



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

Print Date: 11/8/23

Title: OneLab REACH (Rapid Education And Capacity-Building Hub)

Project Id: 0900f3eb82187e98

Accession #: CLSR-TWDB-6/12/23-87e98

Project Contact: Breyanna M Mikel

Organization: CLSR/DLS/TWDB

Status: **Project In Progress**

Intended Use: **Project Determination**

Estimated Start Date: 11/11/2023

Estimated Completion Date: 11/10/2026

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 <i>45 CFR 46.102(l)</i> Program Evaluation Quality Assurance / Improvement	6/15/23	Hummel_Kimberly B. (kbh2) CIO HSC

PRA: PRA Applies		6/15/23	Hummel_Kimberly B. (kbh2) OMB/PRA
ICRO: PRA Applies	OMB Approval date: 3/3/23 OMB Expiration date: 3/31/26	8/15/23	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Date Needed: 06/27/2023

Determination Start Date: 06/15/23

Description:

CDC OneLab REACH is a targeted and customized learning management system specifically for laboratory and testing professionals. OneLab# REACH offers free public health emergency response relevant education and trainings resources, Continuing Education Units (including P.A.C.E.#), and downloadable materials. OneLab REACH LMS provides trainings and workforce development resources to laboratory professionals that work in communities that are underserved, work with people who are part of minority groups and populations, and work within communities that have very limited access to timely, relevant, and accurate resources. OneLab REACH has the short-term goal of strengthening interconnections between clinical, public health, and CDC laboratory education and training professionals to collectively support rapid, large-scale responses (e.g., MPox, COVID-19, etc.) Further, it has the long-term goal of establishing a sustainable learning community to equip the clinical laboratory workforce with necessary tools, resources, and networks. The evaluation of OneLab REACH aims to determine how well the LMS system is performing, how the resources and materials are accessed and used by laboratory and testing professionals, and whether OneLab REACH is meeting both the short-term and long-term goals.

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

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

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

As the Training and Workforce Development Branch (TWDB) continues to expand the OneLab Initiative, it is apparent that with growth that there is a need to assess and track the progress that each of the elements are making and their respective impact and

Goals/Purpose	<p>outcome. OneLab REACH is no different in that it's imperative to collect, measure, and analyze various data and metrics that help demonstrate the importance and value of the LMS for clinical laboratories, public health laboratories, and the testing community. Particularly, in addressing and meeting the needs and demands that the laboratory and testing workforce have. The evaluation of OneLab REACH has the overarching goal and evaluation question to address how OneLab REACH has increased access to laboratory trainings. The additional goals and supportive evaluation questions consist of 1) determining the extent to which laboratory professionals access and use OneLab REACH, 2) determining the features that users have found most helpful on OneLab REACH when looking for a training course or resource, and 3) determining the extent to which the user's experience can be tailored and improved to meet the needs of laboratory professionals.</p>
Objective:	<p>OneLab REACH as a platform has the ability to increase access to laboratory-focused trainings to members of the laboratory community. The objective of the evaluation is to gain additional knowledge and insight about learners' knowledge, skills, attitudes, and behaviors around accessing and using the platform for training and workforce development needs.</p>
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?:	Yes
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	Yes
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Laboratories ; Laboratory Personnel
CDC's Role:	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
Method Categories:	Survey
Methods:	<p>Several surveys will be disseminated around learners' user experience with the OneLab REACH platform and evaluation surveys around the different resources that live on OneLab REACH.</p> <ol style="list-style-type: none"> 1. LMS Profile #Name, email address, password for LMS access; each learner can only access their own information. PII collected # i.e., names, email addresses, and the associated passwords are administrative data. 2. Single Sign-Up (SSU) Survey Demographic section of the SSU is at least 15 questions long; however, the length of the survey may vary based on the skip logic of questions and how learners respond to the survey. For example, if the learner is a student, performs diagnostic testing, or performs point-of-care testing, then they will be asked several more questions related to the specific type of work that they do. The purpose of the SSU Survey is to reduce the number of sign-up surveys that learners must take for each of the elements of OneLab. The SSU Survey will only be taken once by learners. The anticipated number of new subscribers/respondents is 5,000 for the SSU. The SSU will take approximately 20 minutes to complete. The estimated burden time for the SSU is 1,667 hours per year. 3. Learning Data # Pre-/post-test scores and continuing education (CE) certificates linked to individual LMS Profile; each learner can only access their own information. No behavioral data captured. 4. Anonymous Post-Course Evaluation # Predictors of Effectiveness. The post-course evaluation survey will capture information about the effectiveness and relevancy of the course to the learner. Answers not

