

Change Request (v.2)

Pregnancy Risk Assessment Monitoring System

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

March 22, 2022

Summary

We request OMB approval to add a web mode of data collection to the current phone and mail mode options by which respondents can complete the Pregnancy Risk Assessment Monitoring System (PRAMS) survey. PRAMS is not considering replacing phone and/or mail mode for data collection with the web mode. Rather, this activity is part of a phased approach to add a new mode of data collection to the current protocol beginning with 5 early adopter states during April 2022.

Background and Justification

At the time of OMB approval of PRAMS, plans for the web mode of data collection were specified as an approach to further the use of improved information technology. The web mode of data collection may better reach some under-represented populations (e.g., younger mothers) and result in an increase in the response rate overall and improved representativeness of survey respondents.

The questions to be asked through the web mode of data collection are the same as those asked in the existing state multimode (phone, mail, and now web) survey. CDC submits this change request to account for this new data collection mode included in the PRAMS Integrated Data Collection System (PIDS) system to collect responses from PRAMS participants.

CDC, through a contractor, has developed a web mode of data collection in PIDS that is integrated alongside the mail and telephone features. Web versions of the survey have been programmed in PIDS for 5 early adopter sites (MD, VA, PR, WY, SC) with the aim of initial deployment in April 2022 (Supplemental Attachments 1-5).

The web mode of data collection has completed two rounds of User Acceptance Testing [UAT] with the five early adopter sites (MD, VA, PR, WY, SC). UAT was conducted by staff at CDC and the five grantee sites to test various use cases (e.g., ineligible participant, completed survey, break-off, refusal), optimize the display across devices (mobile phone, tablet, laptop, desktop), verify the survey flow and skip patterns, and provide feedback on the usability of the web survey experience. Feedback from UAT was used to further improve the user interface.

The initial implementation of the web mode of data collection will occur as part of ongoing PRAMS data collection by the 5 states that participated in the UAT. Data collection for the 2022 calendar year of births begins in April 2022. The current PRAMS protocol indicates that a pre-survey letter introducing PRAMS and up to 3 mailed surveys be sent to a sampled woman. In states providing the option of completing the survey on the web, letters sent prior to and with the mailed surveys will provide all sampled women with the added option of completing the survey via the web mode of data collection while maintaining the option to complete the survey on paper and return by mail. A URL and a QR code with a unique User ID and Password allowing

the sampled woman to securely access the web mode will be provided. If she does not respond to any of the mailings by completing and returning the paper survey or completing the survey on the web, up to 15 calling attempts for each viable phone number are made. Participants contacted by phone have the option of completing the survey as an interview over the phone or by mail or web.

For the web mode of data collection, respondents access the survey through a secure CDC website which interfaces with the PIDS system to record web responses. Respondents will be able to access the web mode of data collection on a computer, hand-held device, or smart phone. If a respondent elects to complete the survey on the web, mother's year of birth is used to verify a respondent's identity once logged into the web mode of data collection. For the web mode of data collection, a web screen containing informed consent information (Attachments 12i and 12j) is displayed prior to accessing the survey. Women must actively consent before proceeding with the survey.

The web layout for the questionnaire for the 5 early adopter states are included as attachments (Supplemental Attachments 1-5). States will administer their currently approved tailored version of the PRAMS Phase 8 survey (core plus standard modules and ≤ 2 CDC funded supplements). States may choose to customize their informed consents as required by local IRB to reflect their unique circumstances. This change request does not include a change in number of persons sampled or estimated respondent burden.

CDC intends to use lessons learned from initial implementation of the web mode of data collection with five states to refine the web mode approach, as needed, and publish the final approach to web mode data collection as a Federal Register Notice for public comment before implementing in all PRAMS sites as part of a full revision. To understand how the addition of the web mode of data collection for responding to the PRAMS survey influences the representativeness of survey respondents, data quality, and costs, CDC will monitor:

- **Overall and mode-specific response rates by maternal age, race, and education level** to assess the participation of underrepresented subpopulations
- **Item nonresponse rates and partial survey completion rates after initial attempt to complete survey by mode** as indicators of data quality. If fewer than 75% of items are completed during the mail or web mode, a follow-up call is conducted to collect responses to the remaining items.
- **Time to completion** for each monthly processing batch of sampled women as a measure of data quality (i.e., less recall bias with responses made closer to the sampled woman's pregnancy) and of cost savings (i.e., quicker completion indicates fewer follow-up efforts by mail and phone and, thus, savings in staff time and materials)
- **Technical issues** with use of the web mode of data collection identified by participating sites and by the number of user support inquiries received from sampled women.

Monitoring will begin in April 2022 and last for at least 3 months. Comparisons will be made to the same indicators from the 3 months prior to web implementation within the same state. In order to judge whether and how to scale up the number of PRAMS jurisdictions that include the web mode of data collection, CDC will examine whether the key metrics detailed above

(response rates; item nonresponse rates and partial survey completion; time to completion) are the same or improved in the three months of implementation relative to the prior three months.

Findings from the initial implementation of the web mode will provide evidence to support a roll out of the web mode to all jurisdictions or may provide evidence that the addition of the web mode option has unintended adverse impacts to data quality. If all metrics are the same or improved, CDC will pursue expansion of the web mode to all PRAMS jurisdictions. Given the anticipated cost savings associated with the web mode relative to mail or phone mode, even no change in the key metrics supports expanding use of the web mode (i.e., would indicate same data quality at less cost). Though not expected, there is the possibility of unintended adverse impacts on data collection overall where some metrics may worsen. For example, if the web mode improves response rates within subpopulations that have historically been underrepresented in PRAMS data (younger, minority, lower education), but results in lower response rates overall, the improved representation of the sample may justify implementation of the web mode to all PRAMS jurisdictions given the need to collect robust data to address health inequities. Processes have been put in place to address potential unintended adverse impacts to data quality (e.g., to address non-completes for the web mode, call-backs will be conducted for surveys with less than 75% of items completed). Review of the findings and consideration of implementation of the web mode across all PRAMS jurisdictions would be made in consultation with statisticians and maternal and infant health surveillance subject matter experts and posted as a Federal Register Notice as part of a full revision. CDC also will provide OMB with a briefing on the findings of the initial roll out and implications for future plans.

Effect of Proposed Changes on Currently Approved Instruments

The proposed changes will result in the development of a web-based data collection mode of the PRAMS survey with the same content collected in mail and telephone modes. Slight edits to question wording were made to make applicable to administration of the web-mode.

Burden Estimate

The changes will have no impact on study burden for the respondents.

OMB approval is requested, effective immediately.