

Data Use Agreement (DUA) for the International Myositis Assessment and Clinical Studies Groups (IMACS) Outcomes Repository

Provider: The National Institute of Environmental Health Sciences (“NIEHS”) and Recipient (“Recipient Institution”) _____ hereby enter into this Data Use Agreement (“DUA”) as of the date specified on the final page hereof.

NIEHS is operating the IMACS Outcome Repository (“Repository”), as a Non-Genetic study contained within the National Institutes of Health’s (“NIH”) Protocol 94-E-0165 entitled “Studies in the natural history and pathogenesis of idiopathic inflammatory myopathies”. The primary objective of the Repository is prospective validation of outcome measures for myositis trials, including response criteria known as the "Preliminary Definitions of Improvement" (definitions of flare or worsening), and clinical trial design issues. The goals are to develop standardized, validated outcome measures for myositis therapeutic trials, compare responses to therapies, develop predictors of therapeutic response, and further validate the various tools that are in the Repository. To accomplish the Repository’s objectives and goals, pooled data from the Repository will be shared with other researchers for secondary or future research projects who have received approval by the Repository’s Data Use Committee and agreed to the terms of this DUA.

IMACS has obtained a number of data sets from prospective therapeutic trials and natural history studies for adult and juvenile myositis. These data sets (“Repository Data”) refer to the information which has been collected and recorded from study participants through the periodic examinations and follow-up contacts conducted.

Repository Data has been stripped of all personal identifiers but the wealth of data available on them might make possible the individual identification of some subjects. To protect the confidentiality and privacy of these study participants, the Recipient, who is granted access to these Repository Data, must adhere to the requirements of this DUA. Failure to comply with this DUA could result in denial of further access to Repository Data and may leave requesting investigators liable to legal action on the part of study participants, their families, or the U. S. Government.

The IMACS Repository Investigators, defined as research investigators who have contributed data to the IMACS Outcomes Repository, have made a substantial long-term contribution in establishing and maintaining this clinical database. IMACS seeks to encourage appropriate collaborative relationships by outside investigators with the IMACS Repository Investigators and to ensure that the contribution of the IMACS Repository Investigators is appropriately acknowledged.

Recipient and _____ (“Recipient Principal Investigator”), requests access to Repository Data at its sole risk and at no expense to IMACS and NIEHS.

AGREED TERMS AND CONDITIONS

It is mutually agreed as follows:

1. Research Project.

1.1 These Repository Data will be used by Recipient Principal Investigator solely in connection with the Research Project, specifically described in an attached Appendix A. The Research Project should include: project title, a 1-2 paragraph description of the objectives and design, and a brief description of the analysis plan. Recipient agrees that Repository Data will not be used in any research that is not disclosed and approved as part of the Research Project.

The Recipient Principal Investigator also agrees to undergo a review by the IMACS Research Advisory Committee, before or after obtaining Institutional Review Board (“IRB”) approval, and to attempt to incorporate suggested changes into their Research Project.

In order to receive Repository Data, the Recipient and all institutions participating in their study must hold a Federal Wide Assurance Agreement with the U.S. Department of Health and Human Services (“DHHS”) and their IRB or Ethics Committees must also be registered with DHHS. A copy of the Recipient Principal Investigator’s IRB or Ethics Committee approval is included as part of this DUA. Their institution’s Federal Wide Assurance Agreement Number is _____.

Recipient acknowledges that the conditions for use of these Repository Data are not exempt from review and have been approved by the Recipient’s IRB operating under an Office of Human Research Protections-approved Assurance and in accordance with DHHS regulations at 45 CFR Part 46. Recipient agrees to comply fully with all such conditions. Recipient agrees to report promptly to IMACS any proposed change in the Research Project and any unanticipated problems involving risks to subjects or others. This agreement is made in addition to, and does not supercede, any of Recipient’s institutional policies or any local, State, and/or Federal laws and regulations which provide additional protections for human subjects.

1.2. The Research Project includes (check one):

_____ IMACS Repository Investigator(s) as co-investigator(s). The names of the IMACS co-investigators and their roles in the Research Project are described in Appendix B.

_____NO IMACS Repository Investigator(s) as co-investigator(s).

1.3. This DUA covers only the Research Project described in Exhibit A. Recipient will submit a completed DUA for each research project for which Repository Data are requested.

2. Non-transferability. This DUA is not transferable. Recipient agrees that substantive changes made to the Research Project described above, and/or appointment by Recipient of another Recipient Principal Investigator to complete the Research Project, will require execution of a new DUA in which the new Recipient Principal Investigator and/or new Research Project are designated. Furthermore, Recipient agrees to retain control over Repository Data, and further agrees not to transfer Repository Data to any other entity or any individual.

