



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>Qualifies for a statutory waiver:</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

| | |
|---|--|
| Description: | 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. |
| IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission: | Yes |
| IMS Activation Name: | 2019 Novel Coronavirus Response |
| Primary Priority of the Project: | Prevention, mitigation, and intervention strategies |
| 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 |
| Lab-Aid Name: | Not selected |
| Assessment of Chemical Exposure Name: | Not selected |
| Goals/Purpose | 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. |
| Objective: | 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. |
| Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?: | Not Selected |
| Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?: | Not Selected |
| Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?: | Not Selected |
| Activities or Tasks: | Programmatic Work |
| Target Populations to be Included/Represented: | International |
| Tags/Keywords: | Public Health Emergency Management |

| | |
|---|--|
| CDC's Role: | CDC employees will provide substantial technical assistance or oversight |
| Method Categories: | Needs Assessment |
| Methods: | <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> |
| Collection of Info, Data or Biospecimen: | |
| Expected Use of Findings/Results and their impact: | <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> |
| Could Individuals potentially be identified based on Information Collected? | Yes |
| Will PII be captured (including coded data)? | No |
| Is this project covered by an Assurance of Confidentiality? | No |
| Does this activity meet the criteria for a Certificate of Confidentiality (CoC)? | No |
| Is there a formal written agreement prohibiting the release of identifiers? | No |

Funding

Funding yet to be added

HSC Review

HSC Attributes

| | |
|-----------------------------------|-----|
| Program Evaluation | Yes |
| Other - PH Emergency Preparedness | Yes |

Regulation and Policy

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

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

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 | | |

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|---------------------------------------|--|--|
| 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 | | |

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|---|--|--|
| 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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