

**Maternal Mortality Review Information Application (MMRIA)**

New Information Collection Request

**Supporting Statement  
Part A**

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## **Attachments**

- Attachment 1a. Section 301 of the Public Health Service Act (42 U.S.C. 241)
- Attachment 1b. Preventing Maternal Deaths Act
- Attachment 2. Data Flow Diagram
- Attachment 3a. Data Abstraction MMRIA Screenshots
- Attachment 3b. Case Narrative MMRIA Screenshots
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- Attachment 4. Authorization to Operate
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- Attachment 5b. Reponse to Public Comments on the the 60-Day Federal Register Notice
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- Attachment 7. Memorandum of Understanding for Central Hosting of MMRIA
- Attachment 8. Estimates of Pregnancy-Associated Deaths
- Attachment 9. MMRIA Request for Determination of Research Status

- **Goal of the study:** The goal of the Maternal Mortality Review Information Application (MMRIA) is to establish a comprehensive and standardized data collection system for case abstraction from clinical and nonclinical sources, documenting Maternal Mortality Review Committees' (MMRCs) decisions, and analyzing data.
- **Intended use:** MMRIA will provide a comprehensive source of information regarding the causes and circumstances of maternal deaths. This information will be used to develop interventions and strategies to prevent future maternal deaths.
- **Methods to be used to collect the data:** Data will be abstracted from a variety of sources, including vital statistics, autopsy reports, prenatal care records, emergency room visit records, hospitalization and outpatient records, medical transport records, social and environmental profiles, mental health profiles, and informant interviews. Information from these data sources will be used to create case narratives for committee reviews and subsequent decisions in regards to contributing factors and recommendations for prevention of future maternal deaths.
- **Subpopulation:** The subpopulation of interest for MMRIA is women who died during pregnancy or within one year of end of pregnancy whose deaths are reviewed for pregnancy-relatedness.
- **How the data will be analyzed:** Data will be analyzed to provide timely, accurate, and standardized information about deaths to women during pregnancy and the year after the end of pregnancy within and across participating jurisdictions; facilitate an understanding of the drivers of maternal mortality and complications of pregnancy and associated disparities; determine what interventions at patient, provider, facility, system and community levels will have the most impact; and implement data driven recommendations (e.g., evidence-based practices, screenings, patient education by providers).

**A. *Justification***

**1. Circumstances Making the Collection of Information Necessary**

The Centers for Disease Control and Prevention (CDC) requests a three-year OMB approval for a new information collection request—the Maternal Mortality Review Information Application (MMRIA). MMRIA is a standardized data system that allows Maternal Mortality Review Committees (MMRCs) across the country to abstract relevant data (clinical and non-clinical) from a variety of sources, document committee decisions, and analyze data in order to identify maternal deaths and review data and information to identify contributors of maternal deaths for future prevention efforts. CDC is authorized to collect this information under the Public Health Service Act, Title 42, Section 301 (**Attachment 1a**) and the Preventing Maternal Deaths Act (**Attachment 1b**).

The death of a woman during pregnancy, at delivery, or soon after delivery is a tragedy for her family and for society as a whole. Sadly, about 700 women die each year in the United States as a result of pregnancy or delivery complications, a chain of events initiated by pregnancy, or the aggravation of an unrelated condition by the physiologic effects of pregnancy. Furthermore, considerable racial disparities exist, with black women almost four times more likely to die from pregnancy-related complications than white women. However, findings from MMRCs indicate that more than half of maternal deaths are preventable. Understanding the true burden of these deaths at the national level, as well as why they continue to occur, is essential in our efforts to improve care for pregnant and postpartum women, reduce related morbidity and mortality, and eliminate associated disparities. This activity will support a national approach to collecting and sharing data on maternal deaths to aid in that understanding.

