

Welcome to NPC-QIC Research Office Hours

February 25, 2022

Garick Hill



National Pediatric Cardiology
Quality Improvement Collaborative



Mission & Vision

*“Our **mission** is to decrease mortality and improve quality of life for infants with single ventricle congenital heart disease and their families.”*

*“Our **vision** is to dramatically improve the outcomes of care for children with cardiovascular disease.”*



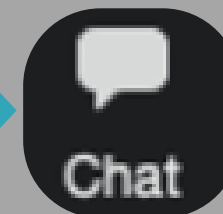
National Pediatric Cardiology *Quality Improvement Collaborative*

**How to
participate**

Reminder:
Please introduce yourself
and your Care Center

You can unmute yourself to
ask a question

OR Use the chat
feature to ask a
question



Confidentiality

All information included in this call is a component of the quality improvement activities of the National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC). This information is confidential, is intended solely for the knowledge and use by call attendees and shall not be disclosed or shared. Call attendees have a responsibility to maintain patient privacy as well as the confidentiality of all NPC-QIC member centers. Any disclosure, copying, distribution or use of this information are strictly prohibited.

This call is being recorded and will be posted on our SharePoint site shortly after the call.

Contributing to the NPC-QIC Community

- Over 60 manuscripts have been published using NPC-QIC data
- Select impactful manuscripts are presented to parents and patients at regular Research Explained meetings

Support for Your Research

- Your proposal will be reviewed by the scientific review committee (SRC), a group of clinicians and parents
- The SRC will offer constructive feedback and support for revisions
- An SRC liaison will check in with your research team quarterly

Why
NPC-QIC?



Draft Your Proposal

Submit Your Project to Your Local IRB

Submit Your Data Request and Approval Documents

Submit Your Manuscript for Approval

Submitting Your Research Proposal



1. Draft Your Proposal

- Complete a Research Proposal Form on npcqic.org
- Draft a thorough proposal
 - Develop a detailed study plan with defined variables
 - Organize and utilize a qualified research team including a statistician
 - Consider and address possible limitations
- Submit proposal to eREG@npcqic.org
- Submission deadlines:
 - April 1
 - July 1
 - October 1



Research Proposal Form

Background/Significance:

State the research question and indicate why the answer is important. Include prior studies, rationale for study and novelty of this project.

Study Aims and Hypotheses:

State the primary aim and secondary aims (if any). Include hypotheses and outcomes for each aim.

Study Design:

Include:

- 1. Study population*
- 2. Inclusion and exclusion criteria*
- 3. Phase 1 data, phase 2 data or both. If both, address how differences between data sets will be handled.*
- 4. Primary outcome variables*
- 5. Secondary outcome variable*
- 6. Predictor variables*
- 7. Additional required data elements*

Research Team:

Include:

- 1. Prior experience with research in this patient population or with similar databases for the Primary Author or mentor.*
- 2. Name of the statistician for the project.*
- 3. If this is a trainee project (student, resident, fellow), name of the primary mentor.*
- 4. Is the study from one center or a multi-institution project? If multi-institutional, list the collaborating personnel/institutions.*

Statistical Analysis Plan:

Consider addressing the following issues in your plan:

- 1. Approach to handling missing data or outliers*
- 2. Methods for testing statistical assumptions*
- 3. Statistical models/tests to be used*
- 4. For the statistical models, list the response and explanatory variables, covariates, interaction terms and other techniques used in the modeling process*
- 5. Consideration for multiple comparison adjustment*
- 6. Mockup of the anticipated tables or figures*



