The Multi-Ethnic Study of Atherosclerosis (MESA)

Data and Materials Distribution Agreement for Collaborating Investigators

MESA and The University of Auckland (Name of Recipient Organization) hereby enter into this Distribution Agreement as of the date it is signed by the Recipient Organization.

RECIPIENT ORGANIZATION is (check one):
☒ Non-profit entity organized under the laws of the State of New Zealand.
☐ For-profit corporation organized under the laws of the State of .
☐ A government agency governed under the laws of .

Investigator: Alistair A. Young, whose principal affiliation is with The University of Auckland, requests access to Study Data and/or Materials.

AGREED TERMS AND CONDITIONS

It is mutually agreed as follows:

1. Data. The MESA Steering Committee agrees to provide Recipient with Data for project described in attached Exhibit A, entitled he Cardiac Atlas Project: Establishment of a Cardiac MRI Database. (See MESA Ancillary Studies Proposal format to be sure that all necessary information is provided, including specification of the Data and/or Material requested.)

2. Materials. The MESA Steering Committee and NHLBI agree to transfer to Recipient the Materials described below for use by the Investigator named above to conduct the research described in Section 1 or as attached. These Materials (including numbers of samples and whether samples are unique or immortalized) are described as follows:

   Cardiac MRI images and derived contours, age (years), gender (M/F), height (cm), weight (kg), systolic and diastolic blood pressure (mmHg), hypertension (class), heart rate (bpm), race/ethnicity (class), diabetes (class), smoking (y/n), alcohol (y/n), ECG (class), angina (NYHA classification).

3. Research Project.

   3.1 These Data and/or Materials will be used by Investigator solely in connection with the following research project ("Research Project"), specifically described in attached Exhibit A: The Cardiac Atlas Project: Establishment of a Cardiac MRI Database.

   3.2 The Research Project involves the following MESA investigator(s) as co-investigator(s): N/A.

   3.3 This Distribution Agreement covers only the above-described Research Project. The Recipient must complete and submit a separate Distribution Agreement (this document) for each research project for which Data and/or Materials are requested.

4. Non-transferability. This Distribution Agreement is not transferable. Recipient agrees that substantive changes made to the Research Project described above, and/or appointment by

Recipient of another Investigator to complete the Research Project, require execution of a new Distribution Agreement in which the new Investigator and/or new Research Project are designated.

5. Publication. The Recipient agrees to comply with MESA Publications and Presentations Policies (found at http://mesa-nhlbi.org). Recipient agrees to provide to the MESA Coordinating Center copies of final manuscripts or abstracts submitted for publication as well as reprints or copies of final publications.

6. Acknowledgments. The Recipient agrees to acknowledge the contribution of the Study Investigators in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data or Materials reviewed under this agreement. The Investigator will acknowledge Study Investigators as co-authors, as appropriate, on any publication. In addition, the manuscript will be reviewed by NHLBI prior to publication and the following acknowledgment will be included:

   "The Multi-Ethnic Study of Atherosclerosis (MESA) is conducted and supported by the National Heart, Lung, and Blood Institute (NHLBI) in collaboration with MESA Investigators. This manuscript has been reviewed by the MESA investigators for scientific content and consistency of data interpretation with previous MESA publications and significant comments have been incorporated prior to submission for publication."

7. Non-Identification. The Recipient agrees that Data and Materials will not be used, either alone or in conjunction with any other information, in any effort to determine the individual identities of any of the subjects from whom Data and Materials were obtained.

8. Use Limited to Research Project. The Recipient agrees that Data and Materials will not be used in any research that is not disclosed and approved as part of the Research Project.

9. Use in Human Experimentation Prohibited. Recipient agrees that Biological Materials, their progeny, or unmodified or modified derivatives thereof will not be used in human experimentation of any kind.

10. Compliance with Subjects' Informed Consent. Recipient agrees that the Data and Materials, their progeny, and unmodified or modified derivatives thereof will not be used for any purpose contrary to a subjects' applicable signed informed consent document(s). It is the responsibility of the Recipient's Investigator to consult with the MESA investigators to ascertain, specifically and in detail, the terms and conditions of applicable MESA informed consent documents.

11. No Distribution, Avoidance of Waste, Return of Materials. Recipient agrees to retain control over Data, Genetic Analysis Data, and Materials, including Biological Materials, their progeny, and unmodified or modified derivatives thereof, and further agrees not to transfer Data, Genetic Analysis Data or Materials, including Biological Materials, their progeny, or unmodified or modified derivatives thereof, with or without charge, to any other entity or individual. Recipient agrees, in handling the Biological Materials, to make reasonable efforts to avoid contamination or waste of the samples. When the Research Project is completed, or three (3) years have elapsed from the effective date of this Distribution Agreement, whichever occurs first, the Data, Genetic Analysis Data, and Biological or Other Materials will be either returned to the MESA Coordinating Center or laboratory designated by the

National Heart, Lung, and Blood Institute, unless other arrangements are agreed upon (e.g., destruction of copied images) or an extension of this Agreement is obtained.

