**Assent to join the**

**Multi-Ethnic Study of Atherosclerosis (MESA)**

**Exam 7 In-person**

# Person in charge of this study at [Field Center] (Principal Investigator):

[PI Name]

# Study Coordinator and Contact Person:

[Research Team Contact Name and Phone Number]

**The sponsor of this study:** The National Heart, Lung, and Blood Institute (NHLBI) and the National Institute of Aging (NIA) from the National Institutes of Health (NIH)

This form tells about the 7th exam for the Multi-Ethnic Study of Atherosclerosis (MESA). MESA is a research study. It is not medical care. Joining MESA Exam 7 is voluntary. You can choose to join or not. No matter what you decide, you can still be part of MESA.

Review this form carefully. It tells all about MESA Exam 7 so you can decide if you want to join. We will give you a copy of it to keep. If you have questions, please ask us.

Here are some key points about MESA Exam 7:

* If you join, we will ask you to:
	+ Give blood, urine and other samples and have some tests
	+ Answer questions about your health and lifestyle
	+ Have some other imaging tests, if you agree
	+ Wear small monitors on your body at home, if you agree
* You will be helping researchers make discoveries. This may help people with health problems in the future. Also, we will give you the results of some of your medical tests. This may or may not help your doctors take better care of you.

To learn more, please read the rest of this form.

# What is MESA?

MESA is an ongoing research study that you joined around the year 2000. About 6800 people joined MESA from around the United States. Our goal is to learn more about heart disease and diseases of the blood vessels. We hope the discoveries we make will help healthcare providers take better care of people.

# Why are you asking me to join MESA Exam 7?

MESA is studying why some people develop heart disease and other diseases, including diseases in the brain and lungs. In order to learn this information, the people in the study are being followed for many years.

# What will you ask me to do?

We will ask you to come to the MESA Clinic for Exam 7 and imaging tests and to complete some of the exam parts at home. We will send study staff to your home, if you would like. You can say yes or no to any part and still be part of MESA Exam 7.

# We will gather samples from you. This will take about 25 minutes.

# We will ask you to complete some questionnaires and tests. This will take about 2 hours.

# We will ask you to wear monitors on your body for several days at home.

# We will ask you to do some imaging tests.

**Computed Tomography (CT) of the Lungs**. We will take pictures of your lungs using a CT scanner, which is like an X-ray. This will take about 20 minutes. If you complete the lung CT, you will be paid an extra $75.

**Brain Magnetic Resonance Imaging (MRI).** If you are eligible and it’s safe for you, we will take pictures of your brain using MRI. You will lay very still on a table inside the machine. There is no injection or contrast dye involved with MRI. It will take about one hour. If you complete the brain MRI, you will be paid an extra $75.

# Are there any risks to joining MESA Exam 7?

Yes, there are risks to joining MESA Exam 7. Review these risks carefully. Ask any questions you have.

***Risk from Lung CT:*** This research study includes exposure to radiation that is for research purposes only. Therefore, your total radiation exposure is more than what is required for your medical care alone. This extra radiation exposure is necessary to obtain the research information desired. The extra radiation exposure necessary to obtain the research information desired is very small and scientists are not sure if there is any risk at all.

***Risk from Brain MRI.*** The MRI used for this test is loud. You will be given earplugs or earphones to wear. There is no radiation involved. You might feel anxious in the MRI if you do not like small spaces. The MRI machine uses a strong magnet that will attract other metals. You cannot have an MRI if you have a pacemaker, an implanted defibrillator, or other implanted electronic or metallic devices, shrapnel, or metal that is attracted to a magnet. You will be able to speak directly to the MRI technologist at all times, and the scan will be stopped at any time upon your request.

# Does it cost anything to participate in MESA?

You do not have to pay any money to participate in MESA. That said, if you have injuries because of participating, you will be treated for the injury. If you have to take extra time off work, you may lose wages.

# Will I be paid?

The tests MESA performs are paid for by the National Institutes of Health. You will be reimbursed for some of your travel expenses related to coming to the clinic.

# What if I get hurt?

If you get hurt because of participating in MESA, we will pay for your care.

For further information contact [PI or Study Coordinator Name and Phone Number].

# Can I be taken out of MESA?

Yes, the MESA team can take you out of MESA. They could remove you if they think it is necessary for your safety. The MESA team will tell you if they remove you from MESA.

# What if I have questions?

Please talk this over with your Legally Authorized Representative or “LAR” before you decide whether or not to join MESA Exam 7. An LAR is someone who can help you make decisions about study participation. We will also ask your LAR if it is okay for you to be in this study. But even if your LAR says “yes” you can still decide not to join. We encourage you to ask questions. If you have any questions about MESA, please contact: **[name(s), phone number(s)].**

# **[SITE SPECIFIC PARTICIPANT REPORTING INFORMATION CAN BE INSERTED HERE]**

# [SITE SPECIFIC HIPAA INFORMATION CAN BE INSERTED HERE]

This form is not a contract. It tells what will happen if you decide to join MESA Exam 7. You are not waiving any legal rights by agreeing to.

# Assent:

I have read this assent form. This research study has been explained to me and all of my questions have been answered.

**Do not sign this form if today’s date is after EXPIRATION DATE: [XX/XX/XXXX]**

(Signature of Participant) (Date)

(Participant's name – printed)

Relationship of Legally Authorized Representative to Participant Date/Time

**Statement of Person Who Obtained Assent**

I reviewed this form with the person who has signed above. I have made sure that all of their questions have been answered.

(Signature of Person who Obtained Consent) (Date)

(Name of Person who Obtained Consent - printed)

**Contacts and Questions:**

*[Insert as needed at each Field Center]*