Maternal Mortality Review is a process by which a multidisciplinary committee at the jurisdiction level identifies and reviews cases of maternal death within one year of pregnancy; a data flow diagram of the process is provided in **Attachment 2**. Members of MMRCs typically represent public health, obstetrics and gynecology, maternal-fetal medicine, nursing, midwifery, forensic pathology, mental health, and behavioral health. Members might also include social workers, patient advocates, and other relevant multidisciplinary stakeholders. Through a

partnership among the MMRC, the state vital records office, and epidemiologists, deaths among women of reproductive age are examined to determine if they occurred during pregnancy or within a year of the end of pregnancy (i.e., pregnancy-associated deaths). Through this process, potential cases of pregnancy-related deaths (i.e., maternal death from any cause related to or aggravated by pregnancy or its management) are then identified. Review committees access multiple sources of clinical and non-clinical information to understand the circumstances surrounding a maternal death as they develop recommendations for action to prevent similar deaths in the future. This multidisciplinary approach encourages collaboration with clinical and non-clinical partnerships to improve quality of care and address social determinants of health to reduce health inequities.

Although the number of MMRCs that exist has increased over the last several years, both newly formed and established MMRCs struggle to achieve and sustain progress toward reviewing and preventing maternal deaths. In 2012, the Association of Maternal and Child Health Programs (AMCHP) and CDC's Division of Reproductive Health (DRH) assessed U.S. capacity to conduct maternal mortality reviews. Several states identified the need for a standardized data system that supports the critical inputs of consistent case abstraction, case review data, and data analysis within an MMRC over time and across MMRCs. Initially in response a prototype system, Maternal Mortality Review Data System (MMRDS) was developed to meet this need. In 2016, with funding from CDC Foundation, DRH in collaboration with AMCHP and Merck for Mothers, began the initiative *Building U.S. Capacity to Review and Prevent Maternal Deaths*.<sup>1</sup> As part of that initiative, resources and tools to guide the MMRC process were developed. As part of that initiative, building upon previous experience with MMRDS, MMRIA, a standardized data system that allows MMRCs across the country to abstract relevant data from a variety of sources, document committee decisions, and analyze data. The system also allows for sharing of data across MMRCs for aggregate reporting.

This information collection aims to provide a better understanding of maternal deaths by using MMRIA to collect standardized data across multiple MMRCs to get the most detailed, complete data in order to better understand contributing factors and preventability and thus develop

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<sup>1</sup> <http://reviewtoaction.org/about-us>

recommendations for prevention.

Although MMRIA is available for voluntary use by any jurisdiction's MMRC, this new information collection is only applicable to the 24 awardees, representing 25 states, who as part of the cooperative agreement (*Preventing Maternal Deaths: Supporting Maternal Mortality Review Committees* awardee (CDC-RFA-DP19-1908) are required to compile a defined set of information about pregnancy-associated deaths into MMRIA. For the purposes of this ICR, a "respondent" represents a state or jurisdiction awardee.

## **2. Purpose and Use of Information Collection**

MMRIA is a standardized data system designed to collect timely, accurate, and standardized information about deaths to women during pregnancy and the year after the end of pregnancy, including opportunities for prevention, within and across jurisdictions. Data will be abstracted and entered into MMRIA from various sources, including death certificates, autopsy reports, birth certificates, prenatal care records, emergency room visits records, hospitalization records, records for other medical office visits, medical transport records, social and environmental profiles, mental health profiles, and informant interviews. Case narratives are automatically populated from the abstracted data for committee review, and subsequent committee decisions are also documented in MMRIA

Key activities to be conducted as part of MMRCs' use of MMRIA by awardees include:

1. Comprehensively identifying pregnancy-associated deaths
  - a. Identify deaths to women that occur during pregnancy or within a year of the end of pregnancy on a routine basis, no later than one year following the date of death
  - b. At a minimum, use death certificates and death certificates linked to sentinel vital statistics data (i.e., birth certificates and fetal death certificates in the year preceding death) to identify pregnancy-associated deaths
2. Completely abstracting available data to support multidisciplinary review of each death
  - a. Abstract and enter comprehensive information about all deaths potentially related to pregnancy into the MMRIA in preparation for committee review within two

