

# **Submission Guidelines for New Research Proposals**

#### 1. Submissions

- Quarterly submission dates are recorded on the quarterly schedule document
- Principal Investigators are limited to one open project at a time, unless an additional proposal is part of a multi-institutional project.
- Submissions should be sent to <u>eREG-NPCQIC@cchmc.org</u>
- Regulatory specialist will:
  - o Review applications for completion
  - o Confirm investigator's center is in good standing with NPC-QIC
  - Email proposal packets (the original submission, a blank review form, and the resubmissions and copies of the decision letters sent out by SRC chair if applicable) to Scientific Review Committee (SRC) members with primary reviewer assigned by SRC chair

#### 2. SRC review

- 1) Each proposal will be reviewed by all SRC members
- 2) Committee member absences send in comments and scores ahead of time
- 3) Primary reviewer responsible for presenting proposal on conference call 2-4 weeks after deadline
- 4) Decision to approve, reject, or request modifications will be made at completion of call
- 5) Resubmissions primary reviewer presents resubmission. Ask investigators to submit track change copy or comments section for changes.
  - (i) Request for minor revisions: investigator can submit for review at any time
  - (ii) Request for major revisions: investigator can submit for review at next quarterly meeting
  - (iii) The investigator can modify and resubmit the same project twice. If the committee feels that the investigator has not adequately addressed its concerns by the third revision, the proposal will be rejected.

### 3. SRC approval

- 1) NPC-QIC regulatory specialist will
  - i) Confirm and store Institutional Review Board (IRB) approval letter, Report Request Form, and Protocol
  - ii) Send NPC-QIC Data Report Request to Investigator
  - iii) After all above documents have been received, send email to data team for report release
  - iv) Store all documents including what was released for 6 years
- 2) Primary reviewer will serve as SRC liaison to assist PI with analysis and presentation
- 3) Quarterly progress reports are required after datasets have been released

### 4. Expected Timeline

- 1) If necessary, IRB submission should take place within 3 months of SRC approval. If it has not been submitted within this time, the proposal will be rejected and the investigator will have to resubmit.
- 2) Projects should be completed within one year of the data release. A project is "complete" when a paper has been submitted to a journal

## 5. Presentation of NPC QIC research studies

- 1) Abstracts must be submitted 2 weeks before deadline
  - i) Primary reviewer, parent representative, and SRC chair all review, statistician as needed
- 2) Manuscripts must be submitted 3 weeks before deadline
  - i) Primary reviewer, parent reviewer, and SRC chair assigned. Secondary reviewer and/or statistician as needed.
- 3) Standards for presentation
  - i) Cite the National Pediatric Cardiology Quality Improvement Collaborative Registry as data source
  - ii) info@npcqic.org as resource for questions
  - iii) Use the following statement on funding "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."
  - iv) Primary reviewer, parent representative, and SRC chair all review, statistician as needed
- 4) Copies of the final revised manuscript submitted to the publisher and publication date as well as the pdf of the published article must be submitted to <a href="mailto:eREG-NPCQIC@cchmc.org">eREG-NPCQIC@cchmc.org</a> for posting on the website.