Pregnancy Risk Assessment Monitoring System (PRAMS)

Existing Collection in Use without an OMB Control Number

Supporting Statement
Part A

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- **Goal of the study:** The goal of the Pregnancy Risk Assessment Monitoring System (PRAMS) is to obtain state-, territory- and tribal-specific information on maternal experiences and behaviors that occur before, during, and shortly after pregnancy.
- **Intended use:** PRAMS data are used by CDC, states, jurisdictions, and researchers to monitor prevalence of maternal behaviors and experiences and assess progress (e.g., Healthy People 2020/2030 targets); to 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.
- **Methods to be used to collect the data**: Self-reported survey data will be collected by mixed-mode methods (i.e., mailing, telephone calls). Data collection procedures and instruments are standardized to allow comparisons between states. Respondents are selected through a stratified systematic sample pulled monthly from the vital records birth certificate or fetal death files in each participating jurisdiction. Ad-hoc sampling strategies such as hospital-based may be used when needed, such as during an emergency response.
- **Subpopulation**: The subpopulation to be studied for PRAMS is women who recently delivered a live born or stillborn infant.
- **How the data will be analyzed:** CDC, states, and jurisdictions produce weighted state and aggregate estimates as part of maternal and child health surveillance activities. Researchers may request access to PRAMS data to answer research and programmatic questions of interest to the field of maternal and child health using analytical techniques, such as econometric or epidemiological modeling.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This application is for an existing data collection, Pregnancy Risk Assessment Monitoring System (PRAMS), currently in use without an OMB control number. PRAMS is administered by states with federal support. Current understanding of the federal role and requirements dictate that OMB approval be sought for this ongoing collection. The initial application period is for a three-year clearance.

PRAMS was begun in 1987 as part of the CDC initiative to reduce infant mortality and low birthweight. In recent years, the program has been expanded to support CDC's Safe Motherhood Initiative to promote healthy pregnancies and the delivery of healthy infants. The PRAMS surveillance system was developed based on research that showed that the US infant mortality and low birthweight rates were no longer declining as rapidly as they had in past years. The number of fetal deaths in the United States is equal to that of infant deaths, and the rate of fetal deaths has remained relatively unchanged since the 1980s.

PRAMS is a population-based surveillance system that provides data not available from other sources and uses a stratified systematic sample of women who recently delivered a live birth or stillbirth to identify and monitor selected maternal experiences and behaviors that occur the months prior to and during pregnancy, as well as the first months after pregnancy. Findings from PRAMS are used to enhance the understanding of maternal behaviors and their relationship with adverse pregnancy outcomes. PRAMS data can also be used by participating states and jurisdictions for needs assessment and to inform program development and evaluation, health care services and policy.

PRAMS serves as an adjunct to states' vital records systems. Birth certificates or fetal death records provide limited information on select topics, while PRAMS data complement with more details on behaviors and experiences from the pre-pregnancy, prenatal and postpartum period. Once the statistical weighting occurs, PRAMS becomes representative of the jurisdictions' live birth or fetal death population.

PRAMS has a core set of questions common across all state and jurisdiction grantees (henceforth referred to as "states"). There are standard modules that states can choose to include on an individual basis to address state-specific priorities or special topics (e.g., adverse childhood experiences, emerging tobacco products). In addition, states can choose to field state-added questions that are independently state-designed. In most states, PRAMS is an ongoing survey that produces annual, state-level estimates. States not intending to implement the survey on an ongoing basis can alternatively employ a point-in-time survey.

Pregnant or postpartum women may have unique needs in emergency circumstances such as disease outbreaks (e.g., Zika virus infection) or natural disasters; PRAMS data can be used to evaluate programs targeted to low income pregnant women (e.g., enrolled in Healthy Start programs) and to collect data on risk factors for chronic conditions that affect women of reproductive age (e.g., family history of cancer). Increasingly, PRAMS infrastructure is used to support special-purpose information collection among this specific and vulnerable population. PRAMS has the capability of rapidly adding supplemental modules to address emerging issues (e.g., maternal disabilities, prescription and illicit opioid use).

In addition, states have historically implemented call back surveys using the PRAMS infrastructure to gather additional information on post-pregnancy experiences, infant, and toddler health. Women who respond to the PRAMS survey may be recontacted through an opt-out consent process at a later time (beyond 6 months post-birth) to collect additional information about post-pregnancy experiences and infant and toddler health. In October 2019, CDC implemented an opioid call back survey targeted to areas with a high burden of opioid overdose deaths and include topics such as opioid misuse and access to medication assisted therapy (MAT); experiences with respectful care; postpartum care; rapid repeat pregnancy; infant feeding practices; and infant health, developmental delays and social services such as well child visit attendance, home visitation, and social supports. Additional call back surveys may be developed to address other emergent issues as they arise.

As part of the questionnaire development process, field testing will be conducted [approximately 2-12 months] prior to implementation of new supplemental modules and call back surveys, as

well as new or substantively revised questions for the core module prior to a new phase. Field testing will identify issues that may affect implementation of module or quality of the data collected. Field testing will *only* be conducted for new or substantively changed questions. Field testing may not be possible for supplemental modules addressing emergency circumstances due to urgency.

Ongoing surveillance efforts that quantify disease and risk factors and identify opportunities for prevention are central to CDC's planning and evaluation efforts. CDC's authority to collect information for this purpose is provided by the Public Health Service Act (PHSA), and PRAMS is authorized under section 317(k). A copy of the PHSA is displayed in **Attachment 1a**. Furthermore, PRAMS data is essential to informing CDC's Safe Motherhood Initiative. Thus, legislative support for PRAMS comes in the form of the following: 1) The Safe Motherhood Act for Research and Treatment (SMART), which supports surveillance of pregnancy-related morbidity data **(Attachment 1b)**; and 2) The Prematurity Research Expansion and Education for Mothers who deliver Infants Early (PREEMIE) Act **(Attachment 1c)**, which supports the use of PRAMS to track pregnancy outcomes and help prevent preterm birth.

2. Purpose and Use of Information Collection

PRAMS is an ongoing, population-based surveillance system based on a stratified systematic sample designed to produce annual estimates of selected maternal experiences and behaviors that occur during the months prior to and during pregnancy, as well as the first months after pregnancy for each site. Data for PRAMS are collected by funded state and jurisdictions from women who recently gave birth to a live born or stillborn infant. As of May 2016, PRAMS is funded in 51 sites and covers 83% of all live births in the United States. Sites that collect data on women with recent livebirths include 47 states, New York City, Washington, DC, Puerto Rico, and the Great Plains Tribal Chairman's Health Board. Utah is the only site also funded to collect data on women with a recent stillbirth.

