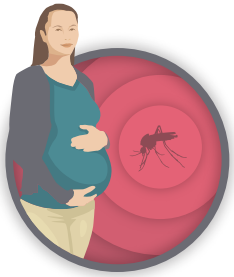
CDC's Response to **Zika**

# US Zika Pregnancy Registry

## Tribal Healthcare Providers: How to Contribute



Zika virus infection during pregnancy has been linked to adverse outcomes, including pregnancy loss and microcephaly, absent or poorly developed brain structures, defects of the eye, and impaired growth in fetuses and infants. Despite these observations, very little is known about the risks of Zika virus infection during pregnancy and to infants. Information about the timing, absolute risk, and spectrum of outcomes associated with Zika virus infection during pregnancy and among infants is needed to direct public health action related to Zika virus and guide testing, evaluation and management of pregnant women and infants exposed to Zika virus.

## US Zika Pregnancy Registry

To understand more about Zika virus infection, CDC established the US Zika Pregnancy Registry and is collaborating with state, tribal, local, and territorial health departments to collect information about pregnancy and infant outcomes among pregnant women with laboratory evidence of Zika virus infection and their infants. The data collected through this Registry will provide additional, more comprehensive information to complement notifiable disease case reporting and will be used to update recommendations for clinical care, to plan for services for pregnant women, children, and families affected by Zika virus and to improved prevention of Zika virus infection during pregnancy.

## How to Participate

CDC and state, tribal, local, and territorial health department request that healthcare providers participate in the Registry by

1. Reporting information about pregnant women with laboratory evidence of Zika virus and identifying and reporting suspected congenital Zika virus exposure to their state, tribal, local or territorial health department.
2. Collecting pertinent clinical information about pregnant women with laboratory evidence of Zika virus and their infants on the Pregnancy and Zika Disease Surveillance forms.
3. Providing the information to state, tribal, local, or territorial health departments or directly to CDC Registry staff if asked to do so by local health officials.
4. Notifying state, tribal, local or territorial health department staff or CDC Registry staff of adverse events (e.g. spontaneous abortion, termination of pregnancy, and perinatal or infant deaths).

## Who is included in the Registry?

Pregnant women and infants meeting the following criteria are eligible for the US Zika Pregnancy Registry: 1) pregnant women in the United States with laboratory evidence of Zika virus infection (positive or equivocal test results, regardless of whether they have symptoms) and 2) periconceptionally, prenatally, or perinatally exposed infants born to these women, including infants with any laboratory evidence of congenital Zika virus infection (e.g., detection of Zika virus or Zika virus nucleic acids in a placental, fetal, or neonatal specimens, or serologic evidence of Zika virus in serum or cerebrospinal fluid).

Some infants who meet the above criteria will have been identified prenatally and reported to the health department in accordance with applicable state, tribal, local, and territorial laws supporting notifiable disease surveillance. However, pediatric healthcare providers may also identify previously unrecognized infants with congenital Zika virus infection or with prenatal or perinatal exposure. Information about these infants should be reported to the state, tribal, local, or territorial health department and are eligible to be included in the US Zika Registry. The US Zika Pregnancy Registry will collect supplemental surveillance information from routine medical care of women through pregnancy and infants through the first year of life.

Enrollment of eligible pregnant women and children in the Registry will not require extra paperwork, and enrolled people will not need to go to extra appointments, have extra tests, or pay money to be part of the Registry. The identity of people in the Registry will be kept confidential, and CDC has obtained a Federal Assurance of Confidentiality, which allows CDC programs to ensure Registry participants that CDC can use no identifiable information for any purpose other than the purpose for which it was supplied unless an individual has consented to that disclosure.

## How to Report to the Registry

- Healthcare providers should contact their state, tribal, local, or territorial health department to arrange for laboratory testing for Zika virus infection in pregnant women and infants who meet the clinical criteria for testing as outlined in the CDC guidelines.[1,2]
- Healthcare providers can also contact the CDC Zika Pregnancy hotline (available through the EOC Watch Desk at 770-488-7100, ZikaMCH@cdc.gov or ZikaPregnancy@cdc.gov or fax at 404-718-2200) to discuss clinical management of women with laboratory evidence of Zika virus infection. If healthcare providers contact CDC for clinical consultation, Registry staff will ensure that state, tribal, local, and territorial health departments are notified. CDC may also learn about pregnant women and infants with laboratory evidence of Zika virus infection through national surveillance of arboviral diseases.

## How the data are collected

Depending on the preference of the state, tribal, local, or territorial health department, either health department staff or CDC Registry staff will contact healthcare providers caring for pregnant women and their infants for data collection. The information collected includes details of the pregnancy, birth history, and findings from physical, developmental, imaging, and laboratory assessments performed during clinical care of the infant at birth and at 2, 6, and 12 months of age.

CDC is requesting the collection of clinical information in identifiable form as a public health authority. As defined in 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"), covered entities (e.g., healthcare providers) may disclose protected health information without patient authorization to a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease (42 CFR § 164.512). Data to be collected include clinical information pertaining to the pregnant woman's health, monitoring and testing during pregnancy, results from evaluation and testing conducted at birth, and clinical/developmental information form the infant through the first year of life. As established in the HIPAA Privacy Rule (45 CFR 164.528), individuals have the right to request from covered entities (i.e., you the healthcare provider) an accounting of the disclosures of their protected health information.

## More Information about Zika

For more information or to contact CDC Registry staff, call the CDC Emergency Operations Centers watch desk at 770-488-7100 and ask for the Zika Pregnancy Hotline or email ZikaPregnancy@cdc.gov. More information on caring for pregnant women, infants, or children with Zika virus infection is available at http://www.cdc.gov/zika.

## CDC Guidance Materials


1. Interim guidance for Health Care Providers Caring for Pregnant Women and Women of Reproductive Age with Possible Zika Virus Exposure – United States, 2016 (April 1, 2016) http://www.cdc.gov/mmwr/volumes/65/wr/mm6512e2.htm
2. Interim Guidelines for Healthcare Providers Caring for Infants and Children with Possible Zika Virus Infection – United States, February 2016 (Feb. 19, 2016) http://www.cdc.gov/mmwr/volumes/65/wr/mm6507e1.htm
3. Zika Virus: Collection and Submission of Fetal Tissues for Zika Virus Testing http://www.cdc.gov/zika/hc-providers/tissue-collection-submission.html
4. Collection and Submission of Body Fluids for Zika Virus Testing http://www.cdc.gov/zika/hc-providers/body-fluids-collection-submission.html