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

Print Date: 8/2/23

Title:	Clinical Laboratory Partners Forum Meeting Evaluation Survey 2023
Project Id:	0900f3eb821c4c1a
Accession #:	CLSR-DLS-7/25/23-c4c1a
Project Contact:	Kunthea Nhim
Organization:	CLSR/DLS
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	09/25/2023
Estimated Completion Date:	11/30/2023
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	7/26/23	Hummel_Kimberly B. (kbh2) CIO HSC
PRA:			

PRA Applies		7/26/23	Hummel_Kimberly B. (kbh2) OMB/PRA
ICRO: **PRA Applies**	OMB Approval date: 6/28/22 OMB Expiration date: 6/30/25	7/28/23	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Determination Start Date:	07/25/23
Description:	This information collection is being conducted to examine the effectiveness of the September 25, 2023 Meeting for the Clinical Laboratory Partners Forum (CLPF), a group of laboratory professional, standard-setting, and accreditation organizations that meets periodically to share information and focus on clinical and public health laboratory partnerships, particularly as related to preparedness and response, laboratory workforce, biosafety, and patient safety and diagnostic excellence. The Division of Laboratory Systems at the Centers for Disease Control and Prevention, who periodically convenes this group or organizations, is seeking feedback from participants to assess the effectiveness and relevance of the September 25, 2023, meeting, in an effort to ensure that meetings of this group are managed effectively and focused on issues of current importance to clinical and public health laboratories.
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
Goals/Purpose	DLS is seeking feedback from participants to assess the effectiveness and relevance of the September 25, 2023 meeting in an effort to ensure that the meetings of this group are managed effectively and focused on issues of current importance to clinical and public health laboratories.
Objective:	This survey will collect participant feedback to assess 1) How useful CLPF is to participants, 2) the effectiveness of the topics and format, and 3) the planning and organization of future meetings.
Does this project include interventions, services, or	No

policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	
Project does not incorporate elements of health equity science:	Yes
Measuring Disparities:	Not Selected
Studying Social Determinants of Health (SDOH):	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	Other - Clinical laboratory professionals
Tags/Keywords:	Clinical Laboratory Services
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:	Quantitative and qualitative data collection using an online survey will be conducted with clinical and public health laboratory professionals. Thematic analysis will be performed for the data collected to inform the effectiveness and relevance of the 2023 Clinical Laboratory Partners Forum. No biospecimens will be collected.
Collection of Info, Data or Biospecimen:	Quantitative and qualitative data will be collected using an online survey. No personally identifiable information will be collected. Descriptive and thematic analysis will be conducted. All results will be in aggregate form, without attribution to any person, to preserve the anonymity of respondents.
Expected Use of Findings/Results and their impact:	The end results will be a comprehensive report that summarizes survey data findings and key takeaways. DLS will conduct quantitative and qualitative analysis to describe findings and generate themes based on collected data. DLS staff will receive briefings on the report, which will be used to inform future planning and organization strategies for CLPF.
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 be submitted to the IRB office	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 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 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

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
Kunthea Nhim	02/15/2024				Program Lead	xmh8@cdc.gov	404-502-1139	DIVISION OF LABORATORY SYSTEMS

Data

DMP

Proposed Data Collection Start Date:	9/26/23
Proposed Data Collection End Date:	11/30/23
Proposed Public Access Level:	Non-Public

Non-Public Details:

Reason For Not Releasing Data:	Other - Data will be for CDC and DLS internal use to inform the meeting's effectiveness.
Public Access Justification:	Information will be used by CDC and DLS internally and will not be released publicly.
How Access Will Be Provided for Data:	The anonymous, deidentified data will be retained on DLS internal SharePoint site so that only authorized staff are permitted access. The data will be stored with adequate security measures in compliance with CDC requirements and adherence with federal records requirements.
Plans for Archival and Long Term Preservation:	Plans for Archival and Long-term Preservation of the Data.

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	07/28/2023	NOA 0920-1050 (2022)	Notice of Action	NOA 0920-1050_2022.pdf
	Nhim_Kunthea (xmh8) Project Contact	07/26/2023	This is the PRA worksheet for the GenIC we used in the previous year with updates on number of respondents for this year.	Paperwork Reduction Act Form	04_Part 2 Worksheet 2022 CLPF Meeting Survey_09-25-2023.pdf
	Nhim_Kunthea (xmh8) Project Contact	07/26/2023	This is email communications that will be used to reach out to the respondents.	Other	03_Invitation to participate September 25 2023 CLPF meeting evaluation survey_Final.docx
	Nhim_Kunthea (xmh8) Project Contact	07/26/2023	This is the Fast Track GenIC form that we have used in the previous year.	Paperwork Reduction Act Form	01_Fast_Track_GenIC_Request_2023.9.25 CLPF Meeting Survey_Clean Final.docx
	Nhim_Kunthea				

Current	(xmh8) Project Contact	07/25/2023	Screenshots of online survey instruments.	Data Collection Form	02_CLPF Meeting Evaluation Survey_2023.09.25 in Qualtrics.docx