Workplan Templates for Ten Regional Centers to Enhance Public Health Preparedness and Response

New [OMB No. 0920-xxxx] [OMB expiration date]

**Supporting Statement A**

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Attachment 1 - Public Health Service Act [42 U.S.C. 241]

Attachment 2 – Federal Register Notice

Attachment 2a – Public Comment

Attachment 3 – ORR 5-Year Workplan Template

Attachment 4 – ORR Evaluation Work Plan Template

Attachment 5 – ORR Cooperative Agreement Work Plan Template

Attachment 6 – Human subject research determination

**JUSTIFICATION SUMMARY**

**Goal of the project:** This project aims to establish up to 10 centers across the designated Health and Human Services (HHS) regions for public health preparedness and response (PHPR). The goal is to improve PHPR practices by increasing the uptake of evidence-based strategies and interventions (EBSIs) that align with the needs of the communities involved. This will be achieved through 1) the development of a five-year workplan that covers known strategies or interventions, plans to implement each strategy or intervention, or the development and evaluation of new approaches in PHPR, 2) the use of a Cooperative Agreement Work Plan Template to monitor performance of activities throughout the funding period and 3) the use of an Evaluation Work Plan Template to support evaluation of implemented work plan activities.

**Intended use of the resulting data:** To support regional centers’ creation of a five-year work plan addressing 1) focus areas and objectives across State, Tribal, Local, and Territorial (STLT) and relevant partners that would benefit from use of new or enhanced PHPR EBSIs, 2) activities to meet objectives, 3) prioritized EBSIs to implement, 3) capability and capacity of STLT health departments and relevant partners to implement and evaluate activities, and 4) regional sustainability for implementation of evidence-based practice beyond the five-year period.

**Methods to be used to collect:** Contractors will collect information from the 10 HHS regional Strategic Coordinators to support development, implementation, and evaluation of activities outlined in individualized work plans for their respective regions. The aim is to increase the implementation of EBSIs for PHPR activities. Focus areas, objectives, and activities supporting the work plans will be developed based on collective work and decisions of a regional coordinating body of applicable state, tribal, local, and territorial health departments and officials, health care facilities, and health care coalitions, academic, public, and private partners. In addition, two other collection instruments will be used including 1) a Cooperative Agreement Work Plan Template serving as a performance monitoring instrument for project tracking through the performance period and 2) an Evaluation Work Plan Template that provides background information needed to understand approaches in evaluating selected strategies or intervention activities.

**The subpopulation to be studied:** HHS Strategic Regional coordinators as described by HHS ([HHS Regional Offices | HHS.gov](https://www.hhs.gov/about/agencies/iea/regional-offices/index.html))

**How data will be analyzed:** CDC, with the support of an independent contractor, will evaluate the collective effort of these work plans to determine collective goals, similarities, and differences, and identified gaps or lessons learned to inform future activities of the 10 Centers for Public Health Emergency Preparedness and Response. Completed evaluations using the Evaluation Work Plan should fill a gap in the evidence base using methods and measures that will allow the results of the evaluation to be disseminated and ultimately aggregated with other studies in the literature.

1. **JUSTIFICATION**

## *A1. Circumstances Making the Collection of Information Necessary*

This is a new ICR requested for six months from approval date. To address needs to increase the uptake of evidence-based interventions, in December 2022, CDC was directed to support not fewer than 10 Centers for Public Health Emergency Preparedness and Response that are equally distributed among the geographical regions of the U.S., consistent with section 319F of the Public Health Service Act (42 U.S.C. 247D-6) as amended by the Consolidated Appropriations Act, 2023, sec. 2231 (**Attachment 1**). Activities must be coordinated with specified entities and efforts to implement evidence-based interventions must be prioritized. To prepare for these centers and document the priorities and planned activities, a five-year Work Plan is needed.

In 2021, with contract support, CDC’s Office of Applied Research (OAR) initiated 12 scoping reviews, 6 landscape analyses, and one systematic review to conduct deeper dives into topics such as trust in public health preparedness and response, emergency communications strategies with people with limited English proficiency, public health emergency preparedness and response (PHEPR) practice in rural and tribal communities, and use of health equity coordinators in incident management. The results of these reviews show great breadth in the PHEPR field as it relates to knowledge available to support current practice and highlights the need to expand knowledge to address specific gaps. These needs and gaps may differ across geographical regions and within those regions at the state or local level.

