

Non-Substantive Change Request to OMB Control Number 0920-1101; CDC Emergency Operations
Center Zika Related Clinical Inquiries and Surveillance

Program Contact

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Circumstances of Change Request for OMB 0920-1101

CDC requests approval for a non-substantive change to OMB Control No. 0920-1101: CDC Emergency Operations Center Zika Related Clinical Inquiries and Surveillance.

All of the proposed changes are being made to information collection instruments and supporting tools associated with the domestic pregnancy registry. These changes are being made because of the updated Council of State and Territorial Epidemiologists (CSTE) case definitions for confirmed and probable Zika virus disease and congenital Zika virus infection. Because of the updated CSTE case definitions, participation in the pregnancy registry is no longer voluntary. State laws mandate reporting of arboviral diseases when identified by a health care provider, hospital, or laboratory. Now that there are specific case definitions for Zika virus disease and congenital Zika virus infection, state and territorial health departments are responsible for determining which reported cases meet the case definitions and notifying CDC of these cases. For an emerging infection like Zika virus, little is known about the spectrum of disease. Case definitions may need to change as more information becomes available about the spectrum of Zika virus disease and congenital infection. The US Zika Pregnancy Registry is designed to allow collection of the clinical and epidemiologic information required to determine whether reported cases meet the case definitions and whether the case definitions accurately capture the spectrum of Zika virus disease. Therefore, the Registry includes pregnant women with laboratory evidence of Zika virus infection who do not meet the current CSTE definition of Zika virus disease, and infants who do not meet the current definition of congenital Zika virus infection and allows mother-infant pairs to be linked, all of which is critical for both fully understanding and responding appropriately to the public health threat from Zika virus.

NCEZID's human subjects advisor reviewed the proposed changes to the project and determined that it still does not meet the definition of research (Attachment M). IRB review is not required.

Estimates of annualized burden hours for this change request remain the same. The burden estimate for the forms included in OMB Control No. 0920-1101 is 705 hours.

Attachments

A. Public Health Service Act (42 USC 241)

- B. Draft 60-day FRN
- C. Website information - Zika Virus Disease and Pregnancy Registry (**changes requested**)
- D. Overview letter (**changes requested**)
- E. Maternal Health History Form (**changes requested**)
- F. Assessment at Delivery Form (**changes requested**)
- G. Infant Health Follow-Up Form (**changes requested**)
- H. Specimen Collection Form
- I. Domestic ZIKA Clinical Inquiries Database
- J. Survey of county-level surveillance records of *Aedes aegypti* and *Aedes albopictus* from 2000 to present
- K. IRB Approval – EOC call center
- L. IRB Approval – Mosquito surveillance survey
- M. IRB Approval – Pregnancy Register (**updated**)
- N. Pregnancy Registry Information Sheet (**changes requested**)
- O. Developmental Milestones for Infant (**new**)
- P. Fact Sheet for Obstetric Healthcare Providers (**new**)
- Q. Fact Sheet for Pediatric Healthcare Providers (**new**)
- R. Fact sheet for Health Departments (**new**)
- S. CSTE Case Definition (**new**)

Description and Justification of Changes

Supporting Statement A

1. Circumstances making the Collection of Information Necessary
 - Updated territories with local Zika transmission to be consistent with current situation; added that local transmission may occur in U.S. states.
 - Added the critical information gaps that the data collection is designed to address
 - Added respondents for registry
 - Updated description of pregnancy registry
 - To reflect case definitions (confirmed and probable for Zika virus disease and congenital zika virus infection) released by the Council of State and Territorial Epidemiologists on February 26, 2016 and add the case definitions as an attachment; to clarify that, in addition to cases meeting the CSTE case definition, the registry will include cases of zika virus infection among pregnant women with laboratory evidence of infection but no reported symptoms.
 - To clarify that CDC plans to collect information from health departments and clinicians about pregnant women and pre- or perinatally exposed infants, whether or not they meet the case definition for confirmed or probable zika virus infection.
 - To replace language about voluntary participation with “The provider will notify pregnant or postpartum women that they have a notifiable disease and that their information will be included in the registry” and discussion of the patients’ rights

concerning disclosure of their protected health information as established by the HIPAA Privacy Rule.

