



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

*Print Date: 1/7/25*

<b>Title:</b>	CDC OneLab Formative Evaluation.
<b>Project Id:</b>	0900f3eb8244d66f
<b>Accession #:</b>	CLSR-TWDB-9/24/24-4d66f
<b>Project Contact:</b>	Amber S Broughton
<b>Organization:</b>	CLSR/DLS/TWDB
<b>Status:</b>	<b>Project In Progress</b>
<b>Intended Use:</b>	<b>Project Determination</b>
<b>Estimated Start Date:</b>	11/26/2024
<b>Estimated Completion Date:</b>	11/25/2026
<b>CDC/ATSDR HRPO/IRB Protocol #:</b>	
<b>OMB Control #:</b>	0920-1154

## **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	10/4/24	Leaumont_Collette (chf3) CIO HSC
PRA: PRA Applies		10/4/24	Leaumont_Collette (chf3) OMB/PRA
ICRO: PRA Applies	OMB Approval date: 3/3/23 OMB Expiration date: 3/31/26	10/8/24	Zirger_Jeffrey (wtj5) ICRO Reviewer

## Description & Funding

### Description

Priority: Standard

Date Needed: 10/18/2024

Priority Justification:

CDC Priority Area for this Project: Not selected

Determination Start Date: 09/26/24

**Description:** In 2021, CDC OneLab was developed to bridge, train, and sustain a capacity-building community among laboratory professionals and testers to collectively support rapid, large-scale responses to public health emergencies. CDC OneLab includes the following elements: OneLab REACH, OneLab Network, OneLab TEST, OneLab VR, OneLab Summit, OneLab Resources, and OneLab Assessments. The seven elements together address the goal of building capacity and establishing a sustainable learning community that equips the laboratory workforce and testing community with essential tools and resources to improve public health and patient outcomes.

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

<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>	<p>It is imperative for our program to understand OneLab's overall user experience and training and educational needs to support the planning and creation of future OneLab resources, trainings, and events. Information gleaned from this evaluation will provide rich insights to better understand the effectiveness of the overall OneLab and five out of seven elements (i.e., OneLab REACH, OneLab Network, OneLab TEST, OneLab VR, and OneLab Summit).</p>
<b>Objective:</b>	<p>The objectives of this formative evaluation are to: Understand the overall OneLab user experience and users' experience of each OneLab element to better serve the training and development needs of the laboratory testing community. Identify opportunities to improve OneLab's development and dissemination of relevant and timely education and training resources. Determine the extent to which each OneLab element and OneLab as a whole contribute to the strengthening of partnerships and connections between clinical laboratories, public health laboratories, testing communities, and CDC. Identify opportunities for real-time program improvements for each OneLab element and OneLab as a whole. Determine the extent to which each OneLab element and the OneLab as a whole sustain learning communities that facilitate the exchange of necessary tools, resources, and networks in order to eventually improve public health and patient outcomes.</p>
<b>Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:</b>	No
<b>Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:</b>	Yes
<b>Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:</b>	No
<b>Activities or Tasks:</b>	New Collection of Information, Data, or Biospecimens
<b>Target Populations to be Included/Represented:</b>	General US Population
<b>Tags/Keywords:</b>	Laboratories ; Laboratory Personnel ; Program Evaluation
<b>CDC's Role:</b>	CDC employees or agents will obtain data by intervening or interacting with participants ; CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens
<b>Method Categories:</b>	Focus Group; Individual Interviews (Qualitative)
<b>Methods:</b>	<p>Qualitative data will be collected via focus group interviews and key informant interviews. Focus groups and key informant interviews will be hosted on a virtual video conferencing platform (e.g., Zoom or Microsoft Teams). OneLab focus group interview and key informant interview participants will include varying levels of laboratory working professionals across the US. The maximum anticipated number of participants is 25 for the key informant interviews and 25 for the focus group interviews. The evaluation team will identify participants based on their level of involvement of OneLab elements. Only eligible participants will be invited for either a key informant interview or a focus group interview, which will take participants approximately 97 minutes or 107 minutes,</p>

respectively, to complete. Both key informant interview and focus group interview questions were reviewed by evaluation experts and pilot-tested to collect the minimum information necessary for the purposes of this formative evaluation. Participation in all key informant interviews and focus group interviews will be voluntary. Interview data will be recorded, aggregated and deidentified.

