 10,000. If you are also receiving a CT scan of the heart, the lung scan will be one minute or less of additional scanning time.

☐ **Spirometry**: Minimal or no risk. Occasionally after receiving the albuterol inhaler, a temporary sensation of "heart racing" and shakiness may develop. This will resolve quickly.

☐ **Discomfort of Interviews:** It is possible that some of the questions asked during the interviews may cause you to feel uncomfortable or embarrassed. You do not have to answer any questions that you do not wish to answer.

☐ **Six Minute Walk Test**: Risks of this test include shortness of breath and chest tightness, and rarely, faintness or heart problems. We will guard against these by asking you questions before the test.

All of the tests, particularly imaging studies (MRI and CT), may identify abnormalities for which you may be recommended to have additional testing. You will be referred to your own doctor for follow-up of all medical information obtained by the study and you, or your insurance company, will be responsible for those costs. MESA will not pay for these tests, except for additional genetic testing and genetic counseling if you are found to have a potentially important DNA finding and wish to be told about it.

- **ANTICIPATED BENEFITS TO SUBJECTS**

This study is not designed to benefit you directly. Nonetheless, one benefit of participating in this study is that a free evaluation of your health will be performed. Information from the tests will be available to you and to your doctor. If a health condition is detected during this evaluation, your doctor or clinic will be notified, if you authorize the study staff to do so. However, please keep in mind that these tests are being performed for research purposes and are not intended to diagnose any specific medical condition. Additionally, MESA is not intended to provide medical care or interfere with your relationship with your own doctor. You will be referred to your own doctor for follow-up of all medical information obtained by the study. If you do not have a local doctor, you can be referred to one.

- **ANTICIPATED BENEFITS TO SOCIETY**

This study may help increase scientific knowledge about the characteristics and factors associated with subclinical atherosclerosis and its progression.

- **ALTERNATIVES TO PARTICIPATION**

The alternative is not to participate.

- **INFORMATION ABOUT YOUR SAMPLE**

On the checklist at the end of this consent form you are asked to let us know if you would like to receive general information about the results of this study. There is also a checklist for you to indicate whether you wish to release the results of the research tests to your personal doctor. You may also choose not to receive any information about the

results of this study and not to release study results to your personal doctor. Obtaining general information from a project may take years.

- **FINANCIAL OBLIGATION**

Neither you nor your insurance company will be billed for your participation in this research.

- **PAYMENT FOR PARTICIPATION**

You will be reimbursed $50 at the end of each visit. The total reimbursement will be up to $ 100.
If you selected to participate in MESA COPD Substudy, you will be reimbursed $100 for the time to complete spirometry, the six minute walk test, the CT scan of the lung and the MRI of the heart.

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

If you are injured as a direct result of research procedures not done primarily for your own benefit, you will receive treatment at no cost. The University of California does not provide any other form of compensation for injury.

- **PRIVACY AND CONFIDENTIALITY**

The only people who will know that you are a research subject are individuals involved in the research and, if you authorize, your personal doctor and nurses. You have been asked for your personal information such as address, phone numbers and social security number. This information, along with your name, will be sent to the MESA Coordinating Center at the University of Washington, where it will be stored in a secure database and who will use the information to send you lab results and to help us to reach you if we lose touch. We will ask you to update this information each year and as necessary.

Information obtained during this research may be released to others for scientific purposes, but only after removing your name, social security number, and any other personal identifiers. Otherwise, no information about you or provided by you during the research will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care).

When the results are published or discussed in conferences, no information will be included that would reveal your identity. Authorized representatives of the National Institutes of Health (NIH) may need to review records of individual subjects. As a result, they may see your name, but they are bound by rules of confidentiality not to reveal your identity to others.

