



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

Print Date: 1/13/25

Title: CDC ENGAGE Functionality Project
Project Id: 0900f3eb82496bf2
Accession #: OPHDST-TIO-11/14/24-96bf2
Project Contact: Virginia U Warren
Organization: OPHDST/DDTP/TIO
Status: **Project In Progress**
Intended Use: **Project Determination**
Estimated Start Date: 01/01/2024
Estimated Completion Date: 04/22/2025
CDC/ATSDR HRPO/IRB Protocol #:
OMB Control #: 0920-1154

Determinations

| Determination | Justification | Completed | Entered By & Role |
|---|---|-----------|---|
| HSC: Does NOT Require HRPO Review | Not Research / Other 45 CFR 46.102(l) Quality Assurance / Improvement | 12/10/24 | Gadsden-Knowles_Kim (klg6) Human Subjects Coordinator |
| PRA: PRA Applies | | 12/10/24 | Gadsden-Knowles_Kim (klg6) OMB/PRA Coordinator |
| ICRO: PRA Applies | OMB Approval date: 6/13/23 OMB Expiration date: 6/30/26 | 12/10/24 | Zirger_Jeffrey (wtj5) ICRO Reviewer |

Description & Funding

Description

Priority: Standard

Date Needed: 12/31/2024

Priority Justification:

CDC Priority Area for this Project: Readiness and Response

Determination Start Date: 11/25/24

Description: Interviews will be done with a sampling of state, tribal, local, and territorial (STLT) public health agencies (PHAs) and related partners in order to collect information that will inform design of CDC ENGAGE. CDC ENGAGE is meant to be a unifying platform for STLT PHA customers to get support and CDC to provide support; it will contain a help desk, knowledge repository, collaboration spaces, and CRM technology.

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

IMS Activation Name: Not selected

Submitted through IMS Clearance Matrix: Not selected

Primary Scientific Priority: Not selected

Secondary Scientific Priority (s): Not selected

Task Force Responsible: 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 purpose of the interviews is to collect user input from state, tribal, local, and territorial (STLT) public health agency (PHA) customers and related partners that will inform design of CDC ENGAGE. Specifically, conversations will inform what features are prioritized in the system. Prior to interviews being planned, steps taken to minimize duplicative efforts included extensive investigation of STLT PHA needs through discussions with CDC staff who have experience working with or in STLT PHAs and review of qualitative research findings from a recent Case Service Design project involving STLT PHAs.

Objective: Primary objective is to validate that the features we have identified for CDC ENGAGE resonate with users. Secondary objective is to detect any features/functionalities that should be prioritized for the system that have not been. These objectives relate to public health response activities in that they affect our ability to provide efficient, effective support to state, tribal, local, and territorial (STLT) public health agencies (PHAs) during public health response activities.

| | |
|--|--|
| Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?: | No |
| Does your project investigate underlying contributors to health inequities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?: | No |
| Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?: | No |
| Activities or Tasks: | New Collection of Information, Data, or Biospecimens |
| Target Populations to be Included/Represented: | Other - State, tribal, local, and territorial/freely associated state government employees |
| Tags/Keywords: | STLT ; Data Modernization ; User interviews |
| 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: | Individual Interviews (Qualitative) |
| Methods: | Twenty-one to thirty people will be recruited, for unstructured conversations, from among state, tribal, local and territorial/freely associated state (STLT) public health agencies (PHAs) that CDC provides data, surveillance, and/or technology support to and related partners. CDC subject matter experts that have institutional knowledge about STLT PHAs are being consulted to determine who to exempt (e.g., due to recent participation in other CDC initiatives that required interviews/surveys). |
| Collection of Info, Data or Biospecimen: | Information will be collected from state, tribal, local and territorial/freely associated state (STLT) public health agency (PHA) epidemiology leads, data leads, informaticians, surveillance epidemiologists, people in similar roles, and people who support those roles. Qualitative feedback gathered from the interviews will be anonymized and aggregated before being shared beyond the interview team. Our goal is to create an interview environment where users feel comfortable sharing their true opinions. |
| Expected Use of Findings/Results and their impact: | Information from interviews will be used to guide design and development decisions for CDC ENGAGE, especially prioritization of features and functionality. Learnings from interviews may be shared with key decision makers stakeholders for CDC ENGAGE, but to preserve privacy, any learnings will be anonymized and aggregated. |
| 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 (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 Type | Funding Title | Funding # | Original Budget Yr | # Years Award | Budget Amount |
|--------------|---------------------------------------|---------------|--------------------|---------------|---------------|
| CDC Contract | Data Modernization Accelerator at CDC | 47QTCK18D0004 | 2024 | | |

HSC Review

HSC Attributes

Quality Assurance / Improvement Yes

Regulation and Policy

Do you anticipate this project will require review by a CDC IRB or HRPO? 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 wavier

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

Will you be working with an outside Organization or Institution? No

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 | CITI Good Laboratory Practice Exp. Date | Staff Role | Email | Phone | Organization |
|-----------------|----------------|---------------------------|------------------------------------|---------------------------------------|---|-------------------------|--------------|--------------|----------------------------------|
| James Kucik | 04/07/2026 | | | | | Technical Monitor | ezk9@cdc.gov | 404-639-6222 | TECHNOLOGY IMPLEMENTATION OFFICE |
| Mitchell Grimes | 04/07/2026 | | | | | Individual Investigator | zwb7@cdc.gov | | |
| Virginia Warren | 08/22/2026 | | | | | Technical Monitor | upe9@cdc.gov | 404-498-2724 | TECHNOLOGY IMPLEMENTATION OFFICE |

Data

DMP

Proposed Data Collection Start Date: 1/1/24

Proposed Data Collection End Date: 4/22/25
Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - Data will be used for program and operational improvement within CDC and has no application for the general public.

Public Access Justification: Data will be used for program and operational improvement within CDC and has no application for the general public.

How Access Will Be Provided for Data: Booz Allen Hamilton will present summary level data to CDC technical monitors and back with interviewees as applicable.

Plans for Archival and Long Term Preservation:

Spatiality

Spatiality (Geographic Locations) yet to be added

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 | 12/10/2024 | NOA 0920-1154 (2023) | Notice of Action | NOA 0920-1154_2023.pdf |
| Current | Warren_Virginia (upe9) Project Contact | 11/25/2024 | Conversation guide with topics, goals, and sample questions. | Other-Enter new type | Conversation Guide_Functionality Project.pdf |



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