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 and infants who do not meet the current CSTE definitions, i.e.:

- Pregnant women with laboratory evidence of Zika infection or unspecified flavivirus infection but without symptoms of Zika virus disease;
- Symptomatic pregnant women with unspecified flavivirus infection; and
- Infants exposed to the mother's Zika or unspecified flavivirus infection before or during birth who do not meet the case definition for congenital Zika virus infection.

It also 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 met 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 the following cases:
            - Pregnant women with laboratory evidence of Zika infection or unspecified flavivirus infection but without symptoms of Zika virus disease;

        - Symptomatic pregnant women with unspecified flavivirus infection; and
        - Infants exposed to the mother's Zika or unspecified flavivirus infection before or during birth who do not meet the case definition for congenital 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	**Race (check all that apply):** ☐American Indian or Alaska

	as): ☐American Indian or Alaska Native ☐Asian ☐Black or African-American ☐Native Hawaiian or other Pacific Islander ☐White	Native ☐Asian ☐Black or African-American ☐Native Hawaiian or other Pacific Islander ☐White
	Indication for maternal serum Zika virus testing: _____	**Indication for maternal Zika virus testing:** ☐Exposure history, no known fetal concerns ☐Exposure history and fetal concerns
	Date of Zika virus disease onset: _____/_____/_____ **-OR-** ☐ Asymptomatic	**Date of Zika virus symptom onset:** _____/_____/_____ **-OR-** ☐ Asymptomatic ***If date not known, trimester of symptom onset*** **_____** **Hospitalized for Zika virus disease** ☐ No ☐ Yes **Maternal Death** ☐ No ☐ Yes
	Symptoms of mother's Zika virus disease: (check all that apply) ☐Fever _____ ^{o}F ☐Rash ☐Arthralgia ☐Conjunctivitis ☐Other Clinical Presentation_____ **Gestational age at onset: _____** weeks	**Symptoms of mother's Zika virus disease: (check all that apply)** ☐Fever _____ ^{o}F (if measured) ☐Rash ☐Arthralgia ☐Conjunctivitis ☐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** ☐No ☐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*** ☐Male ☐Female
	N/A	**Did any male sexual partner(s) travel on this trip?** ☐ No ☐ 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?** ☐ No ☐ Yes **If yes, was there unprotected sexual contact while male partner(s) had illness?** ☐No ☐Yes
	N/A	**If male partner(s) travelled, did he have a test that showed lab evidence of Zika?** ☐ No ☐ Yes
	☐ Mother agrees to participate in this Pregnancy Registry	**N/A** [Removed]
	N/A	**<u>NON-TRAVELLING WOMAN:</u> other possible exposures?** ☐Sexual partner w/travel history, symptomatic, lab evidence of Zika ☐Sexual partner w/travel history, symptomatic, no test results ☐Sexual partner w/travel history, asymptomatic lab evidence of Zika ☐Other, please describe_____ ☐Unknown

	N/A	**Last menstrual period (LMP): __/__/____**
	N/A	**Estimated delivery date based on (check all that apply):** ☐ LMP __/__/____ ☐ U/S (1st trimester) ☐ U/S (2nd trimester) ☐ U/S (3rd trimester)
	N/A	**History:** # pregnancies ___ # living children ___ # miscarriages ___ # elective terminations ___
	N/A	**Prior fetus/infant with microcephaly:** ☐ No ☐ Yes **If yes, genetic cause:** ☐ No ☐ Yes
	Current gestation: ☐Single ☐Twins ☐Triplets	**Gestation:** ☐Single ☐Twins ☐Triplets+
	Underlying maternal illness: Diabetes ☐ No ☐ Yes Maternal PKU ☐ No ☐ Yes Hypothyroidism ☐ No ☐ Yes Hypertension ☐ No ☐ Yes Alcohol use ☐ No ☐ Yes Other underlying illness: _____	**Underlying maternal illness:** Diabetes ☐ No ☐ Yes Maternal PKU ☐ No ☐ Yes Hypothyroidism ☐ No ☐ Yes Hypertension ☐ No ☐ Yes Substance use during this pregnancy: Alcohol use ☐ No ☐ Yes Cocaine use ☐No ☐Yes Smoking ☐No ☐Yes Other underlying illness: _____
	Complications of pregnancy: TORCH infection ☐ No ☐ Yes Gestational diabetes ☐ No ☐ Yes Death of a monozygote twin ☐ No ☐ Yes Pregnancy-related HTN ☐ No ☐ Yes Other ☐ No ☐ Yes _____	**Complications of pregnancy:** Toxoplasmosis ☐positive ☐No ☐Yes ☐Unknown Herpes Simplex ☐positive ☐No ☐Yes ☐Unknown Syphilis ☐positive ☐No ☐Yes ☐Unknown Cytomegalovirus ☐positive ☐No ☐Yes ☐Unknown Rubella ☐positive ☐No ☐Yes ☐Unknown Fetal genetic abnormality ☐No ☐Yes, *diagnosis*_____ ☐Unknown Gestational diabetes ☐No ☐Yes Pregnancy-related HTN ☐No ☐Yes Intrauterine death of a twin ☐No ☐Yes Other_____
	N/A	**Did this pregnancy end in miscarriage or intrauterine fetal demise (IUFD)?** ☐No ☐Yes Date: __/__/____ Gestational age____ weeks
	N/A	**Was this pregnancy terminated?** ☐No ☐Yes *Date:__/__/____ Gestational age ____ weeks*
	N/A	**Maternal Prenatal Imaging and Diagnostics** **Date(s) of Ultrasound(s):**
		__/__/____ ☐*Check if date approximated* *If date not known, gestational age ____ weeks*
		Overall Fetal Ultrasound Results: ☐Normal ☐Abnormal ☐*Check if reported by patient/healthcare provider* ☐ ultrasound report Head Circumference _____cm ☐ Normal ☐ Abnormal (by physician report)_ Biparietal diameter ___ cm Femur Length___ ___cm Abdominal Circumference _____cm ☐ Symmetrical intrauterine growth restriction IUGR (<5% EFW) ☐Asymmetrical IUGR (HC<FL or HC<AC)

