

IMACS Research Project Study Guidelines

I. General Considerations

Investigators who are IMACS members may apply to utilize the IMACS Outcomes Repository. IMACS has established an Outcomes Repository as a collection of prospective therapeutic trials and natural history studies that are collecting data using the IMACS Core Set Measures of Disease Activity. Ancillary data for other measures of disease activity, disease damage, and patient reported outcomes are available for some of the studies. The primary objective of the IMACS Outcomes Repository is prospective validation of the definitions of improvement (including modifications of and refinements in them), and clinical trial design issues. Other applications of the data include comparing responses to therapies and developing predictors of response.

The IMACS Outcomes Repository is open to IMACS members for research projects beyond the planned analyses of the contributing investigators and the IMACS Coordinators. Such studies would ask new questions and would make use of the data available in the Outcomes Repository.

II. Procedures.

Each investigator who contributes data (Contributor) to the IMACS Outcomes Repository may become a member of the IMACS Research Advisory committee, which will review proposals for use of the Repository data and proposed publications and meeting abstracts/presentations. The initial research proposal will be sent by email from the proposing investigator to the Chair of the IMACS Research Advisory Committee who will forward it to the Committee. Their recommendations and any comments will be returned to the Chair of the IMACS Research Advisory Committee within 30 working days. A summary prepared by the Chair of the Research Advisory Committee will be forwarded to the investigator **within 14 working days of receiving the comments.**

- The proposal may be approved subject to the investigator providing a written response to comments raised by the review committee.
- If the proposal is not accepted/approved as submitted, the investigator will be given the opportunity to provide responses and comments to the review committee and the opportunity to request further review and reconsideration of the proposal.

III. Format for Submission of Research Study Proposals to the IMACS Research Advisory Committee.

The Research Study Proposal should contain the following elements:

Specific Aims and Background

Resources required (specific data, samples etc)

Source of funding of project (NIH, The Myositis Association, EULAR, etc.)

Timeline

Relevance to IMACS goals

Risks and safety concerns

Impact on IMACS for data management and analysis

Statistical methods, including power calculations

CV or Biosketch of principal investigator, brief biosketches for other key study personnel.

Following the approval of a research study by the IMAC Research Advisory Committee, the principal investigator should obtain local IRB approval and then submit this to the IMACS coordinators for submission to the NIH IRB.

The investigator will then submit a Data Use Agreement (DUA); the Research Study Proposal should be submitted as Appendix A and B of the DUA.

IV. Study Logistics.

Following acceptance of the proposal by the IMACS Research Advisory Committee, local IRB approval (or exemption) must be obtained. The principal investigator and all participating sites must hold a Federal Wide Assurance Agreement with the Department of Health and Human Services. A Data Use Agreement will then be signed between NIEHS and the principal investigator. IMACS will then release the necessary portion of the database to complete the requested project.

V. Publication Policy

Publications shall include all publicly disclosed oral or written material such as seminar slides, abstracts, research and review papers.

The purpose of a central IMACS Outcomes Repository is not to infringe upon or prevent publications by the primary Contributors who have submitted data to the Repository.

IMACS Outcomes Repository Data includes completed studies/trials as well as studies/trials that are ongoing. In order to give the Contributors of ongoing studies the first option to publish on his/her own data, publication delays may be requested by the IMACS Research Advisory Committee. Such delays may be for up to a period of two years following the locking of a Contributor's study/trial database. However, subsets of Contributors' data may be utilized for a study prior to a database being locked, if the Contributor and the IMACS Research Advisory Committee agree that this use would not infringe on the Contributor's publication of his/her primary data.

The IMACS Outcomes Repository shall be acknowledged in any publications that utilize Repository Data. Authorship of publications should include Contributors of data as co-authors as appropriate, per The Uniform Requirements for Manuscripts Submitted to Biomedical Journals (http://www.icmje.org/ethical_1author.html).

The IMACS Research Advisory Committee shall receive a copy of manuscripts that use these data 30 days prior to submission for publication and copies of meeting abstracts or presentations 15 days prior to submission. The committee will review these materials for content and to see that it has appropriately recognized the contribution of contributing IMACS members.