

**Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS)  
CONFIDENTIALITY AND DATA USE OATH**

Each Center for Birth Defects Research and Prevention (Centers) has been awarded a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). In accordance with Section 301(d) of the Public Health Service (PHS) Act (42 U.S.C. 241(d)), I, as a \_\_\_\_\_ (Centers employee, CDC employee, scientist, contractor, colleague), am permitted access to personally identifiable data. As a condition of this access and my participation in this project, I am required to comply with the following safeguards and policy commitments for individuals against invasions of privacy.

1. I agree to be bound by the following promise:

In accordance with Section 301(d) of the PHS Act (42 U.S.C. 241(d)), all respondents are assured that the confidentiality of their responses in this study will be maintained, and that the privacy of research subjects is protected by the withholding of, from all persons not connected with the study, any personally identifying characteristics of the research subjects.

2. I agree to maintain the following safeguards to assure that confidentiality is protected and to provide for the physical security of the records:

To preclude observation of confidential information by persons not authorized to have access to the information on this project, I shall maintain all records that identify individuals, or from which individuals could be identified, in locked containers or protected computer files, when not under immediate supervision by me or another authorized member of the project. The keys or means of access to these containers or files are not to be given to anyone other than BD-STEPS authorized staff. I further agree to abide by any additional requirements imposed by CDC for safeguarding the identity of individuals.

3. The BD-STEPS Data Sharing Committee must approve uses of the BD-STEPS data. No analysis of data or dissemination of findings from the BD-STEPS may occur without approval from the committee for a specific research purpose. Instructions for submission of research proposals are specified in the Data Sharing Guidelines document available from each Center.
4. The Principal Investigator of the BD-STEPS from each Center is responsible for tracking the use of the BD-STEPS data at their Center and assuring that each person who has access to the data has read and signed this agreement.

5. I understand that the Data Sharing Committee must approve any manuscripts, abstracts, or public presentations based on the analyses before they can be submitted for consideration.
6. I agree not to attempt to identify any individual person whose information is contained in the BD-STEPS data unless required for BD-STEPS activities authorized by the Data Sharing Committee.
7. I agree not to distribute, copy, or share the data with any person(s) other than those designated by the Principal Investigator of the Center.
8. At the conclusion of the research covered by this agreement, I agree to promptly return to the Center from which the data were obtained, any documentation and manuals about the BD-STEPS, and to remove (delete) any electronic files containing data or output from any computer equipment which I have used to gain access to and/or to analyze BD-STEPS data.

My signature below indicates that I have carefully read and understand this agreement and the oath which pertains to the confidential nature of all records to be handled in regard to this project. As a \_\_\_\_\_ (Center employee, CDC employee, scientist, contractor, colleague), I understand that I am prohibited from disclosing any such confidential information that has been obtained under this project to anyone other than authorized staff of BD-STEPS. I understand that any disclosure in violation of this Confidentiality Oath may lead to termination of my employment, as well as other penalties.

\_\_\_\_\_  
(Typed/Printed Name)

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Center PI)

\_\_\_\_\_  
(Date)