12. Recipient's Resulting Data to be Provided to MESA Coordinating Center. Recipient agrees to provide the Coordinating Center copies of all Data, including Genetic Analysis Data, which are developed based on Data or Materials distributed by MESA, within 12 months of its collection.

13. Costs/No Warranties. Cost for distribution of Biological and other Materials, including DNA, will be determined by the appropriate MESA laboratory and should be covered by the investigator. No warranties express or implied, are offered as to the merchantability or fitness for any purpose of the Materials, Genetic Analysis Data, or other Data provided to Recipient under this Agreement, or that the Materials or Data may be exploited without infringing the intellectual property or proprietary rights of any third parties.

14. Non-Endorsement, Indemnification. Recipient agrees not to claim, infer, or imply Governmental endorsement of the Research Project, the entity or personnel conducting the Research Projects or any resulting commercial product(s) except as described in the section on Acknowledgments. To the extent permitted by law, Recipient agrees to hold the United States Government, the MESA Steering Committee, and all other investigator(s) who generated Data and Materials, and the agents and employees of each of them, harmless and to defend and indemnify all such parties for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose of Data, including Genetic Analysis Data, and Biological Materials, their byproducts, or modified or unmodified derivatives thereof.

15. Accuracy of Data and Materials. The United States Government and the MESA Steering Committee are not responsible for the accuracy of Data or Materials provided.

16. Recipient's Compliance with IRB Requirements.

    16.1 Recipient acknowledges that the conditions for use of these Data and Material have been approved by the Recipient's Institutional Review Board (IRB) in accordance with Department of Health and Human Services regulations of 45 CFR Part 46 (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm). A copy of the approval letter must be provided and the date of the IRB approval indicated on the signature page of this document.

    16.2 Recipient agrees to comply fully with all such conditions and with the subjects' informed consent documents, on record with MESA. Recipient agrees to report promptly to MESA any proposed change in the research project and any unanticipated problems involving risks to subjects or others. Recipient remains subject to applicable State and local laws and regulations and institutional policies that provide additional protections for human subjects.

17. Amendments. Amendments to this Distribution Agreement must be made in writing and signed by authorized representatives of all parties.

18. Termination. The agreement may be terminated if the Recipient is in default of any of its conditions and such default has not been remedied within 30 days after the date of written notice to the Recipient by the MESA Steering Committee or NHLBI of such default. The

MESA Steering Committee may terminate the Agreement if Data only, and not Materials, are involved in the breach. If Materials are involved in the breach, the NHLBI, in consultation with the MESA Steering Committee, may terminate this Distribution Agreement. In either case, upon termination of this Distribution Agreement, Recipient agrees to return all unused Biological Materials and Data to MESA or to destroy them as approved by NHLBI, in consultation with the MESA Steering Committee.

19. Disqualification, Enforcement. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional MESA Data or Materials. The United States Government shall have the right to institute and prosecute any appropriate proceedings at law or in equity against the Recipient for violating or threatening to violate the confidentiality requirements of this agreement, the limitations on the use of the Data and/or Materials provided, or both. Proceedings may be initiated against the violating party, legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other appropriate proceedings in law or equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this agreement. In addition, Recipient acknowledges and agrees that a breach or threatened breach of the confidentiality requirements or use limitations of this agreement may subject Recipient to legal action on the part of Study subjects, their families, or both.

20. Accurate Representations. Recipient certifies to the best of his/her knowledge and belief that the contents of any statements made or reflected in this document are truthful and accurate.

21. Conflict of Interest. The Recipient agrees to disclose promptly any direct and indirect conflicts of interest, such as affiliation(s) with any organization with any financial interest, whether direct or indirect, in the subject matter of the proposed research employing Data or Materials from MESA. Examples of such affiliations are employment consultancies, expert testimony, honoraria, stock, or retainers that may affect the work being considered.

22. Intellectual Property. The Recipient is encouraged to contact NHLBI for information about implementation of Cooperative Research and Development Agreements (CRADAs), Material Transfer Agreements (MTAs), and licensing arrangements prior to initiating any discussions with industry regarding the development of intellectual property resulting from research employing MESA Data or Materials.

The following sections pertain to Materials. If no Materials are being requested, proceed to "IRB APPROVAL."

M1. Recipient's Responsibility for Handling Biological Materials. Recipient acknowledges that Biological Materials may carry viruses, latent viral genomes, and other infectious agents. The Recipient agrees to treat Biological Materials as if they were not free of contamination, and that Biological Materials will be handled only by trained persons under laboratory conditions that afford adequate biohazard containment. By accepting Biological Materials, Recipient assumes full responsibility for their safe and appropriate handling.

