Templates for Extramural Data Management Plans

New

Supporting Statement A

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JUSTIFICATION SUMMARY

Goal of the project: To provide contract, grant and cooperative agreement applicants and awardees with templates for the creation of Data Management Plans (DMP).

Intended use of the resulting data: DMPs are required of entities using federal funds to collect or generate new public health data. DMPs will be submitted to CDC by contract, grant and cooperative agreement awardees for assessment to verify that they are concordant with CDC's data sharing policy.

Methods to be used to collect: DMPs will be submitted as standalone sections of the funding applications and workplans; revisions can also be submitted by the awardees whenever needed.

How data will be analyzed: Once DMPs are received, each individual DMP is assessed for completeness and adherence to CDC policy and guidelines. There is no statistical analysis of data gathered in DMPs.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

Each year, approximately 80% of the Centers for Disease Control and Prevention's (CDC) budget is distributed via contracts, grants and cooperative agreements to partners throughout the world to promote health, prevent disease, injury and disability and prepare for new health threats. Generally, under CDC's Policy on Public Health Research and Non-research Data Management and Access ("Data Policy"), the de-identified public health data collected or generated with funding from federally-funded grants and cooperative agreements should be made available to the public (Attachment 5). *Public health data* is defined by CDC as *digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation*. Applicants and awardees describe their intentions relative to the Data Policy in their data management plan (DMP), a document that addresses public health data management from the time of planned data collection/generation, making the data accessible to the public, archiving and long-term deposition of the data. Most extramural research awardees and some non-research awardees are collecting or generating public health data and are required to submit DMPs. The basic requirements of the DMP are described in Additional Requirement 25 (AR-25), a rider to CDC Notices of Funding Opportunity (NOFOs) for grants and cooperative agreements (Attachment 6). CDC has developed similar language to include in contract and task order solicitations when the work is expected to involve collection or generation of public health data (Attachment 7). In addition to AR-25, individual CDC programs can provide additional guidance to applicants and awardees regarding contents of the DMP for individual awards. The information is collected under the authority of the Public Health Service Act (Attachment 1).

A2. Purpose and Use of the Information Collection

CDC project officers assess the DMPs submitted by awardees to ensure awardees' plans are concordant with CDC's policy. If DMPs are not acceptable as written, CDC counsels and works with awardees to bring the DMP into compliance. Currently, CDC does not have a standard template for a DMP, nor are there any OMB-approved DMPs for CDC to use. Due to this fact, CDC NOFOs refer extramural applicants and recipients to external websites for examples on how to construct a DMP. DMPs can be a checklist, paragraph, or any other format and they can be located anywhere in an application. Currently, it is not unusual for CDC to receive DMPs that are incomplete or with components scattered throughout an application; CDC also receives applications that lack needed DMPs and DMPs that are not acceptable per CDC policy. This ICR was developed to obtain OMB approval for standardized templates for DMPs so that they will be

easier to create, easier to review, better ensure compliance with CDC's requirements, and increase the likelihood of first-time approval by project officers.

A3. Use of Improved Information Technology and Burden Reduction

The DMP templates will improve information quality by giving formatting, description, and level of detail guidance to ensure applicants and awardees can minimize errors and need for resubmittal, which will save time and effort for both awardees and CDC. Having the DMPs in the same format for each project will also reduce the workload on reviewers having to scour award applications and workplans for the various DMP elements when they will all be in one place and in order. Applicants and awardees will also know exactly where to make their changes, if necessary, when the project officers or technical monitors provide feedback. Filled templates can be submitted via email or online platforms. Some applications made in response to NOFOs include DMPs; applicant DMPs are submitted electronically via websites called eRA Commons (research) and Grant Solutions (non-research) in response to NOFOs. Some contract applications include DMPs; contract applications are submitted electronically via the Integrated Contracts Expert (ICE) system. Following awards, new and updated DMPs can be submitted via electronic systems for continuations, email, or an external-facing SharePoint site.

A4. Efforts to Identify Duplication and Use of Similar Information

These templates provide a format for a requirement that is already a part of NOFO applications, a Federal reporting requirement for funds received by Awardees. The DMP templates will consolidate and uniformly streamline the information necessary at all stages of the DMP. This ICR was developed by CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) and the templates are intended for NCCDPHP's use as well as other centers CDC-wide. NCCDPHP consulted with the CDC Office of Science to confirm there is no extant CDC or HHS OMB-approved DMP template available or under development. Templates have been contributed by NCCDPHP, CDC's Center for State, Local, Tribal and Territorial Support (CSTLS), CDC's National Center for Injury Prevention and Control (NCIPC), the National Center for Environmental Health / Agency for Toxic Substances and Disease Registry (NCEH/ATSDR), the National Center on Birth Defects and Developmental Disabilities (NCBDDD) and the National Center for Emerging and Zoonotic Infectious Diseases – Division of Healthcare Quality Promotion (NCEZID-DHQP) for OMB approval; these templates have been designed to meet programmatic needs and preferences (Attachment 2). CSTLS has also developed guidance for awardees to ensure the likelihood of compliance (Attachment 8) and other centers are expected to share similar guidance to accompany their own templates. If CDC identifies a need to create additional

templates, they may vary in format or emphasis but will cover the same overarching topics and will be submitted as a non-substantive change or revision request.

A5. Impact on Small Businesses or Other Small Entities

There is no impact on small businesses.

A6. Consequences of Collecting the Information Less Frequently

DMPs are collected in accordance with established CDC policy and thus cannot be collected less frequently. An initial DMP for a grant or cooperative agreement should be included with the application and/or within the first 30 days of initial decision to fund (research) or within 6 months of award (non-research). Contract DMPs are to be submitted with the initial application and can be further developed post-award. DMPs should be updated annually or whenever a major change takes place. Final DMPs should be submitted at the conclusion of the federal funding. The same template is expected to be used for each iteration of a DMP.