- years of the date of death
  - b. Review all deaths potentially related to pregnancy within two years of the date of death
  - c. Document committee decisions about a reviewed death in MMRIA consistent with guidance documents provided at [reviewtoaction.org](http://reviewtoaction.org)
  - d. Enter all information into MMRIA within 30 days of completing the review of a death
  - e. Perform data quality assurance checks within 90 days of completing the review of a death to, at a minimum, ensure completeness
3. Using data from reviewed deaths for action
- a. Analyze MMRIA data to provide information on burden, such as pregnancy-related mortality ratio, counts causes, and distribution of deaths (e.g., by age, race, rurality), and opportunities for prevention
  - b. Disseminate information (e.g., reports, publications, presentations, briefs) from analyses at least once per year to internal and external audiences for informing practice and policy changes

In summary, the information collected as part of this effort will be used to provide timely, accurate, and standardized information about deaths to women during pregnancy and the year after the end of pregnancy within and across participating jurisdictions; facilitate an understanding of the drivers of maternal mortality and complications of pregnancy and associated disparities; determine what interventions at patient, provider, facility, system and community levels will have the most impact; and implement data driven recommendations (e.g., evidence-based practices, screenings, patient education by providers).

In addition to the aforementioned uses, the information compiled in MMRIA can be used by CDC and participating jurisdictions to identify strategies to achieve and inform progress towards Healthy People 2020 goals “MICH-5: Reduce the rate of maternal mortality” and “MICH-6: Reduce maternal illness and complications due to pregnancy (complications during hospitalized labor and delivery).”

### 3. Use of Improved Information Technology and Burden Reduction

MMRIA is a consolidated, standardized data management system that enables MMRCs to collect and analyze data regarding maternal deaths. The system facilitates the process of case review of pregnancy-associated deaths to determine pregnancy-relatedness.

In order to comprehensively review each case of maternal death, MMRCs must capture detailed medical and social information on each woman who dies during pregnancy or within one year of the end of pregnancy in their jurisdiction. MMRCs employ abstractors (typically, but not always, nurse practitioners) within their jurisdictions who collect the pertinent information for each case by accessing various sources of information. The jurisdiction-based abstractors then manually enter relevant case details into MMRIA (**Attachment 3a**). The system produces a semi-automated case narrative that abstractors can then print and present to committee members to read during MMRC meetings, which convene on a routine basis as decided by the committee (typically monthly or quarterly) (**Attachment 3b**). During or shortly after meetings, abstractors enter the committee's findings on preventability, contributing factors, and recommendations for action into MMRIA (**Attachment 3c**).

MMRIA was created using lessons learned from a prototype system developed at CDC, MMRDS, which was implemented in 13 states starting in 2012. MMRDS was a simple system built on the CDC Epi-Info surveillance platform; DRH created MMRDS in response to states' expressed desire for a common data system. Prior to MMRDS, each state used its own data system, ranging from Excel spreadsheets to Access databases to RedCAP; states expressed that they did not have the resources to continuously update and support their own home-grown data systems. MMRDS met this need at that time.

Over several years of working closely with the early adopter states of MMRDS, it became clear that states wanted a more complex, flexible, and adaptable data system than what MMRDS provided. As part of the initiative *Building U.S. Capacity to Review and Prevent Maternal Deaths*, MMRIA was created and released in April 2017. Compared to MMRDS, MMRIA provided multiuser capability, ability to operate on web servers, more timely corrections to errors, and expansion of quality location-based information.

From April 2017 through February 2019, MMRIA was only available to jurisdictions to host on their own servers. This model of “local hosting” created a burden for MMRCs whose IT requirements could cause delays of 6 months to a year, delays in installing updates once available, and result in prohibitive budget costs to MMRCs for the associated IT installation and maintenance support. In addition, the variation in IT requirements and expertise of IT departments across jurisdictions resulted in extensive technical support from the CDC-based MMRIA team, taking time away from MMRIA development and technical assistance to MMRCs.

In April 2019, DRH began making MMRIA available to states as a service via a central CDC server. The transition to CDC hosting, which removes the jurisdiction-specific IT barriers and allows single roll out of MMRIA updates to users, eased the burden both on jurisdictions and the CDC-based MMRIA team. CDC has received an Authorization to Operate for MMRIA (**Attachment 4**).