- To add that “The provider will document in the woman’s medical record that information was provided...”
- To clarify that information collected on the Maternal Health History Form (Attachment E) may be provided in written or electronic form, or verbally.
- To replace language about obtaining consent for participation in the registry with a statement that the Overview Letter (Attachment D) will instruct the health care provider to inform the patient about inclusion in the registry and the patient’s rights as established by the HIPAA Privacy Rule.
- To clarify that information will be requested during pregnancy and that information on infant health (Attachments F, G) will be transmitted in the same manner as for the Maternal History Form.
- To add that the proposed data collection is consistent with efforts to strengthen surveillance in the context of severe disease and emerging infections, which involve working closely with clinicians who diagnose and treat patients.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

- Added (HIPAA Privacy Rule) for collecting personally identified medical information from health care providers.
- Added that application for an Assurance of Confidentiality is in process
- Added that only de-identified data will be presented in case reports and in aggregate form, and that data that could indirectly identify an individual will be suppressed.

Attachment C: Website

- Changes: Removed letter to Health Care Provider (HCP) link and added Fact Sheet for Health Care Providers (Attachment P).
- Justification: Aligns better with web content format.

Attachment D: Overview Letter

- Changes: Clarified how health care providers can report cases and that as a nationally notifiable condition, consent from patients will not be solicited.
- Justification: New CSTE case definition, approved February 26, 2016, includes national notification for pregnant women and infants.

Attachment E: Maternal Health History Form

- Changes: New variables added: maternal hospitalization and death, sexual transmission questions, method to derive estimated delivery date, cocaine use, HC measurement, growth restriction, and prenatal ultrasound findings (was free text, now more text boxes).
- Removed voluntary participation checkbox, not requested for information needed to apply case definitions for a nationally notifiable disease.
- Justification: New findings associated with Zika virus.

Attachment F: Assessment at Delivery Form

- Changes: New variables added: delivery complications, imaging findings, neonatal diagnoses.
- Justification: Information needed to interpret reporting of neonatal outcomes.

Attachment G: Infant Health Follow-Up Form

- Changes: Added infant date of birth, added instruction sheet for developmental interpretation.
- Justification: Ensure appropriate tracking of infant, ensure appropriate surveillance of birth defects and developmental delays.

Attachment N: Pregnancy Registry Information Sheet

- Changes: Removed references to voluntary participation and removed information about specimen collection.
- Justification: Nationally notifiable disease and new CSTE case definition.

Attachment O: Developmental Milestones for Infant

- Changes: Added to provide HCP with information that will allow them to complete information on infant form related to developmental outcomes.

Attachment P: Fact Sheet for Obstetric Health Care Providers

- Changes: Added to provide HCP with information. This will be posted on the website.

Attachment Q: Fact Sheet for Pediatric Health Care Providers

- Changes: Added to provide HCP with information. This will be posted on the website.

Attachment R: Fact Sheet for Health Departments

- Changes: Added to provide health departments with information. This will be posted on the website.

Form	Current Question	Requested Change
Maternal Health History Form (Att. E)	Mother's name: _____	Mother's name: ____ Last ____ First ____ MI Maiden name (if applicable) _____ State/Territory ID: _____
	Race (Please ask the patient to self-identify as): <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African-American <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> White	Race (check all that apply): <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African-American <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> White
	Indication for maternal serum Zika virus testing: _____	Indication for maternal Zika virus testing: <input type="checkbox"/> Exposure history, no known fetal concerns <input type="checkbox"/> Exposure history and fetal concerns
	Date of Zika virus disease onset: ____/____/____ -OR- <input type="checkbox"/>	Date of Zika virus symptom onset: ____/____/____ -OR- <input type="checkbox"/> Asymptomatic