Findings from PRAMS are used to enhance the understanding of maternal behaviors and their relationship with adverse pregnancy outcomes. PRAMS data can also be used by participating

states and jurisdictions for needs assessment and to inform program development and evaluation, as well as health care services and policy. PRAMS data are used to monitor various targets in Healthy People 2020/2030, preconception health and health care indicators, and selected performance measures for various programs and initiatives (e.g., Title V Maternal and Child Health Program and The Collaborative Improvement and Innovation Network to Reduce Infant Mortality).

In addition, PRAMS data has been used as an evaluation component by the Maternal and Child Health Bureau (MCHB) in the Health Resources and Services Administration (HRSA) for the Healthy Start program evaluation. Currently 63 of the 75 continuing Healthy Start grantees eligible for selection are located in states that conduct the PRAMS survey. From among these grantees, MCHB/HRSA randomly selected 15 Healthy Start grantee sites to participate for the one-time oversampling (oversampling of Healthy Start participants for 2017- 2018 only). The goal of the ongoing evaluation is to determine the effect of the Healthy Start program on changes in participant-level characteristics (e.g., health services utilization, preventive health behaviors, health outcomes). For one component of the overall program evaluation, HRSA will compare Healthy Start participants and non-participants using PRAMS and linked vital records for key benchmarks and outcomes such as infant mortality; low birth weight; preterm birth; perinatal depression screening; breastfeeding initiation; safe sleep practices; and health care access into the postpartum period. Future collaborations with federal partners and stakeholders to augment PRAMS to capture special populations will be submitted as a revision or change request for approval.

The negative consequences of not collecting the information is the limited ability to monitor progress in maternal experiences and behaviors that occur before, during, and shortly after pregnancy. Data is used to inform maternal and infant health programs and health policy to reduce maternal and infant morbidity and mortality.

The PRAMS data will be used for several purposes by a diverse set of users. The primary uses of the data are listed below:

- PRAMS data, combined with California's Maternal and Infant Health Assessment (MIHA) survey, will be used to track several Healthy People 2020/2030 objectives

related to Maternal, Infant, and Child Health. When PRAMS state data are combined with California MIHA data, the estimates represent 96% of all US live births. Current Healthy People 2020 objectives using PRAMS data include:

  - MICH-16.2 – Increase the proportion of women delivering a live birth who took multivitamins/folic acid prior to pregnancy
  - MICH-16.3 – Increase the proportion of women delivering a live birth who did not smoke prior to pregnancy
  - MICH-16.4 – Increase the proportion of women delivering a live birth who did not drink alcohol prior to pregnancy
  - MICH-16.5 – Increase the proportion of women delivering a live birth who had a healthy weight prior to pregnancy
  - MICH-16.6 - Increase the proportion of women delivering a live birth who used contraception postpartum to plan their next pregnancy
  - MICH-18 - Reduce postpartum relapse of smoking among women who quit smoking during pregnancy
  - MICH-20 – Increase the proportion of infants who are put to sleep on their backs

- State health departments will use PRAMS data for needs assessment, planning and reviewing programs, and policies aimed at reducing health problems among mothers and babies.
- PRAMS data will be used by state maternal and child health program staff, policy makers, and health providers to identify gaps in health care provision or utilization.
- PRAMS data will be used by researchers to investigate emerging issues in the field of reproductive health.
- PRAMS is a key data source for preconception indicators and will be used by a variety of agencies in planning maternal and infant health programs.
- PRAMS data will be used to compare information describing state-level behaviors and experiences taken from persons residing within all participating sites.
- An annual PRAMS dataset will be available for researcher use. Information available include health status, maternal and child health indicators, and health risk and protective behaviors. Data will be appropriate for trend analyses; tests of differences among (demographic) subpopulations; multivariate analyses of health outcomes; and other

statistical analyses. A researcher can request a multi-state dataset with individual-level data according to the guidelines on the PRAMS website at http://www.cdc.gov/prams/researchers.htm

- An annual summary of maternal and child health indicators derived from PRAMS data are available in aggregate and by state at https://www.cdc.gov/prams/prams-data/mch-indicators.html for public health reporting.

Findings from PRAMS are also used by states to inform program and policy that improve maternal and child behaviors and outcomes as described CDC PRAMS Data to Action Success Stories.

Field testing data will be used to identify issues that may affect implementation of module or quality of the data collected and make further refinements to the data collection instruments as needed.

3. Use of Improved Information Technology and Burden Reduction

The PRAMS data are collected using the PRAMS Integrated Data Collection System (PIDS). PIDS is used to schedule and track data collection activities; record data on mail and telephone results; manage call attempts for telephone interviews; and record survey responses and extraneous comments provided by mothers. The PIDS system revamped several standalone data collections systems for mail data entry, telephone interviewing, and tracking activities into a secure web-based single point-of-entry centralized database. PIDS allows centralized data storage and real-time updates on participants' survey completion status. PIDS is implemented using Commercial off-the-shelf [COTS] software tools that encompasses the latest technology.

PRAMS is a mail survey with telephone follow–up. Due to the flexibility of the PIDS data collection system, women have the option of completing the survey by mail or telephone interview. The combination of multiple contacts and mixed data collection modes has proven effective in increasing response rates in many populations. The specific modes selected for PRAMS complement one another to maximize response rates while minimizing cost. Telephone surveys offer a cost-effective method of data collection and often telephone interviewers arrange call back interviews to accommodate the respondent's schedule. Interviewers use Computer Assisted Telephone Interview (CATI) software to enter data directly

into the centralized database. Use of CATI software promotes efficiency in two ways: skip patterns are programmed in the survey instrument to route interviewers to ask respondents only questions that they are eligible to answer, and real-time quality control checks can be used to eliminate errors which may have been caused by manual data entry procedures.

Data elements (e.g., demographic information) that are already available from the existing source datasets (e.g., birth certificates or fetal death records) for the sample are not collected to reduce participant burden. To determine the accuracy of select PRAMS self-reported survey data and birth certificate data, CDC compared these data to hospital delivery and prenatal care records in 2009. Based on the findings of this internal validity study, modifications were made to the core PRAMS survey to improve efficiency. The PRAMS team used the results to improve and/or remove select items from the current PRAMS survey. For example, past PRAMS surveys asked women about the number of prior live births and whether their last birth resulted in a low birthweight and/or preterm infant--information also captured on the birth certificate. For the most recent PRAMS survey, these items were removed from the core survey due to the high validity on birth certificate; therefore, reducing the length of the PRAMS survey, limiting participant burden, and saving the government time and money. Other items, such as length of hospital stay, were kept on the survey when it was found that PRAMS data provided accurate supplemental information not collected on the birth certificate.