M2. Amplification or Creation of Additional DNA. Recipient agrees not to amplify or otherwise create additional DNA from Materials provided prior to receiving written approval to do so from the MESA Steering Committee and NHLBI.

M3. Genetic Analyses Restricted to Those Approved. Recipient agrees to perform genetic testing as proposed and agreed to by the MESA Steering Committee and NHLBI and not to perform additional testing.

IRB APPROVAL 6/19/2008

Date of IRB approval:

(Attach copy of approval letter.)

Health and Disability Ethics Committees

Multi-region Ethics Committee
Ministry of Health
Level 2, 1–3 The Terrace
PO Box 5013
Wellington
Phone (04) 470 0655
(04) 470 0646
Fax (04) 496 2191
Email: multiregion_ethicscommittee@moh.govt.nz

19 June 2008

Dr Alistair Young
University of Auckland
Department of Anatomy & Radiology
Faculty of Medical & Health Sciences
University of Auckland Private Bag 92019
Auckland

Att: Lana Jordan

Dear Alistair

Cardiac Atlas Project
Dr Alistair Young, Dr Brett Cowan, Dr Christopher J. Occleshaw, Professor Peter Hunter
Auckland City Hospital, Middlemore Hospital
MEC/08/04/052

The above study has been given ethical approval by the **Multi-region** Ethics Committee.

Approved Documents

- **Participant Information Sheet, Version 3.0, dated 21 May 2008**
- **Participant Consent Form, Version 3.0, 05 May 2008**

Accreditation
The Committee involved in the approval of this study is accredited by the Health Research Council and is constituted and operates in accordance with the Operational Standard for Ethics Committees, April 2006.

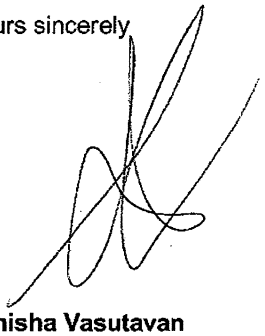
Progress Reports
The study is approved until **19 June 2009**. The Committee will review the approved application annually and notify the Principal Investigator if it withdraws approval. It is the Principal Investigator's responsibility to forward a progress report covering all sites prior to ethical review of the project in **June 2009**. The report form is available at http://www.ethicscommittees.health.govt.nz. Please note that failure to provide a progress report may result in the withdrawal of ethical approval. A final report is also required at the conclusion of the study.

Amendments
It is also a condition of approval that the Committee is advised of any adverse events, if the study does not commence, or the study is altered in any way, including all documentation eg advertisements, letters to prospective participants.

Please quote the above ethics committee reference number in all correspondence.

It should be noted that Ethics Committee approval does not imply any resource commitment or administrative facilitation by any healthcare provider within whose facility the research is to be carried out. Where applicable, authority for this must be obtained separately from the appropriate manager within the organisation.

Yours sincerely



Annisha Vasutavan
Multi-region Administrator

Email: annisha_vasutavan@moh.govt.nz

SIGNATURES

(1) Authorized representative of Recipient Organization (IF DATA ONLY ARE REQUESTED, the Department Chair or other appropriate official from the department of the Investigator):

Name: Peter Hunter

Title: Professor

Organization: University of Auckland Bioengineering Institute

Address: 70 Symonds St, 6th Floor, Auckland, New Zealand

Email address: p.hunter@auckland.ac.nz

Telephone number: +64 9 3737599 ext 88395

Fax number: +64 9 367 7157

Signature: _____

Date: 3/4/09

(2) Investigator:

Name: Alistair A. Young

Title: Associate Professor

Organization: University of Auckland Bioengineering Institute

Address: 70 Symonds St, 6th Floor, Auckland, New Zealand

Email address: a.young@auckland.ac.nz

Telephone number: +64 9 3737599 ext 86116

Fax number: +64 9 3737599 ext 88395

Signature: _____

Date: 5 April 2004

(3) Other (Student, Fellow, Programmer/Analyst) (Add sections as necessary):

Name:

Title:

Organization:

Address:

Email address:

Telephone number:

Fax number:

Signature: _____

Date:

(4) Authorized business official of Recipient Organization (IF MATERIALS ARE REQUESTED):

Name: Mary Grigor

Title: General Manager

Organization: University of Auckland Bioengineering Institute

Address: 70 Symonds St, 6th Floor, Auckland, New Zealand

Email address: mary.grigor@auckland.ac.nz

Telephone number: +64 9 373 7599

Fax number: +64 9 367 7157

Signature: MGrigor

Date: 3rd April '09

Note: If Materials are requested, send signed Agreement to the MESA Project Office at the address below. If Data only are requested, send signed Agreement to the MESA Coordinating Center at the address below.