Asymptomatic	<i>If date not known, trimester of symptom onset</i> _____ Hospitalized for Zika virus disease <input type="checkbox"/> No <input type="checkbox"/> Yes Maternal Death <input type="checkbox"/> No <input type="checkbox"/> Yes
Symptoms of mother's Zika virus disease: (check all that apply) <input type="checkbox"/> Fever _____ °F <input type="checkbox"/> Rash <input type="checkbox"/> Arthralgia <input type="checkbox"/> Conjunctivitis <input type="checkbox"/> Other Clinical Presentation _____ Gestational age at onset: _____ weeks	Symptoms of mother's Zika virus disease: (check all that apply) <input type="checkbox"/> Fever _____ °F (if measured) <input type="checkbox"/> Rash <input type="checkbox"/> Arthralgia <input type="checkbox"/> Conjunctivitis <input type="checkbox"/> Other Clinical Presentation _____ If symptomatic, gestational age at onset: _____ weeks If gestational age not known, trimester of symptom onset _____
N/A	Was Zika virus infection acquired in place of residence <input type="checkbox"/> No <input type="checkbox"/> Yes, if yes, skip to the section on Mother's pregnancy
Countr(ies) of exposure: _____ Date of travel1: _____ _____ Date of travel2: _____ _____ Date of travel3: _____	IF TRAVEL DURING PREGNANCY, answer questions below. If not, skip to <u>non-traveling woman</u> Country of exposure (1) _____ Travel Start __/__/____ Travel End __/__/____ Country of exposure (2) _____ Travel Start __/__/____ Travel End __/__/____ Country of exposure (3) _____ Travel Start __/__/____ Travel End __/__/____
N/A	Mother's sexual partner(s)? please check all that apply <input type="checkbox"/> Male <input type="checkbox"/> Female
N/A	Did any male sexual partner(s) travel on this trip? <input type="checkbox"/> No <input type="checkbox"/> Yes
N/A	If yes, did any male partner(s) have an illness that included fever, rash, joint pain, or pink eye within 2 weeks of travel? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, was there unprotected sexual contact while male partner(s) had illness? <input type="checkbox"/> No <input type="checkbox"/> Yes
N/A	If male partner(s) travelled, did he have a test that showed lab evidence of Zika? <input type="checkbox"/> No <input type="checkbox"/> Yes
<input type="checkbox"/> Mother agrees to participate in this Pregnancy Registry	N/A [Removed]
N/A	NON-TRAVELLING WOMAN: other possible exposures? <input type="checkbox"/> Sexual partner w/travel history, symptomatic, lab evidence of Zika <input type="checkbox"/> Sexual partner w/travel history, symptomatic, no test results <input type="checkbox"/> Sexual partner w/travel history, asymptomatic lab evidence of Zika <input type="checkbox"/> Other, please describe _____ <input type="checkbox"/> Unknown
N/A	Last menstrual period (LMP): __/__/____
N/A	Estimated delivery date based on (check all that apply): <input type="checkbox"/> LMP __/__/____ <input type="checkbox"/> U/S (1 st trimester) <input type="checkbox"/> U/S (2 nd trimester) <input type="checkbox"/> U/S (3 rd trimester)
N/A	History: # pregnancies ____ # living children ____ # miscarriages ____ # elective terminations ____
N/A	Prior fetus/infant with microcephaly: <input type="checkbox"/> No <input type="checkbox"/> Yes If