To further the use of improved information technology, a web module is being developed for pilot testing and deployment in the Fall of 2020. Pilot testing will be used to determine whether the web-based mode of data collection is an appropriate and efficient way of collecting information from PRAMS participants. CDC plans to conduct pilot testing under a generic clearance, and will submit a description of pilot testing under the generic to OMB for review. After web module testing is complete, CDC will also submit a change request to the primary PRAMS information collection request to account for integrating this new data collection mode into the PIDS system.

4. Efforts to Identify Duplication and Use of Similar Information

PRAMS regularly collaborates with other federal agencies to identify other sources of maternal

and infant data that may be duplicative and identify opportunities to leverage and learn from other data collection systems. PRAMS provides the only state-specific population-based data on women recently delivering a live birth or stillborn infant. Because only 1-5% of the general population is pregnant or postpartum at any time, there is a need for data that purposively samples from this population to provide stable estimates that can be stratified by population subgroup as well as to provide state- and jurisdictional-specific estimates of maternal experiences and behaviors that occur before, during, and shortly after pregnancy.

For most states and jurisdictions, PRAMS provides the only source of data amenable to state-level maternal and child health risk indicators. Limited data on maternal health may be available at the national level but are not designed specifically to create state-based estimates. National-level surveys such as the National Survey of Children's Health, the National Survey of Family Growth (NSFG; OMB No. 0920-0314, exp. 6/30/2021), the National Health Interview Survey (NHIS, OMB No. 0920-0214, exp. 12/31/2020), the National Health and Nutrition Examination Survey (NHANES; OMB No. 0920-0950, exp. 11/30/2016), among others, collect data on maternal health (e.g., pregnancy history) for prevalence estimates at the national level. PRAMS differs in that its sample is at the state level and produces direct (i.e., not modeled) estimates for states.

Other state-based surveillance systems such as the Behavioral Risk Factor Surveillance System (BRFSS; OMB No. 0920-1061, exp. 3/21/2021) and the Youth Risk Factor Surveillance System (YRBS; OMB No. 0920-0493, exp. 11/30/2019) collect population-based estimates that may be relevant to maternal health such as use of family planning methods. While BRFSS is a sample of the general population and YRBS is a sample of youth in middle and high school, PRAMS is the only data system specific to women with a recent live birth or stillbirth. New mothers and women currently pregnant may be found among BRFSS- or YRBS-sampled population, but they constitute a population subgroup that is usually too small for detailed analysis. This limitation expresses itself in two ways: small numbers generally preclude making estimates for various topics on the general survey that are specific to this subgroup; and their rarity in the sample makes it inefficient to ask questions specific to pregnancy and childbirth, as the questions would rarely be applicable to respondents.

The National Institutes of Health (NIH) hosts a passive data collection system called PregSource. PregSource uses a crowd-sourcing approach, asking pregnant women to enter information regularly and directly about their pregnancies throughout gestation and the early infancy of their babies into online surveys and trackers via a website and/or mobile application. PregSource does not collect state-specific data, is not designed in a way to generate representative estimates for the full population or subgroups of special interest and is not aligned to inform indicators of national or state interest or the programs informed by PRAMS data.

In August 2016, CDC and the Puerto Rico Department of Health fielded the Zika Postpartum Emergency Response Survey (ZPER; OMB No. 0920-1127, exp. 2/28/2017). The data collection was designed to capture women of any age who recently had a live birth; however, sampling was only done in hospitals. Data was collected to provide a rapid, population-based assessment of maternal behaviors and experiences related to Zika virus exposure among recently pregnant women in Puerto Rico. Additional ZPER surveys for mothers and fathers, and follow-up surveys for infants were collected from November 2017 – April 2018 (OMB No. 0920-1183, exp. 8/31/2017; OMB No. 0920-1127, exp. 9/30/2018). The system used the same base software (SPSS survey software) as the PRAMS' PIDS. The Puerto Rico Department of Health is a currently funded PRAMS site.

From 2005 – 2015, National Center for Birth Defects and Developmental Disabilities supported the expansion of two birth defects tracking systems to ascertain birth defect-related stillbirths. These two tracking systems identified babies with birth defects in their study areas by having staff continually review medical records at multiple healthcare facilities. The information gathered was then reviewed by doctors and other specialists. However, birth defects tracking systems did not provide population-based estimates of stillbirth. In addition, data were administrative in nature and did not include survey questions on experiences before, during, and after pregnancy.

5. Impact on Small Businesses or Other Small Entities

There will be no impact on small business.

6. Consequences of Collecting the Information Less Frequently

PRAMS is an ongoing surveillance system providing annual estimates of maternal behaviors and experiences before, during, and shortly after pregnancy. These data are used for the purposes of monitoring trends; allowing state-by-state comparisons; and used by states and federal agencies for reporting of performance measures and other benchmarks. Collection of data less frequently would prohibit calculation of these annual estimates and inhibit the utility of the data. Trend analyses created from annual estimates and the ability to monitor health impact changes would be interrupted by less frequent data collection. Furthermore, ongoing data collection maintains the infrastructure to monitor the health impacts of any state policy changes and to collect data on emerging issues.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances. This request complies with the regulation of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day notice was published in the Federal Register on August 31, 2018 (Vol. 83, No. 170, pp. 44630-44631) to make the public aware of this information collection (**Attachment 2a**). Four comments were received: two non-substantive and two in support of the data collection; a response was developed (**Attachment 2b**); and no modifications were needed to the information collection plan in response to these comments. A 30-day notice will be published in the Federal Register to allow for additional public and affected agency comments.

The PRAMS questionnaire development process is described in **Attachment 3**. Efforts to consult within and outside of the agency are meant to ensure relevant core and emerging topics are captured; obtain external stakeholder and partner feedback on the survey questions; and ensure continued relevance and utility. Consulted stakeholders are listed in **Table A.8-1**.