Collection of Info, Data or Biospecimen:

linked to individual LMS Profiles. The anticipated number of learners that will complete the post-course evaluation will be 2,000. Learners, on average, take 5 of TWDB#s courses. Each survey will take approximately 3 minutes to complete. The estimated burden time is 500 hours per year. 5. OneLab REACH User Experience Survey # Optional and anonymous survey where learners provide feedback about their experience using OneLab REACH. Answers not linked to individual LMS Profiles. This survey will be administered on a rolling basis once a month. The survey will take approximately 2 minutes to complete. The estimated number of respondents is about 1,000 in a year. The estimated burden time is 33 hours. 6. OneLab REACH Post-Event Survey # Survey that is offered for recordings and live webinars that are hosted on OneLab REACH that learners will complete to provide feedback on the content and speakers of the event. 7. OneLab REACH Mini Lesson and Job Aids Surveys # Survey that is offered and optional for learners to take after using a mini lesson and/or job aid on the OneLab REACH platform. The survey asks about the mini lesson#s and/or job aid#s content, its helpfulness, and its usefulness. 8. OneLab REACH Post Event P.A.C.E.# Survey # Required survey where learners provide feedback about their experience completing a OneLab REACH training for P.A.C.E. # credit. The anticipated number of learners that will complete the post-course evaluation will be 6,000. Learners, on average, take 5 of TWDB#s P.A.C.E. # eligible courses. Each survey will take approximately 3 minutes to complete. The estimated burden time is 1,500 hours per year.

Expected Use of Findings/Results and their impact:

Evaluation data will be reported publicly in anonymized, aggregated summary form. Identifying information will not be released to the public. Post-training survey data and job characteristics survey data will be used to better understand users of OneLab REACH, their needs, and their feedback on available tools, resources, and trainings.

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
Quality Assurance / Improvement 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
Amber Broughton	09/18 /2026				Co-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
Meron Asfaha	03/02 /2026				Co-Investigator	oyi3@cdc.gov	--	DIVISION OF LABORATORY SYSTEMS

Data

DMP

Proposed Data Collection Start Date: 11/11/23

Proposed Data Collection End Date: 11/10/26

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 to address gaps identified in the SSU survey, the course evaluation surveys, the job aid and mini lessons surveys. 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 except for the distribution list populated from demographic entrance survey data # which will not be linked to any of the other data. Access to survey data will be limited to authorized users and will be password protected in order to promote data security and compliance. Supporting documentation will include a data dictionary.

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	08/15/2023	NOA 0920-1154 (2023)	Notice of Action	NOA 0920-1154.pdf
Current	Mikel_Breyanna (qqq5) Project Contact	06/12/2023	The business continuity plan for OneLab REACH.	Other-Enter new type	09_REACH 2021 BCP Waiver_sw.pdf
Current	Mikel_Breyanna (qqq5) Project Contact	06/12/2023	Demographic section of the SSU is at least 15 questions long; however, the length of the survey may vary based on the skip logic of questions and how learners respond to the survey. For example, if the learner is a student, performs diagnostic testing, or performs point-of-care testing, then they will be asked several more questions related to the specific type of work that they do. The purpose of the SSU Survey is to reduce the number of sign-up surveys that learners must take for each of the elements of OneLab. The SSU Survey will only be taken once by learners.	Other-Survey	FINAL_OneLab SSU Survey Clean_v2.docx

Current	Mikel_Breyanna (qqq5) Project Contact	06/12/2023	This attachment is a data collection instrument that asks about the mini lesson#s and/or job aid#s content, its helpfulness, and its usefulness. # Survey that is offered and optional for learners to take after using a mini lesson and /or job aid on the OneLab REACH platform.	Other-Survey	FINAL OneLab Mini Lesson and Job Aid Surveys.docx
Current	Mikel_Breyanna (qqq5) Project Contact	06/12/2023	This file is the SORN/privacy act system notice document for OneLab REACH.	Other-Enter new type	14_REACH 2021 SORN 09-20-0161.pdf
Current	Mikel_Breyanna (qqq5) Project Contact	06/12/2023	This file is the privacy impact assessment (PIA) form for OneLab REACH.	Other-Enter new type	13_REACH 2021 ERAP PIA.pdf
Current	Mikel_Breyanna (qqq5) Project Contact	06/12/2023	This data collection instrument is a survey required for learners interested in obtaining P.A.C.E. credit. Required survey where learners provide feedback about their experience completing a OneLab REACH training for P.A.C. E. # credit.	Other-Survey	FINAL_OneLab REACH PACE Post-Event Survey.docx
Current	Mikel_Breyanna (qqq5) Project Contact	06/12/2023	This data collection instrument will collect information related to Predictors of Effectiveness. The post-course evaluation survey will capture information about the effectiveness and relevancy of the course to the learner. Answers not linked to individual LMS Profiles.	Other-Survey	FINAL OneLab REACH Course Evaluation Survey.docx
Current	Mikel_Breyanna (qqq5) Project Contact	06/12/2023	This file is the authorization to operate (ATO) form for OneLab REACH.	Other-Enter new type	15_Centers-for-Disease-Control-and-Prevention-REACH-2422-CA-09-22-2022-105.pdf
Current	Mikel_Breyanna (qqq5) Project Contact	06/12/2023	This file is the baseline system information (BSI) documentation for OneLab REACH.	Other-Enter new type	11_REACH 2021 ERAP BSI_FINAL.docx
Current	Mikel_Breyanna (qqq5) Project Contact	06/12/2023	This file is the authorization to test (ATT) form for OneLab REACH.	Other-Enter new type	10_REACH 2021 ERAP ATT_sw.pdf



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