	yes, genetic cause: <input type="checkbox"/> No <input type="checkbox"/> Yes						
Current gestation: <input type="checkbox"/> Single <input type="checkbox"/> Twins <input type="checkbox"/> Triplets	Gestation: <input type="checkbox"/> Single <input type="checkbox"/> Twins <input type="checkbox"/> Triplets+						
Underlying maternal illness: Diabetes <input type="checkbox"/> No <input type="checkbox"/> Yes Maternal PKU <input type="checkbox"/> No <input type="checkbox"/> Yes Hypothyroidism <input type="checkbox"/> No <input type="checkbox"/> Yes Hypertension <input type="checkbox"/> No <input type="checkbox"/> Yes Alcohol use <input type="checkbox"/> No <input type="checkbox"/> Yes Other underlying illness: _____	Underlying maternal illness: Diabetes <input type="checkbox"/> No <input type="checkbox"/> Yes Maternal PKU <input type="checkbox"/> No <input type="checkbox"/> Yes Hypothyroidism <input type="checkbox"/> No <input type="checkbox"/> Yes Hypertension <input type="checkbox"/> No <input type="checkbox"/> Yes Substance use during this pregnancy: Alcohol use <input type="checkbox"/> No <input type="checkbox"/> Yes Cocaine use <input type="checkbox"/> No <input type="checkbox"/> Yes Smoking <input type="checkbox"/> No <input type="checkbox"/> Yes Other underlying illness: _____						
Complications of pregnancy: TORCH infection <input type="checkbox"/> No <input type="checkbox"/> Yes Gestational diabetes <input type="checkbox"/> No <input type="checkbox"/> Yes Death of a monozygote twin <input type="checkbox"/> No <input type="checkbox"/> Yes Pregnancy-related HTN <input type="checkbox"/> No <input type="checkbox"/> Yes Other <input type="checkbox"/> No <input type="checkbox"/> Yes _____	Complications of pregnancy: Toxoplasmosis <input type="checkbox"/> positive <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown Herpes Simplex <input type="checkbox"/> positive <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown Syphilis <input type="checkbox"/> positive <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown Cytomegalovirus <input type="checkbox"/> positive <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown Rubella <input type="checkbox"/> positive <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown Fetal genetic abnormality <input type="checkbox"/> No <input type="checkbox"/> Yes, <i>diagnosis</i> _____ <input type="checkbox"/> Unknown Gestational diabetes <input type="checkbox"/> No <input type="checkbox"/> Yes Pregnancy-related HTN <input type="checkbox"/> No <input type="checkbox"/> Yes Intrauterine death of a twin <input type="checkbox"/> No <input type="checkbox"/> Yes Other _____						
N/A	Did this pregnancy end in miscarriage or intrauterine fetal demise (IUFD)? <input type="checkbox"/> No <input type="checkbox"/> Yes Date: __/__/____ Gestational age ____ weeks						
N/A	Was this pregnancy terminated? <input type="checkbox"/> No <input type="checkbox"/> Yes Date: __/__/____ Gestational age ____ weeks						
N/A	<table border="1"> <thead> <tr> <th colspan="2">Maternal Prenatal Imaging and Diagnostics</th> </tr> </thead> <tbody> <tr> <td>Date(s) of Ultrasound(s):</td> <td></td> </tr> <tr> <td>__/__/____ <input type="checkbox"/> Check if date approximated If date not known, gestational age ____ weeks</td> <td> Overall Fetal Ultrasound Results: <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Check if reported by patient/healthcare provider <input type="checkbox"/> ultrasound report Head Circumference ____ cm <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal (by physician report) Biparietal diameter ____ cm Femur Length ____ cm Abdominal Circumference ____ cm <input