AMENDED/EXTENDED

CONFIDENTIALITY CERTIFICATE

Issued to

Employees of

Division of Birth Defects and Developmental Disabilities, National Center on Birth Defects and Developmental Disabilities (NCBDDD), and Contractor Abt Associates Inc. and Other Participants

conducting research known as

BIRTH DEFECTS STUDY TO EVALUATE PREGNANCY EXPOSURES (BD-STEPS)

Contract Number IR49 CE002099

The purpose of the latest Birth Defects Study is to evaluate factors associated with the occurrence of birth defects and to test hypotheses for gene-environment interactions involved in the etiology of birth defects. Information collected during the interview, will provide data for the evaluation of suspected new teratogens, mutagens, or environmental agents that are not prevalent enough to cause epidemics.

In accordance with the provisions of Section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)) this certificate is issued to protect the privacy of research subjects by withholding their identities from all persons not connected with the research.

Under authority vested in the Secretary of Health and Human Services under that section, all persons who

(1) are employed by the NCBDDD, CDC, and their contractors and cooperating agencies; and

(2) have, in the course of that employment, access to the information which would identify individuals who are the subjects of a research project entitled "Birth Defects Study to Evaluate Pregnancy Exposures" are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research, with the exceptions and limitations set forth below.

As provided in Section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)),

"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

The following conditions apply to the protection provided under this certificate:

(1) This certificate does not authorize NCBDDD, CDC, or their contractors or cooperating agencies to refuse to reveal identifying information concerning research subjects if any of the following conditions exist:

   (a) The subject (or, if he or she is legally incompetent, his or her guardian) consents in writing to disclosure of identifying information.

   (b) Authorized personnel of the United States Department of Health and Human Services request such information for audit or program evaluation of the research project, or for investigation of NCBDDD, CDC, and their contractors or cooperating agencies in carrying out the research project.

   (c) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.) or regulations promulgated thereunder (Title 21, Code of Federal Regulations).

(2) This certificate requires that there be no disclosures of identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects, except as provided for in paragraph (1) above.

(3) The confidentiality certificate does not govern the voluntary disclosure of identifying characteristics of research subjects.

(4) This certificate does not represent an endorsement of the research project by the Department of Health and Human Services.

(5) All research subjects in the project will be given a fair, clear explanation of the protection this certificate affords, and of the limitations and exceptions to the protection.

(6) This certificate is effective upon issuance and will expire at the end of February 2019, or sooner if the holder is notified of cancellation in accordance with the procedures set out in 42 C.F.R. § 2a.8. The protection afforded by this certificate of confidentiality is permanent (including after death) for persons who participated as subjects in the research during any time the certificate was in effect.

Date: 2/3/2014

Ron A. Otten, PhD
Acting Deputy Associate Director for Science, CDC