

IBEM-IS Publication Procedures

I. Purpose

One of the goals of the Region 4 Genetics Collaborative Priority 2 Workgroup is the dissemination of findings through high quality presentations and publications. To realize these ends, the Workgroup has established these publication procedures. The procedures confirm the Workgroup's commitment to collaboration, equity, excellence, and timeliness in the publication of study findings and deliberations. It is crafted to ensure that the data generated in this project are available for comprehensive and valid analysis by both Workgroup investigators and scientific collaborators outside of the Priority 2 Workgroup.

II. Ownership of the Research

The Priority 2 Workgroup will retain custody of and have primary rights to the data developed from independent research initiated and conducted in collaboration with partners from within the Priority 2 Workgroup. Any proposal to use data generated by a study protocol must first be approved by a review team and then by the Priority 2 Workgroup. .

For collaborative or co-endorsed studies initiated outside of the Priority 2 Workgroup, MPHI, on behalf of the workgroup and the Region 4 Genetics Collaborative will negotiate rights to data. These rights will be established in a Memorandum of Agreement prior to study initiation. The a review team comprised of representatives of the Priority 2 Workgroup will review and approve any such Memorandum of Agreement.

III. Research Agenda Development and Approval

Proposals will be considered both from within, and beyond the Priority 2 Workgroup. See [Priority 2 Rules for Research and Request of IBEM-IS Data.](#)

IV. Publications and Presentations

A. Approval

Approval of data use for primary analyses occurs when the Priority 2 Workgroup, or the

Review Team on behalf of the Workgroup, approves a Data Request. Any proposal to use data generated by a study protocol for secondary analyses (analyses that are related to new hypotheses not specified in the original data request) must first be approved by the Workgroup, or Review Team established on behalf of the Workgroup.

All abstracts, presentations, and manuscripts related to the IBEM-IS studies/protocols must then be approved by the Priority 2 Workgroup and receive HRSA clearance prior to submission or presentation at any formal meeting. Presentations or submissions without prior approval are inconsistent with the spirit of collaborative research and may result in denial of access to data and a cessation of collaborative support.

Individual Review Teams are empowered by the Priority 2 Workgroup to review and approve an abstract, presentation, or manuscript based on the content of the submission and the related approved protocol. MPHI, on behalf of Region 4, will identify members of the Review Team.

Abstracts and Presentations

The approval process for an abstract or presentation requires at least 10 working days. The abstract or presentation is submitted to MPHI and distributed to the Review Team for approval. The Review Team members review the submission within 5 working days. The abstract and reviewers' comments and recommendations are collected and compiled by MPHI. Compiled recommendations are shared with the review team within 2 days. A simple majority vote is required for approval of the abstract or presentation by the Review Team. If approved with revisions, final sign-off by the reviewers is required. Therefore, the remaining 3 working days will be utilized for the MPHI, on behalf of the Review Team, and the requesting author to work out the required changes, if any.

Manuscripts

A manuscript presented for approval must be submitted at least 10 working days prior to the call/meeting when it is to be reviewed. The manuscript is submitted to MPHI and distributed to a Review Team identified by MPHI. The designated reviewers complete their review of the manuscript within 5 working days. The manuscript and reviewers' comments and recommendations are then distributed to the Priority 2 Workgroup 3 working days prior to the call/meeting when the manuscript will be discussed. The reviewers' recommendations are presented on the call/meeting and time is allowed for discussion. A simple majority vote is required for approval. If approved with revisions, final sign-off by the reviewers is required.

An author's request for use of resources to produce an abstract prior to full manuscript development must be approved by the Priority 2 Workgroup. Analytical work will not be halted to produce data for an abstract de novo unless clinically critical information has been uncovered. In general, papers will be written first and then a meeting at which to present a related abstract can be selected.

Any request to deviate from this full review policy must be submitted to the MPHI, and will only be granted for compelling reasons.

B. Post-Journal Submission

1. If a manuscript is not accepted for publication and reviewer feedback indicates a need to reformulate the essential components of the analyses before the manuscript can be resubmitted or submitted to another journal, the team must submit proposed revisions to the Priority 2 Workgroup.

2. If a manuscript is accepted provisionally with required or recommended changes/additions, if a journal invites a revised draft of the same article, or if an article is being submitted to another journal with minimal changes, the lead author in consultation may respond to the editor. It is the responsibility of the lead author to differentiate between alterations which reflect mere editorial changes and those which essentially

modify the analyses and/or conclusions of the study previously approved by the Priority 2 Workgroup and report these conclusions to MPHI, acting on behalf of the Region 4 Priority 2 Workgroup, prior to responding to the editor requesting the changes/additions/revisions.

C. Site-specific Data Presentations

Data presentations being formally submitted to regional or national meetings descriptive of local activities or data collected through the IBEM-IS should first be cleared through the Priority 2 Workgroup.

D. Manuscript Development

1. Timelines

Initial manuscript work on the main manuscript from each protocol is expected to begin within 30 days of final data cleaning. The lead clinician will provide a monthly status report to the Priority 2 Workgroup.

2. Authorship: All manuscripts shall list all contributors in behalf of the IBEM-IS; i.e., at a minimum the Priority 2 Workgroup should be included as the last entry of the authorship listing...”and the Region 4 Genetics Collaborative Priority 2 Workgroup”.

3. Sponsoring Agency Credit: All manuscripts must credit the sponsoring federal agencies and note the award number of i.e. The Region 4 Genetics Collaborative Is funded by HRSA/MSCH Cooperative Agreement U22MC03963.