type="checkbox"/> Symmetrical intrauterine growth restriction IUGR (<5% EFW) <input type="checkbox"/> Asymmetrical IUGR (HC<FL or HC<AC) Intracranial calcifications <input type="checkbox"/> No <input type="checkbox"/> Yes Ventriculomegaly <input type="checkbox"/> No <input type="checkbox"/> Yes Cerebral atrophy <input type="checkbox"/> No <input type="checkbox"/> Yes Ocular anomalies <input type="checkbox"/> No <input type="checkbox"/> Yes Cerebellar abnormalities <input type="checkbox"/> No <input type="checkbox"/> Yes Arthrogryposis <input type="checkbox"/> No <input type="checkbox"/> Yes Corpus callosum abnormalities <input type="checkbox"/> No <input type="checkbox"/> Yes Hydrops <input type="checkbox"/> No <input type="checkbox"/> Yes Ascites <input type="checkbox"/> No <input type="checkbox"/> Yes Other <input type="checkbox"/> </td> </tr> </tbody> </table>	Maternal Prenatal Imaging and Diagnostics		Date(s) of Ultrasound(s):		__/__/____ <input type="checkbox"/> Check if date approximated If date not known, gestational age ____ weeks	Overall Fetal Ultrasound Results: <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Check if reported by patient/healthcare provider <input type="checkbox"/> ultrasound report Head Circumference ____ cm <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal (by physician report) Biparietal diameter ____ cm Femur Length ____ cm Abdominal Circumference ____ cm <input type="checkbox"/> Symmetrical intrauterine growth restriction IUGR (<5% EFW) <input type="checkbox"/> Asymmetrical IUGR (HC<FL or HC<AC) Intracranial calcifications <input type="checkbox"/> No <input type="checkbox"/> Yes Ventriculomegaly <input type="checkbox"/> No <input type="checkbox"/> Yes Cerebral atrophy <input type="checkbox"/> No <input type="checkbox"/> Yes Ocular anomalies <input type="checkbox"/> No <input type="checkbox"/> Yes Cerebellar abnormalities <input type="checkbox"/> No <input type="checkbox"/> Yes Arthrogryposis <input type="checkbox"/> No <input type="checkbox"/> Yes Corpus callosum abnormalities <input type="checkbox"/> No <input type="checkbox"/> Yes Hydrops <input type="checkbox"/> No <input type="checkbox"/> Yes Ascites <input type="checkbox"/> No <input type="checkbox"/> Yes Other <input type="checkbox"/>
Maternal Prenatal Imaging and Diagnostics							
Date(s) of Ultrasound(s):							
__/__/____ <input type="checkbox"/> Check if date approximated If date not known, gestational age ____ weeks	Overall Fetal Ultrasound Results: <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Check if reported by patient/healthcare provider <input type="checkbox"/> ultrasound report Head Circumference ____ cm <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal (by physician report) Biparietal diameter ____ cm Femur Length ____ cm Abdominal Circumference ____ cm <input type="checkbox"/> Symmetrical intrauterine growth restriction IUGR (<5% EFW) <input type="checkbox"/> Asymmetrical IUGR (HC<FL or HC<AC) Intracranial calcifications <input type="checkbox"/> No <input type="checkbox"/> Yes Ventriculomegaly <input type="checkbox"/> No <input type="checkbox"/> Yes Cerebral atrophy <input type="checkbox"/> No <input type="checkbox"/> Yes Ocular anomalies <input type="checkbox"/> No <input type="checkbox"/> Yes Cerebellar abnormalities <input type="checkbox"/> No <input type="checkbox"/> Yes Arthrogryposis <input type="checkbox"/> No <input type="checkbox"/> Yes Corpus callosum abnormalities <input type="checkbox"/> No <input type="checkbox"/> Yes Hydrops <input type="checkbox"/> No <input type="checkbox"/> Yes Ascites <input type="checkbox"/> No <input type="checkbox"/> Yes Other <input type="checkbox"/>						