To increase the uptake of evidence-based interventions, the program is developing an ICR to advance the development, implementation, and evaluation of activities supporting a five-year workplan for each regional center. The **ORR Five-Year Workplan Template** (**Attachment 3**) addresses 1) priority areas and objectives, and at least 3 focus areas within those priority areas on ways State, Tribal, Local, and Territorial (STLT) and relevant partners can benefit from use of new or enhanced public health preparedness and response (PHPR) evidence-based strategies or interventions (EBSIs), 2) prioritized EBSIs to implement, 3) capability and capacity of STLT health departments and relevant partners to implement and evaluate activities to meet objectives, 4) regional sustainability of evidence-based practice beyond the five-year period.

The ICR also includes two additional instruments including 1) a **ORR Cooperative Agreement Work Plan Template** (**Attachment 5**)to serve as a performance monitoring instrument that supports tracking of project activities throughout the performance period and 2) an **ORR Evaluation Work Plan Template** (**Attachment 4**) that provides background information needed to understand approaches in evaluating selected strategies or intervention activities.

This project and the associated data collection effort is part of a larger effort to 1) increase awareness, availability, and access to effective EBSIs for public health preparedness and response, 2) increase the ability of STLTs to implement EBSIs to support public health preparedness and response and 3) increase communication and sharing of resources among regional participants/partners to increase learning and reduced redundancy in development of new approaches, training, and translation activities.

***A2. Purpose and Use of the Information Collection***

**The ORR *Five-Year Regional Work Plan Template FY2024-2030***is a rigorous collection tool used to establish regional work plans designed to advance the use of new or existing evidence-based strategies or interventions to meet current and future readiness and response needs of respective regions (**Attachment 3**). Work plans will be based on collective work and decisions of a regional coordinating body of applicable state, tribal, local, and territorial health departments and officials, health care facilities, health care coalitions, academic, public, and private partners. Future regional centers will use the workplan to measure changes in numbers of evidence-based strategies and interventions implemented locally, translated for broader use, and adopted as regular practice.

The **Five-Year Regional Work Plan Template** *(***Attachment****3***)* has three sections. Section 1 will establish at least three regional state, territorial, local, and tribal (STLT) focus areas that will benefit from translation, dissemination, and evaluation of promising research findings or evidence-informed or evidence-based practices, particularly to increase health equity. Each focus area will determine 3-5 objectives and subsequent activities to support and advance response and readiness in the focus area. Section 2 will identify partner, roles, and resources needed to accomplish objectives determined in Section1. Finally, Section 3 will capture participants’ engagement in the development of the work plan and strategies for monitoring and evaluating progress towards achieving the objectives for the priority focus areas. Additionally, work plans will drive incorporation of health equity and population-specific considerations and strategies for addressing health equity within each focus area.

The ORR **Evaluation Work Plan Template** (**Attachment 4**) provides background information needed to understand approaches in evaluating selected strategies or intervention activities that are: (a) innovative, and (b) of high interest at a regional level. A complete evaluation using the Evaluation Work Plan should fill a gap in the evidence base using methods and measures that will allow the results of the evaluation to be disseminated and ultimately aggregated with other studies in the literature.

The ORR **Cooperative Agreement Work Plan Template** (**Attachment 5**) serves as a performance monitoring instrument to track project activities throughout the performance period . The instrument captures information on roles and responsibilities, progress and process measures, touchpoints in collaboration and coordination with STLT health departments and partners, and considerations in health equity taken across project activities.

Collectively, the workplans completed because of the contracts will help prioritize efforts to implement evidence-informed or evidence-based practices to improve public health preparedness and response needs of the community, or communities, involved.

**Figure: Regional Centers for Public Health Preparedness and Response Logic Model**



## *A3. Use of Improved Information Technology and Burden Reduction*

CDC developed a Word document-based template for developing the workplan. The use of the Word document template is expected to be used by 100% of the contractors. Direct entry into the template will reduce the costly burden to analyze these data and enable uniform data collection and analysis so that measures are comparable among regional centers.