Table A.8-1. Consulted Stakeholders

Stakeholder Organizations Consulted (2014-present)

Name/Organization	*Subject Matter Expertise Provided*
CDC, Division of Reproductive Health	Contraception, safe infant sleep, weight gain during pregnancy, chronic conditions, disaster preparedness
CDC, Division of Nutrition, Physical Activity, and Obesity	Breastfeeding
CDC, Emergency Operations Center	Zika
CDC, Immunization Services Division	Influenza vaccine, Tdap
CDC, National Institute for Occupational Safety and Health	Occupation
CDC, National Center for Injury Prevention and Control	Opioid use/misuse
CDC, National Center for Birth Defects and Developmental Disabilities	Infant development, folic acid, alcohol use
CDC, Office on Smoking and Health	E-cigarette and hookah use
FDA	E-cigarette and hookah use
HRSA	Infant health care visits, safe infant sleep
NIH	Disability
CMS, SAMSHA	Opioid use/misuse
State Health Department PRAMS/MCH Programs Consulted for Phase 8 Questionnaire Development (2014)	
Alabama	New Mexico
Alaska	New York City
Arkansas	New York State
Colorado	North Carolina
Delaware	Ohio
Florida	Oklahoma
Georgia	Oregon
Hawaii	Pennsylvania
Illinois	Rhode Island
Louisiana	South Carolina
Maine	Tennessee
Maryland	Texas
Massachusetts	Utah
Michigan	Vermont
Minnesota	Virginia
Mississippi	Washington
Missouri	West Virginia
Nebraska	Wisconsin
New Jersey	Wyoming

9. Explanation of any Payment/Gift to Respondents

PRAMS has historically worked with grantees to identify best strategies to improve response rates and has offered grantees the option of providing gifts and rewards since 1989. States--not

CDC--individually decide whether to provide a gift and/or reward. Due to the geographic, cultural, demographic, and economic diversity of the United States, states also choose the type of gift and/or reward that they provide. Each state documents their choice of gift and/or reward in their state PRAMS Protocol that is submitted annually for IRB review at the state level. PRAMS grantees offer incentives in the form of gifts and/or rewards to women who are sampled to participate in the survey. In general, gifts and rewards have been found to be important for encouraging participation in federal surveys, especially for more reluctant responders.[1,2,3] For PRAMS, increasing motivation to respond readily is particularly salient: this survey focuses on a special population during a limited time period following the birth of an infant when women indicate that participating in even simple activities is constrained by lifestyle changes, financial constraints, childcare duties, and fatigue.[4,5] Given these constraints, effective gifts and rewards have been found important for PRAMS and have worked to ensure that all populations of women, including minority women and women with lower education or literacy levels, lower income, and less familiarity or trust in government surveys, are sufficiently represented.[6]

PRAMS grantees have historically conducted experiments to determine what kind of gift or reward is most effective in motivating survey response as part of the PRAMS protocol.[7,8] Small gifts of nominal value are sent to all participants, usually in the first survey mailing. A gift is provided prior to filling out the survey and is independent of participation. Examples of these gifts include pens, refrigerator magnets, thermometers, pocket calendars, and baby bibs. Rewards are provided to individuals who complete the survey. Some states offer rewards to all individuals who complete the survey, and some states only offer rewards to participants who

1 Berry SH, Pevar J, Zander-Cotugno M (2008). Use of Incentives in Surveys Supported by Federal Grants. Rand Corporation, March 2008: http://www.copafs.org/seminars/use_of_incentives_in_surveys.aspx.

2 Singer E, Ye C. (2013) The Use and Effects of Incentives in Surveys. Annals of the American Association of Political and Social Science, 645:112-141: http://journals.sagepub.com/doi/pdf/10.1177/0002716212458082.

3 Singer E, Kulka RA. (2002). Paying Respondents for Survey Participation. In *Studies of Welfare Populations: Data collection and research issues*.105-28. Washington DC: National Academy Press. https://aspe.hhs.gov/system/files/pdf/174381/04.pdf.

4 Van Ryswyk EM, Middleton PF, Hague WM, Crowther CA (2015). Women's views on postpartum testing for type 2 diabetes after gestational diabetes: Six month follow-up to the DIAMIND randomized controlled trial. Prim Care Diabetes. 2015 Aug 27. pii: S1751-9918(15)00100-X. doi: 10.1016/j.pcd.2015.07.003: https://www.ncbi.nlm.nih.gov/pubmed/26320407.

5 Nicklas JM, Zera CA, Seely EB, et al. (2011). Identifying postpartum intervention approaches to prevent type 2 diabetes in women with a history of gestational diabetes. BMC Pregnancy and Childbirth 11:23: https://www.ncbi.nlm.nih.gov/pubmed/25837258.

6 Kim SY, Tucker M, Danielson M, Johnson CH, Snesrud P, Shulman H. (2008). How can PRAMS survey response rates be improved among American Indian mothers? Data from 10 States. Matern Child Health J, 12(Supp 1):119-125: https://www.ncbi.nlm.nih.gov/pubmed/18350261.

7 Liu ST, Geidenberger X. (2011). Comparing incentives to increase response rates among African Americans in the Ohio pregnancy risk assessment monitoring system. Matern Child Health J, 15(4): 527-33: https://www.ncbi.nlm.nih.gov/pubmed/20428935.

8 CDC, Pregnancy Risk Assessment Monitoring System. PRAMS National Meeting Program Booklet, Abstract excerpt. Atlanta, GA, 2015.

respond during a certain phase of the survey (e.g., mail respondents only or phone respondents only). Rewards tend to be higher in value than gifts. Examples of rewards include $10-$25 gift cards to grocery stores or other local retail stores, birth certificates, music CDs, and tote bags.

This is a key strategy for states that are aware of subpopulations within the sample that are responding with lower frequency than other groups. In 2004, New York City PRAMS conducted a short experiment assessing use of three incentives: a change purse, a $10 MetroCard, and a $20 MetroCard. The experiment showed no significant change in response between women receiving the change purse and the $10 MetroCard; however, there was a higher response rate for the $20 MetroCard. NYC selected this as an incentive for regular implementation. Within three months of introducing the $20 MetroCard as an incentive, response rates increased by 14%. In 2009, in order to increase telephone response rates, Missouri PRAMS experimented with adding a $20 gift card for women who responded to the telephone survey. They compared six months of data collection without this reward and six months of data collection with the reward. The telephone response rate increased by 6.5% after the implementation of the reward. During this same time period, mail responders were continued to be offered a $10 gift card with no change. There was no observed increase in the mail response. Louisiana conducted an experiment in 2014 to compare the effect of raising the value of their gift card reward from $10 to $20 on response rates. They observed an increase of 5 percentage points in overall response and a significant increase of 12 percentage points in mail response using the higher value reward. The results also indicated the higher value reward was more cost effective than devoting resources to increased follow-up efforts.

Women with a recent stillbirth experienced a recent pregnancy loss, and they will still be grieving the loss of their stillborn child; thus, gifts and/or rewards will be differentiated from mothers with a recent livebirth for whom their infant has died. Sensitivity considerations should be built in to all components of the data collection methodology.

A full list of gifts and rewards by state is included in **Attachment 4**. During field testing, optional incentives distributed by states are those left over from implementation of PRAMS as outlined.

