DATA MANAGEMENT AND SHARING PLAN

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application involves the generation of large-scale genomic data, the Genomic Data Sharing Policy also applies and must be addressed in this Plan. Refer to guidance on Writing a Data Management and Sharing Plan. When preparing your plan, you should delete the text in italics. There is no "form page" for the Data Management and Sharing Plan. The DMS Plan must be provided in the *format* shown below.

1. Will there be maximum appropriate sharing of scientific data underlying peer-reviewed publications and other findings resulting from the work supported by this award (including preprints, refereed papers reported at conferences, and other findings)?
   Yes☒ No☐

2. Will the scientific data underlying peer-reviewed publications be shared by the time of publication, or for other findings, by the end of the period of performance, which includes no-cost extensions?
   Yes☐ No☒

3. Will shared scientific data be made available for at least as long as required by applicable data repository policies and/or journal policies?
   Yes☒ No☐

4. If you answered "no" to elements 1, 2, or 3, or if you anticipate that sharing will be limited in some other way, please describe these limitations and the ethical, legal, or technical factors for them. Your response should specify a particular reason(s) for limiting sharing. *[300 words maximum]*

The datasets generated and/or analyzed during the proposed study are not publicly available to guarantee the confidentiality of participants and to ensure that data are used in accordance with their consented purposes but may be made available to qualified researchers. To access the data, interested researchers can complete a collaboration request form from any of the participating centers. Requests are reviewed by the Data Sharing Committee. All research participants have previously been consented and data can only be used for the consented purposes. To ensure this, data are not available without collaboration with a center. Prior to the release of data, the investigator will sign a data-sharing agreement that stipulates: 1) a commitment to using the data without the identification of individual participants; 2) a commitment to securing the data; and 3) a commitment to destroying or returning the data after analyses are completed.

The study questionnaires and process for accessing the data used in this proposal are described at https://www.cdc.gov/birth-defects/php/bd-steps-nbdps-data/?CDC_AAref_Val=https://www.cdc.gov/ncbddd/birthdefects/nbdps-public-access-procedures.html The code book and analytic code can be made available upon request. All analyses are also internally replicated. For all publications, we will adhere to the NIH public access policy which requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to PubMed Central immediately upon acceptance for publication.

5. If scientific data derived from human research participants will be shared, will privacy, rights, and confidentiality of participants be protected as outlined in NOT-OD-22-213?
   Yes☒ No☐ Not Applicable☐

6. *In the table below, please list [100 words maximum]*:
   a. *Key types of scientific data anticipated to be generated during the project, including the species and modality, if known (e.g., "human genomic data," "rat functional magnetic resonance imaging*

data"). NIH recognizes that not all data types expected to be generated in the study will meet the definition of scientific data or can be anticipated in advance. If a data type does not appear on the list, it does not imply that that data type will not be shared if it is generated in the study.

Clinical and Interview data from eligible cases with various birth defect phenotypes and liveborn controls throughout the ten participating centers were previously collected. Additional environmental exposures will be assigned to the participants.

b. The repository or an example of a repository where the scientific data may be managed and shared, if the scientific data is known at time of application. NIH expects the use of established repositories for preserving and sharing scientific data when they are available.

Expected Data Type	Established Repository or Example
Data	Data are archived through the National Birth Defects Prevention Study and Birth Defects Study To Evaluate Pregnancy exposureS secure Sharepoint database.

7. For studies subject to the NIH Genomic Data Sharing Policy (GDS) (e.g., using NIH funds to generate large-scale human genomic data):
   a. Will you share all large-scale human genomic and associated data in a NIH-designated repository according to the accelerated timelines expected in the GDS Policy?

   Yes☐ No☐ Not Applicable☒
   If "no," address in element 4.

   b. Do you anticipate that when sharing you will be able to meet the expectations of the Institutional Certification in the GDS Policy?

   Yes☐ No☐ Not Applicable☒
   If "no," address in element 4.