The annualized burden hours for collectively completing work plan template, cooperative agreement work plan template, and the evaluation work plan template are estimated at fifteen hours total as detailed below.

**Estimated Annualized Burden Hours**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of Respondents | Form Name | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) |
| HHS Regional Strategic Coordinators  | Office of Readiness and Response - Regional Centers for Public Health Preparedness and Response: Five-Year Regional Workplan Template FY2024-2030  | 10 | 1 |  5 |
| HHS Regional Strategic Coordinators  | Office of Readiness and Response -Cooperative Agreement Work Plan | 10 | 1 | 2 |
| HHS Regional Strategic Coordinators  | Office of Readiness and Response -Evaluation Work Plan Template | 10 | 1 | 8 |

CDC will retain the work plans according to the Federal Records Retention Schedule for Scientific and Research Project records and make the plans available to the public in accordance with Data Use Agreements (DUA) guidelines set forth in the contract.

## *A4. Efforts to Identify Duplication and Use of Similar Information*

Collaboration with CDC’s Public Health Emergency Preparedness program (PHEP), a program that funds states to build and maintain capacity to carry out 15 public health emergency preparedness and response capabilities, and completion of a landscape analysis were core activities implemented to identify potential duplication and use of similar information. To date there have been no work plans to support regional centers for identification and implementation of evidence-based strategies to support public health preparedness and response. The Administration for Strategic Preparedness and Response (ASPR) supports Regional Emergency Coordinators. These are single representatives for each region. They do not have five-year work plans. The Health Resources & Services Administration (HRSA) supports Regional Public Health Training Centers. These centers provide specialized training for public health students and workers and thus do not have work plans to support identification and implementation of evidence-based practices for public health emergency preparedness and response. The Agency for Toxic Substances and Disease Registry (ATSDR) supports regional offices with regional representatives provide unique expertise, and special technical and field experience from their assigned regions. The regional staff have specific duties that include engaging in some emergency response and preparedness activities, but do not include development of five-year work plans for increasing implementation of evidence-based activities for public health emergency preparedness and response. Additionally, on June 28, 2023, CDC held a town hall consisting of a panel of subject matter experts that further confirmed the lack of existing regional work plans. As such, no pre-existing data collections were available to be responsive to the federal appropriations directive.

## *A5. Impact on Small Businesses or Other Small Entities*

Through market research, it was determined that small businesses in Pool 1, NAICS 541990 All Other Professional, Scientific, and Technical Services are not likely to have the capacity and/or required 10 years of experience needed to perform these services without subcontracting to a large prime contractor as indicated in section 5 under Small Business Analysis. Thus, eligible vendors will consist of academic centers, state and local health departments and/or large private entities.

## *A6. Consequences of Collecting the Information Less Frequently*

Recipients will be required to complete the information collection instruments according to the following schedule during the five-year period of performance:

1. Five-Year Regional Work Plan Template – submitted for review and approval if updated or modified in any way.

2. Evaluation Work Plan Template – annually or when it is determined that a specific strategy or intervention will be evaluated.

3. Cooperative Agreement Work Plan Template – annually.

The frequency of submissions allows for the Office of Readiness and Response to have a baseline framework of identified priorities and strategies for increasing implementation of evidence-based interventions for strengthening emergency preparedness and response for the 10 represented HHS regions. This frequency is necessary for ORR to accurately track program activities and progress. If ORR collected this data less frequently, the office would be unable to accurately track regions’ preparedness for public health emergencies, provide necessary technical assistance, identify best practices, or identify areas of improvement.

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

This request fully complies with the regulation 5 CFR 1320.5.

## *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 May 19, 2023, vol. 88 No. 97, pp. 32222 (**Attachment 2**).

CDC received one non-substantive comment and replied with a standard CDC response. The public comment and CDC response is provided (**Attachment 2a**).

**Part B: CONSULTATION**

The Division of Readiness and Response Science (DRRS)- Science Team works very closely with the Public Health Emergency Preparedness (PHEP) program administered in CDC’s Office of Readiness and Response (ORR), Division of State and Local Readiness (DSLR). For this information collection, DRRS solicited overarching strategic input from their leadership (See Table). As the program continues, CDC plans to be in regular communication with the ASPR, HRSA, and ATSDR program coordinators to determine the continued utility and viability of collection elements and procedures.

