



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)
National Center for Emerging and Zoonotic Infectious Diseases
National Center for Chronic Disease Prevention and Health Promotion
National Center for Birth Defects and Developmental Disabilities

January 24, 2021

Dear Colleagues,

In May 2015, the World Health Organization reported the first local transmission of Zika virus in the Western Hemisphere, with cases identified in Brazil. In some of the Zika-affected areas, an increase in cases of infants born with microcephaly has been reported. Zika virus infections have been confirmed in several infants with microcephaly and in fetal losses of women infected during pregnancy. Despite these observations, very little is known regarding the risks of Zika virus infection during pregnancy.

Zika virus disease and congenital Zika virus infection are nationally notifiable conditions. To ensure complete and accurate case reporting and to facilitate the public health response to the Zika virus disease outbreak, CDC has created a registry to collect information on the impact of Zika virus infection during pregnancy on women and their babies, and is implementing the registry in collaboration with state health departments. CDC is collecting clinical information about the mother during pregnancy, information about the laboratory and prenatal testing, and clinical information about the child at birth and through the first year of the child's life. This information will help define clinical recommendations for management and treatment of Zika virus infection during pregnancy and will provide critical information to inform pregnant women and healthcare providers.

Briefly, health department staff will notify CDC about cases of women with laboratory evidence of Zika virus during pregnancy, whether or not they have symptoms and their infants, whether or not the infant has laboratory evidence of Zika virus congenital infection. Notification may occur through several mechanisms including direct contact with CDC Zika Pregnancy Registry staff, contact with the CDC Clinical Surveillance and Inquiries team or the CDC Zika Pregnancy Hotline, or through ArboNET or birth defects national surveillance programs. A unique US Zika Pregnancy Registry email and secure fax line has been set up for notification and communication purposes. Depending on the preference of the state health department, either health department staff or CDC staff will contact attending physician(s). Healthcare providers are asked to provide health information to staff at state health departments and/or to CDC. CDC will honor patient confidentiality throughout the data collection, transfer, and analysis processes, and will maintain the data in a HIPAA-compliant REDCap database.

For healthcare providers, participation involves: providing brief clinical information about mothers and/or their infants. Information can be provided on CDC case report forms and faxed or emailed, or provided by telephone to CDC registry staff or by other means determined by the state health department. CDC or state health department staff will contact providers twice during the pregnancy for women diagnosed during pregnancy. This will include contact in the second and third trimester, and at a minimum approximately one month prior to the estimated delivery date. Healthcare providers or state health department staff will also be asked to contact CDC registry staff separately if any adverse events are noted (e.g., pregnancy loss, fetal anomalies detected prenatally). At the approximate time of delivery, CDC or state health department staff will contact the healthcare provider to obtain follow up information and to identify the pediatric or primary health care provider for the infant. Subsequently, information will be sought about routine health examinations of the infant performed at approximately 2, 6, and 12 months of age. Infant Children will be followed regardless of their Zika virus status.

The Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations, *Standards for Privacy of Individually Identifiable Health Information* (45 CFR § 164.501)] ("Privacy Rule") permits covered entities (e.g., healthcare providers) to disclose without authorization protected health information to public health authorities that are authorized by law to collect or receive such information for the purpose of preventing or controlling disease.

Pursuant to 45 CFR § 164.512(b) of the Privacy Rule, covered entities such as your organization may disclose, without individual authorization, protected health information to public health authorities: "... authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions..." CDC is requesting these records as a public health authority conducting a public health activity as described by 45 CFR § 164.512(b), and as authorized by section 301 of the Public Health Service Act. The information requested represents the minimum necessary to carry out the public health purposes of this project pursuant to 45 CFR § 164.514(d) of the Privacy Rule. Per Federal standards established in the Privacy Rule as described by 45 CFR §164.522 and §164.528, individuals also have the right to request restriction of uses and disclosures of their protected health information and to receive an accounting of disclosures of such information made by the covered entity.

Thank you for your willingness to participate, and please feel free to call us at 770-488-7100 or email us at ZIKApregnancy@cdc.gov if you have any questions or concerns. For online information on this registry, please visit: <http://www.cdc.gov/zika/hc-providers/pregnancy-registry>.

Sincerely,
Dr. S Hills, Dr D Meaney Delman, Dr D Jamieson, Dr P Honein, Centers for Disease Control and Prevention