This research is covered by a Certificate of Confidentiality issued by the Department of Health and Human Services (DHHS). This Certificate will protect the investigators from being forced to release any research data in which you are identified, even under a court order or subpoena. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

This protection, however, is not absolute. A Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns abut your participation and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this research is VOLUNTARY. If you choose not to participate, that will not affect your relationship with UCLA (or UCLA Medical Center), or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at UCLA.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If you become ill during the research, you may have to drop out, even if you would like to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

- **NEW FINDINGS**

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

- **IDENTIFICATION OF INVESTIGATORS**

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact Dr. Karol Watson, Dr. Christine Darwin, Dr. Arleen Brown, Dr. Deborah Kado or Dr. Preethi Srikanthan during office hours at 626-979-4920, 330 S. Garfield Ave., Suite 308, Alhambra, CA 91801. After office hours

or if you have an emergency, you can page the study doctors by calling the UCLA Page Operator at 310-825-6301 and ask them to page one of the study doctors.

- **RIGHTS OF RESEARCH SUBJECTS**

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the Office for Protection of Research Subjects, 11000 Kinross Ave Suite 102, UCLA Box 951694, Los Angeles, CA 90095-1694, (310) 825-8714.

SIGNATURE OF RESEARCH SUBJECT

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____
Name of Subject

_____ _____
Signature of Subject Date

PERMISSION TO RELEASE RESULTS TO YOUR PERSONAL DOCTOR

Please indicate by checking and initialing the category below whether you want the results of your tests sent to your personal doctor:

☐ _____I want to have the results sent to my doctor.

☐ _____I do not want the results sent to my doctor

Consent to Obtain DNA for Research

I agree to allow MESA to obtain additional DNA at this exam for research purposes. This will allow researchers to read my genetic code in detail and to see if my genetic code is related to diseases I now have or may develop in the future.

☐ Yes, obtain my DNA for research purposes
☐ No, do not obtain my DNA

Consent to Create Cell Lines from Blood Cells

I agree to allow MESA to create cell lines that will live for long periods of time from my blood sample

- ☐ Yes, create cell lines
- ☐ No, do not create cell lines

Request to be Notified, or Not, of Possible Important Genetic Findings

I wish to be notified if results indicate I may have a genetic finding that is known to greatly increase risk of an important disease (CHECK ONE). Please note that very few MESA participants will be checked for these rare genetic findings at present; however a larger number of MESA participants may be checked in the future.

- ☐ Yes, but only if a treatment to prevent or lessen the disease is known
- ☐ Yes, even if no treatment or prevention is known
- ☐ No, do not notify me

Consent for Use of Gadolinium for the MRI of the Heart

I agree to have the gadolinium injection as part of the MRI scan of my heart

- ☐ Yes, I consent to the gadolinium injection
- ☐ No, I do not wish to have the gadolinium injection

Consent for Lung Substudy

I agree to participate in the Lung Substudy to study lung structure and function and their impact on the heart. I understand that the results of spirometry and the CT scan of the lung will be sent to me and, if I so indicated above, to my physician. I also understand that information and samples that I have previously provided or may subsequently provide to MESA (for example, responses to questionnaires, data from CT scans, and genetic materials) may be analyzed for studies of lung disease in MESA.

- ☐ Yes, I consent to participant in the Lung Substudy
- ☐ No, I do not wish to participant in the Lung Substudy

Consent for MESA COPD Substudy

I agree to participate in the COPD Substudy, which includes the breathing test, six minute walking test, CT scan of the lung and the gadolinium injection as part of the MRI scan of my heart. The purpose of this substudy is to study the blood vessels in the lung. I understand that the breathing test will help determine my eligibility for this substudy, and that the results of spirometry and the CT scan of the lung will be sent to me and, if I so indicated above, to my physician. I also understand that information and samples that I have provided or may in the future provide to MESA (for example, responses to questionnaires, data from CT scans, and genetic materials) may be analyzed for studies of lung disease in MESA.

- ☐ Yes, I consent to participant in the MESA COPD Substudy

☐ No, I do not wish to participant in the MESA COPD Substudy

With my signature I also am giving permission for my hospital and/or health clinic to release any of my health records that MESA needs and requests. This permission has no expiration date.