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

Privacy Act Determination

PRAMS data collection activities rely on the PRAMS Integrated Data Collection System, also known as PIDS. PRAMS questionnaires and data collection procedures do not collect personally identifiable information; therefore, the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) Information Systems Security Officer determined that the Privacy Act does not apply to PRAMS data collection. All PRAMS grantees are required to use PIDS. PIDS contains information from state birth/fetal death certificates which does contain PII used by the states. The NCCDPHP Information Systems Security Officer determined that the Privacy Act does apply to the PIDS **(Attachment 5)** that covers both the questionnaire data and the PII from the birth/fetal death certificate.

A text file is created at the state level that contains personally identifiable information (PII) from the birth/fetal death certificate; the text file is imported into PIDS data system. Monthly batch files are imported by PRAMS states into PIDS. Batch files contain PII such as mother's name, date of birth, address, telephone number, and the infant's name and date of birth. To identify the sample for PRAMS, CDC receives from the states through PIDS the birth certificate number and dates of birth. Once the sample is selected, a PRAMS ID is assigned to individual records. The states, but not CDC, have name and addresses for moms selected for the sample. PII maintained in the system is used by states to generate letters and labels to be mailed to respondents for PRAMS surveillance. Similarly, PII is used to verify a respondent's identity when a phone interview is conducted. Because of PII uploaded and retrieved by PIDS, the system is categorized as a moderate level system for security purposes. Moms are assigned a unique ID in PIDS for all data collection functionality including linkages for follow-up surveys. The unique ID is randomly generated and cannot be used to identify respondents. PII maintained at the state level is destroyed when the annual weighted data set is received.

Personally identifiable information (PII) data are transmitted and loaded into PIDS from states to CDC through a secure, encrypted https protocol. All PIDS data are stored and accessed in

accordance with industry standard procedures. No information in identifiable form (IIF) will be filed or retrieved by the name of the individual or other unique respondent identifier such as social security number. PII Data stored in PIDS are only accessible to select state users and contract PIDS developers. CDC staff members, outside of those who conduct statistical weighting and PIDS system maintenance, do not have access to PII data. The System of Records Notice (SORN) being used for PIDS is 09-20-0160: http://www.cdc.gov/SORNnotice/09-20-0160.htm.

Overview of the Data Collection System

The PRAMS sample is drawn from the birth certificate or fetal death record file monthly by collaborators in the state's Vital Records Department. It is delivered to the state PRAMS staff usually within the first week of each month. State PRAMS staff upload the sample file into PIDS. State PRAMS staff clean up the file, making sure addresses are complete and looking up phone numbers or any other missing information. State PRAMS staff initiate the data collection process, starting with contacting women by mail. After the mailing phase is completed, mail non-respondents are contacted by telephone.

The PIDS web-based data collection software system is provided by the CDC to all funded grantees. CDC, through the support of a contractor, programs each state's survey into the data entry and CATI interfaces within the PIDS system. State data entry staff and telephone interviewers record answers to each question in PIDS. Data entry verification for information entered from the mail surveys is performed at the state. States and CDC can view operational summary reports at any time in the PIDS system. States signal the end of data collection for a monthly batch by releasing the data to CDC using a feature in the PIDS system. At the end of data collection for a calendar year, all state data are cumulated, and final cleaning and quality control checks are done at CDC. Once the data are cleaned and checked, data weighting is done. PRAMS does not report discordant self-reported data back to state vital records for corrections to the birth certificate. As part of the final cleaning and quality control checks, for each sampled respondent, CDC verifies the variables captured on the finalized state birth certificate file for the calendar year to ensure alignment with variables captured in the PRAMS data set.

Items of Information to be Collected

A complete PRAMS questionnaire topic reference is provided in **Attachment 6**. The questionnaires are laid out by CDC programmers at the beginning of each data collection cycle. PRAMS core questionnaire for livebirths (**Attachments 7a-7d**) and stillbirths (**Attachments 8a-8d**) includes questions on maternal behaviors and experiences before, during, and shortly after pregnancy and includes information on health status, access to and content of health services, and risk behaviors. Demographic information is generally not collected on the PRAMS questionnaire because that information is already available in the birth certificate or fetal death file from which the sample is drawn.

Standard module questions (for livebirths only) are selected by individual states based on their information needs and are generally implemented as written. However, states may elect to drop options from the list of responses in some cases if they feel they are not applicable in their context. Standard modules cover a range of health topics (**Attachments 9a-9d**). States administer their tailored version of the survey (core plus standard modules) without change throughout the questionnaire phase, which typically lasts between 3 and 5 years.

CDC periodically funds PRAMS states to rapidly implement supplemental modules developed mid-phase to address emerging issues. Planned supplemental modules for 2019 include family history of breast and ovarian cancer, prescription and illicit opioid use, and maternal disability status (**Attachments 10a-10c**). If states elect to add additional supplemental modules to the survey mid-phase to address state-specific emerging needs and priorities, questions are added as attached leaflets to the mail survey or added to the end of questionnaire for the phone data collection mode.

In addition, call back surveys may be implemented to gather additional information on post-pregnancy experiences and infant and toddler health. Women who respond to the PRAMS survey may be re-contacted (opt-out consent process used) at a later time period) to collect additional information about post-pregnancy experiences and infant and toddler health. In October 2019, an opioid call back survey will be conducted at 9 months post birth, among states with a high

burden of opioid overdose deaths and include topics such as opioid misuse and access to medication assisted therapy; experiences with respectful care; postpartum care; rapid repeat pregnancy; infant feeding practices; and infant health and social services such as well child visit attendance, home visitation, developmental delays, and social supports (**Attachments 11a-11b**). New questions underwent cognitive testing under OMB #0920-0222 (exp. 08/31/2021). Additional call back surveys may be developed to address other emergent issues as they arise and will be submitted as a revision or change request.

Field testing will be conducted to identify problems with new or substantively revised questions. Women with young infants who are approximately one year of age or less will be recruited in clinics or doctor's offices per described field testing methodology (**Attachment 17**). Respondents will be asked to answer a short survey and provide feedback on the quality of questions (**Attachment 18**).

Planned Controls

The PIDS system was designed with the highest level of security to ensure data encryption and protection of information. The PRAMS model protocol specifies state-level physical and IT-related security measures that must be implemented at each state. States may customize or enhance these recommended procedures, and they must be documented in the state PRAMS protocol that is submitted annually to the local IRB for review. Compliance with these measures is evaluated during site visits that occur annually or every other year. All state PRAMS staff are required to complete CDC PRAMS-developed Human Subjects Training prior to accessing the PIDS system or any participant information upon hiring, and annually thereafter. A central part of this training is related to ensuring respondents' privacy. States must document attendance at the Human Subjects Training, and quarterly monitoring of trained telephone interviewers. This documentation must be submitted to CDC.

PRAMS staff at the state level have access to personal identifying information (PII) from the birth certificate or fetal death file, such as birth certificate numbers, names, addresses and phone numbers. The birth certificate or fetal death file number is only made available to the CDC statistician who conducts data weighting for the purpose of conducting the weighting procedures.