		<p>No <input type="checkbox"/> Yes, describe</p> <p>Description of abnormal ultrasound findings:</p> <p>Fetal MRI performed: <input type="checkbox"/> No <input type="checkbox"/> Yes (please answer questions below)</p> <p>Overall fetal MRI Results: <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Check if report by patient/healthcare provider</p> <p>Head Circumference ___cm <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal Biparietal diameter ___ cm Femur Length _____cm <input type="checkbox"/> Symmetrical IUGR (<5% EFW) <input type="checkbox"/> Asymmetrical IUGR (HC<FL or HC <AC)</p> <p>___/___/___ <input type="checkbox"/> Check if date approximated</p> <p>If date not known, gestational age ___ weeks</p> <p>Intracranial calcifications <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Ventriculomegaly <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Cerebral atrophy <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Ocular anomalies <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Cerebellar abnormalities <input type="checkbox"/> No <input type="checkbox"/> Yes Arthrogyrosis <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Corpus callosum abnormalities <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Lissencephaly <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Pachygyria <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Hydranencephaly <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Porencephaly <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Hydrops <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Ascites <input type="checkbox"/> No <input type="checkbox"/> Yes Other <input type="checkbox"/> No <input type="checkbox"/> Yes, describe</p> <p>Description of abnormal MRI findings:</p> <p>Amniocentesis performed: <input type="checkbox"/> No <input type="checkbox"/> Yes (date: ___/___/___) Zika virus testing: <input type="checkbox"/> Not performed <input type="checkbox"/> Yes, if yes test results: <input type="checkbox"/> lab evidence of Zika <input type="checkbox"/> negative for Zika Non-Zika infection detected <input type="checkbox"/> No <input type="checkbox"/> Yes if yes, what infection was detected _____ Genetic abnormality detected <input type="checkbox"/> No <input type="checkbox"/> Yes Please describe:</p> <p>Provider Information</p> <p>Provider name: <input type="checkbox"/> Dr. <input type="checkbox"/> PA <input type="checkbox"/> RN <input type="checkbox"/> Mr. <input type="checkbox"/> Ms. _____ Phone: _____ Email: _____ Date of form completion ___/___/___</p> <p>Name of person completing form (if different from provider): _____ Hospital/facility: _____ Phone: _____ Email: _____ Date of form completion ___/___/___</p>
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		Provider Information
		Name of person completing form: _____ Phone: _____ Email: _____ Date of form completion __/__/____
		FOR INTERNAL CDC USE ONLY Mother ID: _____ State ID: _____ Zika T ID: _____
		R number: _____ Mother infection type: <input type="checkbox"/> Confirmed <input type="checkbox"/> Probable <input type="checkbox"/> Possible
Assessment at Delivery Form (Att. F)	N/A	Birth Certificate ID: _____
	N/A	Infant's State/Territory ID _____
	N/A	Mother's State/Territory ID _____
	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Ambiguous/undetermined
	Gestational age at delivery: ____ weeks	Gestational age at delivery: ____ weeks Based on: (check all that apply) <input type="checkbox"/> LMP __/__/____ <input type="checkbox"/> U/S (1 st trimester) <input type="checkbox"/> U/S (2 nd trimester) <input type="checkbox"/> U/S (3 rd trimester) <input type="checkbox"/> Other _____
	Delivery type: <input type="checkbox"/> Vaginal <input type="checkbox"/> Forceps/suction <input type="checkbox"/> Caesarean section	Delivery type: <input type="checkbox"/> Vaginal <input type="checkbox"/> Caesarean section Delivery complication: <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, _____
	N/A	Arterial Cord blood pH: if performed _____ Venous Cord blood pH: if performed _____
	Placental exam (pathologist): <input type="checkbox"/> No <input type="checkbox"/> Yes	Placental exam (based on path report): <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, <input type="checkbox"/> Normal <input type="checkbox"/> Abruption <input type="checkbox"/> Inflammation <input type="checkbox"/> Other abnormality (please describe)
	N/A	Apgar score: 1 min ____/5 min ____
	Infant temp at delivery: _____ °F	Infant temp (if abnormal): _____ °F
	Head circumference: _____ cm <input type="checkbox"/> in	Birth head circumference: ____ cm ____ in <input type="checkbox"/> molding present
	N/A	Repeat head circumference: ____ cm ____ in <input type="checkbox"/> <24 hours <input type="checkbox"/> 24-35hrs <input type="checkbox"/> 36-48 hr <input type="checkbox"/> 48+hr
	Admitted to NICU: <input type="checkbox"/> No <input type="checkbox"/> Yes	Admitted to Neonatal Intensive Care Unit: _____ <input type="checkbox"/> No <input type="checkbox"/> Yes, If yes, reason _____
	Microcephaly <input type="checkbox"/> No <input type="checkbox"/> Yes	Microcephaly (head circumference <3%ile): <input type="checkbox"/> No <input type="checkbox"/> Yes
	N/A	Seizures: <input type="checkbox"/> No <input type="checkbox"/> Yes
	Neurologic abnormalities: <input type="checkbox"/> No <input type="checkbox"/> Yes (please describe)	Neurologic exam: check all that apply <input type="checkbox"/> Nor performed <input type="checkbox"/> Unknown <input type="checkbox"/> Normal <input type="checkbox"/> Hypertonia/Spasticity <input type="checkbox"/> Hyperreflexia <input type="checkbox"/> Irritability <input type="checkbox"/> Tremors <input type="checkbox"/> Other Neurologic abnormalities (please describe below)
	Splenomegaly: <input type="checkbox"/> No <input type="checkbox"/> Yes (please describe)	Splenomegaly by physical exam: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown (please describe)
	Hepatomegaly: <input type="checkbox"/> No <input type="checkbox"/> Yes (please describe)	Hepatomegaly by physical exam: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown (please describe)
	Skin rash: <input type="checkbox"/> No <input type="checkbox"/> Yes (please describe)	Skin rash by physical exam: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown (please describe)
	Other abnormalities identified: <input type="checkbox"/> No <input type="checkbox"/> Yes (please provide clinical descriptions from medical records)	Other abnormalities identified: (please provide clinical description from medical records and include chromosomal abnormalities and syndromes); please check all that apply <input type="checkbox"/> None <input type="checkbox"/> Microphthalmia <input type="checkbox"/> Absent red reflex <input type="checkbox"/> Excessive and redundant scalp skin <input type="checkbox"/> Arthrogryposis (congenital joint contractures) <input type="checkbox"/> Congenital Talipes Equinovarus (clubfoot) <input type="checkbox"/> Other abnormalities (please describe below)
Hearing evaluation performed: <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal (please describe) <input type="checkbox"/> Not done	Hearing screening: (date: __/__/____) <input type="checkbox"/> Pass <input type="checkbox"/> Fail or referred <input type="checkbox"/> Not performed (please describe below)	