#### **4. Efforts to Identify Duplication and Use of Similar Information**

Two major surveillance systems—the National Vital Statistics System (NVSS) and the Pregnancy-related Mortality Surveillance System (PMSS)—have been used to determine rates of maternal deaths nationally.<sup>2</sup>

NVSS provides maternal death counts using death certificates submitted by states and publishes maternal mortality rates (deaths/100,000 live births) by applying the World Health Organization’s International Classification of Diseases codes to death certificates submitted by states. In this system, maternal deaths are defined temporally as deaths that occur during pregnancy or within 42 days of the end of pregnancy. The causality is defined as from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes. NVSS relies solely on ICD-10 codes from death certificates, which are readily available but limited in detail; death certificate data provide a high-level national view of maternal deaths and trends over time but do not enable understanding of what really happened to

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2 St. Pierre A, Zaharatos J, Goodman D, Callaghan WM. Challenges and Opportunities in Identifying, Reviewing, and Preventing Maternal Deaths. *Obstet Gynecol* 2018;131:138-42.

cause a woman's death in regards to contributing factors and preventability.

In 1986, PMSS was developed to examine trends in and identify risk factors or risk groups for pregnancy-related deaths; it introduced the following terms:

- Pregnancy-associated death: umbrella term for all deaths during pregnancy or within one year of pregnancy, regardless of cause
- Pregnancy-related death: the death of a woman while pregnant or within one year of pregnancy—regardless of the outcome, duration, or site of the pregnancy—from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes
- Pregnancy-associated but not related death: the death of a woman during pregnancy or within one year of the end of pregnancy from a cause that is not related to pregnancy

PMSS asks state Divisions of Vital Statistics to cast a broad net to identify potential maternal deaths by using pregnancy checkbox information, cause of death information, and linkages of deaths of women of reproductive age back to birth certificates and fetal death certificates. Medical epidemiologists review death certificates and linked birth or fetal death certificates, determine underlying causes of death, and decide whether a death was pregnancy-related or pregnancy-associated but not related. Deaths are confirmed as pregnancy-related if they occur during pregnancy or within one year of pregnancy and the death results from: 1) complications of pregnancy itself; 2) a chain of events initiated by pregnancy; or 3) aggravation of an unrelated event by the physiologic effects of pregnancy. PMSS then produces a pregnancy-related mortality ratio (pregnancy-related deaths/100,000 live births). Although PMSS allows for an enhanced clinical interpretation that is not possible through NVSS, it remains limited to information primarily derived from death and birth certificates.

MMRCs do not solely rely on vital statistics and examines clinical and nonclinical information from a variety of sources, and are needed to fully understand the causes and circumstances surrounding maternal deaths. MMRIA provides a standardized data collection system that MMRCs can use to abstract data into from the various sources. MMRIA also allows MMRCs to develop case narratives from the abstracted data for review and to subsequently document

committee decisions. This comprehensive, standardized data system will facilitate sharing of results among jurisdictions and development of strategies for maternal mortality prevention. MMRCs are the only comprehensive source of maternal mortality data, with MMRIA facilitating its review.

**Table 4.1.** Comparison of Maternal Mortality Data Sources<sup>3</sup>

|                  | <b>NVSS<sup>a</sup></b>                               | <b>PMSS<sup>b</sup></b>   | <b>MMRCs<sup>c</sup></b>   |
|------------------|---|---|--|
| <b>Timeframe</b> | During pregnancy or within 42 days end of pregnancy   | During pregnancy or within 1 year of pregnancy  | During pregnancy or within 1 year of pregnancy   |
| <b>Source</b>    | Death certificates                                    | Death certificates; linked birth or fetal death certificates                                    | Various clinical and nonclinical sources (including Vital Statistics)                                      |
| <b>Measure</b>   | Deaths/100,000 live births                            | Pregnancy-related deaths/100,000 live births (national)   | Pregnancy-related deaths/100,000 live births (jurisdiction)  |
| <b>Purpose</b>   | Provide maternal mortality rate at the national level | Determine pregnancy-related mortality ratio by analyzing clinical factors associated with death | Understand circumstances around maternal deaths; develop recommendations for maternal mortality prevention |

<sup>a</sup>National Vital Statistics System

<sup>b</sup>Pregnancy-related Mortality Surveillance System

<sup>c</sup>Maternal Mortality Review Committees

## 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

MMRCs aim to identify deaths among women that occur during pregnancy or within one year of the end of pregnancy on a routine basis--no later than one year following the date of death.

