IMACS OUTCOMES REPOSITORY COLLABORATION AGREEMENT

I agree to the request of the International Myositis Assessment and Clinical Studies Group (IMACS), that I shall collect data using the IMACS tools in the prescribed data format that has been supplied to me and submit these data in this format to the IMACS Outcomes Repository within one year of the completion of my clinical study. The primary objective of the Outcomes Repository is prospective validation of the Preliminary Definitions of Improvement (including modifications and refinements of them), and clinical trial design issues. Other applications of the data include comparing responses to therapies and developing predictors of therapeutic response. I understand that other investigators may apply to the IMACS Research Review Committee for approval of studies using the pooled data that may be unrelated to my primary study.

I understand that in order to participate in the IMACS Outcomes Repository, my institution and all institutions participating in my study must hold a Federal Wide Assurance Agreement with the US Department of Health and Human Services (DHHS) and my/their Institutional Review Boards (IRB) or Ethics Committees must also be registered with DHHS. The data repository will store all subjects' data coded and without personally identifying information.

Regarding protection of subjects' confidentiality, I understand that I must choose one of four options to submit the database (please check the one option selected):

_____1) I plan to amend my IRB/Ethics approval of my existing protocol to suggest that the IMACS measures and ancillary data will be contributed to the IMACS Outcomes Repository upon completion of the study. Subjects' consent forms would be modified and subjects would give signed consent for use of their data in the IMACS repository. I will supply documentation of my IRB/Ethics approval to Drs. Rider and Miller.

____2) I have not begun my study at this time. I plan to include information in my IRB/Ethics approval that the IMACS measures and ancillary data will be contributed to the IMACS Outcomes Repository upon completion of my study. Subjects would give signed consent to include their data in the IMACS repository. I will supply documentation of my IRB/Ethics approval to Drs. Rider and Miller.

_____ 3) I will obtain local IRB/Ethics approval for the protocol, "Studies in the Natural History and Pathogenesis of Idiopathic Inflammatory Myopathies". My consent form would include language that the subjects agree to have their coded IMACS measures and ancillary data entered into the IMACS Outcomes Repository. I will supply documentation of my IRB/Ethics approval for Dr. Rider's protocol and a copy of the consent form to Dr. Rider.

____4) I have already completed my research study, or I am in progress with my study and unable to change the protocol/consent forms to include use of the data in the IMACS Repository. Upon completion of my trial/study, data will be anonymized by a third party. After the anonymization is completed, there will not be any link maintained to the clinical data or to personally identifying information. Drs. Rider and Miller would apply to NIH Office of Human Subjects Protection to request an exemption for use of data from my trial/clinical study for the IMACS Outcomes Repository, and would receive the data after obtaining the exemption.

I understand that the purpose of a central IMACS Outcomes Repository is not to preempt publication of any other studies. After completion of my study, the data supplied by me may be pooled with other such data from IMACS members and analyzed collectively to assess the performance of the IMACS tools and develop improved tools and response criteria to assess myositis outcomes.

In terms of the data to be included in the IMACS Outcomes Repository, I understand this will include the

1. IMACS Core Set Measures of Disease Activity (including Physician and Patient/Parent Global Activity Assessment, Manual Muscle Testing, Physical Function measured by the HAQ or CHAQ, muscle enzymes, and Extra-Muscular Activity assessed by the Myositis Disease Activity Assessment Tool), as outlined on the IMACS web site at
http://www.niehs.nih.gov/research/resources/collab/imacs/diseaseactivity.cfm

2. Core Patient Data, Assessment of Trial Status, Assessment of Study Outcomes, and Clinical Trial Design Features will also be completed. These forms are located at
http://www.niehs.nih.gov/research/resources/collab/imacs/imacsforms.cfm

3. Optional data for inclusion are listed below and these will be discussed in advance with Drs. Rider and Miller:
a. Assessment of Disease Damage (Physician and Patient/Parent Global Damage, Myositis Damage Index):
http://www.niehs.nih.gov/research/resources/collab/imacs/diseasedamage.cfm

b. Childhood Myositis Assessment Scale (CMAS)
https://dir-apps.niehs.nih.gov/imacs/docs/activity/cmas.pdf

c. Disease Activity Score (DAS)
http://www.niehs.nih.gov/research/resources/collab/imacs/restrict/forms/dis_act_score.pdf

d. Patient-reported Outcomes (SF-36 or CHQ-PF50)
http://www.niehs.nih.gov/research/resources/collab/imacs/patientoutcome.cfm.

In terms of entry and storage of data from my clinical trial/study in the IMACS Outcomes Repository, I agree to one of the following two options (please check the one option selected):

_____1) To enter data from my trial/clinical study directly into the repository. My co-investigators and I will be given a secure password for data entry upon satisfactory resolution of the ethical/regulatory requirements listed above. I may use the IMACS Outcomes Repository database, an on-line secure Oracle database, as the primary database for my own study, and I will have sole access to my primary data while my study is being conducted and analyzed. Upon completion of the study, I would then release the data to the IMACS repository for possible additional analyses to be undertaken by IMACS members that are unrelated to my study.

____2) I will provide IMACS with the database from my study. The database must be in a format that is compatible with the IMACS Outcomes Repository database. I also agree to provide IMACS with a codebook of variables and variable names, as well as a frequency distribution of the major variables. The database from my study would be posted as part of the IMACS Outcomes Repository and would be available for use by other IMACS investigators as described below. (Note: data contributed through exemption would be contributed this way)

All investigators with IRB or ethics committee-approved protocols will be allowed to access the IMACS Outcomes Repository following an application to the IMACS Research Advisory Committee. The application would include details of the planned study and demonstration of institutional review board/ethics committee approval (including all participating institutions holding a Federal wide assurance agreement with DHHS and having their IRB approved by DHHS). Data recipients will be asked to sign a recipient agreement. I understand that by contributing data to the repository that I would be eligible to

participate in these studies, to contribute to the review of manuscripts resulting from them, and that it is the intent that I would be offered co-authorship on publications resulting from a pooled analysis of any data from my own study that is included in a manuscript using the data in the IMACS Outcomes Repository if I am involved in the project or manuscript in a substantial way.

Name	Signature
Affiliation	
Address	
Phone	email
Date	Federal wide assurance agreement number