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

Print Date: *11/6/24*

Title:	Development of Biosafety Community of a Biosafety Community of Practice Based on the ECHO Methodology
Project Id:	0900f3eb8246906f
Accession #:	CLSR-QSSB-10/11/24-6906f
Project Contact:	Aufraconselia C Araujo
Organization:	CLSR/DLS/QSSB
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	10/11/2024
Estimated Completion Date:	12/31/2026
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-1050

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Program Evaluation	10/22/24	Leaumont_Collette (chf3) CIO HSC
PRA: **PRA Applies**		10/22/24	Leaumont_Collette (chf3) OMB/PRA
ICRO: **PRA Applies**	OMB Approval date: 6/28/22 OMB Expiration date: 6/30/25	10/23/24	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Priority Justification:

CDC Priority Area for this Project: Not selected

Determination Start Date: 10/11/24

Description: Clinical and public health laboratories play an essential role to protect the health of individuals and their communities. Laboratory quality and safety standards and procedures are required to conduct accurate and timely testing without jeopardizing the health of laboratory employees, staff, the environment, or the public. Lessons learned from past outbreaks and discussions with the Association of Public Health Laboratories# Biosafety and Biosecurity Committee highlighted opportunities for improvement in biosafety areas including risk assessment and management; specimen collection, processing, and storage; equipment and instrumentation safety; personal protective equipment; waste management; and employee burnout. In 2024, the focus is on implementation of biorisk Management in laboratories (ISO 35001) and in 2025 the focus will be on other general biosafety topics such as Best Practices in Biosafety and Biosecurity for Bioterrorism Response and The role of Artificial Intelligence in Biosafety.

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 this project is to develop a biosafety community of practice (CoP) based on the Extension for Community Healthcare Outcomes (ECHO) methodology to address biosafety challenges in clinical and public health laboratories.
Objective:	# Discuss biosafety challenges among clinical laboratory professionals # Decrease professional isolation by fostering collaborations and sharing of laboratory safety expertise # Promote application of best safety practices and advance culture and practice of laboratory safety
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:	No Human Population ; Other - Laboratory Professionals
Tags/Keywords:	Biosafety ; Risk Assessment ; Laboratories ; Project ECHO
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:	Survey
Methods:	This project#s objectives include bringing together clinical and public health laboratory professionals, biosafety officers, quality managers, laboratory directors, scientists, and technicians in order to 1) discuss biosafety challenges among clinical laboratory professionals, 2) decrease professional isolation by fostering collaborations and sharing of laboratory safety expertise, and 3) promote application of best safety practices and advance culture and practice of laboratory safety. CDC/DLS will accomplish the project#s goals through development of Biosafety Community of Practice based on ECHO Methodology. This community of practice will bring together the above personnel from multiple locations and facilities to meet at regularly schedule times to present de-identified cases, experiences, and/or lessons learned in regard to the application of biosafety across various laboratory settings. Case-based discussion are supplemented with a short didactic presentation to provide context, increase knowledge, and share evidence-based practices. Following each group discussion, surveys will be used to evaluate the current session and improve future ones. ECHO participants will be identified through collaboration with the Association for Public Health Laboratories (APHL) and invited via email. Participants in ECHO session engage a community of peers to present cases for discussion and recommendations. Through sharing, the community offers support, guidance, and feedback. As a result, participants increase knowledge and competency, reduce professional isolation, and increase the application of best safety practices.

Collection of Info, Data or Biospecimen:	The OLSR/DLS Biosafety ECHO project lead will facilitate ECHO sessions with non-federal stakeholders: subject matter experts (SMEs), low-resource (e.g., rural) laboratories, state/local public health laboratory professionals, commercial laboratories, and laboratory professional organizations (e.g., American Biological Safety Association). We will conduct a total of eleven sessions and will invite no more than 100 participants per session. The participants will be invited by OLSR/DLS based on laboratory safety experience in clinical and public health laboratories and willingness to discuss the challenges encountered. During ECHO sessions, a laboratory SME will deliver a brief didactic presentation followed by a case study on the topic and participants will discuss the laboratory safety challenges, share their experience and propose solutions. Participants will be informed that ECHO sessions will be recorded. Audio and transcript of each session will be available at the DLS ECHO webpage. Data collection will occur through three surveys (during ECHO session registration, immediately after each session, and six-month after sessions one and six) for session evaluation and to assess participants# potential application of knowledge acquired post ECHO sessions. Personally identifiable information (PII) or protected health information (PHI) is not collected in any form during ECHO sessions or the three surveys.
Expected Use of Findings/Results and their impact:	Findings will demonstrate participation and engagement of state/local public health laboratory professionals to discuss biosafety challenges, increase professional networking, improve use of best safety practices and advance culture and practice of laboratory safety. Audio and a transcript of each session will have PII removed and be made available at the DLS ECHO webpage. Summary of feedback obtained post-sessions will be compiled in aggregated report without any identifiable information about the participants or their organizations. Lessons learned and key findings from session evaluation will be used to inform the development of presentations internal to CDC programs, and potentially be presented, at professional conferences or disseminated as s a peer-reviewed manuscript.
Could Individuals potentially be identified based on Information Collected?	No