INFORMATION REGARDING FUTURE STUDIES

Please indicate by checking and initialing the category below whether you permit us to contact you regarding future studies:

☐ _____ I agree to be contacted about future studies.

☐ _____I do not want to be contacted about future studies.

SIGNATURE OF INVESTIGATOR

I have explained the research to the subject and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____
Name of Investigator

_____ _____
Signature of Investigator Date (must be the same as subject's)

UNIVERSITY OF CALIFORNIA LOS ANGELES

RESEARCH PARTICIPANT'S

BILL OF RIGHTS

These rights are the rights of every person who is asked to be in a medical research study. As a research participant, I have the following rights:

1. I have the right to be told what the research is trying to find out.
2. I have the right to be told about all research procedures, drugs, and/or devices and whether any of these are different from what would be used in standard practice.
3. I have the right to be told about any risks, discomforts or side effects that might reasonably occur as a result of the research.
4. I have the right to be told about the benefits, if any, I can reasonably expect from participating.
5. I have the right to be told about other choices I have and how they may be better or worse than being in the research. These choices may include other procedures, drugs or devices.
6. I have the right to be told what kind of treatment will be available if the research causes any complications.
7. I have the right to have a chance to ask any questions about the research or the procedure. I can ask these questions before the research begins or at any time during the research.
8. I have the right to refuse to be part of the research or to stop at any time. This decision will not affect my care or my relationship with my doctor or this institution in any other way.
9. I have the right to receive a copy of the signed and dated written consent form for the research.
10. I have the right to be free of any pressure as I decide whether I want to be in the research study.

If I have any questions or concerns I can ask the researcher or the research assistant. I can also contact the UCLA Office of the Human Research Protection Program (OHRPP) which helps protect research study participants. I can reach the OHRPP by calling 310-825-8714 from 8:00 AM to 5:00 PM, Monday to Friday. If I call this office and do not speak English or Spanish, I should have someone available who can interpret for me. I may also write OHRPP, 11000 Kinross Avenue, Suite 102, Box 951694, Los Angeles, CA 90095-1694.

Version: 09/09

Date *ID#*

Name
Address
City, ST Zip

Dear *Name*:

Thank you again for your participation in the Multi-Ethnic Study of Atherosclerosis (MESA). We appreciate your efforts to help improve our understanding of heart disease and how to prevent it. We are providing results of the blood tests that were done during the MESA examination on ***Exam 5 date***.

Your fasting plasma glucose was _____ mg/dl, which {*is normal / is mildly elevated but not in the diabetic range / is in the diabetic range. This result should be discussed with your physician / indicates that your diabetes is controlled / indicates that your diabetes may not be well controlled / indicates that your diabetes may be out of control and you should see your physician soon*}.

Diabetics only: Your HbA_{1c} (which reflects diabetes control in the preceding three months) was--------%. This indicates that your diabetes is controlled(<7%)/is not well controlled (7.1-11%)/ out of control and you should see your physician soon (>11%).

Your cholesterol level was _____ mg/dl, which is {*normal / borderline elevated / elevated*}.

Your LDL cholesterol level was _____ mg/dl, which is {*normal / borderline elevated / elevated*}.

Your HDL cholesterol level was _____ mg/dl, which is {*in the desired range / below the desired range.*

Your Triglyceride level was _____ mg/dl, which is {*in the desired range / above the desired range.*

Your creatinine level, which reflects kidney function, was _____ mg/dl, which is {*normal / elevated and should be discussed with your physician if you were not previously aware of it*}.

A copy of your laboratory results is enclosed. If you requested it, a copy of your laboratory results has been sent to your doctor. Otherwise, you may wish to take this letter with you when you visit your doctor.

If you have any questions, please call _____ at _____.

Again, thank you for your participation in MESA.

