MESA DUA & DMDA INSTRUCTIONS

Access to individual, participant level (raw) data and/or original materials, whether obtained directly from the MESA Coordinating Center or from a Sponsor or PI, requires one of the following:

MESA DUA:	1-page Data Use Agreement for data access only by MESA-affiliated Investigators (MESA-contracted employees, consultants) and their students or staff, or by MESA NHLBI Project Office employees.
MESA DMDA:	Full Data and Materials Distribution Agreement for all other recipients.

MESA DUA - Specific Instructions:

"Investigator:"	Enter the name of individual recipient.
"MESA Affiliation:"	Enter the title and full contact information for recipient.

MESA DMDA - Specific Instructions:

It is important to note that NHLBI is providing data and/or materials to the scientific community as a courtesy. It is a valuable scientific resource that is being provided at no charge. As such, MESA is reluctant to modify the terms and conditions of the Data and Materials Distribution Agreement (DMDA). The language has been made as widely-accommodating to other institutions and is shared across other NHLBI-funded studies.

Note: To ensure the DMDA execution process goes smoothly, MESA CC staff work with investigators to gather the required information, below pre-fill the DMDA, and then send to the recipient for signatures. This ensures the agreement is accurately completed and minimizes emailing back and forth to make corrections. A review-only version of the DMDA can be shared with your institution for inspection if needed.

Section 1 "Materials:"	Please generally describe what is more explicitly specified in the approved Research Project. (If Research Project involves data only, please enter "n/a" or leave blank).
Section 2 "Data:"	This agreement covers only data described in the approved Research Project. A new DMDA should be filled out for each new project that has a different research plan, even if the same data/materials are being accessed by the same person.

Section 3.1 "Research Project:"	MESA number & title of the approved ancillary study proposal or paper proposal
Section 3.2 "Other Recipients:"	For additional outsourced/contracted biospecimen recipient only
Initial.1 "Recipient's PI:"	Principal Investigator (PI) initials at the end of section 3.
Initial. 2 "Recipient's PI:"	Principal Investigator (PI) initials at the end of section 12.
Initial. 3 "Recipient's PI:"	Principal Investigator (PI) initials at the end of section 13.
Initial. 4 "Recipient's PI:"	Principal Investigator (PI) initials at the end of section 18.
Initial. 5 "Recipient's PI:"	Principal Investigator (PI) initials at the end of section 22.
Section 16.1 "Applicable State Laws"	Insert applicable state laws that prohibit indemnification.
*Section 18 "IRB" / Ethics Review:	Attach photocopy or scan of the current Recipient Institutional IRB review letter associated with the Research Project.
Initial. 3 "Recipient's PI:"	Principal Investigator (PI) initials at the end of section 22.
Sign.1 "Recipient's PI:"	Principal Investigator (PI). Data/materials will be transferred only to PI, who assumes responsibility for students/staff participating in the Research Project (DMDA clause 5). *Please notify the Coordinating Center with the names of any additional persons who will receive access (e.g., author or analyst on a paper).*
Sign.2 "Recip.'s Authorized Rep:"	Institution (usually Business Office, Office of Research, Licensing & Technology, or Grants & Contracts - the signer must have local institutional authority to legally commit the institution to this agreement.) *University of Washington Recipients: please include evidence of Research Project (proposal) approval when*

	forwarding your DMDA to the UW Office of Sponsored Programs (OSP) for this signature. Send either hardcopy or emailed scan of both documents to OSP Box 359472 / osp@uw.edu.
Sign.3 "MESA CC:"	Completed by MESA CC following all of the above
Sign.4 "NHLBI Rep.:"	[Materials requests only] Completed by MESA CC following all of the above

***IRB REVIEW (DMDA clause #18):**

This DMDA *must* include evidence of review by Recipient Institution's IRB (U.S.A.) /Ethics Board (outside the U.S.A.), which may be "exempted", "expedited", or "full." Data and/or materials transferred will contain no personal identifiers per current HIPAA regulations. However, a slight possibility remains that individual participants could be identified, because of the volume of data or because of outliers, dates, and study sites. This additional IRB review is not needed by investigators (MESA-affiliated or not) at MESA-contracted institutions whose project involves only data or biospecimens that are already covered by a local, current IRB-approved contract with MESA. Access to identifiers may likely NOT be exempted.

Please send requests, questions and completed agreements to:

All DUAs (email preferred):

David Vu, MESA Data Manager
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Phone: (206) 897-1913
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All DMDAs (email preferred):

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