



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Print Date: 5/12/21

Title: Public Health Emergency Preparedness Cooperative Agreement Operational Readiness Review 2.0

Project Id: 0900f3eb81b1f212

Accession #: CPR-PSB-4/13/20-1f212

Project Contact: Molly Sanborn

Organization: CPR/DSLR/PIB

Status: **Project In Progress**

Intended Use: **Project Determination**

Estimated Start Date: 07/01/2021

Estimated Completion Date: 07/01/2024

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #:

Determinations

| Determination | Justification | Completed | Entered By & Role |
|---|---|-----------|---------------------------------|
| HSC: Does NOT Require HRPO Review | Not Research / Other <i>45 CFR 46.102(l)</i> Program Evaluation | 5/19/20 | Garcia_Albert D. (asg9) CIO HSC |
| PRA: | | | |

| | | | |
|--|--|---------|---------------------------------------|
| PRA Applies | | 5/29/20 | Garcia_Albert D. (asg9) OMB / PRA |
| HRPO: Returned with No Decision | | 5/29/20 | Logan_Marinda D. (mw18) HRPO Reviewer |
| ICRO: Returned with No Decision | | 5/29/20 | Zirger_Jeffrey (wtj5) ICRO Reviewer |

Description & Funding

Description

Priority: Standard

Date Needed: 06/01/2021

Determination Start Date: 04/13/20

Description:

To help evaluate the country's public health emergency preparedness and response capacity, the Centers for Disease Control and Prevention's Division of State and Local Readiness (DSLRL) administers the Public Health Emergency Preparedness (PHEP) cooperative agreement. The PHEP program is a critical source of funding for 62 state, local, and territorial jurisdictions to build and strengthen their ability to respond to and recover from public health emergencies. The Operational Readiness Review (ORR) is a rigorous, evidence-based assessment used to evaluate PHEP recipients' planning and operational functions. The previous version of the ORR evaluated a jurisdiction's ability to execute a large emergency response requiring medical countermeasure (MCM) distribution and dispensing. The purpose of this new ORR 2.0 is to expand measurement and evaluation to all 15 Public Health Emergency Preparedness and Response Capabilities, which serve as national standards for public health preparedness planning.

IMS/CIO/Epi-Aid/Chemical Exposure Submission: No

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

Secondary Priority(s) of the Project: Not selected

Task Force Associated with the Response: Not selected

CIO Emergency Response Name: Not selected

Epi-Aid Name: Not selected

Assessment of Chemical Exposure Name: Not selected

Goals/Purpose

The purpose of this ICR is to expand the ORR to include all 15 PHEP capabilities so DSLRL can better monitor program impact and support program analysis and improvement across all hazards impacting public health.

Objective:

The ORR 2.0 will have three modules: descriptive, planning, and operational, which will allow DSLRL to analyze the data for the development of descriptive statistics and to monitor the progress of each recipient towards performance goals. It is intended to promote accountability, track recipient progress towards achieving desired programmatic outcomes, and provide key insights into recipients' planning and operational strengths, areas of improvement, and technical assistance needs.

| | |
|---|--|
| Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?: | Not Selected |
| Project does not incorporate elements of health equity science: | Not Selected |
| Measuring Disparities: | Not Selected |
| Studying Social Determinants of Health (SDOH): | Not Selected |
| Assessing Impact: | Not Selected |
| Methods to Improve Health Equity Research and Practice: | Not Selected |
| Other: | Not Selected |
| Activities or Tasks: | New Collection of Information, Data, or Biospecimens |
| Target Populations to be Included/Represented: | No Human Population |
| Tags/Keywords: | Public Health Emergency Preparedness and Response |
| CDC's Role: | Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided |
| Method Categories: | Survey |
| Methods: | As part of the PHEP cooperative agreement, the 62 recipients are required to submit information via the ORR that will describe their activities and progress towards defined preparedness goals/standards. This information will be submitted via forms housed in the ORR online system. |
| Collection of Info, Data or Biospecimen: | The information will be submitted via the ORR online system or fillable PDF forms. |
| Expected Use of Findings/Results: | The findings will be collected to analyze how recipients are progressing towards defined program goals/objectives. The findings will be aggregated to create an annual public health preparedness and response national snapshot that presents aggregated national data and specific recipient data. |
| Could Individuals potentially be identified based on Information Collected? | Yes |
| Will PII be captured (including coded data)? | Yes |
| Does CDC have access to the identifiers? | Yes |
| Is an assurance of confidentiality in place or planned? | Yes |
| Is a certificate of confidentiality in place or planned? | No |
| Is there a formal written agreement prohibiting the release of identifiers? | No |

Funding

| Funding Type | Funding Title | Funding # | Original Budget Yr | # Years Award | Budget Amount |
|---------------------------|--|-------------------|--------------------|---------------|---------------|
| CDC Cooperative Agreement | Public Health Emergency Preparedness Cooperative Agreement | CDC-RFA-TP19-1901 | 2019 | 5 | |

HSC Review

HSC Attributes

Program Evaluation Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children

Population - Minors

Population - Prisoners

Population - Pregnant Women

Population - Emancipated Minors

Suggested level of risk to subjects Do you anticipate this project will be exempt research or non-exempt research