			Intracranial calcifications ☐ No ☐ Yes Ventriculomegaly ☐ No ☐ Yes
			Cerebral atrophy ☐ No ☐ Yes Ocular anomalies ☐ No ☐ Yes
			Cerebellar abnormalities ☐ No ☐ Yes Arthrogryposis ☐ No ☐ Yes
			Corpus callosum abnormalities ☐ No ☐ Yes Hydrops ☐ No ☐ Yes
			Ascites ☐ No ☐ Yes Other ☐ No ☐ Yes, describe
		Description of abnormal ultrasound findings:	
		Fetal MRI performed: ☐ No ☐ Yes (please answer questions below)	
		__/__/____ ☐*Check if date approximated* *If date not known, gestational age* ____ *weeks*	**Overall fetal MRI Results:** ☐Normal ☐Abnormal ☐*Check if report by patient/healthcare provder* Head Circumference ___cm ☐ Normal ☐ Abnormal Biparietal diameter ___ cm Femur Length _____cm ☐ Symmetrical IUGR (<5% EFW) ☐ Asymmetrical IUGR (HC<FL or HC <AC)
			Intracranial calcifications ☐ No ☐ Yes **Ventriculomegaly** ☐ No ☐ Yes
			Cerebral atrophy ☐ No ☐ Yes **Ocular anomalies** ☐ No ☐ Yes
			Cerebellar abnormalities ☐ No ☐ Yes **Arthrogryposis** ☐ No ☐ Yes
			Corpus callosum abnormalities ☐ No ☐ Yes **Lissencephaly** ☐No ☐Yes **Pachygyria** ☐No ☐Yes **Hydranencephaly** ☐No ☐Yes **Porencephaly** ☐No ☐Yes **Hydrops** ☐ No ☐ Yes
			Ascites ☐ No ☐ Yes Other ☐No ☐Yes, describe
		Description of abnormal MRI findings:	
			Amniocentesis performed: ☐ No ☐ Yes (*date: __/__/____)* Zika virus testing: ☐Not performed ☐Yes, *if yes test results:* ☐lab evidence of Zika ☐negative for Zika Non-Zika infection detected ☐No ☐Yes *if yes, what infection was detected*_____ Genetic abnormality detected ☐No ☐Yes *Please describe:*
		Provider Information	
		Provider name: ☐ Dr. ☐ PA ☐ RN ☐ Mr. ☐ Ms. _____	

