

**Request for GenIC Approval**  
**CDC/ATSDR Formative Research and Tool Development**

**0920-1154**

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**CIO:** Office of Laboratory Systems and Response (OLSR), Division of Laboratory Systems (DLS)

**PROJECT TITLE:** CDC OneLab Formative Evaluation

**PURPOSE AND USE OF COLLECTION:**

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.

It's 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).

The objective of this formative evaluation is to gather information to help:

- Understand the overall OneLab user experience and the experience of each OneLab element to better serve the training and development needs among laboratory workforce and testing community.
- Identify opportunities to improve OneLab's development and dissemination of relevant and timely education and training resources.
- Determine how effective each OneLab element and OneLab as a whole contributes 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 how each OneLab element and the OneLab as a whole sustains learning communities that facilitate the exchange of necessary tools, resources, and networks in order to eventually improve public health and patient outcomes.

**DESCRIPTION OF RESPONDENTS:**

The OneLab Qualitative Evaluation will be collecting data from users of the CDC OneLab Initiative, which include varying levels of laboratory working professionals across the US. All the recruited OneLab users will only be interviewed once either in Focus Group setting or a Key Informant Interview setting.

**CERTIFICATION:**

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.

3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. Information gathered will not be used to substantially inform influential policy decisions.
5. The study is not intended to produce results that can be generalized beyond its scope.

Name: Amber Eberhardt

To assist review, please answer the following questions:

**Personally Identifiable Information:**

1. Is personally identifiable information (PII) collected? [ ] Yes [ X ] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [ X ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [ X ] No (Not applicable)

**Gifts or Payments:**

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [ X ] No

## BURDEN HOURS

Category of Respondent	Form Name	No. of Respondents	Participation Time (hours)	Burden in Hours
Individuals or Households	OneLab Key Informant Semi-Structured Interviews	25	97/60	40.4
Individuals or Households	OneLab Focus Group Discussion	25	107/60	44.6
Individuals or Households	Participant Intake Form	50	10/60	8.3
<b>Totals</b>		100		93.3

**FEDERAL COST:** The estimated total annual cost to the Federal government is \$40,927.80. The cost to the federal government includes the salary of CDC staff and contractors to develop the data collection instrument, collect data, and perform data analysis. There are no equipment or overhead costs.

**If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:**

### The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe? ☒ Yes  
☐ No

**If the answer is yes, please provide a description of both below (or attach the sampling plan). If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them.**

For the CDC OneLab Qualitative data collection, the project team will be recruiting participants based on their level of involvement in CDC OneLab and the five out of 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
  - o All participants have to complete at least three courses for the past six months.
  - o Participants need to be identified as active user of OneLab REACH for the past six months.
  - o Must be a laboratory or testing working professional
- OneLab VR
  - o All recruited participants need to complete at least one or two OneLab VR scenarios/micro-learning courses.
  - o Or Participants need to engage at least 30 minutes in OneLab VR open play for the past six months.
  - o Must be a laboratory or testing working professional

For OneLab Network, OneLab Test and OneLab Summit, the project team will utilize a 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.

### **OneLab Network and Test inclusion criteria**

- All participants must attend at least one event in the last three months
- Must be a laboratory or testing working professional

### **OneLab Summit inclusion criteria**

- All participants must have attended the most recent OneLab Summit
- Must be a laboratory or testing working professional

### **Administration of the Instrument**

1. How will you collect the information? (Check all that apply)

☐ Web-based or other forms of Social Media

☐ Telephone

☐ In-person

☐ Mail

☒ Other, Explain (virtual interviews via Microsoft teams or zoom)

2. Will interviewers or facilitators be used? ☒ Yes ☐ No

### **Documentation (Supporting Statements A and B) and Attachments:**

- Attachment 1: OneLab Key Informant Semi-Structured Interview
- Attachment 2: OneLab Focus Group Discussion

- Attachment 3: Emails for OneLab Qualitative Evaluation participants
- Attachment 4: Participant Intake Form
- Attachment 5: Focus Group Consent Form
- Attachment 6: Human Subjects Research Determination