



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

*Print Date: 8/15/23*

**Title:** Public Health Emergency Management Capacity Assessment Tool (PHEM Tool)

**Project Id:** 0900f3eb820df056

**Accession #:** CPR-EMTA-1/11/23-869b3

**Project Contact:** Wendy P Smith

**Organization:** CPR/DEO/GEMCD/EMTA

**Status:** **Pending Regulatory Clearance**

**Intended Use:** **Project Determination**

**Estimated Start Date:** 02/28/2023

**Estimated Completion Date:** 09/30/2025

**CDC/ATSDR HRPO/IRB Protocol #:** Not Applicable

**OMB Control #:** Not Applicable

## Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(1)(2)</i>  Not Research / Other <i>45 CFR 46.102(1)</i>	3/4/23	Garcia_Albert D. (asg9) CIO HSC

	Program Evaluation Other - PH Emergency Preparedness		
PRA: PRA Applies	<p><b>Qualifies for a statutory waiver:</b></p> <p>21st Century Cures Act - Sec. 3087 (Public Health Emergency)</p> <p><i>Justification:</i> # Project Title: Public Health Emergency Management Capacity Assessment Tool (PHEM Tool) # POC (Project Officer/Principle Investigator): Wendy Smith # Estimated date of project completion: 9/9/025 # Priority Topics (relationship to COVID-19 response): To create an easy to use and comprehensive PHEM Program and PHEOC assessment tool for use in Global Health Security Agenda as well as USG/ CDC priority countries. # Efforts made to assess duplication of data collection efforts: The organization of the PHEM Tool avoids duplication of questions or redundancy as relates to programs and projects outside of the scope of PHEM. # Statistical methods review: PHEM Tool data will be used to tailor technical assistance and programmatic activities in participant countries. # Estimated Burden hours (# Respondents x Time/Response = TOTAL Burden Hours): 20 x hours Program plans on submitting ICR to cover information collection after PHE PRA terminates</p>	3/6/23	Garcia_Albert D. (asg9) OMB / PRA
ICRO: PRA Applies	OMB Approval date: 3/21/23 OMB Expiration date: 12/31/99	3/21/23	Zirger_Jeffrey (wtj5) ICRO Reviewer

## Description & Funding

### Description

**Priority:** Urgent

**Date Needed:** 03/16/2023

**Priority Justification:** Due to COVID-19, GEMCD is requested to provide technical assistance (TA) to GHSA countries for PHEM and PHEOC areas. The Tool is needed to perform systematic assessment, to guide TA support.

**Determination Start Date:** 03/06/23

The Global Emergency Management Capacity Development (GEMCD) Team provides technical assistance to Global Health

<b>Description:</b>	Security Agenda priority countries to assist them in developing and maintaining public health emergency management (PHEM) programs and public health emergency operations centers (PHEOCs). The Public Health Emergency Management Capacity Assessment Tool (PHEM Tool) is intended to provide a systematic approach to collecting data pertaining to PHEM programs and PHEOCs in countries where technical support is being provided. Data collected will help GEMCD identify programmatic and PHEOC strengths and weaknesses to guide short and long term technical assistance and project planning.
<b>IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:</b>	Yes
<b>IMS Activation Name:</b>	2019 Novel Coronavirus Response
<b>Primary Priority of the Project:</b>	Prevention, mitigation, and intervention strategies
<b>Secondary Priority(s) of the Project:</b>	Not selected
<b>Task Force Associated with the Response:</b>	Not selected
<b>CIO Emergency Response Name:</b>	Not selected
<b>Epi-Aid Name:</b>	Not selected
<b>Lab-Aid Name:</b>	Not selected
<b>Assessment of Chemical Exposure Name:</b>	Not selected
<b>Goals/Purpose</b>	The goal of the PHEM Tool is to provide an easy to use but comprehensive questionnaire to assess public health emergency management (PHEM) program capacity and public health emergency operations centers' (PHEOC) capabilities, for the purpose of identifying areas of technical assistance support.
<b>Objective:</b>	1. To create an easy to use and comprehensive PHEM Program and PHEOC assessment tool for use in Global Health Security Agenda as well as USG/ CDC priority countries. 2. To use data collected using the tool to identify focus areas for programmatic activities and Technical Assistance. 3. To use tool each program year to document improvements or decreases in public health emergency management and/ or Public Health Emergency Operations Center capabilities.
<b>Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:</b>	Not Selected
<b>Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:</b>	Not Selected
<b>Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:</b>	Not Selected
<b>Activities or Tasks:</b>	Programmatic Work
<b>Target Populations to be Included/Represented:</b>	International
<b>Tags/Keywords:</b>	Public Health Emergency Management

