

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

Dear Investigator:

This letter is to inform you of the American College of Rheumatology (ACR)-sponsored International Myositis Assessment and Clinical Studies Group (IMACS) Outcomes Repository and to solicit your participation by providing data from your ongoing trial or clinical study in myositis. The ACR has supported IMACS' effort to prospectively validate the Preliminary Definitions of Improvement for Myositis. IMACS is establishing a database repository of core set measures and responses to therapy from a number of prospective therapeutic trials and natural history studies. These data will be pooled for analyses to prospectively validate the Preliminary Definitions of Improvement and to derive new response criteria for clinical trials. The repository will also be available to investigators with IRB- or ethics- committee approved protocols as a resource for other questions. The contribution of your data in the repository would qualify you for authorship on any resulting publications.

The IMACS database is a secured on-line Oracle database which is one way de-identified. Only coded data is entered and contributing IMACS investigators maintain the link to the code, which they will not share with IMACS. Data may be entered into the IMACS database during the course of your clinical trial or study; only the investigators participating in your study would have access to the data until its conclusion and publication of results, at which time you would release the data to IMACS. Alternatively, data can be retrospectively entered into the IMACS database. A third way you can participate is to utilize your own database for your study, which can later be released to IMACS, but in this case you must provide a codebook of variables and a compatible format.

To participate in the IMACS Outcomes Repository, there are two major requirements: regulatory requirements and an agreement to contribute the minimum required data.

Regulatory Requirements:

For your study to be included in the IMACS Outcomes Repository, you must have local ethics committee or institutional review board approval (IRB) for your study and approval to contribute this study to the IMACS Outcomes Repository. All participating centers must hold a Federal Wide Assurance agreement and their IRB's must have approval by the US Department of Health and Human Services http://www.hhs.gov/ohrp/assurances/assurances_index.html and <http://www.hhs.gov/ohrp/assurances/index.html>:

There are 3 mechanisms for your study to be formally involved in the IMACS database repository:

- A. For studies with local ethics committee or IRB approval, the local protocol can include or be amended on site to approve submission of data to the IMACS data repository. The data that is submitted would be coded, de-identified data in which the local investigators will maintain the code key, but not share this with IMACS study personnel. The consent form would include permission for use of the core set measures and other requested data in the IMACS Outcomes Repository, if required by the local IRB/ethics committee. You would need to submit a copy of your local IRB approval and consent form to us to include your trial/study in the IMACS Outcomes Repository.
- B. We have a NIH IRB approved natural history of myositis protocol, which includes collection of the IMACS core set measures and establishment of the repository. This

protocol could be approved locally at your institution and your center can be approved for participation by the NIH IRB. This mechanism may be appropriate for one or a few centers participating in a study.

- C. If your study has been completed and has been terminated (is no longer under IRB/ethics committee review), existing data could be submitted to the IMACS Outcomes Repository as one-way de-identified data, with submission of a request for exemption to your local IRB/ethics office. Often in these cases, the IRB also does not require that the patients be re-consented for contribution of the data to IMACS. You would submit a copy of the local IRB exemption document that enables you to contribute data to the IMACS Outcomes Repository.

Under all of these mechanisms, after the IRB approval or exemption has been obtained, you and NIEHS personnel would sign the Data Submission Agreement, which is a data transfer agreement with NIEHS that outlines the regulatory requirements of the submission and stipulates which data are being received by the IMACS Outcomes Repository. Please seek the guidance of your local technology transfer office and if modifications of the agreement are needed, NIEHS technology transfer personnel would conduct negotiations for changes to the agreement.

Data Requirements:

A minimum data set that will be acceptable for entry into the IMACS data repository will include the following IMACS forms. We are willing to discuss this further with you if your trial has most of the required elements, but not all of them.

Here we provide the form number and link to the IMACS members' web site where you can view the specific forms (they may all be viewed at:

<http://www.niehs.nih.gov/research/resources/collab/imacs/diseaseactivity.cfm>.

1. Physician Global Assessment of Disease Activity: IMACS Form 02, found at http://www.niehs.nih.gov/research/resources/collab/imacs/docs/activity/phys_glob_act.pdf.
2. Patient/Parent Global Assessment of Disease Activity: IMACS Form 03, found at http://www.niehs.nih.gov/research/resources/collab/imacs/docs/activity/pt_parent_glob_act.pdf
3. Manual Muscle Testing: MMT8 is the minimum dataset required. IMACS Form 04, found at <http://www.niehs.nih.gov/research/resources/collab/imacs/docs/activity/mmt.pdf>
4. Functional Assessment Tool: Health Assessment Questionnaire or Childhood Health Assessment Questionnaire. IMACS Form 05a or 05b, found at <http://www.niehs.nih.gov/research/resources/collab/imacs/docs/activity/hag.pdf> and <http://www.niehs.nih.gov/research/resources/collab/imacs/docs/activity/chag.pdf>.
5. Muscle enzymes: at least 2 for each patient assessment in your study. IMACS Form 06, http://www.niehs.nih.gov/research/resources/collab/imacs/docs/activity/lab_musc_enzy.pdf
6. Myositis Disease Activity Assessment Tool: IMACS Form 07a, 0-4 version 2, 2005, see http://www.niehs.nih.gov/research/resources/collab/imacs/docs/activity/mdaat_2005_0-4_ver2.pdf
7. IMACS Trial Status (IMACS Form 12, found at <http://www.niehs.nih.gov/research/resources/collab/imacs/restrict/forms/12trialstatusfinal.pdf>
8. IMACS Assessment of Study Outcomes: (IMACS Form 11, found at http://www.niehs.nih.gov/research/resources/collab/imacs/restrict/forms/11assessmentstudy_outcomes.pdf
9. IMACS Core Patient Data: IMACS Form 01, found at <http://www.niehs.nih.gov/research/resources/collab/imacs/restrict/forms/01corepatientdata.pdf>
10. IMACS Trial Design Features: This form is completed one time for your study. <http://www.niehs.nih.gov/research/resources/collab/imacs/restrict/forms/00trialdesigntool.pdf>

Extended Data: The following data are not required for inclusion in the IMACS data repository, but the option to enter this data into the IMACS Outcomes Repository will exist:

12. Childhood Myositis Assessment Scale (CMAS): IMACS Form 05c, found at <http://www.niehs.nih.gov/research/resources/collab/imacs/docs/activity/cmas.pdf>
13. Disease Activity Score: IMACS Form 13, found at http://www.niehs.nih.gov/research/resources/collab/imacs/restrict/forms/dis_act_score.pdf
14. Physician and Patient/Parent Global Damage and the Myositis Damage Index. These can be found at <http://www.niehs.nih.gov/research/resources/collab/imacs/diseasedamage.cfm>
15. Patient reported outcomes - either the SF-36 or the Child Health Questionnaire (CHQ-PF50), found at <http://www.niehs.nih.gov/research/resources/collab/imacs/patientoutcome.cfm>.

We greatly appreciate your considering collaborating in this important IMACS initiative to improve clinical assessments and ultimately the treatment of myositis subjects. Our next steps in this process would be to proceed with IRB approval for your study to contribute to the IMACS Outcomes Repository and completion of the Data Submission Agreement, followed by our providing you access to the on-line IMACS Outcomes Database on the IMACS website to enter data from your trial/clinical study.

We would also like all contributors to the IMACS Outcomes Repository to serve on the Research Advisory Committee that will review proposals for use of the IMACS Repository data. Please consider whether you are willing to serve on the Research Advisory Committee for the repository, and let us know.

Please contact us with any questions on this proposal.

Sincerely,



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And



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