		Phone: _____ **Email:** _____ **Date of form completion** __/__/____
		Name of person completing form ***(if different from provider):*** **_____** **Hospital/facility:_____** **Phone:_____ Email:_____ Date of form completion** __/__/____
		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: ☐ Confirmed ☐ Probable ☐ 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: ☐Male ☐Female	**Sex:** ☐Male ☐Female ☐Ambiguous/undetermined
	Gestational age at delivery:___ weeks	**Gestational age at delivery:___** weeks Based on: (*check all that apply)* ☐LMP __/__/____ ☐U/S (1st trimester) ☐U/S (2nd trimester) ☐U/S (3rd trimester ☐Other _____
	Delivery type: ☐ Vaginal ☐ Forceps/suction ☐ Caesarean section	**Delivery type:** ☐ Vaginal ☐ Caesarean section **Delivery complication:** ☐ No ☐ Yes If yes, _____
	N/A	**Arterial Cord blood pH:** *if performed* _____ **Venous Cord blood pH:** *if performed* _____
	Placental exam (pathologist): ☐No ☐Yes	**Placental exam (based on path report):** ☐No ☐Yes If yes, ☐Normal ☐Abruption ☐Inflammation ☐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 ☐in	**Birth head circumference:** ____☐cm ___☐in ☐*molding present*
	N/A	**Repeat head circumference:** _____☐cm _____☐in ☐<24 hours ☐24-35hrs ☐36-48 hr ☐48+hr
	Admitted to NICU: ☐No ☐Yes	**Admitted to Neonatal Intensive Care Unit:** _____ ☐No ☐Yes, If yes, *reason*_____
	Microcephaly ☐No ☐Yes	**Microcephaly** (head circumference <3%ile): ☐No ☐Yes
	N/A	**Seizures:** ☐No ☐Yes
	Neurologic abnormalities: ☐No ☐Yes (please describe)	**Neurologic exam:** *check all that apply* ☐Nor performed ☐Unknown ☐Normal ☐Hypertonia/Spasticity ☐Hyperreflexia ☐Irritability ☐Tremors ☐Other Neurologic abnormalities (*please describe below)*
	Splenomegaly: ☐No ☐Yes (please describe)	**Splenomegaly** *by physical exam***:** ☐No ☐Yes ☐Unknown (please describe)
	Hepatomegaly: ☐No ☐Yes (please describe)	**Hepatomegaly** *by physical exam***:** ☐No ☐Yes ☐Unknown (please describe)
	Skin rash: ☐No ☐Yes (please describe)	**Skin rash** *by physical exam***:** ☐No ☐Yes ☐Unknown (please describe)

<table>
<tr><td></td><td>Other abnormalities identified: ☐No ☐Yes (please provide clinical descriptions from medical records)</td><td>Other abnormalities identified: (please provide clinical description from medical records and include chromosomal abnormalities and syndromes); please check all that apply
☐None ☐Microphthalmia ☐Absent red reflex ☐Excessive and redundant scalp skin ☐Arthrogryposis (congenital joint contractures) ☐Congenital Talipes Equinovarus (clubfoot) ☐Other abnormalities (please describe below)</td></tr>
<tr><td></td><td>Hearing evaluation performed: ☐Normal ☐Abnormal (please describe) ☐Not done</td><td>Hearing screening: (date:__/__/____) ☐Pass ☐Fail or referred ☐Not performed (please describe below)</td></tr>
<tr><td></td><td>Ophthalmologic evaluation performed: ☐Normal ☐Abnormal (please describe) ☐Not done</td><td>Retinal exam (with dilation): ☐Not Performed ☐Unknown
If performed: (date:__/__/____) please check all that apply:
☐Microphthalmia ☐Chorioretinitis ☐Macular pallor ☐Other retinal abnormalities (please describe below)</td></tr>
<tr><td></td><td>Imaging study result: ☐N/A ☐Normal ☐Abnormal (please list type, date, and describe)</td><td>Imaging study: ☐Cranial ultrasound (date:__/__/____) ☐MRI (date:__/__/____) ☐CT (date:__/__/____) ☐Not performed
Findings: check all that apply ☐Microcephaly ☐Cerebral (brain) atrophy ☐Intracranial calcification ☐Ventricular enlargement ☐Lissencephaly ☐Pachygyria ☐Hydranencephaly ☐Porencephaly ☐Abnormality of corpus callosum ☐Other abnormalities (please describe below)</td></tr>
<tr><td></td><td>Lumbar puncture performed: ☐No ☐Yes If yes, ☐Normal ☐Abnormal (please describe)</td><td>Was a lumbar puncture performed: ☐Yes ☐No ☐Unknown (date:__/__/____)</td></tr>
<tr><td></td><td>TORCH testing result: ☐ Not done ☐ Negative ☐ Positive (if positive, please specify pathogen and test (e.g., PCR, IgG, IgM))</td><td>Congenital infection testing: if performed, please specify test (i.e. PCR, IgG, IgM)
<table>
<tr><td></td><td>Toxoplasmosis</td><td>Cytomegalovirus</td><td>Herpes Simplex</td><td>Rubella</td><td>Other</td></tr>
<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>
</table></td></tr>
<tr><td></td><td>Other tests/results:</td><td>Other tests/results/diagnosis (include dates):</td></tr>
<tr><td></td><td>Provider name ☐Dr. ☐PA ☐RN ☐Mr. ☐Ms. _____
Phone:_____
Email: _____</td><td>Neonatal Provider name: ☐Dr. ☐PA ☐RN ☐Mr. ☐Ms. _____ Phone:_____ Email: _____ Date of form completion __/__/____</td></tr>
<tr><td></td><td>N/A</td><td>Pediatric Provider Name: ☐Dr. ☐PA ☐RN ☐Mr. ☐Ms. _____ Phone:_____ Email: _____ Date of form completion __/__/____</td></tr>
<tr><td></td><td>Name of person completing form: (if different from provider):
Hospital/facility:_____ Phone:_____</td><td>Name of person completing form: (if different from provider)_____ Hospital/facility:_____ Phone:_____
Name of Infant Pediatrician:_____ Phone:_____
Email:_____ Date of form completion __/__/____</td></tr>
<tr><td></td><td>N/A</td><td>Health Department Information
Name of person completing form:_____
Phone:_____ Email:_____ Date of form completion __/__/____</td></tr>
<tr><td>Infant Health Follow-up Form</td><td>N/A</td><td>DOB: _____</td></tr>
<tr><td></td><td>N/A</td><td>Infant’s State/Territory ID:
Mother’s State/Territory ID:</td></tr>
<tr><td></td><td>N/A</td><td>Sex: ☐Male ☐Female ☐Ambiguous/undetermined</td></tr>
</table>

