

## *The International Myositis Classification Criteria Project (IMCCP)*

Dear Colleagues,

We appreciate your willingness to share your expertise with us and collaborate in The International Myositis Classification Criteria Project (IMCCP). The goal of this project is to develop new and valid classification criteria for adult and juvenile myositis and its major subgroups for use in clinical and basic research studies. We are writing to ask for your help in patient data collection. Based on statistical power calculations we will collect information from 1 000 patients with idiopathic inflammatory myopathies (including both adult and juvenile-onset) and 1 000 patients with non-inflammatory myopathies, other systemic autoimmune diseases and mimicking cutaneous conditions (including adult and pediatric control groups) as a comparator group.

In the first phase, we request that you contribute clinical and laboratory data from a minimum of 10-15 patients and if possible up to 30 patients with adult or juvenile inflammatory myopathies and the same number (minimum of 10- 15 patients and up to 30 patients) who do not have myositis but where myositis could be within the general differential diagnosis. If you have submitted information on up to 15 cases and 15 comparator cases and if enrollment goals are not achieved, we will re-contact you to request information on additional patients and/or comparators (the maximum number per site is 60 cases). Following institutional review board (IRB) or ethics approval, the collected data will be entered in a coded format into a web-based questionnaire, so that no identifying information on the patients will be revealed. A paper version is also available if you prefer that method of submission.

This project first requires approval from your local IRB (ethical review board) or the IRB may recommend that this retrospective study of patient records could be exempted. To facilitate IRB approvals we have posted templates for IRB forms on the IMACS web-site together with the list of variables to be collected and a glossary. These can be obtained at: <http://www.niehs.nih.gov/research/resources/collab/imacs/classificationcriteria.cfm>. After you have obtained IRB approval, please scan and email or fax the IRB approval to Ingrid Lundberg (for address, please see below). After the IRB approval is received, you will receive an Identification Center number which is to be used to assign your case ID-numbers. You will also receive the website address and a log-in to obtain access to the web-based survey where you enter your patient data. If you prefer, you can instead use the paper questionnaire with variables for submission. This questionnaire is posted on the IMACS website at the link provided above.

The data collection phase will be followed by statistical analyses. Based on these analyses, new sets of criteria will be proposed. These proposed criteria will be sent out to get your input before finalizing the set of criteria. This will be validated in a new set of patients.

This procedure may result in some costs for you. We have received limited funding for the project from The Myositis Association. Thus there is a possibility to receive some limited reimbursement up to a maximum of \$ 400 US dollars per center for the medical record review which may include IRB fees, costs of pulling charts from medical records, and costs of the record review, including payment of a physician or clinical research associate to do the review. As the funding is limited, we will provide funding to those who complete their case submissions first (submitting the minimum number of 15 myositis cases, 15 comparators).

Unfortunately when the funding runs out, there may not be possibilities for reimbursement. The reimbursement will be sent to you after we have received your patient data and confirmed its accuracy with you and when all questions to the submitter have been satisfactorily resolved.

Participants who contribute with the minimal number of cases (10- 15) will be listed as co-authors of resulting manuscripts. How this will be done will depend on the guidelines of the journal to which we will submit the manuscript.

In advance, we thank you for your contribution in this exciting project and we will keep you updated on the progress.

Stockholm 2008- 01- 12

*Ingrid Lundberg, MD, PhD*

Chair, International Myositis Classification Criteria Project Steering Committee

On behalf of the other Steering Committee members:

Anthony A. Amato, Rick Barohn, Marianne de Visser, Gerald Hengstman, Peter A. Lachenbruch, Matthew Liang, Frederick W. Miller, Clarissa Pilkington, Lisa G. Rider, Richard Finkel and Vicky Werth

Contact information:

IMACS website: <http://www.niehs.nih.gov/research/resources/collab/imacs/main.cfm>

For questions on the IRB documents: Anthony A. Amato, M.D. Email:

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For general questions or questions on the survey:

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