**Table. Consultations within CDC**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name**  | **Title**  | **Affiliation**  | **Phone**  | **Email**  | **Role** |
| Chris Kosmos, RN, MS | Division Director | DSLR | 404-664-9262 | htv4@cdc.gov | Strategic input |
| Rachel Avchen, PhD  | Branch Chief  | DSLR, Eval. and Analysis  | 404-639-0617  | rja5@cdc.gov  | Strategic input |
| Todd Talbert , MA  | Assoc. Director | DSLR, OD | 404-734-4278  | eup2@cdc.gov  | Strategic input |
| Noelle Anderson | Senior Advisor  | DSLR, OD | 404-772-4630 | xwq3@cdc.gov | Strategic input |
| Kate Noelte, MPH  | Deputy Division Director | DSLR, OD | 404-639-7744  | xjr8@cdc.gov  | Strategic input |

***A9. Explanation of Any Payment or Gift to Respondents***

No payment or gift to respondents will be offered. Awarded contractors, one for each of the 10 HHS regions, will be tasked with the information collections and required to submit the three completed instruments as part of the contract.

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

The Office of Readiness and Response’s (ORR’s) Information Systems Security Officer (ISSO) reviewed this submission and determined the Privacy Act does not apply to this information collection. Activities do not involve the collection of sensitive or individually identifiable information (IIF). Although the contact information is obtained for each funded recipient (i.e. contractor), the contact person provides information about the organization, not personal information. No system of records will be created under the Privacy Act.

Information will be kept secure in a shared file system with access limited to project team members. No IIF will be distributed. CDC only includes aggregate and summary information in reports and does not include information that may identify respondents.

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

CDC’s Study Tracking and Reporting System (STARS) project determination program reviewed the instrument and determined the information collection is necessary and does not meet the definition of human subjects research. IRB approval is not required (**Attachment 6**). This information collection does not include sensitive questions.

## A12. Estimates of Annualized Burden Hours and Costs

The Five-Year Regional Work Plan, the Evaluation Work Plan Template, and the Cooperative Agreement Work Plan Template are the only data collection forms for this project that are required for all awardees to complete.

The **Five-Year Regional Work Plan Template** is comprised of three sections: Section 1- Focus Area, Priorities, and Multi-Year Objectives; Section 2- Partner, Roles, and Resources Needed to Accomplish Objectives; and Section 3-General Questions. The estimated average burden per respondent is 300 minutes (5 hours) yielding a total estimated annualized burden of 50 hours.

The **Evaluation Work Plan Template** provides background information needed to understand approaches in evaluating selected strategies or intervention activities. The estimated average burden per respondent is 480 minutes (8 hours) yielding a total estimated annualized burden of 80 hours.

The **Cooperative Agreement Work Plan Template** serves as a performance monitoring instrument that supports tracking of project activities throughout the performance period. The estimated average burden per respondent is 120 minutes (2 hours) yielding a total estimated annualized burden of 20 hours.

**Table A12A: Estimated Annualized Burden (Hours)**

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours |
| --- | --- | --- | --- | --- | --- |
| HHS Strategic Regional Coordinators | Office of Readiness and Response - Regional Centers for Public Health Preparedness and Response: Five-Year Regional Workplan Template FY2024-2030 | 10 | 1 | 5 | 50 |
| HHS Regional Strategic Coordinators  | Office of Readiness and Response -Evaluation Work Plan Template | 10 | 1 | 8 | 80 |
| HHS Regional Strategic Coordinators  | Office of Readiness and Response -1010 | 10 | 1 | 2 | 20 |
|  | **Grand Total** |  |  |  | **150**  |

The total annualized cost burden requested from respondents is $6,493.50, as summarized below in Table A12B. Estimates of the annualized cost burden to respondents for the collection of information are based on the Department of Labor Bureau of Labor Statistics “May 2022 National Occupational Employment and Wage Estimates, United States” (see <https://www.bls.gov/oes/current/oes_nat.htm#19-0000>). The occupation title and hourly wage of employees who will complete the information collection varies by awardee type, including academic centers, jurisdictions, and private consulting firms. For the purpose of this cost burden analysis, a proxy occupation was used to represent the average employee involved in the information collection. The mean hourly wage for HHS Strategic Regional Coordinators recipients, classified as Public Health Professionals, is $43.29.