Sincerely,

_____
Title

UCLA IRB # 99-11-057-23B
Expiration Date: SEP 13 2010

Date ***ID#***

Doctor Name
Doctor Address
Doctor City, ST Zip

Dear ***Doctor Name***:

Your patient, _____ (Date of Birth: _____), is a participant in the Multi-Ethnic Study of Atherosclerosis (MESA), an epidemiologic study of subclinical cardiovascular disease and risk factors. He/She volunteered for an examination during _____ of _____ and requested that the findings from the tests and examinations be forwarded to you. Enclosed is a copy of the letter sent to _____ describing some of the examination results. If you have any questions, please contact _____ at _____. Thank you.

Sincerely,

_____

Title

UCLA IRB # 99-11-057-23B
Expiration Date: SEP 13 2010

MESA Laboratory Results

MESA # _____
Name: _____
Date of Birth: _____
Examination Date: _____

Plasma Glucose (fasting)	: _____	mg/dl
Serum Cholesterol	: _____	mg/dl
LDL-Cholesterol*	: _____	mg/dl
HDL-Cholesterol	: _____	mg/dl
Triglycerides	: _____	mg/dl
Creatinine	: _____	mg/dl
HbA1c	: _____	%

National Cholesterol Education Program Recommendations for Lipids:

	Desirable	Borderline	Elevated
Cholesterol	less than 200	200-239	more than 239
LDL-Cholesterol	less than 130	130-159	more than 159
Triglycerides	less than 200		
HDL-Cholesterol	more than 40		

American Diabetes Association Reference Ranges for Fasting Glucose:

< 100 mg/dl	normal
100 – 125 mg/dl	borderline high
126 and higher	diabetic range

Reference Range for Creatinine (mg/dl) †:

Female	Male
0.60 – 1.30	0.80 – 1.50

Normal range for Hemoglobin A1c: 4.3 - 6.0 %

* LDL cholesterol is calculated when possible, not measured directly
† Reference range for the lab at which creatinine was measured

UCLA IRB # 99-11-057-23B
Expiration Date: SEP 13 2010

Date *ID#*

Participant Name
Address
City, State Zip

Dear Ms./Mr.:

Thank you again for your continued participation in the Multi-Ethnic Study of Atherosclerosis (MESA). We appreciate your efforts to help improve our understanding of heart disease and how to prevent it. The purpose of this letter is to provide you with the results of the carotid ultrasound / CT scan / MRI scan / retinal photographs spirometry you underwent as part of your examination in MESA.

- The ultrasound study (done on *scan date*) of the carotid arteries (the large blood vessels in your neck) showed *no significant clinical findings / significant (Doppler flow velocity > 120 and < 250 cm/sec) narrowing (50% or more) in the right side and suggests the need for further evaluation and possible treatment / significant (Doppler flow velocity > 250 cm/sec) narrowing (80% or more) in the left side and suggests the need for further evaluation and possible treatment.*
- The **CT scan of the heart** (done on *scan date*) showed that you have a total coronary artery calcium score of zero. The coronary arteries are the vessels that supply blood to the heart. The presence of calcium (that is, a score higher than zero) is correlated with hardening of these arteries. However, a calcium score of zero does not necessarily mean that no hardening of these arteries is present.

OR

- The **CT scan of the heart** (done on scan date) showed that you have a total coronary artery calcium score of ____. Your previous CT scan done on _____ showed that you had a total coronary artery calcium score of ____. The calcium score indicates the amount of calcium found in the walls of these arteries. Your calcium score indicates that you have some hardening of these arteries. For your age, you have *a less than average/an average/a greater than average* amount of calcium in your arteries.

  If bypass or angioplasty was indicated: *If you have had a stent placed in the past, there may be a small error in your calcium assessment.*

- The **CT scan of the lung** (done on *scan date*) showed that you have (no/mild/moderate/severe) emphysema in the lungs. Emphysema is a loss of the tissue in the lungs, and can cause shortness of breath. If you have questions, please contact the principal investigator of the Lung sub-study, R. Graham Barr, M.D., Dr.P.H. at 212-305-4895.