Requested consent process wavers

| | |
|---|--------------|
| Informed consent for adults | No Selection |
| Children capable of providing assent | No Selection |
| Parental permission | No Selection |
| Alteration of authorization under HIPPA Privacy Rule | No Selection |

Requested Waivers of Documentation of Informed Consent

| | |
|---|--------------|
| Informed consent for adults | No Selection |
| Children capable of providing assent | No Selection |
| Parental permission | No Selection |

Consent process shown in an understandable language

| | |
|--|--------------|
| Reading level has been estimated | No Selection |
| Comprehension tool is provided | No Selection |
| Short form is provided | No Selection |
| Translation planned or performed | No Selection |
| Certified translation / translator | No Selection |
| Translation and back-translation to/from target language(s) | No Selection |
| Other method | No Selection |

Clinical Trial

| | |
|--|--------------|
| Involves human participants | No Selection |
| Assigned to an intervention | No Selection |
| Evaluate the effect of the intervention | No Selection |
| Evaluation of a health related biomedical or behavioral outcome | No Selection |
| Registerable clinical trial | No Selection |

Other Considerations

| | |
|--|--------------|
| Exception is requested to PHS informing those bested about HIV serostatus | No Selection |
|--|--------------|

Human genetic testing is planned now or in the future No Selection

Involves long-term storage of identifiable biological specimens No Selection

Involves a drug, biologic, or device No Selection

Conducted under an Investigational New Drug exemption or Investigational Device Exemption No Selection

Institutions & Staff

Institutions

Institutions yet to be added

Staff

| Staff Member | SIQT Exp. Date | CITI Biomedical Exp. Date | CITI Social & Behavioral Exp. Date | CITI Good Clinical Practice Exp. Date | Staff Role | Email | Phone | Organization |
|---------------|----------------|---------------------------|------------------------------------|---------------------------------------|------------------|--------------|--------------|------------------------------|
| Molly Sanborn | 03/22/2023 | | | | Program Official | qbo4@cdc.gov | 404-718-5058 | DLSR PROGRAM SERVICES BRANCH |

Data

DMP

Proposed Data Collection Start Date: 7/31/21

Proposed Data Collection End Date: 7/31/24

Proposed Public Access Level: Public

Public Access Justification: An annual public health preparedness and response national snapshot occurs each year that presents aggregated national data and specific recipient data. This will continue and will reflect data collected in the proposed system.

How Access Will Be Provided for Data: Although CDC will collect some individually identifiable information (IIF) related to the official roles of respondents, including name, phone number, email, and PHEP awardee jurisdiction, all information will be kept on the HHS Secure Access Management Services

(SAMS) system and will only be accessible to project team members.

Plans for Archival and Long Term Preservation: Recipient data will be kept on the HHS Secure Access Management Services (SAMS) system.

Spatiality

| Country | State/Province | County/Region |
|---------------|----------------|---------------|
| United States | Montana | |
| United States | Nebraska | |
| United States | Nevada | |
| United States | New Hampshire | |
| United States | New Jersey | |
| United States | New Mexico | |
| United States | New York | |
| United States | Alabama | |
| United States | Alaska | |
| United States | Arizona | |
| United States | Arkansas | |
| United States | California | |
| United States | Colorado | |
| United States | Connecticut | |
| United States | Delaware | |
| United States | Florida | |
| United States | Georgia | |
| United States | Hawaii | |

| | | |
|---------------|----------------|--|
| United States | Idaho | |
| United States | Illinois | |
| United States | Indiana | |
| United States | Iowa | |
| United States | Kansas | |
| United States | Kentucky | |
| United States | Louisiana | |
| United States | Maine | |
| United States | Maryland | |
| United States | Massachusetts | |
| United States | Michigan | |
| United States | Minnesota | |
| United States | Mississippi | |
| United States | Missouri | |
| United States | North Carolina | |
| United States | North Dakota | |
| United States | Ohio | |
| United States | Oklahoma | |
| United States | Oregon | |
| United States | Pennsylvania | |
| United States | Rhode Island | |
| United States | South Carolina | |
| United States | South Dakota | |

| | | |
|--------------------------|------------------|-------------|
| United States | Tennessee | |
| United States | Texas | |
| United States | Utah | |
| United States | Vermont | |
| United States | Virginia | |
| United States | Washington | |
| United States | Washington, D.C. | |
| United States | West Virginia | |
| United States | Wisconsin | |
| United States | Wyoming | |
| United States | New York | New York |
| United States | Illinois | Cook |
| United States | California | Los Angeles |
| American Samoa | | |
| Guam | | |
| Micronesia | | |
| Northern Mariana Islands | | |
| Puerto Rico | | |
| Palau | | |
| Marshall Islands | | |
| U.S. Virgin Islands | | |

Dataset

| Dataset Title | Dataset Description | Data Publisher /Owner | Public Access Level | Public Access Justification | External Access URL | Download URL | Type of Data Released | Collection Start Date | Collection End Date |
|----------------------------|---------------------|-----------------------|---------------------|-----------------------------|---------------------|--------------|-----------------------|-----------------------|---------------------|
| Dataset yet to be added... | | | | | | | | | |



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