**Table A12B Hourly Wage Estimates for HHS Strategic Regional Coordinators Recipients**

|  |  |  |
| --- | --- | --- |
| Occupation Code | Occupation Title | Mean Hourly Wage |
| 11-9161 | Emergency Management Directors | $42.74 |
| 13-1082 | Project Management Specialists | $45.85 |
| 19-1041 | Epidemiologists  | $41.29 |

**Table A12C: Estimated Annualized Burden Costs**

| Type of Respondents | Form Name | Total Annual Burden Hours | Average Hourly Wage Rate | Total Respondent Labor Cost |
| --- | --- | --- | --- | --- |
| HHS Strategic Regional Coordinators | Office of Readiness and Response - Regional Centers for Public Health Preparedness and Response: Five-Year Regional Workplan Template FY2024-2030 | 50 | $43.29 | $2,164.50 |
| HHS Regional Strategic Coordinators  | Office of Readiness and Response -Evaluation Work Plan Template | 80 | $43.29 | $3,463.20 |
| HHS Regional Strategic Coordinators  | Office of Readiness and Response -Cooperative Agreement Work Plan | 20 | $43.29 | $865.80 |

##

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

There will be no direct costs to the respondents other than their time to participate in each information collection. Capital and start-up costs will not be required for this information collection.

## *A14. Annualized Cost to the Federal Government*

The total annualized cost to the federal government is $362,168 based on the costs itemized below in Table A14-A.

* The anticipated funding for the five-year cooperative agreement is $800,000 per year per region (total 10 regions).
* The total cost of the development of the Five-Year Regional Work Plan Development, Evaluation Work Plan Template and the Cooperative Agreement Work Plan Template is $8,218 (Table A14-B).

 **Table A14.-A.** Annualized Cost to Federal Government

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Aspect of Project** | **Employment Level** | **# of employees** | **% of time** | **Annual Wage** | **Total Cost** |
| Project oversight and monitoring | GS-15 | 1 | 40% | $182,270 | $72,908 |
| GS-14 | 4 | 40% | $146,352 | $234,163 |
| GS-13 | 1 | 40% | $137,743 | $55,097 |
| **Total** |  |  | **$362,168** |

**Table A14.-B.** Estimated Annualized Federal Government Cost Distribution

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Aspect of Project** | **Employment Level** | **Hours Worked** | **Hourly Wage Rate** | **Total Cost** |
| Development of content | GS-15 | 60 hours | $81.81 | $4,908.60 |
| GS-14 | 4 hours | $63.91 | $255.64 |
| GS-13 | 60 hours | $50.90 | $3,054.00 |
| **Total** |  | **$8,218** |

## *A15. Explanation for Program Changes or Adjustments*

This is a new information collection.

## *A16. Plans for Tabulation and Publication and Project Time Schedule*

A national report will be developed based on the data collected across the ten HHS Regional Coordinating Centers. This will present aggregated national data and region-specific data. CDC anticipates results of the project will be developed into several scientific and non-scientific products. Dissemination of scientific and non-scientific products to stakeholders include reports, professional meeting presentations, and peer-reviewed and non-peer-reviewed publications.

**Table A.16**. Estimated Time Schedule for Project Activities

|  |  |
| --- | --- |
| **Activity** | **Schedule** |
| Date of Awards | September, 2024 |
| OMB Approval Obtained | November, 2024 |
| TA on all workplan templates  | December, 2024 |
| Information Collection  | November, 2024 – November 2027 |
| Reporting | November, 2024 – November 2027 |

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

The display of the OMB expiration date is appropriate.

## *A18. Exceptions to Certification for Paperwork Reduction Act Submission*

There are no exceptions to the certification.

**List of Attachments**

Attachment 1 - 1. Public Health Service Act [42 U.S.C. 241]

Attachment 2 – Federal Register Notice

Attachment 2a – Public Comment

Attachment 3 – ORR 5-Year Workplan Template

Attachment 4 – ORR Evaluation Work Plan Template

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Attachment 6 – Human subject research determination