- The MRI study of the heart and blood vessels (done on *MRI date*) showed that your heart structure and function were within an acceptable range for your age.

OR

- The MRI study of the heart and blood vessels (done on *MRI date*) showed the following abnormalities (findings?):

  Finding in layman's language (e.g. "The wall of the heart is thickened")

  Report of clinically significant myocardial scar in layman's language

- The spirometry breathing test done on DD/MM/YY showed that your FEV1 (a measure of how fast you can blow out) was ___% of predicted for someone your age, your FVC (a measure of how much you can blow out) was ___% of predicted for someone your age, and their ratio was ___. <These results show a possible moderate reduction in your breathing capacity.>

- No significant abnormalities were found in the back of your eyes.

OR

- Your fundus photographs showed the following abnormalities:
  Specific abnormality in layman's language and recommendation (e.g. "There were changes in the retina that are often found people with diabetes and occasionally in people with hypertension. These changes were found in both eyes. Further evaluation by an ophthalmologist is recommended.")

OR

- No significant abnormalities were found in the back of your right/left eye.
- Specific abnormality reported in other eye

Everyone, whether he/she has a low or high calcium score, should strive to lead a heart-healthy lifestyle and control any heart-related risk factors that they have (for example, high cholesterol, high blood pressure, and cigarette smoking, among others).

Please note that the above studies were performed as a part of a research study and may not be the same as tests done as a part of a patient's medical care. Nonetheless, we recommend that you discuss any abnormal findings with your doctor. If you requested it, a copy of this letter will be sent to your doctor. Otherwise, you may wish to take this letter to your doctor.

Once again, we greatly appreciate your participation in MESA. If you have any questions, please call _____ at *phone #.*

Sincerely,

_____

_____

For the MESA-Lung Spirometry Participants Results Letter, other possible spirometry test interpretations include:

<u>Participant Results Letter Interpretations:</u>

Your current test results indicate a possible borderline reduction in your breathing capacity.
Your current test results are within normal limits.
Your current test results indicate a possible mild reduction in your breathing capacity.
Your current test results indicate a possible moderate reduction in your breathing capacity.
Your current test results indicate a possible moderately severe reduction in your breathing capacity.
Your current test results indicate a possible severe reduction in your breathing capacity.
Your current test results indicate a possible very severe reduction in your breathing capacity.
Your current test has insufficient acceptable curves to accurately interpret the results.
Although your current test results are below the normal limits, the current test results are not reproducible and cannot be accurately interpreted.
The FEV1 improved by **% after administration of a bronchodilator.

Date *ID#*

Doctor Name
Address
City, State Zip

Dear Dr.:

Your patient, _____ (Date of Birth:_____), is a participant in the Multi-Ethnic Study of Atherosclerosis (MESA). She volunteered for an examination during *month* of *year*. Enclosed is a copy of the letter sent to Mr/Ms. _____ describing the results of the carotid ultrasound / CT scan / MRI scan / spirometry. Please note that these tests were performed as a part of a research study to answer certain research questions. They are therefore limited in scope and may not be equivalent to tests done as a part of routine medical care.

Cardiac MRI

	Value	Normal Ranges in the MESA cohort	
		M	F
Left ventricular end diastolic volume	_____ ml	Low-High	Low-High
Left ventricular end systolic volume	_____ ml	Low-High	Low-High
Ejection Fraction	_____ %	Low-High	Low-High
Stroke Volume	_____ ml	Low-High	Low-High
Left Ventricular Mass	_____ g	Low-High	Low-High
Left Ventricular Mass index	_____ g/m2	Low-High	Low-High
% predicted LV mass*	%	Low-High	Low-High
Myocardial scar (>5 g)**	present or absent		

* % predicted based on 8XX non-obese non-hypertensive participants in the MESA study, adjusted for body size.

