Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS)
OMB # 0920-0010

Revision

Supporting Statement B

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January 28, 2021

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B. Collection of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

Cases for BD-STEPS in Atlanta are selected from the Metropolitan Atlanta Congenital Defects Program (MACDP) surveillance system, and cases for all other Centers are selected from established state surveillance systems. The collection of information for cases of selected birth defects does not employ statistical methods because all infants with one of the 17 birth defects are included in Birth Defects surveillance systems, not just samples. Individual birth defects are rare occurrences so it is necessary to ascertain all cases in order to have enough cases of specific defects to study. However, the controls in the BD-STEPS are selected by a sampling process.

For BD-STEPS, each of the Centers for Birth Defects Research and Prevention (CBDRPs) will select randomly from the population (from either vital records or hospital birth logs) approximately 75 eligible controls each year for inclusion in the study. Whether hospital records or birth certificates are used as the source for control-infants, the records are reviewed to ensure that, given the available information, the selected control- infant does not have a birth defect. Records are also reviewed to abstract information for the purpose of follow up and contact.

B.2. Procedures for the Collection of Information

State-specific birth defects surveillance data are used to identify case subjects for the BD-STEPS. The selection of BD-STEPS controls is described in Section B.1. Once the children are identified for the study, a clinical geneticist reviews the information abstracted from the medical record to determine if they meet the case definition and are eligible for the study. Once eligibility has been established, the names and contact information for the families are sent to the Centers for the initial contact. The first contact is an introductory letter (**Attachment O**), along with a "Human Subjects" fact sheet **(Attachment P**), and a "Question and Answer" sheet (**Attachment N)** that are sent by mail to the mothers.

Approximately 10 days after the introductory packet has been sent, the centralized interview contractor will make follow up phone or email contact with the family (see **Attachment T** for email and voicemail contact scripts). If email contact is made, arrangements are made for a follow up phone call. During this phone call, the interviewer obtains oral consent for the interview and either conducts the interview then or schedules the interview at a time convenient for the mother. The interview is conducted with a computer assisted telephone interview (CATI) (see **Attachment G** for a hard copy of the questionnaire). The script used in the telephone interview (including oral consent) is in **Attachment K**. The script varies slightly depending on the status of the child: control, living case, and died or stillborn case. At the end of the interview, the mother is told that she will be receiving a kit in the mail for the collection of saliva samples. Next a saliva collection kit is sent to the mother that includes a letter describing the study (**Attachment U**), a written informed consent (**Attachment L**), and instructions for collecting the saliva samples for parent and child (**Attachments Q and R).** After saliva

collection kits are returned and consent forms are removed and stored securely, the saliva specimens are sent to a centralized laboratory at CDC until they are shipped to a storage facility.. The samples are stored in a manner that permits efficient retrieval and optimum stability; they can be identified only by the study identification number. A letter of thanks to the family (**Attachment V**) follows the interview and completion of the saliva collection kit. For participants who do not complete the saliva collection, the final thank you letter is mailed after the interview.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

The response rate during the first year of the NBDPS was approximately 60% for cases and controls. With the addition of the $20 money order in the introductory packet, interview participation rates increased initially to over 70% in 2000. Given the changing communication landscape with increasingly difficult initial contact of potential new participants, in May of 2010, NBDPS recruitment tracking and tracing procedure was revised and approved by CDC IRB to include the use of e-mail. Interview participation rates ranged from approximately 60-70% from 2005-2009.

Subjects received a $20 money order in the NBDPS cheek cell collection packet. The average overall participation rate for the cheek cell collection portion of NBDPS for 2010 was approximately 60-70%, and was higher than before this incentive structure was instituted. BD-STEPS will continue the same incentive structure to maximize response rates.

B.4. Tests of Procedures or Methods to be Undertaken

As mentioned before, a large portion of the BD-STEPS interview has been maintained from the NBDPS to make pooling of the CBDRP's NBDPS and BD-STEPS data possible. Innovative questions were added for BD-STEPs and are detailed in section A.3.
In addition, new for BD-STEPS (as mentioned in section A.6), at the end of the interview, requests will be made of participants with certain procedures/conditions for mailing an additional consent for medical/dental records. Medical records contain specific information that might be hard for women to recall, and medical record review allows validation of exposures reported by the mother in the CATI. Initial topics for which medical records will be requested include fertility treatments and dental treatments (See **Attachments W and X** for medical records request letter and medical records request form).

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The statistical aspects of the design of the BD-STEPS are the responsibility of the Principal investigator:

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Additional consultation on the development of the BD-STEPS was obtained from the Principal Investigators of the CBDRP (**Attachment I**). Abt Associates is currently contracted by CDC to manage the BD-STEPS contractor activities.

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Analysis of BD-STEPS data is the primary responsibility of Dr. Reefhuis, with assistance from the Principal Investigators of the CBDRP.