

**Data Submission Questionnaire Form for Multi-State Study Participants 8/9/22**

*Top portion and the first part of Question #8 to be completed by lead program*

**Lead state program information**

**Study Title:** \_\_\_\_\_

**Lead program Principal Investigator:**

**Name:** \_\_\_\_\_

**Address:** \_\_\_\_\_

**Phone:** \_\_\_\_\_

**email:** \_\_\_\_\_

**Lead program study contact:**

**Name:** \_\_\_\_\_

**Address:** \_\_\_\_\_

**Phone:** \_\_\_\_\_

**email:** \_\_\_\_\_

**Key eligibility criteria and data restrictions, if applicable:**

**Records for this study are limited to** \_\_\_\_\_.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**IRB information:**

- a. Does this study have IRB approval? **Yes/No/Pending/N/A**
- b. If Yes, what is the IRB number? \_\_\_\_\_
- c. When does the IRB expire? \_\_\_\_\_

**If No, please explain why approval is not required:**

\_\_\_\_\_

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**Participating program information**

**State Program Name:** \_\_\_\_\_

**State Program Director or PI name, address, phone, and email:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**State Program Study Contact name, address, phone and**

**email:** \_\_\_\_\_

\_\_\_\_\_

Please respond to the following questions:

- 1. **Are all requested study cohort years available? (Y/N)**  If not, which years can your program provide?

\_\_\_\_\_

Example: MA can only provide data through 2017 birth cohort.

2. **If applicable, are all requested follow up years available? (Y/N)**  If not, which years can your program provide?

Example 1: Linked infant mortality data only available through first year of life.

Example 2: Death data only available through 2020.

3. **Are all requested defects collected by your program?(Y/N)**  If not, which requested defects can your program provide (or not provide)? Please attach in an Appendix if need more space.

  

Examples: AZ does not collect rectal atresia; As a passive system without verbatim diagnosis, state X cannot distinguish between cleft lip alone and cleft lip +/- cleft palate or between gastroschisis and omphalocele

4. **Are all requested study variables available? Y/N**  If not which ones can your program provide (or not provide)? If needed, give details in attached appendices, noting any differences from what was requested.

  

Examples: MA cannot provide height or weight prior to 2012.

State ZZ cannot provide height or pre-pregnancy weight information.

State Z cannot provide education information before 2011.

5. **Are requested variables provided in the requested data dictionary format? Y/N**  If needed, give details in attached appendices, noting any differences from what was requested. Be sure to note if there are differences in variable availability or format in different study years.

  

6. **Are your birth defects and Vital records linked? (Y/N)**  If Yes, what is the linking variable(s)?

7. **Is your program sending separate numerator and denominator files? (Y/N)** . If yes, are all variables coded in the requested format for the numerator files? (Y/N)  For the denominator files? (Y/N)

If needed, give details in attached appendices, noting any differences from what was requested. Be sure to note if there are differences in variable availability or format in different study

years.:

8. **If applicable: Records for this study are limited to** . **Is your program providing information limited to these? (Y/N)**

9. **If not, what variables being provided to allow subsetting to the group of interest?**

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*(Examples: Females only, those with a prior live birth, etc.)*

10. Can your program defer to the lead program IRB, if applicable? (Yes/No/N/A)

11. If not, does your program require a Data Use Agreement, local IRB approval, or both?

12. If a DUA or IRB are required, please provide contact information for all the relevant people involved, including name, address, phone number, and email address in the space below.

**Birth defects data use or human subjects contact information:**

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**Vital Records data use or human subjects contact information:**

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**Other data use or human subjects contact information:**

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**Appendix 1.**

**Notes on differences from Multi-state Data Call for Cases**

**Case information/Birth Defects**

<b>Birth Defect</b>	<b>Availability</b>	<b>Difference from Request</b>
VSD	Starting in 2014	Prior to 2014 muscular VSD was not routinely collected
Hypospadias	Only Gr. 2 and 3 available prior to 2014	Didn't collect Gr. 1 or NOS prior to 2014

**Appendix 2.**

**Notes on differences from Multi-state Data Call for Denominator or Covariates**

<b>Variable name</b>	<b>Availability</b>	<b>Difference from Request</b>
Height	Not available until 2012	MA Cannot provide before 2012
Payment method	Not available	MA Cannot provide

Is there a cost to obtain data from your program? If so, please estimate and indicate would a waiver be possible?