(Att. G)	**N/A**	**Infant death:** ☐No ☐Yes, date __/__/____ ☐Unknown
	Infant physical exam: ☐Normal ☐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:** ☐Microcephaly (head circumference <3%ile) ☐Arthrogryposis (congenital joint contractures) ☐Hypertonia/Spasticity ☐Splenomegaly ☐Absent red reflex ☐Congenital Talipes Equinovarus (clubfoot) ☐Hyperreflexia ☐Hepatomegaly ☐Excessive and redundant scalp skin ☐Irritability ☐Tremors ☐Skin rash ☐Microphthalmia ☐Swallowing/feeding difficulties **Please list other abnormal findings:**
	Infant development: ☐Normal ☐Abnormal (please describe)	**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) ☐Normal ☐Abnormal ☐Unknown **If developmental delay, in what area?** Please check all that apply ☐Gross motor ☐Fine motor ☐Cognitive, linguistic and communication ☐Socio-Emotional
	CT/other imagine scan: ☐Yes ☐No	**Imaging study:** ☐Cranial ultrasound (date:__/__/____) ☐MRI (date:__/__/____) ☐CT (date:__/__/____) ☐Other _____ ☐Not Performed **Findings:** check all that apply ☐Microcephaly ☐Cerebral (brain) atrophy ☐Intracranial calcification ☐Ventricular enlargement ☐Lissencephaly ☐Pachygyria ☐Hydranencephaly ☐Porencephaly ☐Abnormality of corpus callosum ☐Other abnormalities (please describe below)
	Hearing evaluation performed: ☐Yes ☐No	**Hearing screening or re-screening:** ☐Not performed ☐Unknown *If performed: (date:__/__/____)* ☐Pass ☐Fail or referred, please describe
	Dysmorphology exam: ☐Yes ☐No	**Audiological evaluation:** ☐Not performed ☐Unknown *If performed: (date:__/__/____)* ☐Normal ☐Abnormal, please describe
	Ophthalmologic exam: ☐Yes ☐No	**Retinal exam (with dilation):** ☐Not Performed ☐Unknown *If performed: (date:__/__/____) please check all that apply:* ☐Microphthalmia ☐Chorioretinitis ☐Macular pallor ☐Other retinal abnormalities (please describe below)
	Other (*please describe):* ☐Yes ☐No	**Other abnormal tests/results/diagnosis (include dates):** ☐No ☐ Yes (*date: __/__/____)* Please describe
	Provider name ☐Dr. ☐PA ☐RN ☐Mr. ☐Ms. _____ **Phone:_____** **Email: _____**	**Neonatal Provider name:** ☐Dr. ☐PA ☐RN ☐Mr. ☐Ms. **_____ Phone:_____ Email: _____ Date of form completion __/__/____**
	N/A	**Pediatric Provider Name:** ☐Dr. ☐PA ☐RN ☐Mr. ☐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 __/__/____**

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 *Aedes aegypti* and *Aedes albopictus*	500	1	3/60	25
Total					705