PII maintained at the state level is destroyed when the annual weighted data set is received. PII data is encrypted and stored on the CDC network, and complies with all agency physical (e.g., gated campus and building access) and administrative (e.g., password-protected network) security measures. Access is managed through CDC's Secure Access Management Services [SAMS] portal and employs common and consistent enterprise controls for user identity management, identity proofing, authentication and authorization. Access to the data center is limited only to select authorized personnel. Records at CDC are retained and disposed in accordance with the Scientific and Research Project Records Control Schedule.

How Information Will Be Shared and For What Purpose

State health departments and/or their designees are the data collectors for PRAMS (i.e., information will originate with the states), and then data are released by the states to CDC on a monthly basis. CDC does not transmit data from one state to any other, and only provides annual weighted data sets to each state through a secure file transfer system accessible through PIDS. CDC receives only de-identified records. States maintain responses to the PRAMS questionnaire separately from sample files. After data collection and receipt of the final weighted dataset, sample files are destroyed. State-level datasets are owned by individual states, include all variables, and are used for state purposes at the discretion of the state. Historically (data through 2011), a subset of state data was uploaded into PRAMStat, a public access data platform available to the public that displays only pre-determined tables of a subset of indicators from the full dataset. More recent years of data for maternal and child health indicators are available in aggregate and by state are available at https://www.cdc.gov/prams/pramstat/mch-indicators.html

PRAMS does not have a public use dataset. However, state data that meets the response threshold (as of 2015, 55%) may be released to individuals who submit a request/application to CDC. The CDC PRAMS team coordinates an application review process, which involves state review, prior to releasing a PRAMS dataset to a requestor. Within any released file, the data set has been stripped of several variables that could potentially identify a respondent (e.g., full date of birth, hospital of birth, county of residence). Other demographic variables are only provided in grouped categories. Investigators sign a data use agreement stipulating the approved use of data. A data sharing agreement is signed between CDC and each PRAMS grantee at the

beginning of each funding cycle specifying exactly how variables will be categorized for release and which variables are not to be released.

After field testing, the results are compiled into a report and used to assess the performance of the questions as part of the questionnaire development process. The information in the report does not reflect a summation of responses to the questions, but rather women's impressions or difficulties with the questions. No personal identifying information will be collected during field testing.

Impact of the Proposed Collection on Respondents' Privacy

PRAMS sample files include names, addresses, and some phone numbers. The names, addresses, and phone numbers are maintained at the state level and used solely for the purpose of contacting respondents. They are not provided to CDC and never included in any research datasets. Other information, including maternal age, race/ethnicity, and infant characteristics available from the birth certificate file, are released in grouped categories in the datasets that are released to requestors to protect the confidentiality of respondents. Other potentially identifying information such as birth certificate number or birth dates are not released to researchers. A Certificate of Confidentiality provides additional protections to respondents for sensitive questions such as substance use. Section 301(d) of the Public Health Service Act (PHS) Act, which authorizes the use of Certificates, was amended by the 21st Century Cures Act amends Section 301(d) of the Public Health Service Act (PHS) and automatically issues Certificates to biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected.

How Individuals Are Informed That Providing Information Is Voluntary Or Mandatory

Individuals participating in PRAMS are informed that they do not have to participate and that they may refuse to answer any question. A description of the protections and limitations of the Certificate of Confidentiality is provided.

Opportunities to Consent

For the mailed survey, informed consent information is provided with each survey (**Attachments 12a -12d**). Completing and returning the self-administered booklet by mail is understood as consent to participate. Verbal consent is obtained during the introduction for telephone interviews (**Attachments 12e-12h)**. The introductory script, including the voluntary nature of the survey and ability to refuse to answer sensitive questions, precedes the phone survey questions with a prompt asking if it is okay to proceed with survey administration. States may modify the informed consent to reflect state and local context (e.g., abuse reporting laws). These modifications are approved by the CDC (**Attachment 14**) and local IRBs.

If states are participating in the opioid call back survey, women who respond to the PRAMS survey may be re-contacted (opt-out consent process used) at a later time to collect additional information about post-pregnancy experiences and infant and toddler health (**Attachments 13a-13d**). CDC or states participating in the field testing of questions will obtain the permission from the directors of relevant Health Department Clinics and private pediatrician's offices to recruit women in their office waiting rooms to complete the survey. Approximately 4-6 health department clinics and 2-4 private pediatrician's offices may be contacted, and testing will only occur in those that agree to participate. When recruiting women in clinics or doctor's offices, CDC PRAMS staff will approach women who are waiting for appointments in the clinic setting with infants approximately aged 1 year or less. Each woman will be read a consent script that specifies that her participation is voluntary, no identifying information will be collected, and no information will be shared outside the PRAMS questionnaire group (**Attachments 19a-19b**). She will be informed that her participation will not affect any of the services at the clinic or office, nor will it change her place in line or the timing of her appointment.

How Information Will Be Secured

Access to state datasets will be limited to the states themselves and CDC contractors and staff who conduct weighting and data cleaning procedures. Security measures include: 1) Physical controls: CDC facilities are secure, ID-accessed buildings. Data will not be stored in hard copy formats; and 2) Technical controls: all electronic data are stored on secured servers protected

with firewalls and passwords. All employees are trained on data security measures by taking appropriate HHS courses online. All data collection and records management practices and systems adhere to HHS and CDC IT policies and procedures.

Surveys from field testing may be retained during the questionnaire development process but are destroyed within two years.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The PRAMS Protocol is submitted annually for continuing review to the CDC Institutional Review Board (**Attachment 14**) as well as local IRB in implementing states. All modifications to the data collection protocol, as well as changes to core and standard modules, and new supplemental modules are submitted as amendments for review by the CDC IRB, as well as the state IRBs. Additional state specific modifications also receive local and CDC IRB review. The PRAMS core questionnaire has included some questions that may be considered sensitive such as those regarding substance use during pregnancy; experience of intimate partner violence, experience of stressful life events; experiences with depression or anxiety; and HIV and STI testing. Standard questions are available for additional sensitive topics such as maternal drug use. States may be funded to collect data as supplemental modules and/or a call back survey that also contain sensitive data. This sensitive information reveals state needs for health programs and services for emerging health issues. The informed consent preceding data collection expresses the voluntary nature of the survey and ability to refuse to answer sensitive questions. Per the 21st Centuries Cure Act, all federally funded research that collects sensitive data are automatically granted a Certificate of Confidentiality to provide additional protections to the privacy of research participant responding to sensitive questions. Sensitivity considerations are built into all components of the data collection methodology, especially as some respondents are grieving a stillbirth or recent loss of a live born child. Any questions of the sensitive nature are not asked during field testing when administering the verbal interview format to protect the confidentiality of respondents.

