

## CDC ASSURANCE OF CONFIDENTIALITY

### DATA COLLECTION ACTIVITIES RELATED TO PREGNANCY AND INFANT OUTCOMES FOLLOWING ZIKA VIRUS INFECTION: PREGNANCY AND BIRTH DEFECTS TASK FORCE EMERGENCY OPERATIONS CENTER

Surveillance for adverse pregnancy and infant outcomes following Zika virus infection in pregnancy is being collected in U.S. states and territories through the U.S. Zika Pregnancy Registry (USZPR), except in Puerto Rico where these data are collected by CDC-funded Puerto Rico Department of Health contractors for the Zika Active Pregnancy Surveillance System (ZAPSS). These data are being shared with CDC. Population-based surveillance for birth defects that might be related to Zika virus infection during pregnancy is being conducted in U.S. state, territorial, tribal and local jurisdictions through the Zika-related Active Birth Defects Surveillance System (ZABDS). Additionally, CDC is collecting data on Zika virus persistence through the study Zika Virus RNA Persistence in Pregnant Women and Congenitally Infected Infants in Puerto Rico (ZiRP), and information on congenitally infected infants is being collected through the study Congenital Infection and Developmental Outcomes in Infants Prenatally Exposed to Zika (CIDPEZ). The collection of information through all of these activities is being coordinated by the Pregnancy and Birth Defects Task Force, Zika Virus Response, Emergency Operations Center, Centers for Disease Control and Prevention (CDC), an agency of the United States Department of Health and Human Services (Pregnancy and Birth Defects Task Force), as authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment 1**).

In addition, as part of an agreement to provide technical assistance to the National Health Institute/Instituto Nacional de Salud (INS) in Colombia (**Attachment 2**), INS is sharing de-identified Colombian national data on Zika pregnancy, birth, and infant outcomes surveillance with CDC as a part of Proyecto Vigilancia de Embarazadas con Zika (VEZ). INS and CDC also are collaborating on a prospective cohort study of Zika virus infection in pregnancy, Zika en Embarazadas y Niños en Colombia (ZEN), and are conducting case investigations of microcephaly and pediatric infections in Colombia.

The information requested by and shared with CDC includes reports of pregnant women and infants with suspected or confirmed Zika virus disease, and questionnaire responses and laboratory results from women and their partners with potential exposure to or confirmed Zika infection. The information collected by and shared with CDC is abstracted from laboratory, clinical, and other medical or public health records of suspected or confirmed Zika virus cases among pregnant women and their infants,, or is prospectively collected as part of a research data set including persons with Zika virus infection or possible exposure. The Pregnancy and Birth Defects Task Force requested and received authorization under 308(d) of the PHS Act (42 U.S.C 242m(d)) to give assurance of confidentiality for this data.

In the U.S., surveillance data collection is conducted by state, tribal, local and territorial health departments which communicate information to CDC, including patient and physician names and other identifying or locating information. The data are used for de-identified case reports, statistical summaries and research by CDC scientists and cooperating state, tribal, local and territorial health officials to understand and control the spread of Zika virus infection to pregnant women and to infants

through prenatal or perinatal transmission and improve the care for women, infants and their families who have been affected. Through this data collection CDC staff may collect and maintain information that could directly identify individuals.

Information reported to CDC will be used primarily for statistical and analytic summaries and for evaluations of the surveillance program in which no individual or institution on whom a record is maintained can be identified.. Surveillance information may also be used in de-identified case reports for illustrative purposes. When necessary for confirming surveillance information or in the interest of public health and disease prevention, CDC may confirm information contained in case reports with health care providers or may notify other medical personnel or health officials of such information; in each instance, only the minimum information necessary will be disclosed.

Data collected through the activities outlined above will be kept confidential. Only authorized employees of the Centers for Disease Control, contractors, guest researchers, fellows, visiting scientists, and authorized external collaborating researchers, research interns, and graduate students who participate in activities jointly approved by CDC and all sponsoring institutions will have access to the information. Authorized individuals are required to handle the information in accordance with procedures outlined in the Confidentiality Security Statement for Data Collection Activities Related to Pregnancy and Infant Outcomes Following Zika Virus Infection (**Attachment C**).

Data will only be released to other components of CDC, or to agencies of the federal, state, or local government, or to select members of the public for public health purposes in accordance with policies for data release that prevent direct or indirect identification of individual(s). Should the Pregnancy and Birth Defects Task Force need to transfer identifiable information to another unit within the CDC -- specifically the Infectious Diseases Pathology Branch (IDPB) for Zika Virus Testing of Pathologic Specimens -- this information will only be transferred upon receipt of explicit authorization of the jurisdiction providing the data, and will no longer be protected by the Assurance of Confidentiality (**Attachment K**).

Information shared with CDC or collected by CDC under Sections 304, 306, and 307 of the Public Health Service Act (42 U.S.C. 242b, 242k, and 242l) as part of USZPR, ZAPSS, ZABDS, ZIRP, or CIDPEZ or through the collaboration with INS that would permit direct or indirect identification of any individual or institution on whom a record is maintained is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in this Assurance, and will not otherwise be disclosed or released without the consent of the individual or institution in accordance with Section 308 (d) of the Public Health Service Act (42 U.S.C. 242m(d)).

No information collected through the activities outlined above that could be used to identify any individual or institution on whom a record is maintained, either directly or indirectly, will be made available to anyone for non-public health purposes. In particular, such information will not be disclosed to the public; to family members; to parties involved in civil, criminal, or administrative litigation, or for commercial purposes; to agencies of the federal, state, or local government. This protection lasts forever, even after death. However, CDC is in compliance with applicable federal law requiring the protection of federal computer networks from cybersecurity risks like hacking, internet attacks, and other security weaknesses; computer network experts working for, or on behalf, of the government, may intercept and review information sent through government networks for cyber threats if the information sent through the government network triggers a cyber threat indicator.

To notify persons about the inclusion of their information in the USZPR/ZAPSS Surveillance Systems and the Assurance of Confidentiality, a set of fact sheets has been developed. Specifically, one set of fact sheets has been developed for medical providers (obstetric providers: **Attachment 10**; pediatric providers: **Attachment 11**). A second set of fact sheets has been developed for patients (Pregnant women: **Attachment 12**; Parents: **Attachment 13**). For the research studies, information about the Assurance of Confidentiality has been included in the informed consent forms (ZiRP **Attachment 14a-14b**; ZEN **Attachment 14a-15c**).