<b>CDC's Role:</b>	CDC employees will provide substantial technical assistance or oversight
<b>Method Categories:</b>	Needs Assessment
<b>Methods:</b>	<p>GEMCD team emergency management technical advisors (EMTAs) will use the PHEM Tool to assess the public health emergency management program capabilities in targeted Global Health Security Agenda and USG/ CDC priority countries. The PHEM Toll will be administered to CDC Country Office staff and/ or Ministry of Health (MoH) staff. Data will be collected in excel and analyzed to determine strengths and weaknesses of PHEM programs and PHEOCs, using criteria consistent with the WHO Joint External Evaluation (JEE) Tool, the gold standard in achieving the International Health Regulations (IHR) requirements. Using the findings collected via the from PHEM Tool, EMTAs will create project plans to provide countries' with programmatic support and technical assistance. The DEO Information Technology (IT) Team#s CDCReady will host the PHEM Tool. The IT Team will provide technical support to GEMCD such as summary reports of PHEM Tool findings, for each country and for combinations of countries, over time. The IT Team will act as the Data Manager (DM) for the PHEM Tool data, ensuring that it is maintained over time and providing recommendations on the use of CDCReady analytic and visualization tools. GEMCD team members will collect data via excel and submit to data manager directly or through specified mechanism. Standard reports will be generated on demand for the GEMCD Team but special reports will require 2-4 weeks to create, based upon IT Team availability.</p> <p>GEMCD Team EMTAs will use the PHEM Tool to guide interviews with key informants at CDC country offices and/ or Ministries of Health. Duration of the interview is anticipated to be less than one day. Additional time may be required if key informants choose to provide corroborating plans to support their responses to survey questions. Excel based data will be managed through the DEO Information Technology Team and CDCReady portal. GEMCD requests the PRA waiver for COVID-19 as we continue to assess its impact on PHEM capacity in countries. The PHEM Tool as described herein will continue to be used once the waiver has expired and we will address PRA coverage beyond the timeframe of the current waiver. The point of contact for the activity is Sharanya Krishnan, noted in the application. The organization of the PHEM Tool avoids duplication of questions or redundancy as relates to programs and projects outside of the scope of PHEM. The administration of the PHEM Tool may be accomplished in a matter of 4 hours, but longer, up to one full day for the GEMCD team member and one or more respondents from the CDC Country Office or the MOH for 4-8 hours. The data collected will yield descriptive statistics, analyzed using excel.</p>
<b>Collection of Info, Data or Biospecimen:</b>	
<b>Expected Use of Findings/Results and their impact:</b>	<p>PHEM Tool data will be used to tailor technical assistance and programmatic activities in participant countries. PHEM Tool data will be available to participant CDC country teams, in report form. In addition, these reports may be shared with Ministry of Health officials, at the discretion of the CDC Country or Regional Teams. GEMCD may use data collected using the PHEM Tool to develop reports for programmatic use, internal to DEO, CPR, of Global Health. Aggregated or de-identified PHEM Tool data may also be used in publications pertaining to emergency management, capacity development, public health workforce development, etc. Publications external to CDC will reference country specific data in an anonymous format or as one of many represented in the case of regional comparisons. PHEM Tool data for use in external publications or presentations will be submitted through CDC#s approval and clearance process.</p>
<b>Could Individuals potentially be identified based on Information Collected?</b>	Yes
<b>Will PII be captured (including coded data)?</b>	No
<b>Is this project covered by an Assurance of Confidentiality?</b>	No
<b>Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?</b>	No
<b>Is there a formal written agreement prohibiting the release of identifiers?</b>	No

## Funding

Funding yet to be added .....