(5) NHLBI:

Name:

Organization: National Heart, Lung, and Blood Institute

Address: 6701 Rockledge Drive MSC 7934, Bethesda, MD 20892-7934

Email address:

Telephone number:

Fax number:

Signature: Elaine Bird

Date: June 2, 2009

(6) MESA Authorized Representative (MESA Coordinating Center):

Name: Craig Johnson

Title: Project Director, MESA Coordinating Center

Organization: University of Washington, Collaborative Health Studies Coordinating Center

Signature: Craig Johnson

Date: June 10, 2009

Send a completed copy to the MESA Coordinating Center at Building 29, Suite 310
6200 NE 74th Street, University of Washington, Box 354922, Seattle, WA 98115

MESA Data and Materials Distribution Agreement for Collaborating Investigators

Introduction

The National Heart, Lung, and Blood Institute (NHLBI) has supported collection of data from participants in the Multi-Ethnic Study of Atherosclerosis (MESA), hereafter referred to as "MESA" or "Study". This well-characterized population provides a valuable scientific resource. In order to take full advantage of such resources and maximize their research value, these data are being made widely available to qualified investigators, according to appropriate terms and conditions. The NHLBI seeks to promote the development of valuable discoveries and inventions beneficial to the public health based upon use of the MESA repository of valuable materials and data. The primary purposes of the Data and Materials Distribution Agreement (DMDA) are to assure protection of participant privacy and responsible handling of data and materials.

Data collected by the Study have been stripped of all personal identifiers, but the wealth of data available might enable individual identification of some subjects. To protect the confidentiality and privacy of participants, Recipients of MESA Data and/or Materials must adhere to the requirements of the appropriate Distribution Agreement. Failure to comply with a Distribution Agreement could result in denial of further access to MESA Data and Materials. Violation of the confidentiality requirements of this agreement may leave requesting investigators liable to legal action on the part of Study participants, their families, or the U.S. government.

The Study Investigators have made a substantial long-term contribution in establishing and maintaining the Database and Materials repositories. The Study Investigators seek to encourage appropriate collaborative relationships with outside investigators and to ensure that the contributions of the Study Investigators are appropriately acknowledged.

As the authorized representative of the study, the MESA Coordinating Center will oversee and coordinate the distribution agreements for collaborating investigators. This includes verifying that Collaborating Investigators and the Recipients sign the appropriate agreements and keeping them on file. The MESA Coordinating Center will serve as the initial contact for the distribution of Data and Materials and will coordinate Materials distribution in conjunction with the appropriate MESA laboratory. The DMDA will be reviewed and signed by the MESA Coordinating Center before distributing Data, or will be reviewed and signed by both the NHLBI Project Office and the MESA Coordinating Center before distributing Materials.

Definitions

Ancillary study – Study involving participants and/or utilizing data from MESA but which itself is funded from non-MESA contract funds, such as grants or internal university funding.

Collaborating Investigator (also Investigator) – Research investigator who does not have a current MESA contract or subcontract, including ancillary study investigators who do not have MESA contracts and other investigators who request data sets to collaborate with Study Investigators on data or materials analyses.

Data – Information that has been collected and recorded from Study participants, including examinations and follow-up contacts conducted pursuant to the MESA Investigators' contract with the NHLBI. It also includes data that were collected by ancillary studies and provided to the Coordinating Center for inclusion with other data, according to the Ancillary Studies Policies (generally 12 months after data collection). Data include Genetic Analysis Data (see definition). Data do not include blood, urine, or DNA samples or original images from scans.

Genetic Analysis Data – Data derived from the analyses of DNA samples contained in Biological Materials including, but not limited to, genotyping analysis, anonymous marker polymorphisms, single nucleotide polymorphisms, DNA sequence information, mutation analysis, mapping, and other genetic analyses including data derived from statistical analyses linking genetic with clinical or other data.

Materials - Biological Materials, including blood, urine, DNA and other tissue, and products thereof, including immortalized lymphocytes and extracted DNA, collected and prepared in MESA. Materials also include any finite or original images from scans, such as videotapes.

MESA Authorized Representative – Individual with responsibilities for data management and Data and Materials distribution designated by the Coordinating Center.

MESA Investigator (also Study Investigator) -- Research investigator with a current and active contract or consulting agreement with NHLBI to work on MESA, or a subcontractor to a MESA contractor, who is proposing the research project and is directly responsible for its conduct and for adhering to this agreement.

Programmer/Analyst – Individual with access to data set who is not an investigator but is conducting data analysis for the proposed study.

Recipient (also Recipient Organization) – Representative of the institution with which the Investigator is affiliated and where requested Data and/or Materials are to be sent. For *Materials*, the representative should be from the institutional business office. For *Data*, the representative may be the Department Chair or other appropriate official from the department of the Investigator.