# MESA Ancillary Study Proposal Form *(v.11)*

**This form may be used to submit either of the following:**

1. Proposals to collect new data in MESA, whether directly from participants or from previously collected samples, images, or other sources (e.g., medical records).
2. Proposals to analyze existing MESA data as part of a new external funding application, for which additional MESA Coordinating Center (CC) services will be requested beyond downloading of data already available on the MESA website (e.g., analysis by a CC Statistician or preparation of a unique dataset).

Note: as of November, 2010, analysis-only grants involving no such additional CC services require the submission of a Manuscript Proposal form, but not an Ancillary Study Proposal Form. Submit the Manuscript Proposal form online and see MESA Publications submission details at: <http://www.mesa-nhlbi.org/Publications.aspx>. To check the availability of online data, please contact your MESA Sponsor.

## Submission deadlines:

Proposals involving biospecimens: **8 weeks** prior to grant deadline

All other study proposals: **6 weeks** prior to grant deadline

*Note: Ancillary studies involving a subcontract to the Coordinating Center must have their final budget negotiated and approved for internal University of Washington review no later than* ***5 weeks*** *prior to a funding application.*

Agreement with the Coordinating Center and, if applicable, the MESA Central Biorepository about the costs needed to perform an ancillary study is required for Steering Committee approval.

## Contact information:

General questions: Sandi Shrager, MESA Coordinating Center

 sandis@uw.edu, 206-897-1907

Budget questions related to Cynthia Marks, MESA Coordinating Center

Coordinating Center services: sonora@uw.edu,

 206-897-1902 (Tue, Thur); 206-685-9498 (Mon, Wed, Fri)

Biological specimens: Elaine Cornell, MESA Central Blood Laboratory Elaine.Cornell@uvm.edu, 802-656-8963

Investigators who are not affiliated with MESA are welcome to propose ancillary studies. These investigators, however, need to work with a MESA investigator (sponsor). A list of potential sponsors appears on the MESA web site at <http://www.mesa-nhlbi.org/personnel.aspx>.

To propose an ancillary study in MESA, please complete this form after reviewing the MESA Ancillary Studies Policies and Procedures, available at <http://www.mesa-nhlbi.org/ancillary.aspx>.

Send completed proposal to: Sandi Shrager at sandis@uw.edu

## PART 1: Basic Study Information and Projected Impact on MESA

1. **Draft / Modification Date**:
2. **Title of study:**
3. **Initiating Investigator(s**) (name, address, phone and fax numbers, e-mail address):
4. **MESA Sponsor:**
5. **All other Co-investigators:**
6. **Please confirm that you have reviewed any potential areas of overlap by checking the current list of approved ancillary studies at** [**http://www.mesa-nhlbi.org/Mesa-Internal/AncillaryS/**](http://www.mesa-nhlbi.org/Mesa-Internal/AncillaryS/)**:**
7. **Collaboration approval:** Does this ancillary study use data from or rely upon the use of data from another approved ancillary study? **:** Yes [ ]  No [ ]  If Yes, please provide the Ancillary Study name and number, as well as documentation of approval of this collaboration from the Ancillary Study PI.

1. **Keywords:**
2. **Funding**
	1. Source:
	2. If NIH, funding mechanism:
	3. Grant due date:
	4. Proposed grant start date:
	5. Proposed grant end date:
	6. Grant title (if different from study title):
	7. Does this study involve the support or collaboration of a for-profit entity?

Note: for-profit involvement requires that the dataset exclude participants who did not consent to their data being used by private companies. (See also item 10 in [Ancillary Study Policy)](https://www.mesa-nhlbi.org/PublicDocs/MESA_AS_Policy_11-30-13.doc)

* 1. Estimated direct costs per year (please provide an estimate even if a final figure is not available):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **FY01** | **FY02** | **FY03** | **FY04** | **FY05** |
| $       | $       | $       | $       | $       |

Note: You must have pre-approval from NIH to submit an application with estimated direct costs ≥ $500K in any year.

1. **Sample Size:** Explicitly state the size and any special characteristics of the participant sample.

1. **Participant Involvement:** Will participants be contacted, interviewed, or examined (even if only to report results from this study)?

If yes, please describe participant involvement and estimate the time required of each participant.

Radiation exposure level (if applicable):

1. **Biological Specimens:** Do you propose to use stored specimens?       If yes:

*Investigators must view the MESA Rules and Guidelines for Biospecimen Use posted online at*

[*http://www.mesa-nhlbi.org/ancillary.aspx*](http://www.mesa-nhlbi.org/ancillary.aspx) *and obtain a Repository Impact Report from the MESA Central Blood Laboratory before completing this section. (See p. 1 of this form for contact details).*

1. Date of Repository Impact Report included with this submission:
2. Specimens:
3. DNA :

Specify amount of DNA:

1. Blood or urine (specify):
2. Study year(s) for which blood or urine samples are to be used:
3. Sample type (e.g., serum, EDTA, citrate):
4. Sample volumes:
5. Sample Rationale: Do you propose use of any item below?       If yes, please provide justification:
* Exam 1 (baseline) blood samples, and whether they include Group 3 (MESA 1000).