Common Errors & Solutions

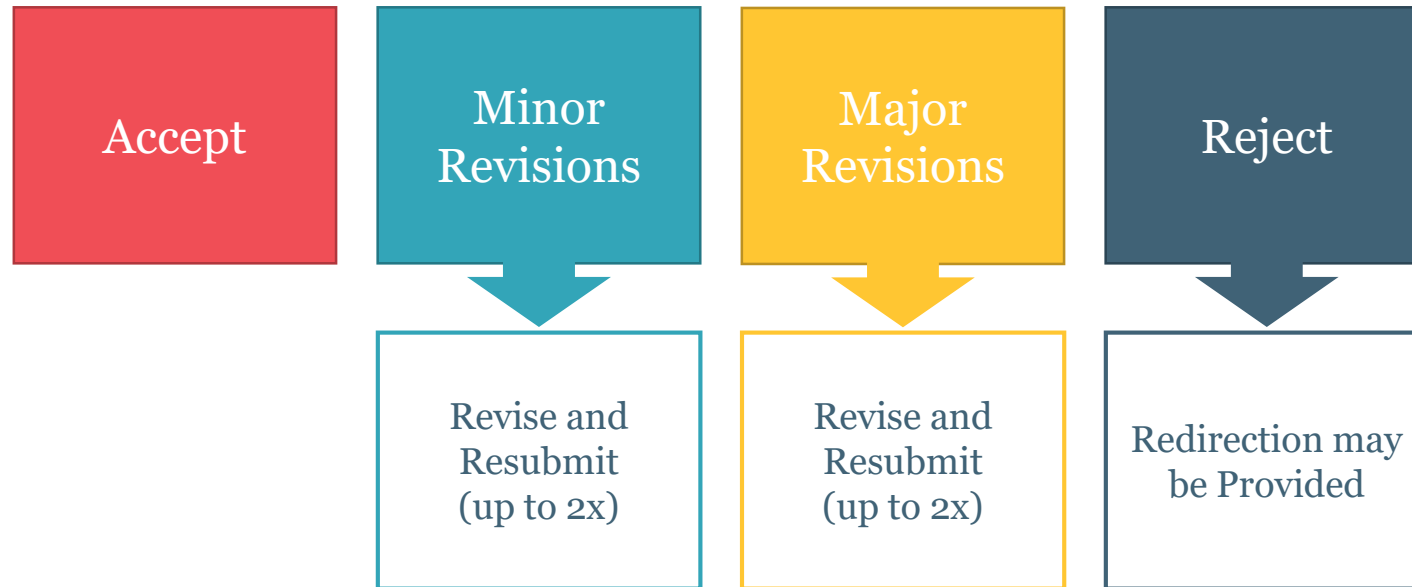
- **Too many or too broad aims**
 - No more than 3 aims; limit many outcomes in a single aim
- **Asking questions, the database can't answer**
 - Review the variables available in the database
- **Generic statistical analysis sections**
 - Consult a statistician
 - Include mock tables and diagrams

2. Submit Your Project to Your Local IRB

- Submit an IRB protocol
- IRB approval or non-HSR determination is required before data is released



SRC Proposal Review



3. Submit Your Data Request Form and IRB Approval

- Once your proposal is accepted, send IRB approval documents to eREG@npcqic.org within 3 months of SRC approval
- Regulatory coordinator will send data request form
- Complete form with requested variables and return
- Data will be sent electronically



4. Submit Your Abstract or Manuscript for Approval

- Receive quarterly check-ins from your SRC contact
- Analysis should be completed within 1 year of data release
- Adhere to NPC-QIC authorship guidelines
- Submit abstracts 2 weeks before deadline
- Submit manuscripts 3 weeks before deadline
- Provide final accepted publication to NPC-QIC



Frequently Asked Questions

Q Do I need a DUA in place with CCHMC to receive data?

A NPC-QIC does not require a DUA to release a dataset

Q My research proposal was returned with minor revisions—what should I do next?

A Work with your SRC liaison to address revisions and resubmit your proposal to be reviewed at any time

Q My research proposal was returned with major revisions—what should I do next?

A Work with your SRC liaison to address revisions and resubmit your proposal to be reviewed at the next quarterly meeting

