



Standard Operating Procedures

The purpose of this document is to describe the steps for a research project involving the IMACS registry. The process should be fully collaborative and result in a publication. The IMACS Research Committee (RC) is ultimately responsible for the entire process. The IMACS DCC at KIRSO will assist the IMACS RC. The following steps of the entire research process are necessary to ensure both good science and collaboration. For ease of use, the dates listed in exhibit B are assuming that the abstract and manuscript will be submitted to the International Society of Heart and Lung Transplant.

1. Call for proposals:

- Applications may be submitted by any qualified investigator (junior investigators are encouraged) affiliated with a participating IMACS center or contributing collective (e.g., EUROMACS), who is also an ISHLT member in good standing. Collectives may coordinate requests on behalf of their member centers. Industry applications are not eligible. An application from an investigator affiliated with a center not participating in IMACS may exceptionally be accepted after adequate justification of why they cannot participate in IMACS and will require approval by the RC. In this case, the senior faculty member or co-investigator must belong to a participating IMACS center or be the project liaison from the RC.
- Authorship of the application by a trainee or junior faculty member (assistant professor level) is strongly encouraged. If the proposal is developed with major input and/or supervision from a senior faculty member of the applying institution, a participating IMACS center, or member of the RC of the IMACS, this should be indicated on the application. If the applicant suggests that the proposal would strongly benefit from inclusion of an external specialist (e.g. Oncologist, Nephrologist, Neurologist, Geneticist etc.) as part of the writing group, this should be indicated in the application and suitable individuals should be named in the application including contact information.
- Applications are limited to one proposal per principal investigator(PI). Institutions may submit multiple applications with different PIs.

2. Submission of a research proposal:

The purpose of the proposal is to present the background, specific aims/hypotheses, and strategy for utilization of IMACS data, anticipated results and a brief timeline. See Exhibit A for the IMACS application. In order to ensure a fair and timely process, applications will not be accepted from researchers who have ongoing IMACS research projects that have not yet resulted in a submitted manuscript. This requirement may be waived at the discretion of the RC. The timeline for proposal submission and notification is shown in Exhibit B.

3. Review of applications by the Research Committee:

The RC will review each blinded proposal for both scientific merit and the ability of IMACS data to address the hypotheses and aims. Before review of a proposal, the IMACS DCC will update the RC on the regulatory status of the applicant's institution, including status of the local Institutional Ethics Review Board (IRB) approval, and current completeness of IMACS data. If necessary, the committee will ask the applicant to participate in a conference call to present their proposal and/or answer questions about the proposal. RC members will score the projects using Exhibit C. The RC representatives from each collective are responsible for reviewing internal studies to ensure overlap does not exist with a project being conducted by the individual collective.

4. Notification of acceptance/rejection of proposal:

The Vice Chair of the RC will provide written notification of the proposal status to each applicant as outlined in Exhibit B. In addition to acceptance or rejection, the RC may choose to delay a proposal for various reasons (e.g. additional data collection). The RC will also create a writing group consisting of other IMACS Investigators as outlined in the charter.

One RC member will be assigned to each accepted project to serve as the **Project Liaison**. The role of this individual will be to:

- Collaborate with DCC statisticians and primary investigators on study design and analysis
- Assist in developing timelines in line with Exhibit B
- Ensure the study stays within the scope of the submitted proposal
- Provide critical review of abstracts, presentations, and the final manuscript
- Confirm all authors have had the opportunity to review manuscripts and provide comments prior to submission
- Ensure all IMACS projects are submitted to the entire RC for review and approval

5. Applicant becomes the Principal Investigator (PI):

Once a proposal is accepted, the applicant now becomes the PI for the study. The PI is responsible for all steps of the research project.

- For analyses performed by the DCC, the IMACS DCC will collaborate with the PI but the primary responsibility for the research project belongs to the PI.
- The PI should provide suggestions for co-authors to the IMACS RC.

6. Authorship and Writing Group Selection:

- For each research proposal and data analysis, the IMACS Steering Committee must approve the PI to serve as chairperson of the project writing group (WG).
- The PI assigned to each specific research proposal and data analyses will be primarily responsible for all phases of manuscript preparation, from conception through publication. Responsibilities include:
 - Preparation of project outlines and the identification of data analyses needed from the DCC
 - Assignment of tasks to WG members, clear deadlines for completion of these tasks, and assuring that the tasks are completed on schedule.
 - Assuring that the manuscript has approval of the WG before submission of the penultimate draft to the IMACS Steering Committee.
 - Ensuring all abstracts, presentations and manuscripts are submitted to the IMACS RC for approval.
 - Submission of the order of authorship on the manuscript to the IMACS RC. The major criterion for this determination will be the effort and contribution made by the members of the WG in preparation of the manuscript. (WG members who do not contribute substantially shall not be listed as authors). Final approval of the order of authorship will be made by the IMACS RC.
 - Recommendation of a journal to which the manuscript will be submitted with priority given to the *Journal of Heart and Lung Transplantation*, but not required. The final choice of journal remains at PI discretion, provided it is a peer-reviewed journal of appropriate scientific standing.
 - Correspondence with co-authors, communication with the IMACS RC, responses to the pre-submission ISHLT review, and correspondence with journal editors.
- The rest of co-authors will be assigned as follows:
 - One member of the RC will be assigned as the Project Liaison.
 - Senior author proposed by the PI. If the PI has no senior author, the Project Liaison could act as senior author or suggest a senior author.
 - One member from the DCC who will be involved in the project to merit authorship.
 - The IMACS Chair and the IMACS Vice Chair of data studies if they are sufficiently involved in the project to merit authorship.

