IMACS Research Project Study Guidelines

I. General Considerations

Investigators who are IMACS members may apply to IMACS for collaborative research in several areas.

1. Use of 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 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 These studies must be independently funded by the investigator or by resources obtained by the investigator and must be IRB or ethics board approved studies.

2. New IMACS Studies.

These studies are not currently part of IMACS, but propose questions and test hypotheses that are relevant to, and congruent with, the goals and purposes of IMACS. Such studies may require additional tests or data that are not obtained by the IMACS Outcomes Repository or other ongoing IMACS studies. These studies may involve IMACS participants and clinical sites or others, depending on the eligibility criteria of the study, sample size needed, and interest of IMACS investigators in participating. Ideally, such a study will require modest demands on the time and effort of participants, clinicians, and clinical center coordinators. These studies must be independently funded by the investigator or by resources obtained by the investigator and must be institutional review board or ethics board approved studies.

If IMACS data are to be used for the study, these data will become part of the IMACS archive. Raw and "processed" data will be archived and publications will be listed on the IMACS website.

II. Procedures.

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. Comments from the research advisory committee will be returned to the Chair of the IMACS Research Committee within 30 working days. The investigator is requested to incorporate suggested changes from the Research Advisory Committee. A summary prepared by the Chair of the Research Review 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 advisory committee.
- The investigator will be given the opportunity to provide responses and comments to the advisory committee and the opportunity to request further review and reconsideration of the proposal.

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

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
Acknowledgment of IMACS in any publications that develop
CV or Biosketch of principal investigator, brief biosketches for other key study personnel

III. Final Submission for Use of the IMACS Outcomes Repository

Once the proposal is reviewed by the research advisory committee and appropriate comments incorporated, a final proposal is submitted to the IMACS Coordinators (Lisa Rider and Frederick Miller) to obtain NIH institutional review board approval. The submission package would include:

-The final research proposal
- A copy of the institutional review board approval (or exemption if using anonymized data), including demonstration that the principal investigator and all participating sites hold a Federal Wide Assurance Agreement with DHHS and their IRB/Ethics Committee has approval from DHHS
-A signed NIH Data Distribution Agreement.

Following approval by the NIH institutional review board, the investigators will be provided with an anonymized portion of the database pertinent to their project, as well as with the codebook of IMACS variables. It is expected that projects using IMACS data will include the appropriate IMACS members as co-authors on resulting publications.