



NPC-QIC Report Request

Reports from the NPC-QIC Registry Database may be provided by Cincinnati Children's Hospital Medical Center (CCHMC) to an active Registry participant (Participant) in good standing. Reports are provided "as is" without additional data cleaning.

Reports will include de-identified and limited data information only, both as to individual and as to site (example: dates cannot be provided). No attempt may be made to re-identify individual patients or individual NPC-QIC sites on the basis of the data provided or other information that may be available in the public domain. Reports may not be shared in any fashion that links program identities to their specific registry data or risks accidental re-identification of the site. Data may not be used in any fashion that promotes any individual center. If your study will involve limitations to the IRB and DUA, then a data analysis will be done at CCHMC.

1. Process for Requesting Reports

- A. PI must have a written protocol that outlines the research question and identifies the exact data variables that are requested for the study.
- B. The PI shall submit an NPC-QIC Research Proposal Form and protocol to the Scientific Research Committee (SRC) for review.
- C. After proposal approval, a signed original NPC-QIC Report Request must be received by the SRC.
- D. PI receives local IRB approval or Non-Human Subjects (NHS) Research determination and sends to eREG-NPCQIC@cchmc.org.
- E. Once a specific research proposal is approved, and documentation of any required review is received, a report from the NPC-QIC Registry necessary for completion of the study as approved, and a data dictionary, will be provided. This report **may not be used** for any other study or purpose without the prior explicit approval of the SRC.
- F. Approval for use of the report is granted **for a one year period**, by which time it is expected that an abstract and/or manuscript will have been completed and submitted to the SRC (see below). At the end of the year the PI will return or destroy the report and notify the SRC. The PI may apply for an extension by submitting a written request to the SRC.
- G. The PI will report **quarterly** to the R&P Committee how the project is progressing and regarding any upcoming abstract or manuscript submissions.

2. Abstract Submissions

It is expected that studies will generate abstract submissions to national meetings. The following process is to be followed:

- A. Clear attribution must appear in the abstract that the report is from the National Pediatric Cardiology Quality Improvement Collaborative Registry.
- B. The final Abstract must be submitted for approval to the R&P Committee **at least 2 weeks prior** to the abstract submission deadline.
- C. The abstract, or any revision of the abstract, **may not be submitted** without prior SRC approval.
- D. NPC-QIC is to be notified (eREG-NPCQIC@cchmc.org) upon acceptance of abstract.

3. Manuscript Submissions

It is expected that studies will result in Manuscript submissions. The following process is to be followed:

- A. Clear attribution must appear in the manuscript abstract and text that the report is from the National Pediatric Cardiology Quality Improvement Collaborative Registry.
- B. The final manuscript **must be submitted** for approval to the SRC. The manuscript, or any revision of the manuscript, **may not be submitted** without prior SRC approval. The SRC may need up to 3 weeks for this review; this timeline should be taken into account for manuscript submissions.
- C. Description of Data – the manuscript should include a description of the NPC- QIC dataset. The following paragraph is an example of such a description:
 “The NPC-QIC includes a voluntary registry that receives data from over 60 pediatric cardiac programs. There is a standard dataset with data definitions, online web-based data entry, and data quality checks. The data are housed in a secure server at Cincinnati Children’s Hospital Medical Center.”
- D. Limitations of Data – the manuscript should include acknowledgement of the limitations of the NPC-QIC dataset. The following paragraph describes some of the limitations: “The NPC-QIC dataset contains retrospective, observational data that are voluntarily submitted from programs participating in the improvement collaborative. Therefore, limitations in the data may relate to patient selection bias, partial datasets for some patients, and/or the heterogeneous composition of participating programs of different sizes and geographic locations.”
- E. Acknowledgements – the manuscript should describe funding sources for NPC- QIC as follows: “Current funding sources for National Pediatric Cardiology Quality Improvement Collaborative include (1) participation fees from enrolled centers; (2) a grant from the Children’s Heart Association of Cincinnati; (3) a federal grant to the pediatric Center for Education and Research in Therapeutics at Cincinnati Children’s Hospital Medical Center, funded by the federal Agency for Healthcare, Research and Quality [#U19HS021114 AHRQ]. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality.”
- F. NPC-QIC is to be notified (eREG-NPCQIC@cchmc.org) upon publication of manuscript.
- G. Copies of the final revised manuscript submitted to the publisher as well as the pdf of the published article must be submitted to eREG-NPCQIC@cchmc.org for posting on the npcqic.org website.

I agree to the above and will assure that they are followed during the project referenced below.

Research / Quality Improvement Project Proposal Title: _____

Phase I Data Phase II Data

Are these data being requested by or being sent to an external network? Yes No

Primary Investigator's Name: _____

Primary Investigator's Signature: _____ Date: _____