12. Estimates of Annualized Burden Hours and Costs

Burden estimates are based on data collection for Phase 8 of the core survey. The current core survey is planned from April 2016 to March 2021 and will not change during this period. The process for revising the core survey is described in **Attachment 3**. New supplemental modules may be introduced. CDC will use the change request mechanism to provide updates when needed on the content of any components of the PRAMS survey; any changes in the group of states participating in PRAMS; and estimated burden per response for the PRAMS survey.

The expected number of completed PRAMS interviews among women with a recent live birth are provided in **Attachment 15.** For this estimation, resident birth totals for each participating jurisdiction are based on the most recent year (2017) of fully weighted data. The base total number of interviews is similar across years and is assumed the same in subsequent years. Although the sample size varies from state to state—based on the stratification scheme and the number of births—annual sample sizes with anticipated completed number of surveys range from approximately 500 to 1600 for continuous livebirths surveillance, for an estimated for a total of 52,070 survey responses annually. The Great Plains Tribal Chairman's Health Board point in time surveillance was completed in 2017 and is not included in burden hour calculations. The oversampling of PRAMS respondents for the MCHB HRSA Healthy Start program was completed in 2018 and is not included in burden hour calculations.

Each state participating in PRAMS currently administers a mail survey and a telephone survey. Both English and Spanish language versions are available. States decide if they are going to use a Spanish version at the initiation of each Questionnaire Phase based on their state population. Information collection is conducted primarily by mail survey with telephone follow-up for mail non-responders. Each state has its own version of the survey that consists of a combination of core questions (used by all participating states) and state-selected standard modules. The total number of questions on the survey will vary by state, but all states must adhere to a 14-page space limit on the English mail survey and use only corresponding questions on the Spanish mail survey. The phone version of the survey contains the same set of questions as the mail version. All sampled women are eligible to participate, so there are no screening procedures administered.

The PRAMS survey experiences a very low drop-off rate for phone respondents and very few partially completed mail surveys. Based on interview duration data from previous years of PRAMS administration, we estimate the average burden for the introduction and consent process for the livebirth mail (**Attachments 12a-12b**) and telephone (**Attachments 12e-12f**) surveys is 1 minute. The burden for the core livebirth (**Attachments 7a-7d)** is estimated to be 15 minutes. Questions from standard modules (**Attachments 9a-9d)** chosen by the state is estimated to be 10 minutes. Total time estimated for women with a recent live birth completing the survey, inclusive of informed consent, is 26 minutes.

Periodically, the PRAMS surveillance infrastructure is used for fielding emerging priorities or interest or to address emergency response activities. Emerging priorities or emergency response activities may happen under rapidly evolving circumstances and cannot always be planned for. For example, questions related to the H1N1 Influenza pandemic were fielded as a supplement to the PRAMS questionnaire in 2009. 17 states were funded to collect supplemental data on Zika in 2017 (AL, CT, DC, FL, GA, IN, IL, MA, MO, NJ, NYS, PA, PR, SC, TN, VA, WI); that same year 6 states were funded to collect supplemental data on substance use (AK, ME, NM, NYS, PA, WV). In 2019, states are funded to collect supplemental modules on having a family history of breast and ovarian cancer (CO, MI, UT, WA); disabilities (CO, DC, FL, GA, KS, LA, ME, MD, MA, MI, MS, MO, MT, NE, NV, NM, NY, ND, OR, RI, SC, SD, VT, VI, WV) and prescription and illicit opioid use (AL, AZ, CO, CT, DC, FL, GA, IL, IN, IA, KS, KY, LA, MD, MA, MI, NV, NH, NY, ND, OR, PA, PR, RI, SC, SD, TN, UT, VT, WA, WV, WY). Using the expected numbers of completed PRAMS interviews in 2017, there will be 61,230 responses completed annually for supplemental modules **(Attachment 15)**; it is anticipated that similar supplemental collections with similar response estimates will be fielded during subsequent years of approval. Future supplements that are funded and sponsored by federal agencies for collection using the PRAMS surveillance system will be submitted as change request for approval. Supplemental modules are currently only funded for livebirth survey respondents. We estimated time for completion of each funded supplemental module averages 5 minutes based on previous experience with supplements.

In 2019, a call back survey (approximately 9 months after livebirth) will be implemented in 7 states (KY, LA, MA, MO, PA, UT, WV) with a high burden of opioid-related overdoses to collect additional information about post-pregnancy experiences and infant and toddler health. Sampling procedures and methods are described (**Attachment 16**). The opioid call back survey includes topics such as opioid misuse and access to medication assisted therapy; experiences with respectful care; postpartum care; rapid repeat pregnancy; infant feeding practices; and infant health, developmental delays, and social services such as well child visit attendance, home visitation, and social supports (**Attachment 11a-11b)**. In these 7 states, women who respond to the initial PRAMS survey have an option to opt-out of being recontacted, so we do not estimate any additional time for informed consent (**Attachments 13a-13d**). We estimate 55% of women sampled in the initial PRAMS survey will participate in the call back survey based on experiences with previous state-led call back surveys. We estimate 3,961 responses and approximately 30 minutes to complete the currently planned call back survey. Additional call back surveys may be developed to address other emergent issues as they arise. To allow for the potential for call back survey collections to occur annually, we retain that estimate of burden hours annually for the period of approval. CDC will use the change request mechanism to provide updates to the content of any components of the PRAMS survey.

The stillbirth survey, administered in the state of Utah at the time of request for approval, only includes a core survey instrument. It is estimated that there will be approximately 160 responses for the stillbirth surveillance in Utah. The total time estimated for completing on the introduction and consent is 1 minute (**Attachments 12c-12d**). The burden for the stillbirth survey (**Attachments 8a-8d)** is estimated to be 24 minutes. Total time estimated for women with a recent stillbirth completing the survey, inclusive of informed consent is 25 minutes.

Field testing containing new and modified questions from core survey, standard modules, supplemental modules, and call back surveys will be conducted. Upon verbal consent, women will be offered a self-administered version of the field-testing survey or the survey will be offered in an interview format. Following the survey, women will be asked to provide feedback on the quality of our questions (**Attachment 18**). We recruit a total sample of no more than 50 women field testing with approximately 3 field tests administered each year. The field-testing

process inclusive of verbal consent, survey administration and debriefing questions takes approximately 20 minutes to complete.

The total number of respondents are estimated at 52,380 (total number of women with live birth or still birth that will respond to a data collection instrument). The total annual burden hours are estimated at 29,765 hours.