	Ophthalmologic evaluation performed: <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal (please describe) <input type="checkbox"/> Not done	Retinal exam (with dilation): <input type="checkbox"/> Not Performed <input type="checkbox"/> Unknown If performed: (date: __/__/__) please check all that apply: <input type="checkbox"/> Microphthalmia <input type="checkbox"/> Chorioretinitis <input type="checkbox"/> Macular pallor <input type="checkbox"/> Other retinal abnormalities (please describe below)																														
	Imaging study result: <input type="checkbox"/> N/A <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal (please list type, date, and describe)	Imaging study: <input type="checkbox"/> Cranial ultrasound (date: __/__/__) <input type="checkbox"/> MRI (date: __/__/__) <input type="checkbox"/> CT (date: __/__/__) <input type="checkbox"/> Not performed Findings: check all that apply <input type="checkbox"/> Microcephaly <input type="checkbox"/> Cerebral (brain) atrophy <input type="checkbox"/> Intracranial calcification <input type="checkbox"/> Ventricular enlargement <input type="checkbox"/> Lissencephaly <input type="checkbox"/> Pachygyria <input type="checkbox"/> Hydranencephaly <input type="checkbox"/> Porencephaly <input type="checkbox"/> Abnormality of corpus callosum <input type="checkbox"/> Other abnormalities (please describe below)																														
	Lumbar puncture performed: <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal (please describe)	Was a lumbar puncture performed: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown (date: __/__/__)																														
	TORCH testing result: <input type="checkbox"/> Not done <input type="checkbox"/> Negative <input type="checkbox"/> Positive (if positive, please specify pathogen and test (e.g., PCR, IgG, IgM))	Congenital infection testing: if performed, please specify test (i.e. PCR, IgG, IgM) <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Toxoplasmiasis</th> <th>Cytomegalovirus</th> <th>Herpes Simplex</th> <th>Rubella</th> <th>Other</th> </tr> </thead> <tbody> <tr> <td>Positive</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Negative</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Not Done</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Date</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Toxoplasmiasis	Cytomegalovirus	Herpes Simplex	Rubella	Other	Positive						Negative						Not Done						Date					
	Toxoplasmiasis	Cytomegalovirus	Herpes Simplex	Rubella	Other																											
Positive																																
Negative																																
Not Done																																
Date																																
	Other tests/results:	Other tests/results/diagnosis (include dates):																														
	Provider name <input type="checkbox"/> Dr. <input type="checkbox"/> PA <input type="checkbox"/> RN <input type="checkbox"/> Mr. <input type="checkbox"/> Ms. _____ Phone: _____ Email: _____	Neonatal Provider name: <input type="checkbox"/> Dr. <input type="checkbox"/> PA <input type="checkbox"/> RN <input type="checkbox"/> Mr. <input type="checkbox"/> Ms. _____ Phone: _____ Email: _____ Date of form completion __/__/__																														
	N/A	Pediatric Provider Name: <input type="checkbox"/> Dr. <input type="checkbox"/> PA <input type="checkbox"/> RN <input type="checkbox"/> Mr. <input type="checkbox"/> Ms. _____ Phone: _____ Email: _____ Date of form completion __/__/__																														
	Name of person completing form: (if different from provider): Hospital/facility: _____ Phone: _____	Name of person completing form: (if different from provider) _____ Hospital/facility: _____ Phone: _____ Name of Infant Pediatrician: _____ Phone: _____ Email: _____ Date of form completion __/__/__																														
	N/A	Health Department Information Name of person completing form: _____ Phone: _____ Email: _____ Date of form completion __/__/__																														
Infant Health Follow-up Form (Att. G)	N/A	DOB: _____																														
	N/A	Infant's State/Territory ID: Mother's State/Territory ID:																														
	N/A	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Ambiguous/undetermined																														
	N/A	Infant death: <input type="checkbox"/> No <input type="checkbox"/> Yes, date __/__/__ <input type="checkbox"/> Unknown																														
	Infant physical exam: <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal (please describe)	Infant findings for corrected age at examination: (For infants born preterm, please account for corrected age: chronological age minus weeks born before 40 weeks gestation) Check all that apply: <input type="checkbox"/> Microcephaly (head circumference <3%ile) <input type="checkbox"/> Arthrogyposis (congenital joint contractures) <input type="checkbox"/> Hypertonia/Spasticity <input type="checkbox"/> Splenomegaly <input type="checkbox"/> Absent red																														