A7. Special Circumstances Relating to the Guidelines of 5 CRF 1320.5

None.

A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency

Part A: PUBLIC NOTICE
A 60-day Federal Register Notice was published in the *Federal Register* on August 8, 2019, vol. 84 No. 153, pp. 38987 (see Att 3).
CDC did not receive public comments related to this notice.

Part B: CONSULTATION
The templates were designed by staff within NCCDPHP, CTSTLS, NCIPC, and NCEH/ATSDR. In some CIOs, draft templates were reviewed by a DMP consultation workgroup that includes scientists, evaluators, and project officers. The draft ICR was shared with all of CDC's CIO Associate Directors for Science for comment. Staff within the CDC Office of Science's Office of Scientific Integrity with responsibility for promulgating and monitoring compliance with the Data Policy were also consulted.

A9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive payments or gifts for providing information.

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent

NCCDPHP's Information Systems Security Officer has reviewed this Information Collection Request and determined that the Privacy Act is not applicable. The templates do not involve collection of sensitive or identifiable personal information other than the name of the awardee's data steward. DMPs are not retrieved using PII. DMPs will not be shared with any other entities.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The proposed DMP templates do not collect sensitive information. This is not research and does not require institutional review board approval. A non-research determination was made and is being submitted with this package (Attachment 4).

A12. Estimates of Annualized Burden Hours and Costs

Estimated Annualized Burden Hours

Based on CDC's experience to date working with extramural awardees and creating intramural DMPs, the estimated average time to complete a DMP is one hour. The creation of the first version of each DMP will take longer than the annual updates. The final update will likely take longer than the other annual updates because more information is being added than in earlier years, but should still take less time than the original creation.

The anticipated number of extramural DMPs is based on the typical number of awards that involve public health data. CDC typically funds grants and cooperative agreements for 3-5 years. The requirement for DMPs began with awards initiated in fiscal year 2017, so the number of DMPs received (new DMPs plus annual updates) will increase for the next few years and then stabilize. Although DMPs can be updated at times other than annually, i.e., if a major change occurs, we expect the number of out-of-cycle DMPs to be negligible. The annual number of awards needing DMPs cannot be calculated precisely as agency budgets and projects vary from year to year. However, previous experience can be used to estimate an approximate number of DMPs that will be received.

The expected burden was calculated by each CIO that plans to use the templates, as follows:

- NCCDPHP recorded 390 awardee DMPs in 2019. Given that some of these were initial DMPs and that continuing awards require annual DMPs, NCCDPHP expects to receive approximately 500 in 2020, 600 in 2021, and then stabilize at up to 700 in 2022 and subsequent years.
- NCEH/ATSDR estimates that there will be 120, 160, 200 applicants and awardees using their extramural DMP template during years 2020-2022, respectively.
- CSTLTS expects to receive approximately 50 DMPs annually, averaged over 2020-2022.
- NCIPC expects to receive about 300 DMPs annually.
- NCBDDD expects to receive approximately 40 DMPs annually through 2022
- NCEZID-DHQP expects to receive approximately 40 DMPs annually

Thus, the total number of DMPs for 2020-2022 is estimated at 3570, from 1330 unique respondents. The average number of respondents per year is 1190. The estimated annualized burden for the approximately 3570 DMPs, combined across centers, received during the three-year requested approval period (2020-2022) of this information collection request is 1190 hours. This is illustrated in table 12a. The actual number of DMPs received will be tracked by each CIO.

Table A12-A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of respondents	Number of responses per respondent	Average burden per respondent (in hours)	Total burden (in hours)
Applicants and Award Recipients	DMP Template	1190	1	60/60	1190

Estimated Annualized Cost to Respondents

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics' reporting, which was released in May 2019 (http://www.bls.gov/oes/current/oes_nat.htm). Based on DOL estimates, the average hourly wage for occupational employment for a Medical and Health Services Manager is $55.37. To account for benefits and overhead, this amount has been multiplied by 2 in accordance with the HHS Guidelines for

Regulatory Impact Analysis, 2016 (https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf, page 25). Thus, the average hourly cost is $110.74. The total estimated annualized cost is as summarized in Table A.12-B.

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

Type of Respondents	Total burden (in Hours)	Average Hourly Cost (Wage, Benefits, and Overhead)	Total Cost
CDC Award Recipients	1190	$110.74	$131,780.60

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

No capital or maintenance costs are expected. Additionally, there are no start-up, hardware or software costs. Because it will be easier for users to fill the templates than to create their own formats based on the limited instructions provided to them in NOFOs, it is expected that users will realize time savings (relative to having no template) the first time they use a template.

A14. Annualized Cost to the Federal Government

A. Development, Implementation, and Maintenance
The average annualized cost to the Federal Government is $2,953.63, based upon a GS13 Program Evaluator taking an average of 30 minutes to review each DMP. In the absence of standardized templates for DMPs, more federal staff time would be needed for these reviews.

A15. Explanation for Program Changes or Adjustments

This is a new request.

A16. Plans for Tabulation and Publication and Project Time Schedule

A. Time schedule for the entire project
OMB approval is being requested for three years beginning in 2020. DMPs will be generated by the awardees per the DMP requirements. The initial DMP must be submitted before data collection can begin and updated annually or whenever major changes occur. Final submission is required at the end of federal funding.

B. Publication plan
Information submitted by the awardees will be reviewed by internal CDC staff and not published.

C. Analysis plan
CDC will not use statistical methods for analyzing information.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

The DMP templates will display the expiration date for OMB approval.

A18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification statement.