

**NPC-QIC Research Proposal Form**

**Contact Information:**

Proposal Submission Date:

Primary Author’s Name:

Primary Author’s E-mail Address:

Primary Author’s Affiliated Institution:

**Project Title:**

**Checklist:**

Primary institution currently submits data to the NPC-QIC:

Yes  No

Will protected health information (dates, zip codes) be needed:

Yes  No

Variable request appendix or table completed:

Yes  No

Data requested from:

Phase 1  Phase 2

Submission type (please track changes if a resubmission):

Resubmission  New

**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*

**Limitations:**

**References:**

**Funding Sources:**

**Human Subjects Research Review:**

Has the proposed project been submitted to your institution’s Institutional Review Board?

* Yes □ No

If not, why not? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Note: The IRB approval letter and IRB Protocol or the IRB waiver of review must be submitted to eREG-NPCQIC@cchmc.org).

**Other Comments:**

Please submit to the NPC-QIC Research and Publication (R&P) Committee at [info@npcqic.org.](mailto:info@npcqic.org)

**Appendix: Requested Data Variables**

NPC-QIC provides data reports for research from the variables collected on Phase I and Phase II NPC-QIC forms. The Phase I forms can be reviewed [here](https://portal.npcqic.org/For%20Researchers/1.%20Materials%20for%20Starting%20a%20Research%20Project/1.%20Phase%20I%20Data%20Dictionary.xlsx?d=wc9a4cc4371ec40e49224ac36e703b86b&csf=1&e=6QxkIN). The Phase II forms can be reviewed [here](https://portal.npcqic.org/For%20Researchers/1.%20Materials%20for%20Starting%20a%20Research%20Project/2.%20Phase%20I%20Variable%20Frequencies%2020Mar2018.xlsx?d=wf55c6214439149258b6ee91c5908368b&csf=1&e=iJ4nBG).

Only variables requested with your proposal, and subsequently approved by the SRC Committee, will be provided. Therefore, please complete the table below with all of the individual data variables you are requesting. This table will be used for review; once your study has been approved, we will ask you to submit a separate data request form to the data team. All data will be released electronically.

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| **Phase I**  **NPC-QIC Data Collection Form** | **Q #** | **Question Name** | **HIPAA Identifier** |
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| Example: Enrollment Form | 5 | Birthweight (kg) | No |
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| **Phase II**  **NPC-QIC Data Collection Form** | **Q #** | **Question Name** | **HIPAA Identifier** |
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