

ATTACHMENT F

EVALUATING THE QUALITY OF INTERVIEW DATA COLLECTED BY TERATOLOGY INFORMATION SERVICES ABOUT PREGNANCY OUTCOMES, MATERNAL AND INFANT HEALTH, FOLLOWING MEDICATION USE DURING PREGNANCY AND LACTATION

Confidentiality Pledge to be Signed by all Staff with Access to Study Data

Data collection by Teratology Information Services (TIS) for the study entitled “Evaluating the Quality of Interview Data Collected by Teratology Information Services About Pregnancy Outcomes, Maternal and Infant Health, Following Medication Use During Pregnancy and Lactation” is covered by the Privacy Act of 1974 (5 U.S.C. § 552a). In addition, each TIS study site has been awarded a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC) under the Public Health Service Act (section 301[d] of the Public Health Service Act 42 U.S.C. 241 [d]).

As a _____ (TIS employee, TIS contractor, CDC employee, CDC contractor, colleague), I 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 password protected computer files with limited access 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 authorized study staff. I further agree to abide by any additional requirements imposed by CDC for safeguarding the identity of individuals.

3. The Study Coordinator at each TIS site is responsible for tracking the use of the study data at their site and assuring that each person who has access to the data has read and signed this agreement.
4. I agree not to attempt to identify any individual person whose information is contained in the study data.
5. I agree not to distribute, copy, or share the data with any person(s) other than those designated by the Study Coordinator at my TIS site.
6. At the conclusion of the research covered by this agreement, I agree to promptly return to the Study Coordinator at the TIS site from which the data were obtained, any documentation and manuals about the study, 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 study 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 _____ (TIS employee, TIS contractor, CDC employee, CDC 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 members of the project staff. I understand that any disclosure in violation of this Confidentiality Pledge may lead to termination of my employment, as well as other penalties.

(Typed/Printed Name)

(Signature)

(Date)

(Study Coordinator's Signature)

(Date)

(Name of TIS Site)
