



Priority 2 Rules for Research and Use of IBEM-IS Data

1. All participating centers entering data in the registry will have access to non-PHI.
2. All publications will credit the entire group. The lead author or presenter will be the person(s) who does/do the majority of the work to set up the project, but they will still credit the Region 4 Priority 2 workgroup.
3. The Region 4 logo should be included on all electronic presentations and materials.
4. There are two types of research projects: 1) Data mining (use of registry data) and 2) establishing a study cohort from the IBEM-IS (expanded data).
5. Individual projects need to be reviewed/approved by a scientific review team. Each proposed project will follow the same review and assessment process. However, for Data Mining Projects, the decision can be made by the four person review and the Priority 2 Workgroup notified of the review team decision. For Cohort Projects, the review team will recommend action on the proposal to the Priority 2 Workgroup. Decision will be made by formal action (motion and vote) of the Priority 2 workgroup members and will be recorded in meeting notes.



Review and Assessment of Proposals

1. Proposals will be accepted and reviewed on a quarterly basis. Proposal quarters coincide with the calendar year (January 1 – March 31, April 1 – June 30, July 1 – September 30, and October 1 – December 31). Proposals received up to thirty days before the first day of a given quarter will be reviewed during that quarter (e.g. received on or before June 1 for review in quarter beginning July 1). ***(Exceptions may be considered to address timeliness issues such as funding deadlines or policy changes. Researcher must provide a written request explaining the need for the exception).***
2. Proposals may be made from within and beyond the Priority 2 Workgroup.
3. MPHI receives proposals
4. MPHI forms a 4-person review team comprised of a) public health b) parent/family member or Region 4 Parent Coordinator, c) clinician, and d) methodologist. Reviewers cannot include any person(s) proposing the research or someone from the proposing institution. First review is anonymous. Reviewers identify will not be shared by MPHI.
5. MPHI disseminates materials – proposal and review tool
6. MPHI collects, compiles reviewer comments, questions and recommendations
7. MPHI provides questions to researcher
8. MPHI receives responses from researcher; reviews to see if questions have been answered, and forwards responses to reviewers.
9. MPHI receives final comments, decision from reviewers. ***In the event discussion among reviewers is required to reach consensus, MPHI will facilitate a telemeeting discussion.***
10. MPHI identifies one team member to provide a summary for the Priority 2 workgroup
 - a. For data mining – decision and summary are shared with Priority 2 workgroup during next telemeeting
 - b. For Cohort projects – Summary and recommendation are shared with Priority 2 workgroup during next telemeeting. Workgroup members must indicate conflict of interest, if applicable. Decision is determined by workgroup action in the form of motion and vote. Decision is recorded in meeting notes.
11. MPHI notifies researcher of review decision and specifies documentation required prior to release of data (e.g. copy of IRB approval, data use agreement, etc.)