Most of the jurisdictions (with the exception Colorado) are collecting ≤ 2 supplements (**Attachment 15**). Therefore, the burden statement on data collection instruments for the livebirth questionnaires (**Attachment 7a-7d**) and informed consent (**Attachment 12a-12b, 12e-12f**) are indicated as a range of 25-35 minutes. States may also choose to customize their informed consents as required by local IRB to reflect their unique circumstances.

Table A.12-1. Estimated Annualized Burden to Respondents

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	PRAMS Phase 8 Questionnaire (Core Questions plus state-selected standard modules)	52,070	1	26/60	22,564
	Supplemental modules	61,230*	1	5/60	5,103
	Call Back Surveys	3,961**	1	30/60	1,981

	Field Testing	150***	1	20/60	50
Women who recently delivered a still birth	PRAMS Stillbirth Questionnaire	160	1	25/60	67
Total					29,765

*This value does not represent additional *respondents*, but the estimated number of *responses* to three planned supplemental modules: the disability supplements (PRAMS respondents to complete = 24,925), the Family History of Breast and Ovarian Cancer supplements (PRAMS respondents to complete = 6,100) and the prescription and illicit opioid supplement (PRAMS respondents to complete = 30,228); as some participants are completing more than one supplemental module.
**This value does not represent additional *respondents*, but the estimated number of *responses* to the planned call back surveys. It is estimated that 55% of respondents to the original PRAMS survey in the states funded to do a call back survey will respond.
***Field testing will be conducted approximately three times/year, with no more than 50 respondents each time.

Annualized burden costs are summarized in the table below. These calculations assume the average hourly wage of $24.54 for all jurisdictions included in the PRAMS. Hourly rates were taken from the most recent publicly available Current Employment Statistics of the Bureau of Labor Statistics and are based upon the average hourly earnings for October 2012 from the Current Employment Statistics survey conducted by the Bureau of labor Statistics (available at http://data.bls.gov/cgi-bin/surveymost). We estimate the total annual burden cost to be $730,433.10.

Table A.12-2. Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	No. of Respondents	Total Burden (in hrs.)	Average Hourly Wage Rate	Total Cost Burden
Women who recently delivered a live born infant	PRAMS Phase 8 Questionnaire (Core Questions plus state selected standard modules)	52,070	22,564	$24.54	$553,720.56
	Supplemental Modules	61,230	5,103	$24.54	$125,227.62
	Call Back Survey	3,961	1,981	$24.54	$48,613.74
	Field Testing	150	50	$24.54	$1,227.00
Women who recently delivered a stillbirth	PRAMS Stillbirth Questionnaire	160	67	$24.54	$1,644.18

Total	$730,433.10

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no maintenance or capital costs to respondents.

14. Annualized Cost to Federal Government

Costs that are presented below include data collection, weighting and sampling, as well as data distribution (i.e., websites and production of data sets). These are based on the funds provided to states for data collection as well as internal PRAMS costs.

Annualized Estimated Cost to the Federal Government

Estimated funds provided to states	$5,616,000
Estimated CDC PRAMS budget	$1,409,000
Total	$7,025,000

15. Explanation for Program Changes or Adjustments

Although the PRAMS has been conducting surveys for many years, this request is the first for OMB review due to the evolution of the PRAMS as an important data source for federal agencies.

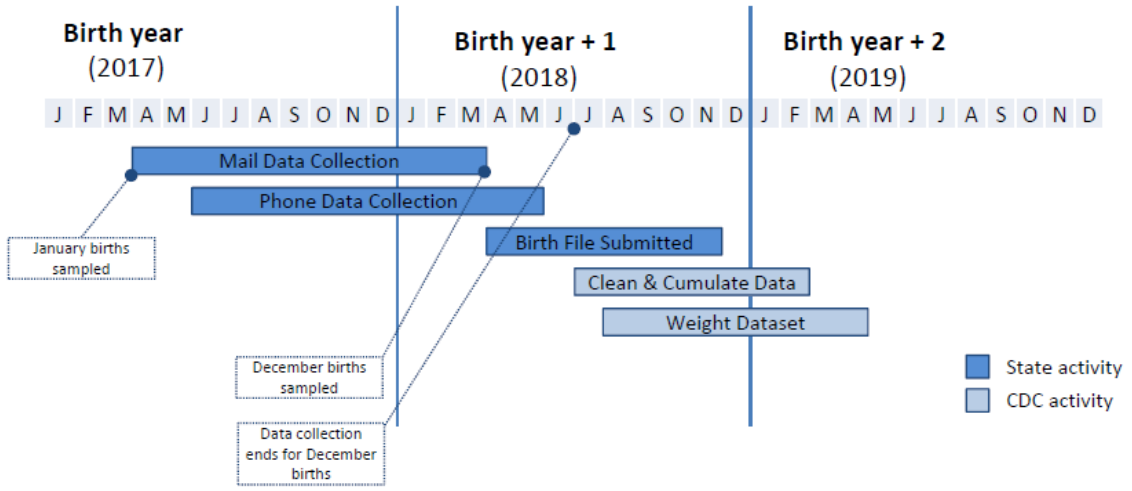
16. Plans for Tabulation and Publication and Project Time Schedule

PRAMS data collection is ongoing. Data collection for each year of PRAMS begins in April of that year and continues to approximately August of the subsequent year. Births occurring in January are sampled in April to ensure all infants are at least two months old at the time the survey is completed. Data collection for December births start March of the subsequent year and continue up to 6 months postpartum. Data is submitted monthly to CDC for editing and cleaning. Real-time data quality reports can be generated by states using the PRAMS Integrated Data Collection System (PIDS). Editing, cleaning, and weighting of the data will be conducted by CDC, is ongoing, and usually begins in July of the subsequent year.

States must submit final birth files for the year to CDC for use in the weighting process. Final weighted data sets will be returned to the states as they are weighted. State data that meets the response threshold set by CDC and participating states (55% beginning in 2015) are released for use by external researchers. There is no PRAMS public use dataset. Data availability by states can be found on the PRAMS website https://www.cdc.gov/prams/prams-data/researchers.htm#data. Researchers must submit a proposal to access the PRAMS analytic file; guidelines on requesting analytic files are found on the PRAMS website at http://www.cdc.gov/prams/researchers.htm. Supporting technical documentation including a detailed description of PRAMS standardized data collection methodology, questionnaire and weighting process is available on the PRAMS website at https://www.cdc.gov/prams/methodology.htm.

When a national estimate is required (e.g. Healthy People 2030), all PRAMS state data is used without a response rate threshold. When PRAMS state data are combined with California MIHA data the estimates represent 96% of all US live births.

Figure 1. PRAMS Data Collection Timeline



17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable. The expiration date of OMB approval will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.