MMRCs routinely abstract data to support multidisciplinary review of each death by abstracting and entering comprehensive information about all deaths potentially related to pregnancy into MMRIA in preparation for committee review. MMRCs convene on a routine basis as decided by the committee (typically monthly or quarterly)The consequences of collecting the information less frequently are the limited ability to assess the pregnancy-relatedness of maternal deaths and

<sup>3</sup>Adapted from: St. Pierre A, Zaharatos J, Goodman D, Callaghan WM. Challenges and Opportunities in Identifying, Reviewing, and Preventing Maternal Deaths. *Obstet Gynecol* 2018;131:138-42.

the drivers of pregnancy-related deaths and to determine which interventions will be most effective in preventing pregnancy-related deaths. Data will be used to inform maternal health programs and health policy to reduce maternal mortality.

**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 June 20, 2019, Vol. 84, No. 119, pp. 28819-28820 with the title “The Maternal Mortality Review Information Application (MMRIA)” (**Attachment 5a**). CDC received four comments related to this notice and were all supportive (**Attachment 5b**). CDC has provided response to comments (**Attachment 5b**). No changes to the data collection has been made in response to these comments.

A number of representatives from MMRCs and stakeholders were consulted on identifying the initial content of MMRIA and its precursor MMRDS. Since identification of the initial content, additional changes to the content have occurred based on informal user feedback.

| <b>Maternal Mortality Review Committees (MMRC) Initially Consulted (2013-14)</b>          |                    |
|---|--------------------|
| MMRC  |                    |
| California  | Michigan           |
| Colorado  | New Jersey         |
| Delaware  | New York (State)   |
| Florida   | Ohio               |
| Georgia   | Philadelphia       |
| Iowa  | Utah               |
| Louisiana   | Virginia           |
| Massachusetts   | Wisconsin          |
| <b>Additional Maternal Mortality Review Committees (MMRC) Consulted (2015 to present)</b> |                    |
| MMRC  |                    |
| Hawaii  | North Carolina     |
| Illinois  | Oklahoma           |
| Maryland  | South Carolina     |
| Mississippi   | Tennessee          |
| New Mexico  | Texas              |
| New York City   | Washington (State) |

| <b>Additional Stakeholder Organizations Consulted (2013-present)</b> |  |
|--|--|
| <b>Name/Organization</b>   | <b>Subject Matter Expertise Provided</b>   |
| American College of Obstetricians and Gynecologists                  | Obstetric care   |
| Association of Maternal and Child Health Programs                    | Title V Maternal and Child Health Block Grants and associated programs in states |
| CDC, Division of Reproductive Health                                 | Maternal Mortality Measurement and Surveillance                                  |
| CDC, Center for Global Health  | Maternal Mortality Measurement and Surveillance                                  |
| CDC, Center for Surveillance, Epidemiology, and Laboratory Services  | EpilInfo 7   |
| Society for Maternal and Fetal Medicine                              | High risk obstetric care   |

**9. Explanation of any Payment/Gift to Respondents**

Not applicable.

**10. Protec**

**tion of the Privacy and Confidentiality of Information Provided by Respondents**

*Privacy Act Determination*

A Privacy Impact Assessment has been completed for the MMRIA platform (**Attachment 6**). CDC’s Privacy Officer has advised that the Privacy Act does not apply to deceased individuals. However, a System of Records Notice (SORN) does apply because PII is stored and the information is retrieved by a personal identifier; and this requirement is not altered by the death of the person whose identifiers are stored. The System of Records Notice (SORN) being used is 09-20-0166: <http://www.cdc.gov/SORNnotice/09-20-0166.htm>.

*Overview of the Data Collection System*

MMRIA is a standardized data system that collects timely, accurate, and standardized information (clinical and non-clinical) about deaths to women during pregnancy and within one year of the end of pregnancy within and across jurisdictions. MMRIA can also be used to create case narratives, document committee decisions, and analyze data. The data gathered, reviewed, and analyzed by MMRCs will provide a better understanding of the contributors of maternal deaths, and thus inform efforts to prevent future maternal deaths.

