

US Zika Pregnancy Registry

Health Departments: How to Participate

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

US Zika Pregnancy Registry

CDC established the US Zika Pregnancy Registry and is collaborating with state, tribal, local, and territorial health departments to collect and share information about pregnancy and infant outcomes following Zika virus infection during pregnancy. The aggregate data collected through this Registry will provide additional, 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 and families affected by Zika virus, and to improve prevention of Zika virus infection during pregnancy.

Reasons to Participate

Reporting to the US Zika Pregnancy Registry will allow aggregate data to inform public health efforts at the local level as well as broader recommendations. Some states have already implemented enhanced surveillance for pregnant women and infants. The US Zika Pregnancy Registry staff can help by notifying states of new Zika virus cases among pregnant women that come to Registry staff's attention when healthcare providers contact CDC for clinical consultation. Registry staff are also available to help with follow-up data collection, if requested.

How to Participate

State, tribal, local, and territorial health departments can participate in the US Zika Pregnancy Registry by

- Identifying pregnant women and infants eligible for Zika virus testing in accordance with State or [CDC guidelines](#).
- Coordinating testing for those eligible at a State Public Health Laboratory or CDC.
- Reporting cases of Zika virus infection among pregnant women and infants who meet the CSTE case definitions for Zika virus disease and congenital Zika virus infection to ArboNET (information will be sent to the US Zika Pregnancy Registry).
- Collecting enhanced surveillance data about cases of pregnant women and their infants who are eligible for the Registry.
- Working with CDC to determine state-specific methods for collecting and sharing information.

Who is Eligible to be in the Registry

People who are eligible for inclusion in the Registry

- Pregnant women in the United States¹ with laboratory evidence of Zika virus infection (positive or inconclusive test results, regardless of whether they have symptoms) and prenatally or perinatally exposed infants born to these women.
- Infants with laboratory evidence of congenital Zika virus infection (positive or inconclusive test results, regardless of whether they have symptoms) and their mothers.

How to Collect the Data

Various methods (e.g., medical record abstraction, telephone consultation) can be used to collect surveillance information for the Registry. Depending on the preference and capacity of the state, tribal, local, or territorial health department, health department staff might choose to contact healthcare providers or CDC Registry staff are available to provide follow-up assistance.

Health departments may obtain data collection forms by contacting the Zika pregnancy hotline or emailing the Zika pregnancy email address (ZikaPregnancy@cdc.gov). In addition, a shared website for State Zika Coordinators and Registry staff and a secure file transfer protocol (FTP) will be established. CDC staff will also provide health departments with forms when Registry eligible cases are identified through laboratory testing at CDC.

Time points for data collection

Initial Identification of case

2nd and 3rd trimester

At delivery

Infant: 2, 6, and 12 months

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 from the infant through the first year of life.

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). As established in the HIPAA Privacy Rule (45 CFR 164.522, 164.524, 164.526, and 164.528), individuals have the right to request from covered entities (i.e.,

¹ Puerto Rico is establishing a separate Zika Active Pregnancy Surveillance System (ZAPSS) to collect information on eligible cases in the Commonwealth of Puerto Rico.

the healthcare provider) disclosing their PHI certain restrictions, access, amendments, and accounting of the disclosures of their protected health information.

The identity of people in the Registry will be kept private and secured. US Zika Pregnancy Registry data will be transferred and stored in accordance with the highest security standards for confidential records.

How to Report Registry Data Securely to CDC

CDC Registry staff is identifying State Zika Coordinators to tailor data collection, reporting, and sharing of information in accordance with the specifications of each state. Health officials can submit case report information to CDC Registry staff by

- Electronic data transfer through FTP (e.g. CSV, Excel, Access, Word, PDF files)
- Encrypted email to ZIKApregnancy@cdc.gov
- Secure fax at 404-718-2200
- Telephone report (770-488-7100)
- Electronic data entry into the HIPAA-compliant U.S. Zika Pregnancy Registry REDCap database (requires training and enrollment for access to the secure web portal)

More Information

For more information, call the CDC Emergency Operations Center watch desk at 770-488-7100 and ask for the Zika Pregnancy Hotline or email ZIKApregnancy@cdc.gov. More information on Zika virus infection is available at <http://www.cdc.gov/zika/index.html>.

Thank you for your interest and participation in the US Zika Pregnancy Registry.