## HSC Review

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### HSC Attributes

Program Evaluation	Yes
Other - PH Emergency Preparedness	Yes

## Regulation and Policy

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Do you anticipate this project will need IRB review by the CDC IRB, NIOSH IRB, or through reliance on an external IRB? No

Estimated number of study participants

Population - Children

Protocol Page #:

Population - Minors

Protocol Page #:

Population - Prisoners

Protocol Page #:

Population - Pregnant Women

Protocol Page #:

Population - Emancipated Minors

Protocol Page #:

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

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### 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
Sharanya Krishnan	11/02/2023				Program Lead	eug9@cdc.gov	404-426-3313	EMTA TEAM 1

## Data

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### DMP

Proposed Data Collection Start Date: 3/1/23

Proposed Data Collection End Date: 10/1/27

Proposed Public Access Level: Non-Public

Non-Public Details:

**Reason For Not Releasing Data:**

Other - Data are sensitive and relate to critical infrastructure.

**Public Access Justification:**

Data collected through the PHEM Tool regarding jurisdictional capabilities are sensitive and inappropriate for public distribution unless appearing in a de-identified or aggregate form.

**How Access Will Be Provided for Data:**

The DEO Information Technology (IT) Team#s CDCReady will host excel based data that are collected using the PHEM Tool. The IT Team will act as the Data Manager (DM) for the PHEM Tool data, ensuring that it is maintained over time in the CDCReady platform, available to specific, role based programmatic staff.

**Plans for Archival and Long Term Preservation:**

PHEM Tool data will be managed by the DEO IT Team, ensuring that it is maintained over time in the CDCReady platform. Data archived in the system will be maintained indefinitely.

## Spatiality

Country	State/Province	County/Region
Republic of Kenya		
Republic of Tajikistan		
Republic of South Africa		
Republic of Sierra Leone		
Republic of India		
Republic of Senegal		
Republic of Panama		
Republic of Nicaragua		
Republic of Mozambique		
Republic of Mali		
Republic of Malawi		
Republic of Honduras		
Republic of Costa Rica		
Dominican Republic		
Republic of Zambia		



Republic of Zimbabwe		
South Sudan		
United Republic of Tanzania		
Republic of Uganda		
Republic of the Philippines		
Republic of Peru		
Republic of Guinea		
Republic of Ghana		
Lao People's Democratic Republic		
Democratic People's Republic of Korea		
Republic of Azerbaijan		
Republic of Armenia		
Republic of Liberia		
Mexico		
Islamic Republic of Pakistan		
Republic of Indonesia		
Republic of Rwanda		
Belize		
Jamaica		
Guadeloupe		
Republic of El Salvador		
Kingdom of Cambodia		

Independent State of Papua New Guinea		
Turkmenistan		
Republic of Haiti		
Republic of Djibouti		
Republic of Botswana		
Plurinational State of Bolivia		
Libya		
Bangladesh		
Republic of Cote d'Ivoire		
Republic of Cameroon		
Republic of Angola		
Islamic Republic of Mauritania		
Malaysia		
Kingdom of Lesotho		
Kingdom of Eswatini		
Burkina Faso		
Republic of Uzbekistan		
Federal Republic of Nigeria		
Federal Democratic Republic of Ethiopia		
Democratic Republic of the Congo		
Kyrgyz Republic		
Federative Republic of Brazil		
Socialist Republic of Vietnam		

Ukraine		
Kingdom of Thailand		
Republic of Kazakhstan		
Republic of Colombia		
Georgia		

## 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...									

## Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	03/21/2023	Activity approved under PHE PRA Waiver. A 60d FRN and PRA package will need to be submitted.	Notice of Action	PHE PRA Waiver Approval COVID.docx
Current	Smith_Wendy P (wvj7) Project Contact	03/16/2023	Please see attached, revised PHEM Tool, including additional COVID-19 focused questions.	Data Collection Form	PHEM Tool Additional C19_16 MAR 23.xlsx
	Smith_Wendy P (wvj7) Project Contact	02/09/2023	Attached is draft PHEM Tool for review and revision, as recommended.	Data Collection Form	PHEM Tool Draft UAZ3 12 DEC 22.xlsx



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