

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:<br>Does NOT Require HRPO<br>Review | Not Research / Other<br><i>45 CFR 46.102(1)</i><br>Program Evaluation<br>Quality Assurance / Improvement | 6/15/23   | Hummel_Kimberly B. (kbh2) CIO HSC |
|   |  |           |                                   |

| PRA:<br>PRA Applies         |   | 6/15/23 | Hummel_Kimberly B. (kbh2) OMB/PRA   |
|-----------------------------|---|---------|-------------------------------------|
| ICRO:<br><b>PRA Applies</b> | OMB Approval date: 3/3/23<br>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<br>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  |

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   | 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.   |
|---|--|
| Objective:  | 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.  |
| Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:   | Νο   |
| Does your project investigate underlying<br>contributors to health inequities among populations<br>/groups experiencing social, economic, geographic,<br>and/or environmental disadvantages?: | Yes  |
| Does your project propose, implement, or evaluate<br>an action to move towards eliminating health<br>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:  | 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.  |
|   | 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 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<br>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 No by the CDC IRB, NIOSH IRB, or through reliance on an external IRB?

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 waviers**

| Informed consent for adults                             | No Selection |
|---|--------------|
| Children capable of providing assent                    | No Selection |
| Parental permission                                     | No Selection |
| Alteration of authorization under HIPPA Privacy<br>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<br>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<br>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 identfiable biological specimens                               | No Selection |
| Involves a drug, biologic, or device   | No Selection |
| Conducted under an Investigational New Drug<br>exemption or Investigational Device Exemption | No Selection |

## Institutions & Staff

#### Institutions

Institutions yet to be added .....

### Staff

| Staff<br>Member    | SIQT<br>Exp. Date | CITI Biomedical<br>Exp. Date | CITI Social &<br>Behavioral Exp. Date | CITI Good Clinical<br>Practice Exp. Date | Staff Role          | Email            | Phone                | Organization                                 |
|--------------------|-------------------|------------------------------|---------------------------------------|--|---------------------|------------------|----------------------|--|
| Amber<br>Broughton | 09/18<br>/2026    |                              |                                       |  | Co-<br>Investigator | oev8@cdc.<br>gov | 404-<br>498-<br>5815 | TRAINING AND WORKFORCE<br>DEVELOPMENT BRANCH |
| Breyanna<br>Mikel  | 08/31<br>/2026    |                              |                                       |  | Co-<br>Investigator | qpq5@cdc.<br>gov | 404-<br>498-<br>4095 | TRAINING AND WORKFORCE<br>DEVELOPMENT BRANCH |
| Meron<br>Asfaha    | 03/02<br>/2026    |                              |                                       |  | Co-<br>Investigator | oyi3@cdc.<br>gov |                      | DIVISION OF LABORATORY<br>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<br>laboratory partners to address gaps identified in the SSU survey, the course evaluation surveys, the job aid and mini lessons<br>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     | Dataset                 | Data Publisher | Public Access | Public Access | External   | Download | Type of Data | Collection | Collection End |
|-------------|-------------------------|----------------|---------------|---------------|------------|----------|--------------|------------|----------------|
| Title       | Description             | /Owner         | Level         | Justification | Access URL | URL      | Released     | Start Date | Date           |
| Dataset yet | Dataset yet to be added |                |               |               |            |          |              |            |                |

# Supporting Info

| Current | CDC Staff<br>Member and<br>Role             | Date Added | Description   | Supporting Info Type | Supporting Info                       |
|---------|---|------------|---|----------------------|---------------------------------------|
|         | Zirger_Jeffrey<br>(wtj5)<br>ICRO Reviewer   | 08/15/2023 | NOA 0920-1154 (2023)  | Notice of Action     | NOA 0920-1154.pdf                     |
| Current | Mikel_Breyanna<br>(qpq5)<br>Project Contact | 06/12/2023 | The business continuity plan for<br>OneLab REACH.   | Other-Enter new type | 09_REACH 2021 BCP Waiver_sw.pdf       |
| Current | Mikel_Breyanna<br>(qpq5)<br>Project Contact | 06/12/2023 | Demographic section of the SSU is<br>at least 15 questions long;<br>however, the length of the survey<br>may vary based on the skip logic<br>of questions and how learners<br>respond to the survey. For<br>example, if the learner is a student,<br>performs diagnostic testing, or<br>performs point-of-care testing, then<br>they will be asked several more<br>questions related to the specific<br>type of work that they do. The<br>purpose of the SSU Survey is to<br>reduce the number of sign-up<br>surveys that learners must take for<br>each of the elements of OneLab.<br>The SSU Survey will only be taken<br>once by learners. | Other-Survey         | FINAL_OneLab SSU Survey Clean_v2.docx |

|         | 1   | 1          | 1   | l                    |  |
|---------|---|------------|---|----------------------|--|
| Current | Mikel_Breyanna<br>(qpq5)<br>Project Contact | 06/12/2023 | This attachment is a data<br>collection instrument that asks<br>about the mini lesson#s and/or job<br>aid#s content, its helpfulness, and<br>its usefulness. # Survey that is<br>offered and optional for learners to<br>take after using a mini lesson and<br>/or job aid on the OneLab REACH<br>platform. | Other-Survey         | FINAL OneLab Mini Lesson and Job Aid Surveys.docx                                  |
| Current | Mikel_Breyanna<br>(qpq5)<br>Project Contact | 06/12/2023 | This file is the SORN/privacy act<br>system notice document for<br>OneLab REACH.  | Other-Enter new type | 14_REACH 2021 SORN 09-20-0161.pdf  |
| Current | Mikel_Breyanna<br>(qpq5)<br>Project Contact | 06/12/2023 | This file is the privacy impact<br>assessment (PIA) form for OneLab<br>REACH.   | Other-Enter new type | 13_REACH 2021 ERAP PIA.pdf   |
| Current | Mikel_Breyanna<br>(qpq5)<br>Project Contact | 06/12/2023 | This data collection instrument is a<br>survey required for learners<br>interested in obtaining P.A.C.E.<br>credit. Required survey where<br>learners provide feedback about<br>their experience completing a<br>OneLab REACH training for P.A.C.<br>E. # credit.   | Other-Survey         | FINAL_OneLab REACH PACE Post-Event Survey.docx                                     |
| Current | Mikel_Breyanna<br>(qpq5)<br>Project Contact | 06/12/2023 | This data collection instrument will<br>collect information related to<br>Predictors of Effectiveness. The<br>post-course evaluation survey will<br>capture information about the<br>effectiveness and relevancy of the<br>course to the learner. Answers not<br>linked to individual LMS Profiles.         | Other-Survey         | FINAL OneLab REACH Course Evaluation Survey.docx                                   |
| Current | Mikel_Breyanna<br>(qpq5)<br>Project Contact | 06/12/2023 | This file is the authorization to<br>operate (ATO) form for OneLab<br>REACH.  | Other-Enter new type | 15_Centers-for-Disease-Control-and-Prevention-REACH-<br>2422-CA-09-22-2022-105.pdf |
| Current | Mikel_Breyanna<br>(qpq5)<br>Project Contact | 06/12/2023 | This file is the baseline system<br>information (BSI) documentation<br>for OneLab REACH.  | Other-Enter new type | 11_REACH 2021 ERAP BSI_FINAL.docx  |
| Current | Mikel_Breyanna<br>(qpq5)<br>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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