Funding

Funding yet to be added .....

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 waviers

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 identfiable 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? Yes

Institution	FWA #	FWA Exp Date	Funding	Funding Restriction Amount
University of Niew Mexico Health Sciences Project ECHO			Non-Financial Support	

Institution	Funding Restriction Percentage	Funding Restriction Reason	Funding Restriction has been Lifted
University of Niew Mexico Health Sciences Project ECHO			

Institution	Institution Role(s)	Institution Project Title	Institution Project Tracking #	Prime Institution
University of Niew Mexico Health Sciences Project ECHO	Providing Technical Assistance	Project ECHO Biosafety Laboratory Challenges		

Institution	Regulatory Coverage	IRB Review Status
University of Niew Mexico Health Sciences Project ECHO	IRB Review is Not Required	

Institution	Registered IRB	IRB Registration Exp. Date	IRB Approval Status
University of Niew Mexico Health Sciences Project ECHO			

Institution	IRB Approval Date	IRB Approval Exp. Date	Relying Institution IRB
University of Niew Mexico Health Sciences Project ECHO			

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
Alicia Violette	07/17/2026					Co-Investigator	sho6@cdc.gov	404-498-0080	DIVISION OF LABORATORY SYSTEMS
Ashley Marshall	07/10/2026		02/25/2022			Co-Investigator	isg6@cdc.gov	404-639-7202	DIVISION OF LABORATORY SYSTEMS
George Xiang	10/04/2026					Co-Investigator	obn1@cdc.gov	404-498-5423	DIVISION OF LABORATORY SYSTEMS
Sabrina DeBose	08/23/2026					Project Coordinator	sof7@cdc.gov	404-718-2062	QUALITY AND SAFETY SYSTEMS BRANCH

Data

DMP

Proposed Data Collection Start Date: 10/11/24

Proposed Data Collection End Date: 12/31/26

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - The demographics information and session evaluation feedback will not be released to protect participants privacy and confidentiality. Answers will be anonymized and reported only in aggregate form.

Public Access Justification: Reason for Restricting the Data: The demographics information and session evaluation feedback from the participants will not be released for public to protect their privacy and confidentiality. Respondents# individual answers will be anonymized and reported publicly only in aggregate form.

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 and will not be linked to any of the other identifiable data. Access to questionnaire data will be limited to authorized users and will be password protected in order to promote data security and privacy. Supporting resources will include a data dictionary.

Plans for Archival and Long Term Preservation:	The anonymous, deidentified survey data will be initially retained on DLS#s password protected Qualtrics account. The data will be downloaded onto CDC internal servers and deleted from Qualtrics at least every two months throughout the network#s existence. 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	10/23/2024	NOA 0920-1050 (2022)	Notice of Action	NOA 0920-1050_2022.pdf
	Araujo_Aufraconselia A. (aka8) Project Contact	10/21/2024	Survey Instruments	Other	02_Biosafety_2025 ECHO_Survey_Screenshots_Compiled_AUG2024.docx
	Araujo_Aufraconselia A. (aka8) Project Contact	10/21/2024	Request for Approval Form	Other	01_Fast_Track_GenIC_Request Template for 2025 ECHO Biosafety_AUG2024.docx
	Araujo_Aufraconselia A. (aka8) Project Contact	10/21/2024	Survey Invitation Email Messages	Other	03_Biosafety_2025 ECHO Biosafety_Emails_AUG2024.docx
Current	Araujo_Aufraconselia A. (aka8) Project Contact	10/11/2024	PAPERWORK REDUCTION ACT SUBMISSION WORKSHEET	Data Collection Form	01497 Form_Fast Track GenIC Part 2 Worksheet_2025 Project ECHO Biosafety Community of Practice.pdf