** Report and brief explanation of myocardial scar (if present)

No focal wall motion abnormalities were present in the left ventricle.

OR

Abnormalities:

Specific finding

UCLA IRB # 99-11-057-23B
Expiration Date: SEP 13 2010

Carotid Ultrasound (*scan date*)

Doppler Flow Velocity:

Right Internal Carotid: _____ cm/sec

Left Internal Carotid: _____ cm/sec

(Values above >120 cm/sec indicate >50% narrowing of carotid artery and >250 cm/sec indicate >80% narrowing)

Coronary Computed Tomography (*scan date*)

Coronary Calcium Score: _____

Retinal Photo

No significant abnormalities were found in the retinas of your patient.

OR

Your patient's fundus photographs showed the following abnormalities:

Specific abnormality

If you have any questions, please contact _____ at *phone #*. Thank you.

Sincerely,

_____

_____

UCLA IRB # 99-11-057-23B
Expiration Date: SEP 13 2010

Multi-Ethnic Study of Atherosclerosis (MESA)
Lung Function Sub-study
<Field Center Name> Field Center

Name: <ENTER NAME HERE>
ID: <ENTER MESA ID HERE> Race: Asian
Acrostic: <ENTER ACROSTIC HERE> DOB:
Test Age: 57 yrs Test Ht: 180.0 cm
Session: 50 Gender: M

Calibration Verified: 10/6/2004 Temp: 25.0 C. BP: 760 BTPS Factor: 1.0733
Spirometer: WYI06428 Vers: 5.01 Normals Used: RA Factor: 0.88

Pulmonary Function Report 10/6/2004 2:36:09 PM

		Best Values	Pred	%Pred	LLN
FVC	L	4.11	4.41	93.3%	3.57
FEV1	L	3.00	3.36	89.2%	2.65
FEV1/FVC%	%	72.9%	76.3%	95.6%	66.6%
PEF	L/s	9.38	8.47	110.7%	6.38
FEV6	L	3.91	4.22	92.6%	3.41
FEV1/FV6%	%	76.6%	69.9%	109.6%	62.0%
FET	sec	11.8			

Reproducible Test. FVC, FEV1 and PEF reproducible.
6 of 6 trials had acceptable start of expiration; 0 had acceptable plateau.
5 of 6 trials were used for the best test values.
1 of 6 trials were Rejected.
Session Effort: Maximal, Position: Sitting

INTERPRETATION -

Normal expiratory flows and a normal FVC.

If you have questions, please contact the principal investigator of the Lung sub-study, R. Graham Barr, M.D., Dr.P.H. at 212-305-4895.
Ref: 43, Operator: 748

Dear MESA participant,

Enclosed is a questionnaire asking you about your usual dietary habits over the previous year. Please follow the instructions given on the first two pages of the questionnaire and answer the questions as accurately as possible. We understand that some questions may be more difficult to answer than others. Just do your best to estimate. You will have an opportunity to ask questions at the clinic when you arrive for your examination, but please try to answer most, if not all, of the questions before you arrive.

The questionnaire should take between 30 to 60 minutes to complete. You are welcome to take short breaks if you need them, but please try to complete the questionnaire in one sitting.

Of course, as with all aspects of the MESA study, completing this questionnaire is entirely voluntary. If for any reason you do not wish to participate in this portion of the MESA study, you can elect not to complete the questionnaire. Non-participation in the dietary portion of the exam will not affect your participation in other portions of the exam nor will it detract from your value to MESA. We greatly appreciate your time and dedication to the MESA study.

Sincerely,

Jennifer Nettleton, Ph.D.
Assistant Professor and MESA Nutrition Coordinating Center Principal Investigator
The University of Texas School of Public Health, Division of Epidemiology
Health Sciences Center—Houston
Phone: 713-500-9367
E-mail: Jennifer.A.Nettleton@uth.tmc.edu

UCLA IRB # 99-11-057-23B
Expiration Date: SEP 13 2010