

Publication Guidelines

- 1. MISHC will have a Proposal Review Committee which will be comprised of nine physicians, including both surgeons and interventional cardiologists, to review and approve proposals for statistical analysis.
 - Four reviewers will be the MISHC Program Co-Directors.
 - Three reviewers will be represented by the 3 highest volume sites in the State of Michigan, exclusive of Michigan Medicine. These three sites will each appoint one reviewer to the committee. Volume will be re-assessed every two years.
 - Two reviewers will be invited to participate who represent geographies, health systems, and/or other diverse characteristics not already represented on the committee. Invited reviewers will serve on the committee for two years.

Five reviews must be provided at a minimum, per proposal, and including review by at least two surgeons and two interventional cardiologists.

- 2. The MISHC Coordinating Center will oversee this process, compile the reviews and communicate results to the investigators. The Committee will target a turnaround time of 30 days.
- 3. The Coordinating Center will provide quarterly updates to the Publication Committee on the progress of approved manuscripts.
- 4. No one can use analysis of Consortium data for research or analytic purposes independent of the work of the Consortium (meaning that participants can't take data from the Consortium for private research or analysis without going through the Proposal Review Committee process.)
- 5. Each individual participating center can use its OWN data as it sees fit, but not to actively compete in the market place (e.g., not to compare its complication rates to those of others, derived from comparative performance reports, in public settings). Individual research not within the QA/QI domain may be subject to local IRB rules.
- 6. A preliminary review of all proposals will be conducted by the Coordinating Center to assess whether a proposal meets feasibility requirements:
 - The proposed analysis is for data collected by the ACC/STS/TVT
 - A sufficient number of cases exists in the database to test the proposed hypothesis
 - No other proposals have been submitted to test the same hypothesis
 - The proposal meets the requirements of the publication guidelines

Data Analysis Requests and Authorship Guidelines



- 1. Request for Consortium Data Analysis:
 - a. Access to Collaborative-wide data will be provided through analysis by the statisticians at the Coordinating Center.
 - i. If a surgeon submits a proposal for analysis and is intended as first author, data analysis will be provided by the statistician at MSTCVS with a collaborative review performed by the statistician at BMC2.
 - ii. If the submission is made by an interventional cardiologist, data analysis will be provided by the BMC2 statistician with a collaborative review performed by the MSTCVS statistician.
 - iii. If the proposal is made by a surgeon/cardiologist team, the analysis will be performed by the available statistician with a secondary review by the other statistician.
 - All requests will be submitted to the registry project managers, (Patty Theurer <u>ptheurer@med.umich.edu</u> and Annemarie Forrest <u>avassalo@med.umich.edu</u>). Requests must be made using the Publication Proposal Submission Form found at mishc.org on the Publications page. Annemarie and Patty will distribute the proposal for review to the statistician(s) and Publication Committee.
 - c. Sites will be provided with their own data on request.
 - d. The hospital physician champion should determine who from the site is qualified and to submit proposals to MISHC for access to Collaborative data and statistical analysis. *Qualified individuals are not limited to physicians.*
 - i. The physician champion should be copied on the email submission of the Publication Proposal Submission Form.
 - ii. The physician champion should determine if the individual submitting the proposal should have a designated sponsor co-submit the proposal in order to provide mentorship and guidance through the analysis and publication process.
 - iii. At minimum, fellows and residents must have a sponsor to co-submit a proposal to MISHC, and must have ongoing guidance and oversight of the project from faculty.
 - iv. The sponsor will be copied on all correspondence about the analysis and manuscript.
 - v. Fellows must have at least submitted one manuscript before they can submit another proposal for consideration by MISHC.
 - e. Sites can do as they choose with their own site data; no proposal to MISHC is needed.
 - f. All proposal submissions will include:
 - i. Reason for requesting data
 - ii. Brief description of what data is needed
 - iii. If data requested is for an abstract, include hypothesis and data fields needed and a basic statistical plan.
 - iv. Timeline (i.e. if data requested is needed for an abstract deadline)
 - g. For "first authors",



- i. One proposed paper per analysis must be submitted; prospective authors cannot obtain an approved "blanket proposal" for any paper they might wish to write in a subject area.
- ii. May serve as lead author on only one proposal at a time.
- h. Approved proposals will be given a timeline for statistical analysis. This timeline will depend on availability of a statistician.
- i. All communications with the assigned statistician should include the Project Directors. Any "new" analysis requests must have the approval. PD involvement in each project is essential because the PDs understand strengths and weaknesses of the available data. The PDs will help to facilitate the investigators communications with the Coordinating Center.
- 2. Abstract/Manuscript Submission:
 - a. The MISHC Coordinating Center must be informed prior to submission of all abstracts and manuscripts. The MISHC Coordinating Center should also have ongoing information about the status of acceptance. The MISHC Coordinating Center is responsible to notify BCBSM of manuscripts from CQI work at the time of journal submission and acceptance of publishing. BCBSM is to be provided a copy of published manuscripts and information regarding reprinting, reposting and/or redistributing articles.
 - b. Author sign-off should be obtained prior to abstract/ manuscript submission.
 - c. Manuscript submissions must contain acknowledgements of support if publisher allows: "Support for MISHC is provided by Blue Cross and Blue Shield of Michigan and Blue Care Network as part of the BCBSM Value Partnerships program" and the disclaimer "Although Blue Cross Blue Shield of Michigan and MISHC work collaboratively, the opinions, beliefs and viewpoints expressed by the author do not necessarily reflect the opinions, beliefs and viewpoints of BCBSM or any of its employees."
- 3. Authorship Guidelines:
 - a. Eligibility for inclusion as a co-author includes active commitment to and involvement in the project as evidenced by <u>at least one</u> of the following:
 - i. actively participating in discussions of the publication and substantively contributing to the development of a study project, and/or resultant analysis and interpretation of the findings
 - ii. idea inception
 - iii. providing scientific guidance in carrying out the project
 - iv. manuscript development and review
 - b. Authors are responsible for following publisher's guidelines related to number and contribution requirements of co-authors.



- c. Prospective authors on a manuscript should be described on the proposal request form for review by the publication committee. Co-authors will include:
 - i. Lead interventional cardiologist, surgeon, and one trainee from the authoring site
 - ii. Statistician
 - iii. Program directors, unless they choose to remove themselves
 - iv. Other participating physicians from a variety of participating hospitals from within the MISHC to be chosen by the lead author and must contribute to the discussion and provide pertinent value to the review
 - v. At least one surgeon and one interventional cardiologist must be included as authors on any MISHC manuscript.
- d. Co-authors will be updated on the status of manuscript submission and acceptance.
- e. If 6 months have elapsed without a completed manuscript, the author should engage the consortium Directors in dialogue about how to bring the project to conclusion in the form of a completed manuscript. Alternatively, if the author does not take this initiative, the Consortium Directors, may do so and arrange an appropriate assignment of a primary author role in order to maintain project momentum. Discussion will include active involvement of the initial primary author.

The primary author is expected to respond to reviewer's comments and submit an updated manuscript within 1-2 months of peer review. If the author is unable to meet these deadlines, he/she should approach the consortium Directors for necessary help and guidance. Alternatively, if the author does not take this initiative, the Consortium Director, may do so and arrange an appropriate assignment of a primary author role in order to maintain project momentum. Discussion will include active involvement of the initial primary author.