Change Request Pregnancy Risk Assessment Monitoring System

(OMB Control No. 0920-1273; Exp. date 11/30/2022) July 28, 2022

Summary

CDC requests OMB approval for 2 supplemental modules as part of Pregnancy Risk Assessment Monitoring System project (OMB Control No. 0920-1273; Exp. date 11/30/2022). These 2 supplemental modules include a 15-question supplement on COVID-19 related experiences and a 6-question supplement on experiences related to COVID-19 vaccination during pregnancy. These modules were approved for cognitive testing and data collection under the COVID-19 Public Health Emergency (PHE) Paperwork Reduction Act (PRA) waiver. With the anticipated end of the public health emergency declaration, CDC requests approval for continued data collection for 2022 births.

Background and Justification

The Pregnancy Risk Assessment Monitoring System (PRAMS) provides data that is not available from other sources. PRAMS is approved to collect information on maternal behaviors and experiences before, during and shortly after pregnancy on a variety of topics, including those related to the social context of childbearing. PRAMS is a key data source used by CDC, states, jurisdictions, and researchers to monitor prevalence of maternal behaviors and experiences, investigate emerging issues in the field of reproductive health and to assess impacts of programs and policies aimed at reducing health problems among mothers and babies.

PRAMS is approved to provide states the option of collecting supplemental modules to address emerging and priority topics. The goal of the COVID-19 experience module is to provide site/state-level population-based data on COVID-19 related experiences during pregnancy that are not available from other sources on types of care and barriers to receipt of care during the prenatal and postpartum period and child's early infancy due to COVID, use and barriers to use of protective measures to reduce exposure to COVID-19 during pregnancy, delivery hospital experiences during COVID-19, and economic hardship faced during pregnancy as a result of COVID-19 (**Attachments 1 and 2**). The goal of the COVID-19 vaccination module is to provide site/state-level population-based data on experiences related to COVID-19 vaccination during pregnancy, barriers to vaccination during pregnancy, trusted sources of information, and occupational exposure to COVID-19 that are not available from other state and population-level data sources (**Attachments 3 and 4**).

Both modules were developed in collaboration with the CDC Emergency Operations Center's COVID-19 Responses Pregnancy and Infant Linked Outcomes Team (PILOT) of the Epidemiology Task Force. This group was instrumental in identifying gaps in information related to COVID-19 and COVID-19 vaccination among pregnant women that are not available from other surveys or data collection instruments and ensuring harmonization with other surveillance efforts within the COVID-19 Response. Drafts of the surveys also were circulated widely to experts throughout CDCs Division of Reproductive Health, including Maternal and Child Health Field Assignees located in state health departments, who also provided feedback on critical data gaps for which data were unavailable from other sources at the

state and local level. The questions were reviewed and cleared by the COVID-19 responses Vaccine Task Force. Cognitive testing occurred for both modules in collaboration with contracted agencies.

Cognitive testing and implementation for the COVID-19 experience module was approved under the COVID-19 PHE PRA waiver. Implementation began in October 2020 with 34 sites that received federal funding to implement. Though funding ended, 22 sites continued to implement for 2021 births and 10 sites are implementing for 2022 births. Data from this module has been used extensively by CDC, states/territories, and external researchers.

Similarly, cognitive testing and implementation for the COVID-19 vaccine module was approved under the COVID-19 PHE PRA waiver and began implementation in April 2021 with 25 funded sites. For 2022 births, 11 sites are implementing without additional funding. The data collected for 2021 births will be made available to internal and external researchers in the Fall of 2022.

These data are critical to inform the impacts of the COVID Public Health Emergency (PHE) for pregnant and postpartum persons. In anticipation of the end of the COVID19 PHE PRA waiver and given that PRAMS is approved to provide states the option of collecting supplemental modules to address emerging and priority topics these modules are submitted as a non-substantive change.

Burden Estimate

Ten sites have elected to include the COVID-19 experience supplement and eleven sites have elected to include the COVID-19 vaccine supplement in their overall PRAMS survey. Continued collection of these supplemental modules for calendar year 2022 births totals an additional 3,875 hours than what is currently approved. Respondents are those who are already participating in a jurisdiction's PRAMS survey with an estimated 15,000 additional responses to the COVID-19 experience supplement and 16,500 to the COVID-19 vaccine supplement.

Types of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average hours per response (in hours)	Total Burden Hours
Women who recently delivered a live birth	COVID-19 Experience Supplement	15,000	1	10/60	2,500
	COVID-19 Vaccine Supplement	16,500	1	5/60	1,375
	Total for COVID-19 Changes	31,500*			3,875

 $^{^*}$ This value does not represent additional *respondents*, but the estimated number of *response*s to the supplemental modules.

Effect of Proposed Changes on Currently Approved Instruments and Attachments

Non-substantive change for supplemental data collection module on COVID-19 experiences and module on COVID-19 vaccines.

OMB approval is requested, effective immediately.