Data Distribution Agreement

The National Institute of Environmental Health Sciences (NIEHS) and _____ (Name of Recipient Organization) hereby enter into this Distribution Agreement as of the date specified on the final page hereof.

The International Myositis Assessment and Clinical Studies (IMACS) Group has obtained a number of data sets from prospective therapeutic trials and natural history studies for adult and juvenile myositis.

Data collected by the IMACS Outcomes Repository have 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 participants, the Recipient who is granted access to these data must adhere to the requirements of this Distribution Agreement. Failure to comply with this Distribution Agreement could result in denial of further access to Study Data. Violation of the confidentiality requirements of this agreement is considered a breach of confidentiality and 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 clinical database. The IMACS Group seeks to encourage appropriate collaborative relationships by outside investigators with the Study Investigators and to ensure that the contribution of the Study Investigators is appropriately acknowledged.

DEFINITIONS

For purposes of this agreement, “Data” refers to the following information, which has been collected and recorded from Study participants through the periodic examinations and follow-up contacts conducted:

Data from the Study refers to the IMACS Outcomes Repository.

An “IMACS Repository Investigator” is defined as a research investigator who has contributed data to the IMACS Outcomes Repository.

Principal Investigator requests access to Study data at its sole risk and at no expense to the Study and NIEHS.

Principal Investigator:
_____, with a principal address at
_____ (**"**PI") requests access to Study data at no expense to the Study and NIEHS.

AGREED TERMS AND CONDITIONS

It is mutually agreed as follows:

1. Research Project.

    1.1. The PI requests (check one)
    ___Non-Commercial Purpose Data Set
    ___Commercial Purpose Data Set

1.2 These Data will be used by Recipient's Principal Investigator solely in connection with the following research project ("Research Project"), specifically described in an attached Exhibit A. The project description 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 Data will not be used in any research that is not disclosed and approved as part of the Research Project.

The principal investigator also agrees to undergo a review by the IMACS Research Advisory Committee, before or after obtaining IRB approval, and to attempt to incorporate suggested changes into their research plan.

In order to receive data from the IMACS Outcomes Repository, the principal investigator's institution and all institutions participating in their study must hold a Federal Wide Assurance Agreement with the US Department of Health and Human Services (DHHS) and their Institutional Review Boards (IRB) or Ethics Committees must also be registered with DHHS. A copy of the principal investigator's IRB or Ethics Committee approval is included. Their institution's Federal Wide Assurance Agreement Number is
_____.

Recipient acknowledges that the conditions for use of these Data are not exempt from review and have been approved by the Recipient's Institutional Review Board (IRB) operating under an Office of Human Research Protections (OHRP) - approved Assurance and in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipient agrees to comply fully with all such conditions. Recipient agrees to report promptly to the IMACS Group 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.

1.3. The Research Project (circle one); [does][does not] involve IMACS Repository Investigator(s) as co-investigator(s). If the Project does involve IMACS Repository Investigator(s), their names are:

and the work they will perform is described the project description in an attached Exhibit B:

1.4. This Distribution Agreement covers only the above-described Research Project. Recipient will submit a completed Distribution Agreement (this document) for each research project for which Data are requested.

2. 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 Principal Investigator to complete the Research Project, require execution of a new Distribution Agreement in which the new Principal Investigator and/or new Research Project are designated. Furthermore, Recipient agrees to retain control over Data, and further agrees not to transfer Data to any other entity or any individual.

3. Publication. Prompt publication or any public disclosure of the results of the Research Project is encouraged. Recipient agrees to provide to IMACS a copy of any manuscript or other disclosure document thirty (30) days in advance of submission for publication, in order to ensure compliance with the confidentiality requirements set forth in paragraphs 4,5,6,7,and 8 of this Agreement. The principal investigator understands that the purpose of a central IMACS Outcomes Repository is not to preempt publication of any other studies by the primary contributing investigators.

4. Acknowledgments. 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.

4.1. Collaborations/Acknowledgments. If the Research Project involves a collaboration with IMACS Repository Investigators, then the manuscript will be reviewed by contributing IMACS Outcomes Repository Investigators and Recipient will provide co-authorship to contributing IMACS Repository Investigators and/or participants. In addition, the Recipient will acknowledge the source of the 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 IMACS Group and NIEHS.

4.2. Other Studies/Acknowledgments. If the Research Project does not involve a collaboration with IMACS Repository Investigators, then the manuscripts or other disclosure documents should be submitted to the IMACS Group thirty (30) days in advance of submission for publication. The manuscripts will be reviewed by the IMACS Coordinators and Recipient will use the acknowledgment printed below.

> "This Manuscript was prepared using a limited access dataset obtained by the International Myositis Assessment and Clinical Studies (IMACS) Group and does not necessarily reflect the opinions or views of IMACS or the NIEHS." The IMACS investigators who contributed data to the investigator's data set will also be acknowledged.

Acknowledgement of the contribution of specific IMACS investigators is also expected in all oral and written presentations.

5. Non-Identification. Recipient agrees that 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 Data were obtained.

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

7**.** No Distribution. Recipient agrees to retain control over Data, and further agrees not to transfer Data, with or without charge, to any other entity or any individual.

8. Non-Data. Notwithstanding the definition of "Data" or the agreed Terms and Conditions of this Distribution Agreement, Recipient's obligations under this Distribution Agreement 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 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.

9. 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 any resulting commercial product(s) except as described in paragraph 4. To the extent permitted by law, Recipient agrees to hold the United States Government, Study Investigators, and all other investigator(s) who generated Data 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.

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

11. Termination. NIEHS may terminate this Distribution Agreement if Recipient is in default of any condition of this Distribution Agreement and such default has not been remedied within 30 days after the date of written notice by NIEHS' Authorized Representative of such default.

12. Disqualification, Enforcement. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional 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 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 Study subjects, their families, or both.

13. Accurate Representations. Recipient expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.

Signatures begin on the next page.

This Distribution Agreement is entered into as of: _____
(effective date)

RECIPIENT:

Name of Recipient Organization:_____

Name and Title of Recipient's Authorized Institutional Business Official:_____

_____

Signature and Date of Recipient's Authorized Institutional Business Official:_____

_____

PRINCIPAL INVESTIGATOR:

Principal Investigator's Name and Title:_____

_____

Principal Investigator's Surface Mail Address:_____

_____

Principal Investigator's E-Mail Address:_____

Principal Investigator's Telephone Number: _____

Principal Investigator's Fax Number:_____

Signature and Date: Principal Investigator:_____

IMACS Group (NIEHS):

IMACS Coordinator Representative:

Signature and Date of IMACS Coordinator: _____

_____

Name and Title of NIEHS Authorized Representative: _____

_____

Signature and Date of NIEHS Authorized Representative: _____

_____