3. Publication. Recipient agrees to provide to IMACS a copy of any manuscript document thirty (30) days in advance of submission for publication and fifteen (15) days in advance of submission or presentation for all meeting abstracts and presentations, in order to ensure compliance with the confidentiality requirements set forth in paragraphs 1.2, 2, 4, 5, and 6 of this Agreement. These documents will be reviewed by the IMACS Research Advisory Committee for appropriate content and acknowledgements (below). The purpose of a central IMACS Outcomes Repository is not to infringe upon or prevent publications by the primary contributing investigators (Contributors) who have submitted data to the Repository. While, prompt publication or any public disclosure of the results of the Research Project is encouraged, the Recipient Principal Investigator understands that if the data requested in appendix A of this DUA is data from an ongoing study, Recipient may be asked to delay publication utilizing such data for a period of up to two years after a Contributor's trial data has been locked, in order to allow Contributor first option to publish Contributor's own primary data. A subset of the Contributors' databases may be utilized for a study prior to two years after the Contributors' databases have been locked, if the Contributors and the IMACS Research Advisory Committee agree that this use would not infringe on the Contributors' publication of his/her primary data.

Recipient Principal Investigator agrees to abide by IMACS Outcomes Repository publication policies (<http://www.niehs.nih.gov/research/resources/collab/imacs/researchguidelines.cfm>).

4. Acknowledgments. Recipient agrees to acknowledge the contribution of the IMACS Repository Investigators in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Repository Data. Acknowledgement of the contribution of specific IMACS Repository Investigators is expected in all oral and written presentations. Recipient will acknowledge the source of the Repository Data by including language similar to the following either in the acknowledgment or in the text of the manuscript:

“This manuscript was prepared using a limited access dataset obtained from the International Myositis Assessment Clinical Studies Group, however manuscript does not necessarily reflect the opinions or views of IMACS Group or the National Institute of Environmental Health Sciences”.

4.1. Collaborations. If the Research Project involves collaboration with IMACS Repository Investigators, then the manuscript will also be reviewed by contributing IMACS Repository Investigators and Recipient will provide co-authorship to contributing IMACS Repository Investigators and/or participants, if scientifically appropriate.

5. Non-Identification. Recipient agrees that Repository Data will not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the subjects from whom Repository Data were obtained.

6. Non-Data. Notwithstanding the definition of “Repository Data” or the agreed Terms and Conditions of this DUA, Recipient’s obligations under this DUA shall not extend to any information:
 - (a) that can be demonstrated to have been publicly known at the time of disclosure; or
 - (b) that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to Recipient from another source prior to the disclosure; or
 - (c) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by Recipient; or
 - (d) that can be demonstrated as independently developed or acquired by Recipient without reference to or reliance upon Repository Data provided under this Agreement; or
 - (e) that is required to be disclosed by law, provided the Recipient takes responsible and lawful actions to avoid and/or minimize such disclosure.

7. Non-Endorsement, Indemnification. Recipient agrees not to claim, infer, or imply Governmental endorsement of the Research Project, the entity, or personnel conducting the Research Project or a resulting commercial product(s) except as described in paragraph 4. It is the intention of the Recipient that Provider not be liable to any parties for any liabilities, demands, damages, expenses, or losses arising from the Recipient’s use for any purpose of Repository Data. No indemnification is provided or intended by either Party.

8. Amendments. Amendments to this DUA must be made in writing and signed by authorized representatives of all parties.

9. Termination. NIEHS may terminate this DUA if Recipient is in default of any condition of this DUA and such default has not been remedied within 30 days after the date of written notice by NIEHS’ authorized representative of such default.

10. Disqualification, Enforcement. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional Repository Data. The United States Government shall have the right to institute and prosecute any proceeding 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 Repository Data 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 proceeding 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 Repository subjects, their families, or both.

The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient Institution: _____
Address: _____

Signature of Recipient's Authorized Official Date

Name of Authorized Official: _____
Title of Authorized Official: _____
Email of Authorized Official: _____

Signature of Recipient Scientist Date

Name of Recipient Scientist: _____
Title of Recipient Scientist: _____
E-mail for Recipient Scientist: _____

PROVIDER INFORMATION AND AUTHORIZED SIGNATURES

Provider Institution: National Institute of Environmental Health Sciences
Address: 111 T.W. Alexander Drive, MD A2-09
Research Triangle Park, NC 27709

Signature of Provider's Authorized Official Date

Name of Authorized Official: Dr. Elizabeth M. Denholm
Title of Authorized Official: Director, Office of Technology Transfer
Email of Authorized Official: _____

Signature of Provider Scientist Date

Name of Provider Scientist: Lisa G. Rider, M.D.
Title of Provider Scientist: Deputy Chief, Environmental Immunology Group
E-mail for Provider Scientist: _____

PLEASE RETURN SIGNED FORM AS A PDF TO: denholme@niehs.nih.gov

Appendix A
Research Project

Appendix B

Participating IMACS Repository Collaborators and their role in the work