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

Print Date: 12/12/23

Title:	Project Firstline Continuing Ed 3-week Follow-up Amendment 1
Project Id:	0900f3eb82275f1d
Accession #:	CSELS-ODSIO-11/9/20-2d49d
Project Contact:	Jessica M Waechter
Organization:	NCEZID/DHQP
Status:	**Pending Regulatory Clearance : Amendment**
Intended Use:	**Project Determination**
Estimated Start Date:	11/23/2020
Estimated Completion Date:	05/31/2026
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-1071

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Quality Assurance / Improvement	11/24/23	Peterson_James M. (iyr1) CIO HSC
PRA:			

PRA Applies		11/27/23	Vice_Rudith (nhr9) OMB / PRA
HRPO: **Concur**		11/12/20	Cope_James R. (voz4) HRPO Reviewer
ICRO: **PRA Applies**	OMB Approval date: 5/10/21 OMB Expiration date: 5/31/24	11/28/23	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Date Needed: 11/12/2020

Determination Start Date: 11/16/23

Description: Project Firstline#s goal is to provide necessary infection prevention and control (IPC) knowledge to prevent transmission of COVID-19 in healthcare settings and thereby ensure the safety of frontline healthcare personnel and patients. Through partnership between Project Firstline and CDC#s Education & Training Services Branch (ETSB), Project Firstline videos are available for both formal training for continuing education (CE) credit and informal viewing (not for CE). Anyone viewing these videos are provided an opportunity to complete a post-training evaluation, but only those pursuing CEs are required to complete a survey. Those obtaining CE#s are also offered an opportunity to complete a follow-up survey 3 weeks after receipt of CEs, but this is voluntary. These trainings are slated to launch by the end of November.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission: Yes

IMS Activation Name: 2019 Novel Coronavirus Response

Primary Priority of the Project: Protection of healthcare personnel and patients

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

TCEO currently administers a standard twenty-one question post-training survey as a required step for receiving CE credit as well as a six-question follow-up survey to all CE recipients 3 weeks after receiving CE credit. We propose adding five brief questions to the post-training survey and three brief questions to the standard survey instrument, to understand better (1) the outcomes of the training and (2) ongoing awareness of Project Firstline as a program, (3) demographic characteristics of participants, and (4)

Goals/Purpose	perceived value and improved understanding of participants. The standard follow-up survey will remain unchanged for non-Project Firstline trainees. Those who view the Project Firstline videos informally (not for CE credit) are provided an opportunity to complete a post-survey that consists of the same 5 add-on questions used in the TCEO survey described in paragraph above. TCEO#s standard 21 question survey is not included (only applies to those pursuing CEs). This information will inform programmatic decisions to improve this and future Project Firstline activities. Describe efforts to minimize duplication across CDC and other U.S. government agencies: This data collection is specific to experiences with the implementation of Project Firstline. Since Project Firstline is a new initiative and these are brand new trainings developed in response to COVID-19, information on trainee impressions do not exist elsewhere at CDC or within other U.S. government agencies and will not be collected by others.
Objective:	The purpose of this specific data collection is to understand who attended the training (professional role/setting, geographic location), whether they found the information to be of value, whether their understanding of the topic improved, and how trainees have used what they learned from the training and if they have pursued additional information about infection control. This information will be used by the program to identify areas for improvement, such as modifying training content or informing subsequent Project Firstline activities, to better provide infection control training to frontline healthcare personnel during the COVID response.
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?:	Yes
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	Healthcare Provider
Tags/Keywords:	Infection Control ; Infection control and prevention ; Training Support ; Program Evaluation ; IMS Task Force
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:	To ensure quality of the project, the proposed data collection efforts will be led by CDC. CDC is developing the questions to use in data collection and will be responsible for analyzing data. CDC is also responsible for using the findings to inform training development in the midst of the COVID-19 response. Statistical methods have not been reviewed. The data will be analyzed using basic descriptive statistics. There is no plan to generalize findings. Findings will be used for program reporting and to inform ongoing internal CDC decisions on training content and delivery. Data will be collected via CDC#s TRAIN and TCEO systems.CDC#s TCEO system currently administers a standard twenty-one question post-training survey as a required step for receiving CE credit as well as a six-question follow-up survey to all CE recipients 3 weeks after receiving CE credit. We propose adding five brief questions to the post-training survey and three brief questions to the standard survey instrument, to understand better specific aspects of Project Firstline that are not captured in the standard follow-up survey. The standard follow-up survey will remain unchanged for non-Project Firstline trainees. Participation is

Collection of Info, Data or Biospecimen:	voluntary. CDC will receive and analyze the data, using basic descriptive statistics. Findings will be used for monitoring and improvement purposes. No PII will be collected for this specific data collection. TCEO might capture and house PII for training and registration purposes, but, again, PII is not part of this specific data collection and will not be used for analyses described here. The exact burden estimate will depend on the number of trainees viewing Project Firstline videos (either formally for CE credit or informally). We estimate 3,000 survey completions annually for those viewing for CE and a survey completion time of 5 minutes, resulting in 250 burden hours annually. We estimate 25,000 participants will view PFL videos informally and choose to complete an evaluation, and a survey completion time of 2 minutes, resulting in 833 burden hours annually.
Expected Use of Findings/Results and their impact:	Findings will be used for program reporting and to inform ongoing internal CDC decisions on training content and delivery.
Could Individuals potentially be identified based on Information Collected?	No

Funding

Funding yet to be added .....

HSC Review

HSC Attributes

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 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

Will you be working with an outside Organization or Institution? No

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
Margaret Paek	08/31/2026		09/07/2021		Co-Investigator	kvz3@cdc.gov	404-718-6423	OD Science/Informatics Office

Data

DMP

Proposed Data Collection Start Date: 11/23/20

Proposed Data Collection End Date: 5/31/26

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - This information is intended to inform project implementation and is not intended for public distribution.

Public Access Justification: This information is intended to inform project implementation and is not intended for public distribution.

How Access Will Be Provided for Data: CDC's TCEO system will provide the project team with the data. We do not intend to collect or store PII.

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

No Supporting Info

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