Supporting Statement Part B
National Birth Defects Prevention Study
OMB 0920-0010
Revision

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B. Collection of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

Cases for the NBDPS in are identified from existing birth defect surveillance systems in the different states. The collection of information for cases of selected birth defects does not employ statistical methods because all infants with these birth defects in the selected geographical area with between 35,000 and 75,000 births are included, not just a sample. 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 NBDPS are selected by a sampling process.

For the NBDPS, controls consist of a random sample from the same geographical area, centers are supposed to interview a total of 100 controls per year. To allow for about a 75% response rate and the exclusions listed below, 150 prospective controls must be chosen initially. Controls are selected either from birth hospitals (California, New York and Texas) or from birth certificate files (Arkansas, Georgia, Iowa, Massachusetts, North Carolina, and Utah). The birth hospital control selection is weighted by the number of births per hospital per year. The birth certificate control selection is weighted by the number of births in the region by month of birth.

Exclusion criteria for controls are: 1) infant is actually a case or has major birth defects ascertained in MACDP; and 2) infant is not a resident of the five-county area at the time of delivery.

B.2. Procedures for the Collection of Information

MACDP surveillance data is used to identify case subjects for the NBDPS. The selection of NBDPS 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 Battelle Memorial Institute, the current organization contracted to do the interviews. (Note: The contract extension of this organization is set to expire in the fall of 2008. The contracting company to replace Battelle will be Abt Associates.) Abt Associates will first send a letter (**Attachment L**) and pamphlet (**Attachment K)** to the mothers. The letters are slightly different depending on the status of the eligible infant: control, living case, and died or stillborn case.

Approximately 10 days after the letter has been sent, a contract interviewer from Abt Associates makes a follow up phone call to the family. She obtains oral consent for the interview and either conducts the interview then or schedules the interview at a time convenient for the family. The interview is conducted with a CATI (see **Attachment E** for a hard copy of the questionnaire). The script used in the telephone interview is in

Attachment N. Again 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 cheek cells. Next a cheek cell collection kit is sent to the mother that includes a letter describing the study (**Attachment Q**), a written informed consent (**Attachment O**), and instructions for collecting the cheek cells (**Attachment R**). The cheek cell kits will be returned by mail to the CDC, NCEH, Environmental Health Lab where they will be processed and sent for long term storage to the CDC and ATSDR Specimen Packaging, Inventory, and Repository (CASPIR). The biologic samples can be retrieved from CASPIR at any time when needed for analysis. A letter of thanks to the family (**Attachment P**) follows the interview or completion of the cheek cell kit. For participants who do not complete the cheek cell kit, the 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 about 62% for cases and controls. With the addition of the $20 money order in the introductory packet, interview participation rates increased to approximately 75% in 2000. Interview participation rates continue to range between 70-75%.

Subjects receive a $20 money order in the cheek cell collection packet. The current average overall participation rate for the cheek cell collection portion of NBDPS is 61%, but this varies tremendously by site with the lowest biologics participation rates (37% - 52%) in the following sites: New York, New Jersey, Massachusetts, and Atlanta. The pilot study in New York and Atlanta that included an additional $20 money order after the cheek cell kit is returned slightly increased the response rate.

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

There were no major changes to the maternal questionnaire since the last OMB approval date of December 2004. Minor changes are described in section A.3.

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

The statistical aspects of the design of the NBDPS are the responsibility of the Principal investigator:

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Additional consultation on the development of the NBDPS was obtained from the Principal Investigators of the CBDRP (**Attachment H**). Battelle Memorial Institute is currently contracted by CDC to collect the interview data until the Fall of 2008. A replacement contracting company has just been determined to be Abt Associates. The current contact for Abt Associates is listed below.

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