Jurisdiction-level datasets for each MMRC are owned by individual jurisdictions and are used for purposes at the discretion of the jurisdiction. Each jurisdiction is assigned a separate URL. Users only have access to their own URL. Each awardee can only view data they have entered into MMRIA. As part of central hosting, users of MMRIA will have a Memorandum of Understanding with CDC governing the terms of utilizing MMRIA for their jurisdiction

**(Attachment 7).**

*Items of Information to be Collected*

Data entered into MMRIA pertaining to maternal death may include data abstracted from death certificates, autopsy reports, birth certificates, prenatal care records, emergency room visits records, hospitalization records, records for other medical office visits, medical transport records, social and environmental profiles, mental health profiles, and informant interviews (**Attachment 3a**). Case narratives are auto-populated from the abstracted data to facilitate committee review (**Attachment 3b**). MMRCs will review the case narratives developed from MMRIA to understand the circumstances around and preventability of the deaths; committee decisions and findings will be entered in MMRIA (**Attachment 3c**). Each case record may contain up to 1000 data elements. A full list of all data elements collected is currently available at [demo.mmria.org/data-dictionary](http://demo.mmria.org/data-dictionary). Approximately 30 fields should be completed for each case after committee review.

*How Information Will Be Shared and For What Purpose*

The information collected in MMRIA will ultimately be used to provide timely, accurate, and standardized information about deaths to women during pregnancy and within one year of the end of pregnancy within and across participating jurisdictions; facilitate an understanding of the drivers of maternal mortality and complications of pregnancy and associated disparities; determine what interventions at patient, provider, facility, system and community levels will have the most impact; and implement data driven recommendations (e.g., evidence-based practices, screenings, patient education by providers). In conjunction with states, CDC will perform quality checks to clean and edit data, as well as and analyze data to better understand the contributors of maternal deaths (aggregate analyses will be performed with MMRC data from states that give permission to do so). At a minimum, an annual data brief will be published. Topical reports and publications will also be routinely published to address emerging issues and to provide more in-depth analysis of select topics.

MMRCs may share raw data and/or summary data with each other at their discretion. There will be no MMRIA public use dataset.

### *Impact of the Proposed Collection on Respondents' Privacy*

Personally identifiable information (PII) can only be viewed and edited by a limited set of users assigned the Abstractor user role within each jurisdiction. PII in MMRIA is necessary for abstractors to produce a de-identified case narrative of events preceding each woman's death, which is then provided to committee members who review each case. Abstractors must be able to identify individual records by name in order to locate records and enter data accurately.

Abstractors remove all PII before presenting a case to the committee. No PII is shared from MMRIA to any external systems without written approval from the awardee or unless required by applicable law.

MMRIA employs role-based access to ensure the concept of "Least Privilege" is implemented and only those who need access will have access. There are 3 MMRIA roles in use within each awardee's MMRIA instance: Jurisdiction Administrator, Abstractor, and Committee Member.

- Jurisdiction Administrator: has read/write access to users and jurisdiction. Activity Administrator is responsible for creating, maintaining, and deleting user accounts for Abstractors and Committee Members in their jurisdiction. Note: this is a separate role from the Secure Access Management Services (SAMS) Activity Administrator; however, one person can have both SAMS Activity Administrator and MMRIA Jurisdiction Administrator roles.
- Abstractor: has read/write access to the case database for cases within their assigned jurisdiction. An Abstractor has access to PII.
- Committee Member: has read access to a de-identified case database for cases within their assigned jurisdiction. The de-identified case database contains no PII.

MMRIA data is not accessible to CDC staff for analysis purposes unless the jurisdiction specifically grants approval in writing. Some software support situations will require access to a jurisdiction's data. CDC has identified only a few individuals who may need to access MMRIA data for software support; access is limited to those individuals.

A modification of the current Assurance of Confidentiality (Section 308[d] of the Public Health Service Act) for the Pregnancy Mortality Surveillance System (PMSS) will be applied by to

securely protect information in MMRIA.