- The PI can suggest up to 3 other co-authors with due justification.
- Members of the RC can suggest other authors, who are members of the participating collectives, with adequate justification to merit authorship.
- A statement of “on behalf of the IMACS investigators” will be included for every abstract and publication.
- The first and senior authors of the project will arrange a discussion call regarding study design, methodology and core data analysis with the IMACS statistical and support staff and the Project Liaison prior to a first writing group call. Deadlines for abstract submission and preferred journal for submission can also be discussed / established at that time.

7. Detailed plan of work:

The PI will create a detailed plan of work including a quantitative review of the literature, specification of the endpoints, creation of templates for figures and tables, anticipated results of the analyses and a detailed timeline.

8. The research collaboration:

The actual analyses will be a collaborative effort. The IMACS DCC will produce the requested analyses and will review these analyses with the PI. The PI is responsible for updating and including all members of the IMACS Writing Group assigned to the abstract, including scheduling of regular conference calls, email updates, etc. for all steps of the project including detailed analyses plans, abstract generation and manuscript preparation.

9. Abstract for conference presentation:

The PI will generate the proposed abstract based on the collaborative analyses. The abstract must be completed one month prior to the abstract submission deadline.

- For analyses performed by the DCC, the IMACS DCC and the IMACS RC will review the abstract during the month before the deadline. The PI is responsible for distribution of the abstract to the co-authors and to the current members of the IMACS DCC.
- Actual submission of the abstract will be done by the PI.

10. Once the PI is notified that the abstract is accepted for presentation at a meeting, the PI must notify the co-authors of the abstract and the IMACS manuscript:

The PI is responsible for generating the manuscript.

- For analyses performed by the DCC, the IMACS DCC will produce the “journal ready” figures and tables using precise direction from the PI.
- The PI is responsible for circulating the manuscript to the co-authors and providing the IMACS DCC with a copy one month before submission for review by the RC. Ideally, the manuscript would be submitted to a journal at the same time as the conference presentation. The IMACS leadership strongly recommends that the manuscript be submitted at the time of presentation. If not submitted at the time of conference presentation or intended to be submitted to another journal, the manuscript must be completed within one year of receipt of data.
- All manuscripts, abstracts, and presentations must acknowledge IMACS and contributing collectives, and follow ICMJE authorship guidelines.

11. Presentation:

- The PI is responsible for the presentation.

- For analyses performed by the DCC, the IMACS DCC will almost always prepare the figures and the tables.
- The PI must circulate the presentation to the co-authors prior to the conference.

12. Adjudication of Disagreements (Writing Groups): Appeals regarding the selection of WG membership and assignment of a Chairperson will be sent to the IMACS Steering Committee at which time a conference call will be arranged among the investigator submitting the appeal to attempt resolution.

Disagreements between authors will be settled by discussion and consensus whenever possible or, if consensus cannot be achieved, by the IMACS Steering Committee.

13. Adjudication of Disagreements (Authorship): Disagreements regarding authorship, which cannot be resolved by the Chairperson of the WG, will be resolved by the IMACS Steering Committee and the ISHLT Board.

14. Informal Presentations: Presentations of the study rationale, design and plan of the study are encouraged as a recruiting strategy to begin at any time and continue throughout the study. However, presentation of outcome data prior to its formal presentation at an international or national meeting and based on a printed abstract is prohibited. These data should be regarded as privileged by IMACS investigators until they become part of the public domain. Caution is required about undue publicity of data presented orally but not yet published.

15. Destruction of IMACS data: It is the responsibility of the PI to destroy all IMACS data within 24 months of project acceptance or upon acceptance of the final manuscript, whichever comes first. It is also the responsibility of the PI to notify IMACS in writing of the date of data destruction.

The International Committee of Medical Journal Editors has recommended the following criteria for authorship; these criteria are appropriate for those journals that distinguish authors from other contributors.

- Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined above and editors will ask these individuals to complete journal-specific author and conflict of interest disclosure forms. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name. Journals will generally list other members of the group in the acknowledgements. The National Library of Medicine indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript.
- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Some journals now also request that one or more authors, referred to as “guarantors,” be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.

Increasingly, authorship of multi-center trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship.

The order of authorship on the byline should be a joint decision of the co-authors. Authors should be prepared to explain the order in which authors are listed.

* Available at: <https://www.icmje.org>.



Imacs

Agreement

I agree that I have read and understood the terms of completing a proposal.

By signing this form, I agree that I will abide by all deadlines and tasks as a research applicant.

Name (printed)

Signature

Date