

NBDPN Data Call Template for a Multistate Project without Examples

Project Title: _____

Principal Investigator name, title, affiliation, address and email:

Lead program contact name, affiliation, address, and email:

Initial Request Date: _____

Funding source(s), if applicable: _____

Program Project Investigators/Study Personnel Contact Information and Backup Contact information

Provide contact information below for the lead study contact, principal investigator, and any co-investigators at your site involved in the study, as well as their level of access to confidential data below:

Note: At the time of initial participation and at least once a year thereafter, participating programs will be asked to review the list of study personnel with their contact information and level of data access and provide updates as needed.

Name, Degree, and Title	Email	Phone numbers(s)	Affiliation and address	Role in study	Access to confidential data (including unsuppressed small cell counts?) Y/N

Note: Any personnel with confidential access must have completed human subjects training, with proof submitted as part of IRB application.

Key requirements for participation

Note: This section should include the most important requirements for study data to help programs quickly determine whether they can participate.

Please include here a brief list of the criteria that states must meet in order to be able to participate, such as:

- **Study years:** _____
- **Data structure: individual or aggregate:** _____
- **Required defect(s): (List in Appendix if needed):** _____
- **Estimated deadline for data submission:** _____
- **Number of years of follow-up, if applicable:** _____

- **Data Sources:** (List all data sources for Numerator and Denominator (live births). Examples: Vital Records, Birth Defects program, National Death Index, etc.):

- **Birth Outcomes for cases:**

Study Proposal

Introduction/Background

Include a brief description of the research question/What is known and not known, including references and description of the public health impact/importance of the question:

Study Objectives

Primary aim: *If you are hypothesis-testing, please state the hypothesis*

- ---

Secondary aim(s) (if applicable): *If you are hypothesis-testing, please state the hypothesis*

- ---
- ---

Study Design and Data Collection/Study Population

For Primary Aim I and Secondary Aim 1

Detailed Study Inclusion and Exclusion Criteria:

Note: Detailed variable information and variable coding, including defects required are provided in Appendices.

1. Case information, including birth outcomes requested, and coding system used

ICD-9-CM	ICD-10-CM	CDC/BPA

2. ***Provide Appendices Listing Defects and Other Variables Requested.*** Please note any of the requested defects that your state does not collect on the accompanying Data Submission Questionnaire Form.
3. *Inclusion criteria (list below):*

4. Exclusion criteria (list below):

5. **Data Sources:**

6. **List of Variables required for cases (Attach in Appendix if necessary):** *Please note any variables not collected in your state program or not available during the requested time period in the accompanying Data Submission Questionnaire Form.*

7. **List of Variables required for denominator/controls (Attach in Appendix if necessary):**

8. **Requested Data Structure** (Line level or aggregate, separate numerator and denominator files, etc.)

9. Time period of data requested (birth cohort years) and follow-up time period, if applicable:

If for some reason, participating programs cannot meet the above requirements, differences should be noted on the Data Questionnaire that accompanies the data submission.

Analysis Plan

Predictor Variable(s):

Outcomes of Interest

Birth Defects (attach in appendix, as needed)

Other Outcomes

Analysis Plan

Documentation of status of IRB approval

Data submission method

Please describe secure file transfer method requested and note what types of files participating programs can submit. (N/A if not applicable).

How will data be stored securely? Brief description of where and how data will be stored by lead state.

Data Destruction Plan

Anticipated Study Start and End dates

Anticipated Start Date: _____

Anticipated End Date: _____

List of other participating programs, if known: _____

***Lead Program Primary Contact Information for Data Submission Questions (name, address, phone, email)**

List any other lead program contact information below, if applicable (for example, Vital Records contact or IRB contact):

Detailed description of Case Data with required formats should be provided in Appendices.

REFERENCES

Appendix Example table shells below.

Appendix 1. Birth Defects Requested (Line Level data)

Birth Defects	ICD-9-CM Codes	ICD-10 CM codes	CDC BPA Codes	Notes

APPENDIX 2: Individual level data elements for infants and mothers to be included in “Call for Data”

Variable	Source (C=Created, BC=birth certificate, BD=birth defects registry)	Variable name	Variable type	Notes