The OneLab qualitative evaluation will collect data from users of the CDC OneLab Initiative, which are US laboratory professionals and individuals who perform testing in non-laboratory settings such as point-of-care sites. All the recruited OneLab users will be interviewed only once either in a focus group or a key Informant interview setting. For the CDC OneLab qualitative data collection, the project team will recruit participants based on their level of involvement in five of the seven OneLab elements (i.e., OneLab REACH, OneLab Network, OneLab TEST, OneLab VR, and OneLab Summit). The inclusion and exclusion criteria will vary based on the group of interest. All participants will be asked about their overall experience as it relates to the initiative as a whole. For OneLab REACH and OneLab VR, the project team will utilize the OneLab REACH course completion list to identify participants. Furthermore, the following inclusion criteria will be used to select participants for OneLab REACH and OneLab VR. OneLab REACH and VR inclusion criteria OneLab REACH: # Must be a laboratory professional or #tester# # an individual who performs testing in non-laboratory settings such as point-of-care sites # Must have completed at least three courses on OneLab REACH in the past six months OneLab VR: # Must be a laboratory professional # Must have completed at least one OneLab VR practice scenario/micro-learning course or explored the OneLab VR #open play# environment for at least 30 minutes in the past six months. For OneLab Network, OneLab Test and OneLab Summit, the project team will utilize registration and attendance lists from the most recent OneLab event to identify the participants. The following inclusion criteria will be used to select participants for OneLab Network, OneLab Test or OneLab Summit. One Network and Test inclusion criteria # Must be a laboratory professional or #tester# # an individual who performs testing in non-laboratory settings such as point-of-care sites # Must have attended at least one event in the past three months OneLab Summit inclusion criteria # Must be a laboratory professional or #tester# # an individual who performs testing in non-laboratory settings such as point-of-care sites # Must have attended the most recent OneLab Summit

#### Collection of Info, Data or Biospecimen:

#### Expected Use of Findings/Results and their impact:

Explore how the overall OneLab increases access to laboratory trainings, resources, materials, and communities of practice among laboratory professionals and the testing community in order to better meet their needs. In addition, the collected data will drive insights to support the planning and creation of future OneLab resources, trainings, and events as well as opportunities to improve OneLab as a whole.

Could Individuals potentially be identified based on Information Collected? No

## Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
Other Federal Funding	OneLab Laboratory Capacity- Building Community	BAC C6M1161101	2021	5	

## HSC Review

---

## HSC Attributes

Program Evaluation

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

<b>Children capable of providing assent</b>	No Selection
<b>Parental permission</b>	No Selection

### **Consent process shown in an understandable language**

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

### **Clinical Trial**

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

### **Other Considerations**

<b>Exception is requested to PHS informing those bested about HIV serostatus</b>	No Selection
<b>Human genetic testing is planned now or in the future</b>	No Selection
<b>Involves long-term storage of identifiable biological specimens</b>	No Selection
<b>Involves a drug, biologic, or device</b>	No Selection
<b>Conducted under an Investigational New Drug exemption or Investigational Device Exemption</b>	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
Amber Broughton	09/18 /2026					Principal Investigator	oev8@cdc.gov	404-498-5815	TRAINING AND WORKFORCE DEVELOPMENT BRANCH
Breyanna Mikel	08/31 /2026					Co-Investigator	qpq5@cdc.gov	404-498-4095	TRAINING AND WORKFORCE DEVELOPMENT BRANCH

## Data

### DMP

**Proposed Data Collection Start Date:** 2/3/25

**Proposed Data Collection End Date:** 2/3/26

**Proposed Public Access Level:** Public

**Public Access Justification:** Project results will be reported publicly in anonymized, aggregated summary form to inform CDC and other public health and clinical laboratory partners. Identifying information for responding laboratories and organizations will not be released to the public.

**How Access Will Be Provided for Data:** Data collected and generated by this project will be transferred and stored to CDC internal servers. All data will be deidentified. Access to qualitative data will be limited to authorized users and will be password protected in order to promote data security and compliance.

**Plans for Archival and Long Term Preservation:** The data will be stored with adequate security measures in adherence to federal records requirements.

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	10/08/2024	NOA 0920-1154 (2023)	Notice of Action	NOA 0920-1154_2023.pdf
Current	Broughton_Amber (oev8) Project Contact	09/26/2024	Email template that will be used for participant recruitment	Other-Email Template	Email Template_InterviewInvitation_IntakeFrom.docx
Current	Broughton_Amber (oev8) Project Contact	09/26/2024	This is the consent form that will be administered to all participants	Consent Form	Focus Groups Consent Form .docx
Current	Broughton_Amber (oev8) Project Contact	09/26/2024	This document is the current draft for the GenIC request for this project.	Other-GenIC Request	CDC OneLab Qual Evaluation _GenIC Request_final draft.docx
Current	Broughton_Amber (oev8) Project Contact	09/26/2024	This form will be used for participant recruitment	Other-Participant Intake Form	Participant Intake Form.docx
Current	Broughton_Amber (oev8) Project Contact	09/26/2024	This document consists of the key informant interview guide for this project	Data Collection Form	CleanVersion_OneLab_Qual Evaluation_ KII Guide.docx
Current	Broughton_Amber (oev8) Project Contact	09/26/2024	This document consists of the focus group interview guide for this project	Data Collection Form	CleanVersion_OneLab_Qual Evaluation_ Focus Group Discussion Guide.docx
Current	Broughton_Amber (oev8) Project Contact	09/26/2024	This document is the supporting statement for the GenIC request	Other-Supporting Statement B	OneLab Qual Evaluation_Supporting Statement B_Final.docx
Current	Broughton_Amber (oev8) Project Contact	09/26/2024	This document is the supporting statement for the GenIC request	Other-Supporting Statement A	OneLab Qual Evaluation_Supporting Statement A_Final.docx



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