

Biomedical IRB
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APPROVAL OF MODIFICATION

DATE: August 16, 2016

TO: Dr. Kiang Liu

FROM: Office of the IRB

DETERMINATION DATE: 8/16/2016

APPROVAL DATE: 8/5/2016

EFFECTIVE DATE: 8/16/2016

EXPIRATION DATE: 4/27/2017

The Northwestern University IRB has reviewed and approved the submission described below:

Type of Submission:	Modification
Review Level:	Committee
Title of Study:	Multi-Ethnic Study of Atherosclerosis (MESA)
Principal Investigator:	Kiang Liu
IRB ID:	STU00021057-MOD0010
Funding Source:	National Heart, Lung, and Blood Institute, Funding Source ID: R01HL127695

National Heart, Lung, and Blood Institute, Funding Source ID: HHSN268201500003I

National Heart, Lung, and Blood Institute, Funding Source ID: R01HL130506

NIH-NHLBI, Funding Source ID: R01HL133860

National Heart, Lung, and Blood Institute, Funding Source ID: R01HL127028

National Heart, Lung, and Blood Institute, Funding Source ID: R01HL077612

National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK), Funding Source ID: R01DK104842

Documents Reviewed:

- ICIQ-FLUTS (US English).pdf, Category: Recruitment Materials;
- Lung Questionnaire.pdf, Category: Recruitment Materials;
- KCCQ-12.pdf, Category: Recruitment Materials;
- MESA Exam 6 Protocol, Category: IRB Protocol;
- ICIQ-MLUTS (UK English).pdf, Category: Recruitment Materials;
- PROMIS_Phys.Function.pdf, Category: Recruitment Materials;
- Digit Span.pdf, Category: Recruitment Materials;
- MESA Ex6 Consent, Category: Consent Form;
- Medical_History.pdf, Category: Recruitment Materials;
- PhysicalActivityQuestionnaire.pdf, Category: Recruitment Materials;
- Digit Symbol.pdf, Category: Recruitment Materials;
- CASI.pdf, Category: Recruitment Materials;
- MESA Exam 6 Invitation Letter, Category: Recruitment Materials;
- Spirometry Completion.pdf, Category: Recruitment Materials;
- Radiation Dosimetry Form, Category: Other;
- Medications.pdf, Category: Recruitment Materials;
- Personal_History.pdf, Category: Recruitment Materials;
- MESA Exam 6 HighTech Result, Category: Recruitment Materials;
- MESA Exam 6 Recruitment Phone Script, Category: Recruitment Materials;
- MESA Follow Up 18 English Form Packet, Category: Recruitment Materials;
- MESA Exam 6 Lab Results, Category: Recruitment Materials;
- MESA Exam 6 Exit Report, Category: Recruitment Materials;

Description of the modification:

- The study sponsor, The National Institute of Health has awarded funding for another MESA clinic examination to take place Sept 1, 2016 and continue for 18 month.

The IRB requires the following actions:

- Current subjects will be notified of these changes.

In conducting this study, you are required to follow the requirements listed in the Northwestern University (NU) Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the eIRB+ system.

NU IRB approval does not constitute or guarantee institutional approval and/or support. Investigators and study team members must comply with all applicable federal, state, and local laws, as well as NU Policies and Procedures, which may include obtaining approval for your research activities from other individuals or entities.

For IRB-related questions, please consult the NU IRB website at <http://irb.northwestern.edu>. For general research questions, please consult the NU Office for Research website at www.research.northwestern.edu.