A random sample of 1000 participants (called “Group 3”) has had a large number of laboratory tests using baseline blood samples. For these participants the baseline blood repository volumes are smaller than for the other 5814 participants. To minimize depletion of these specimens, ancillary study investigators who wish to measure an analyte at baseline on the full cohort must provide specific justification for their use. Otherwise, Group 3 will not be included, leaving 5814 available participants. Group 3 restrictions apply only to baseline blood specimens.

* Blood sample volume in any Exam year that exceeds 250 microliters (uL)
* Last thawed aliquot from any Exam year
1. Requirement for frozen vs. previously thawed samples (if the latter, please indicate whether there are any limitations on the number of freeze-thaw cycles):
2. Efforts to integrate sample needs with those of other studies to conserve sample and/or limit freeze-thaw cycles:
3. Labwork Location and personnel:

* + - * 1. Projected timeline for:
* pulling samples and shipping:
* sample analysis:
* return of samples to Lab:
1. **MESA Reading Centers:** Yes [ ]  No [ ]  If yes,

Describe materials (including scans, tapes, digital images, tracings, …) from a MESA Reading Center to be used.(These source materials are from chest CT, abdominal CT, ECG, cardiac MRI, carotid MRI, carotid ultrasound, brachial endothelial function, spirometry, and retinal photography. Data already derived from readings are available without the involvement of a Reading Center.)

1. **MESA Field Centers:** Yes [ ]  No [ ]  If yes,

Indicate which Field Centers have agreed to participate, and describe the effort and estimated time required of MESA staff at each participating Field Center.

1. **MESA Coordinating Center Involvement:** Yes [ ]  No [ ]  If yes,

Describe the effort and estimated time required of MESA Coordinating Center staff. Specifically:

* + 1. Will the following work be done at the Coordinating Center? (please check all that apply)

­­­[ ]  Sample selection

[ ]  Data set preparation *(ie, preparation of a unique dataset not available online)*

[ ]  Consultation

[ ]  Statistical analysis

* + 1. Verification: Do you want the Coordinating Center to verify the results of statistical analyses conducted by ancillary study investigators? (required for locally-analyzed studies that wish to protect intellectual property or that involve restricted funding from a for-profit entity. (See MESA Verification policy at <http://www.mesa-nhlbi.org/ancillary.aspx> )
		2. How many manuscripts do you estimate will be written from the ancillary study?
		3. Will the Coordinating Center be involved in data collection or preparation of forms or software?
		4. If a Reading Center is involved, will data be sent directly from the Reading Center to the Coordinating Center for processing?
1. **MESA Data**: State the data from the MESA main study (demographics, risk factors, events, etc.) and analyses needed for the ancillary study:
2. **Genetic information** (defined as any data from a participant’s DNA):
	1. Does your proposal contain the use of genetic data? (please check one)

[ ]  No (go to question 17) [ ]  Yes (continue with questions 16 b-e)

* 1. Name the gene(s) to be investigated:
	2. Is genetic information used to address a primary aim or secondary aim of the MESA? (please check one or both)

[ ]  Primary aim (heart and vascular disease)

[ ]  Secondary aim (other health conditions)

* 1. Should genetic results be reported to patients’ physicians? Base your response on your knowledge of existing literature and current practice regarding increased risk and availability of treatment for adverse outcomes associated with the gene mutations to be studied. Describe the plan for addressing any relevant clinical or other (ethical, legal, or social) implications of the findings.
	2. If your proposal requires genetic informed consent, state the estimated number of participants who have the appropriate consent.
1. **Clinical Implications:** Will the findings have clinical implications? If so, describe the plan for reporting results to participants and providing recommendations for follow-up.
2. **Patent Intent:** Do you intend to use the data to patent any process, aspect or outcome of the analysis?
3. **Rationale and Impact:** Advantage of conducting the study within the MESA cohort:

## PART 2: Description of the Proposed Ancillary Study

Please provide a **brief (maximum 4 pages not including citations)** description of the proposed study. Include the following:

### 1. Abstract

Summarize background information and literature, and state how they lead to the question(s) of interest. Include a concise justification and explanation of the research question(s) to be addressed. End by stating the aim of the ancillary study and summarizing the method(s) that will be used to address the questions.

### 2. Background and Rationale

Explain in detail, the background information summarized in the Abstract paragraph. Explain why this information is lacking with regard to the ancillary study question(s) of interest, and how the proposed study will address that gap. Finally, explain how the methods and/or information from the MESA will address the ancillary study question(s). Acknowledge any limitations or concerns related to the proposed methods, and explain how they have been or will be dealt with.

### 3. Specific Aims

Detail the research questions or hypotheses to be addressed by the ancillary study

### 4. Methods

1. Study Population

Describe the sample of interest (the entire MESA cohort or certain subgroups). Include the

anticipated time frame of participant involvement (if any).

1. Data Collection

Describe information to be collected and any methods or equipment to be used. Include detailed explanations and protocols for each method in the ancillary study. Explain how the information from the method or equipment will address the question(s) of the study. Attach copies of any study instruments (questionnaires and forms) that MESA participants or administrators will be expected to complete. Include an estimate of the time necessary to complete them. Describe the data needed from the MESA main study (including outcomes/events).

1. Statistical Analysis

Explain how each study hypothesis (from section 3 - Specific Aims) will be analyzed. Include any current hypotheses or information that might influence the approach to the analysis or the question itself.

### 5. Sample Size Calculations

### 6. Literature References