Non-Substantive Change Request to OMB Control Number 0920-1143; US Zika Pregnancy Registry

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Circumstances of Change Request for OMB 0920-1143

CDC requests approval for a non-substantive change to OMB Control No. 0920-1143: US Zika Pregnancy Registry.

The proposed change is being made to continue information collection from exposed children through 2 years of age to monitor health outcomes and infant test results from child heath visits and testing which is already recommended. The current ICR only includes follow-up for one year. It will not require or suggest additional care outside of recommended care. Health departments and clinicians will simply be asked to submit follow-up information for a longer period of time. There are no other changes to the project's methods or purpose.

Findings from the US Zika Pregnancy Registry to date have influenced clinical guidance and public health action as our knowledge about Zika virus and birth defects evolves. An extension of the follow-up of children from 1 year to 2 years is necessary to assist with updating guidance on infant testing and clinical care of children with possible congenital Zika virus infection.

In CDC's current infant guidance, plaque reduction neutralization testing is indicated at 18 months because maternal antibodies in the infant are expected to wane by 18 months, and this testing assists in some cases with confirming a congenital infection. In the current US Zika Pregnancy Registry protocol, these test results would not be collected, and thus we would not include important data that would influence updated clinical guidance and care. In addition, some infants who appear normal at birth manifest Zika-associated outcomes after the perinatal period. In order to get a true picture of the scope of this public health emergency, the US Zika Pregnancy Registry needs to extend the follow-up period to include data collection for children up to 2 years of age. Also, this extension of follow-up will identify what care practices children with possible congenital Zika virus infection are receiving and guide public health actions if appropriate care is not being routinely practiced.

In summary, extending the period of follow-up of children will build capacity to monitor infant and childhood outcomes through age of 2 years, describe the scope of the public health risks posed by Zika virus infection during pregnancy, and impact clinical guidance and public health action.

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 2). IRB review is not required.

Estimates of annualized burden hours for this change request have been updated based on experience to date and to reflect estimates from October 2017 onward. The annual burden estimate for the forms included in OMB Control No. 0920-1143 is 5,387 hours. Additionally, the type of respondent for Assessment at Delivery Form and the Infant Health Follow-up Form has been revised to also include State, Territorial and Local Health Departments. This more accurately reflects the shared burden in jurisdictions.

Despite the longer follow-up period, the estimated annual burden is expected to fall from 23,833 hours to 5,387, a reduction of 18,446 hours. This is due to revised estimates of new cases reported to the registry.

The estimated burden has been revised to reflect expected reductions in new cases reported annually through 2018 and an increase in follow up time points (see below). The number of cases reported to date is 2,196 (approximately 115/month). We estimate that an average of 25 cases will be reported per month through November 2018 at which time no new cases will be reported for the remainder of the project period. This results in an estimate of 665 cases reported per year for the project period (February 2016-November 2019). Additionally, we estimate an average of 600 cases per year will result in a liveborn infant and require follow-up.

Attachments

1. Infant Health Follow-Up Form (for 2, 6, 12, 18 and 24 months of age) ***(Change requested)***
2. Updated Review by Human Subjects Expert on Non-research Determination

Description and Justification of Changes

Attachment 1: Infant Health Follow-Up Form

- Changes: Added follow-up form for 18 and 24 months of age. There are no changes in the data collected other than the time point for collection.
- Justification: Reflects extended follow-up time points up to 2 years of age.

Form	Current Question	Requested Change
Infant Health Follow-Up form	**Infant follow up:** ☐2 months ☐6 months ☐12 months ☐___ months	**Infant follow up:** ☐2 months ☐6 months ☐12 months ☐18 months ☐24 months ☐___ months

Updated Table A. Estimates of Annualized Burden hours

Type of	Form	No. of	No. of	Average	Total Burden

Respondent	Name	Respondents	Responses per Respondent	Burden per Response (in hours)	Hours
State, Territorial and Local Health Departments	Maternal Health History Form	665	5	30/60	1663
	Supplemental Imaging Form	665	5	20/60	1109
	Laboratory Results Form	665	2	30/60	665
State/ Territorial/ Local Health Departments, Clinicians, and Other Providers	Assessment at Delivery Form	600	1	60/60	600
	Infant Health Follow-Up Form	600	3	45/60	900
Total					5,387

Currently approved burden table:

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
State, Territorial and Local Health Departments	Maternal Health History Form	1100	10	30/60	5500
	Supplemental Imaging Form	1100	10	10/60	1833
	Laboratory Results Form	1100	10	15/60	2750
Clinicians and Other Providers	Assessment at Delivery Form	1100	10	30/60	5500
	Infant Health	1100	30	15/60	8250

	Follow-Up Form				
Total					23,833