### *Opportunities to Consent*

Because the data abstracted pertains to deceased individuals, informed consent is not applicable.

### *How Information Will Be Secured*

MMRIA is hosted on a CDC Cloud Services solution. As a cloud service, it is subject to full security assessment, authorization, and continuous monitoring under the Federal Risk and Authorization Management Program (FedRAMP). MMRIA will be secured for confidentiality and integrity at a moderate level based on the requirements of the Federal Information Security Management Act (FISMA).

MMRIA data is protected from unauthorized access, use, disclosure, duplication, modification, diversion, or destruction—whether accidental or intentional—in order to maintain confidentiality, integrity, and availability. The security and privacy controls that provide this protection meet minimum federal requirements with additional risk-based and business-driven control implementation achieved through a defense-in-depth security structure.

Data is encrypted in transit and at rest following the National Institute of Standards and Technology's Federal Information Processing Standard (FIPS 140-2) for Security Requirements for Cryptographic Modules. FIPS 140-2 specifies the security requirements that will be satisfied by a cryptographic module 2 are accepted by the Federal agencies for the protection of sensitive information.

Per FedRAMP requirements, MMRIA employs more than 300 security controls. More information on the required FedRAMP security controls for systems deemed moderate can be found at <https://www.fedramp.gov/understanding-baselines-and-impact-levels/>.

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

IRB approval was not required as this project was approved as public health practice

**(Attachment 9).** The purpose of this surveillance system is to prevent maternal mortality in a defined population by producing information about the population from whom the data were collected.

Some information surrounding the circumstances of maternal death entered into MMRIA may be considered sensitive; such information may include topics of medical conditions, mental health profiles, and autopsy report findings. However, all of this information is necessary to facilitate an understanding of the drivers of maternal mortality and to thus determine the most effective and targeted prevention interventions to prevent future maternal deaths.

These deaths are usually highly visible in the community and often the subject of litigation. Therefore, release of information from MMRIA could be used in some way, directly or indirectly, to identify individuals and institutions is a very sensitive concern for the privacy of the families and the protection of the health care providers. In cases where the pregnancy outcome for a woman who dies is a live birth, a linked live birth certificate is also collected; therefore, the assurance of confidentiality is also needed to protect the identity of the living child. The identification of women whose deaths are related to abortion is of even greater concern. If the identity of individual women or their physicians is made known or if the identity of institutions where abortions are performed is known, harassment, intimidation, and even harm can occur. A modification of the current Assurance of Confidentiality (Section 308[d] of the Public Health Service Act) for the Pregnancy Mortality Surveillance System (PMSS) will be applied for in order to securely protect information in MMRIA.

## **12. Estimates of Annualized Burden Hours and Costs**

Although MMRIA is available for use by any jurisdiction's MMRC, burden estimates presented here are only applicable to the 24 awardees, representing 25 states, of CDC-RFA-DP19-1908 (see **Attachment 8** for a list of awardee states), who as part of the cooperative agreement are required to compile a defined set of information about pregnancy-associated deaths into MMRIA. The funded jurisdiction is considered the respondent.

Estimates of the anticipated number of pregnancy-associated deaths each year (based on a 3-year average) were derived for each of the 25 states covered by CDC-RFA-DP19-1908 funding using CDC Wonder<sup>4</sup> data (2014-16) (**Attachment 8**). CDC Wonder is an online database for the analysis of public health data. From this approach, we estimate an annual total of 757 pregnancy-associated deaths on average. Annually, this equates to an average 30 responses for each of the 25 states (24 awardees) per year.

Burden is assessed for each awardee’s total staff time to abstract and enter abstracted data the information into MMRIA (case narratives are autocompleted and not included in burden hours) as well as enter the committee decision after review. Based on an average of 15 hours to complete abstraction of each death and enter into MMRIA (**Attachment 3a**)—and an additional 24 minutes to enter the committee decision (**Attachment 3c**)—we estimate an average total annual burden of 11,550 hours (**Table A.12-1**).