	<p>reflex <input type="checkbox"/> Congenital Talipes Equinovarus (clubfoot) <input type="checkbox"/> Hyperreflexia <input type="checkbox"/> Hepatomegaly <input type="checkbox"/> Excessive and redundant scalp skin <input type="checkbox"/> Irritability <input type="checkbox"/> Tremors <input type="checkbox"/> Skin rash <input type="checkbox"/> Microphthalmia <input type="checkbox"/> Swallowing/feeding difficulties Please list other abnormal findings:</p>
<p>Infant development: <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal (please describe)</p>	<p>Development assessment for corrected age at examination: (For infants born preterm, please account for corrected age: chronological age minus weeks born before 40 weeks gestation) <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown If developmental delay, in what area? Please check all that apply <input type="checkbox"/> Gross motor <input type="checkbox"/> Fine motor <input type="checkbox"/> Cognitive, linguistic and communication <input type="checkbox"/> Socio-Emotional</p>
<p>CT/other imagine scan: <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Imaging study: <input type="checkbox"/> Cranial ultrasound (date: __/__/__) <input type="checkbox"/> MRI (date: __/__/__) <input type="checkbox"/> CT (date: __/__/__) <input type="checkbox"/> Other _____ <input type="checkbox"/> Not Performed Findings: check all that apply <input type="checkbox"/> Microcephaly <input type="checkbox"/> Cerebral (brain) atrophy <input type="checkbox"/> Intracranial calcification <input type="checkbox"/> Ventricular enlargement <input type="checkbox"/> Lissencephaly <input type="checkbox"/> Pachygyria <input type="checkbox"/> Hydranencephaly <input type="checkbox"/> Porencephaly <input type="checkbox"/> Abnormality of corpus callosum <input type="checkbox"/> Other abnormalities (please describe below)</p>
<p>Hearing evaluation performed: <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Hearing screening or re-screening: <input type="checkbox"/> Not performed <input type="checkbox"/> Unknown <i>If performed: (date: __/__/__)</i> <input type="checkbox"/> Pass <input type="checkbox"/> Fail or referred, please describe</p>
<p>Dysmorphology exam: <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Audiological evaluation: <input type="checkbox"/> Not performed <input type="checkbox"/> Unknown <i>If performed: (date: __/__/__)</i> <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal, please describe</p>
<p>Ophthalmologic exam: <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Retinal exam (with dilation): <input type="checkbox"/> Not Performed <input type="checkbox"/> Unknown <i>If performed: (date: __/__/__)</i> please check all that apply: <input type="checkbox"/> Microphthalmia <input type="checkbox"/> Chorioretinitis <input type="checkbox"/> Macular pallor <input type="checkbox"/> Other retinal abnormalities (please describe below)</p>
<p>Other (please describe): <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Other abnormal tests/results/diagnosis (include dates): <input type="checkbox"/> No <input type="checkbox"/> Yes (date: __/__/__) Please describe</p>
<p>Provider name <input type="checkbox"/> Dr. <input type="checkbox"/> PA <input type="checkbox"/> RN <input type="checkbox"/> Mr. <input type="checkbox"/> Ms. _____ Phone: _____ Email: _____</p>	<p>Neonatal Provider name: <input type="checkbox"/> Dr. <input type="checkbox"/> PA <input type="checkbox"/> RN <input type="checkbox"/> Mr. <input type="checkbox"/> Ms. _____ Phone: _____ Email: _____ Date of form completion __/__/__</p>
<p>N/A</p>	<p>Pediatric Provider Name: <input type="checkbox"/> Dr. <input type="checkbox"/> PA <input type="checkbox"/> RN <input type="checkbox"/> Mr. <input type="checkbox"/> Ms. _____ Phone: _____ Email: _____ Date of form completion __/__/__</p>
<p>Name of person completing form: (if different from provider): _____ Hospital/facility: _____ Phone: _____</p>	<p>Name of person completing form: (if different from provider) _____ Hospital/facility: _____ Phone: _____ Name of Infant Pediatrician: _____ Phone: _____ Email: _____ Date of form completion __/__/__</p>
<p>N/A</p>	<p>Health Department Information Name of person completing form: _____ Phone: _____ Email: _____ Date of form completion __/__/__</p>

Estimates of Annualized Burden hours (unchanged from approved ICR)

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
State and Local Health Departments	Clinical Inquiries Database	420	1	15/60	105
	Maternal Health History Form	100	5	30/60	250
	Specimen Collection Form	100	1	15/60	25
Clinicians and Other Providers	Clinical Inquiries Database	800	1	15/60	200
	Assessment at Delivery Form	100	1	30/60	50
	Infant Health Follow-Up Form at 2 months of age	100	1	30/60	50
Vector control professionals, entomologists, and Public health biologists	Survey of county-level surveillance records of <i>Aedes aegypti</i> and <i>Aedes albopictus</i>	500	1	3/60	25
Total					705