

ATTACHMENT A

CDC ASSURANCE OF CONFIDENTIALITY

FOR SURVEILLANCE OF PREGNANCY AND INFANT OUTCOMES FOLLOWING ZIKA VIRUS INFECTION AND SURVEILLANCE-RELATED DATA (INCLUDING SURVEILLANCE INFORMATION, CASE INVESTIGATIONS AND SUPPLEMENTAL SURVEILLANCE PROJECTS, RESEARCH ACTIVITIES, AND EVALUATIONS)

Data for surveillance of 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, except in Puerto Rico where these data are collected by CDC-funded Puerto Rico Department of Health contractor for the Zika Active Pregnancy Surveillance System (ZAPSS)/Sistema de Vigilancia Activa de Zika en Embarazos, and shared with CDC. The U.S. Zika Pregnancy Registry and ZAPSS is 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. (**Attachment L**). In addition, as part of an agreement to provide technical assistance to the National Health Institute/Instituto Nacional de Salud (INS) in Colombia, INS is sharing de-identified Colombian national data on Zika pregnancy, birth, and infant outcomes surveillance with CDC. The information requested by and shared with CDC includes reports of pregnant women with suspected or confirmed Zika virus disease and infants born to mothers with evidence of Zika virus infection, and reports of persons participating in studies designed to evaluate the surveillance program and/or the surveillance case definitions, or better characterize affected populations, inform prevention interventions, and identify unmet needs for services. 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; collected through case investigations and from surveys of persons in recognized Zika virus risk groups or known to have a diagnosis of Zika virus infection. The Pregnancy and Birth Defects Task Force, Zika Virus Response, Emergency Operations Center 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 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 and local health officials to understand and control the spread of Zika virus infection to pregnant women and to infants through prenatal or perinatal transmission. Because Zika virus is an emerging infection about which little is known, expert CDC staff, at the invitation of state or local health departments, may participate in research or case investigations or cases of potential threat to the public health. In these instances, CDC staff may collect and maintain information that could directly identify individuals.

Surveillance 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, and secondarily, for special research investigations of the characteristics of populations suspected or confirmed to be at increased risk for infection with Zika virus and of the natural history and epidemiology of Zika virus infection. 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.

Information collected for Surveillance of Pregnancy and Infant Outcomes Following Zika Virus Infection and Surveillance-Related Data will be kept confidential. Only authorized employees of the Centers for Disease Control and certain persons with an official relationship with CDC would have access to information collected under this assurance, with restrictions as follows. Authorized employees of the Centers for Disease Control, CDC contractors, and fellows will have access to identifiable information. In addition to authorized CDC employees, contractors and fellows, authorized non-employees, including guest researchers, visiting scientists, and authorized external collaborating researchers, research interns, and graduate students who participate in activities jointly approved by CDC and the sponsoring academic institution, and the like, will have access to de-identified information. Authorized individuals are required to handle the information in accordance with procedures outlined in the Confidentiality Security Statement for Surveillance of Pregnancy and Infant Outcomes Following Zika Virus Infection and Surveillance-Related Data.

No CDC surveillance information from the U.S. Zika Pregnancy Registry, ZAPSS, Colombian national Zika pregnancy, birth, and infant outcomes surveillance information shared by INS, or research information 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. 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).

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 the U.S. Zika Pregnancy Registry, the Puerto Rico Zika Active Pregnancy Surveillance System (ZAPSS) or the collaboration with INS that would permit direct or indirect identification of any individual or institution on whom a record is maintained, and any identifiable information collected during the course of an investigation on either persons supplying the information or persons described in it, 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)). This protection lasts forever, even after death. Health care providers will be asked to give their patients who are included in the U.S. Zika Pregnancy Registry/ZAPSS a fact sheet about Zika pregnancy, birth, and infant outcomes surveillance that includes notice of the Assurance of Confidentiality (**Attachment P**).