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

| <b>Types of Respondents</b> | <b>Form Name</b>   | <b>Number of Respondents</b> | <b>Number of Responses per Respondent</b> | <b>Average hours per response (in hours)</b> | <b>Total Burden Hours</b> |
|-----------------------------|--------------------|------------------------------|---|--|---------------------------|
| Awardees                    | Data abstraction   | 25                           | 30  | 15   | 11,250                    |
|                             | Committee decision | 25                           | 30  | 24/60  | 300                       |
| <b>Total</b>                |                    |                              |   |  | <b>11,550</b>             |

Given that most, but not all, case abstractors are nurse practitioners, the estimates of hourly wages for Nurse Practitioner abstractors were obtained from the Department of Labor, Bureau of Labor Statistics.<sup>5</sup> The Median hourly wage for Nurse Practitioner is \$51.50. The total estimated annualized cost to respondents is \$594,825 (**Table A.12-2**).

<sup>4</sup><https://wonder.cdc.gov/>

<sup>5</sup> [https://www.bls.gov/oes/current/oes\\_nat.htm#29-0000](https://www.bls.gov/oes/current/oes_nat.htm#29-0000)

**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 |
|---------------------|--------------------|--------------------|------------------------|--------------------------|-------------------|
| Awardee             | Data abstraction   | 25                 | 11,250                 | \$51.50                  | \$579,375         |
|                     | Committee decision | 25                 | 300                    | \$51.50                  | \$15,450          |
| Total               |                    |                    |                        |                          | \$594,825         |

**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**

The total annual cost to the government is \$9,449,493; it is based on funding to awardees through CDC-RFA-DP19-1908 and CDC personnel and time (**Table A.14**).

**Table A.14. Annualized Cost to the Federal Government**

| Expense Type          | Expense Explanation  | Annual Costs (dollars) |
|-----------------------|--|------------------------|
| Cooperative Agreement | Cooperative Agreement DP19-1908 with 25 Maternal Mortality Review Committee Awardees | <b>\$8,700,000</b>     |
| CDC Personnel         | Information Technology Manager GS-14, 100% of FTE                                    | \$148,812              |
|                       | Epidemiologist GS-13, 80%  | \$124,250              |
|                       | Public Health Advisor GS-13, 100%  | \$125,931              |

|  |                                     |                    |
|--|-------------------------------------|--------------------|
|  | Public Health Advisor GS-13, 100%   | \$125,931          |
|  | Public Health Advisor GS-13, 100%   | \$142,721          |
|  | Team Lead, GS-14, 50%               | \$ 81,848          |
|  | <b>Subtotal, CDC Personnel</b>      | <b>\$749,493</b>   |
|  | <b>TOTAL COST TO THE GOVERNMENT</b> | <b>\$9,449,493</b> |

**15. Explanation for Program Changes or Adjustments**

Not applicable.

**16. Plans for Tabulation and Publication and Project Time Schedule**

MMRIA data collection is ongoing. Data is submitted bi-annually to CDC for editing and cleaning. Data quality reports will be generated and returned to each state within 3 months of receiving data. Editing, cleaning, and analysis of the data will be conducted by CDC on an ongoing basis. There will be no MMRIA public use dataset. Aggregate analyses will be performed with MMRC data from states that give permission to do so. At a minimum, an annual data brief will be published. Topical reports and publications will also be routinely published to address emerging issues, and to provide more in-depth analysis of select topics.

**Table A.16-1. Anticipated Project Time Schedule for Awardees<sup>a</sup>**

| <b>Task</b>                                | <b>Timeframe</b>                                 |
|--|--|
| Data abstraction begins                    | December 2019                                    |
| Case narrative developed                   | Within the 14 days prior to committee review     |
| Committee review                           | Within 3 months from completing data abstraction |
| Committee decision documented              | Within 30 days of committee review               |
| Data quality assurance                     | Quarterly  |
| Data submitted to CDC for editing/cleaning | Bi-annually                                      |

|                            |                                |
|----------------------------|--------------------------------|
| Data returned to awardees  | Within 3 months of CDC receipt |
| Analysis of aggregate data | At least annually              |
| Reports/publications       | At least annually              |

<sup>a</sup>Cooperative agreement awardees=ICR respondents

**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.