



## Perinatal Quality Foundation

*Improving the quality of obstetrical medical services*

### **PQF data analysis & research collaboration proposals:**

To request data from any of the PQF programs for secondary analysis of data or for research collaboration with the PQF, the investigator should answer all questions on this form and submit to the Research Committee of the Perinatal Quality Foundation at [jspitz@perinatalquality.org](mailto:jspitz@perinatalquality.org)

PQF available databases and programs include: CLEAR, NTQR, FMC, and GEM. NEXT has a separate application and data use rules with Ariosa/Roche as a co-investigator.

Analysis proposal requests should provide sufficient detail to allow evaluation of the data required and comparison of the proposal with other proposed or approved analyses to assess duplication.

If overlapping proposals are submitted, the Research Committee will discuss with the investigators to allow collaboration or revisions of the proposals to avoid duplication or to assist with developing collaboration. If multiple investigators propose similar projects, the PQF research committee may suggest collaboration of the different groups.

It is goal of PQF to support and encourage and research. If the project is extensive, involves a large grant submission, or is otherwise beyond the scope of these brief estimates, we would be very interested in working directly with collaborators to develop these proposals.

### Timeline of applications:

- Analysis proposals may be submitted at any time during the year.
- Because of the lead-time required to complete a large analysis in time for major meeting abstract deadlines, it is recommended that new analysis proposals intended for submission at least 3 months in advance of abstract submission dates.
- PQF research, board, and program committee members (with the exception of PQF staff) serve on a volunteer basis. Therefore, initial timing for proposal review is typically approximately one month after application to receive feedback.
- The PQF research committee may request further information or clarifications of areas of scientific concern. If further revisions are needed, this may require additional time for review and approval.
- Applicants may be asked to do a conference call with the PQF research committee to explain and clarify, present their ideas, and to brainstorm with the committee about improvements to the application. In-person presentations and meetings with the team at SMFM are also possible if timing is appropriate.

After considering the scientific value and feasibility, the research committee will decide whether to approve the proposal and provide access to the project data or systems for analysis or collaboration. The committee will consider the potential for publication during its review of the proposed analysis and is unlikely to approve requests for analyses that are unlikely to be publishable in a national or international journal.



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**Please limit proposals to no more than 2 pages, 12 point font.**

Outline for research proposal:

1. Title: A brief summary of the primary question to be addressed.
2. Primary Author: The investigator who will be primarily responsible for the analysis and subsequent publication.
3. Co-investigators: The other investigators who will be involved in the design and conduct of the project, and co-authors on resulting presentations and publications.
4. Primary Author contact information: Please include e-mail, telephone number, and site affiliation.
5. Background: Why is this an important project? How will it change practice or improve patient outcomes?
6. Objective: A brief description of the purpose of the analysis. Include defined primary and secondary questions and endpoints.
7. Primary Hypothesis
8. Inclusion/exclusion criteria: Describe whether all or a subset of participants in a program will be included. If a subset, describe inclusion/exclusion criteria. If using a program for analysis or evaluation of a study group, then describe the study group.
9. Outcomes:
  - a. Delineate primary and secondary outcomes (variables) to be evaluated.
  - b. If possible, refer to specific data fields from the data dictionary for each database (appendixes).
10. Analyses: Describe the analyses to be conducted. Specific questions that should be answered include:
  - a. Planned analysis and analysis statistics (in detail)
  - b. Will the requesting investigator do the analyses, or are you requesting that the analyses be conducted by the PQR statistical staff? Please note- for the NTQR data set – the number of measurements included (>5 million) may require additional processing power)
  - c. Statistical software purchase/license is your responsibility if you are completing statistics and analysis. R is an free open-source option.
  - d. Collaborators will be given access to a project folder in our SharePoint site, <https://perinatalquality.sharepoint.com/>, where documents can be posted and shared and are expected to utilize this data, project files, etc.
  - e. For data analysis, individual Amazon WorkSpaces will be created for each project, Collaborators/statisticians will be able to load their own statistical software, i.e. SAS or R, on their workspace to perform analysis. These are single individual based, and therefore a statistician must be identified for each project.
11. Expenses & Budget: All expenses including chart review, analysis, and IRB costs are the responsibility of the investigator. Sources of funding must be documented and known to the PQR research committee.
  - a. Please provide budget and the sources of funding for any such costs.
  - b. It is goal of PQR to support and encourage and research. If the project is extensive, involves a large grant submission, or is otherwise beyond the scope of these brief estimates and brief proposal, we would be very interested in working directly with collaborators to develop these proposals.



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- c. Grant applications & support letters (as needed)
- 12. Timeline: Please provide detailed information on when the data is needed, the planned analysis or manipulation timeline, the proposed completion date, and the planned meeting/journals and their deadlines.
- 13. Other information needed:
  - a. Acknowledgement of data use agreement & POF publication policy
  - b. COI statement from PI
  - c. Collaborators are expected to receive IRB approval for projects and must submit this approval to POF research committee before any data access will be given.

Send the completed proposal to [jspitz@perinatalquality.org](mailto:jspitz@perinatalquality.org)



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