



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/DSL/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 DSLR 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 DSLR 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
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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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