



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

Print Date: 12/12/24

Title: Evaluating Content and Usability of CDCs Clinical Heat Guidance Amendment 1

Project Id: 0900f3eb8249c338

Accession #: -NCEH-2/12/24-049a4

Project Contact: Laura C Seeff

Organization: NCEH/ATSDR

Status: **Pending Regulatory Clearance : Amendment**

Intended Use: **Project Determination**

Estimated Start Date: 01/06/2025

Estimated Completion Date: 02/01/2026

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> Quality Assurance / Improvement	12/12/24	Ding_Yan (Shirley) (yad6) CIO HSC
PRA: PRA Applies		12/12/24	Ding_Yan (Shirley) (yad6) CIO OMB / PRA
ICRO: PRA Applies	OMB Approval date: 6/13/23 OMB Expiration date: 6/30/26	12/12/24	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Date Needed: 12/20/2024

Priority Justification:

CDC Priority Area for this Project: Readiness and Response

Determination Start Date: 11/19/24

Description:

The impact of heat on our health has been included as one of the priority risks associated with CDC's 2024 priority - #Readiness and Response to Health Threats. Extreme heat presents a growing concern as the frequency and intensity of extreme heat events continue to increase each year, with the heat season beginning earlier each year. Extreme heat is associated with increased morbidity and mortality for all persons, and particularly among certain more sensitive populations. Public health heat resilience planning has not traditionally engaged the healthcare delivery system, a system well positioned to help protect those most at risk from heat. In addition, clear and simple guidance has not been widely available for clinicians, patients, and the general public to enable planning ahead for heat protection before the start of the heat season. In response to this public health need, in April 2024, CDC released first-ever heat-related clinical guidance to help clinicians counsel patients on preventing health harms from heat for individuals at increased risk from heat, such as children with asthma, pregnant women, and adults with cardiovascular disease, and for the general public. A pilot project was approved in April 2024 to obtain feedback from 9 CHC clinicians on the materials pre-release and refine the materials accordingly. This amendment seeks approval to conduct a survey of all 1,496 CHCs across the nation on their use of the clinical heat guidance since the April 2024 release during summer 2024, the hottest summer ever recorded. Approval of this project will allow CDC to: 1. Assess how and to what extent CHCs have used CDC's new clinical heat guidance. 2. Assess the content and usability of the clinical heat guidance in supporting CHC efforts to reduce the impact of heat on their patients' health. 3. Identify barriers, facilitators, and areas of need and support for CHCs in using CDC's new clinical heat guidance.

IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure

No

Submission:

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 goal of this overall initiative is to reduce the impact of heat on the health of patients. The specific goal associated with this amendment request is assess content and usability of the heat guidance that was released in April 2024 through survey the nations 1,496 CHCs on their use of the guidance. The purpose of the data collection is to: 1. Assess how and to what extent CHCs have used CDC's new clinical heat guidance. 2. Assess the content and usability of the clinical heat guidance in supporting CHC efforts to reduce the impact of heat on their patients' health. 3. Identify barriers, facilitators, and areas of need and support for CHCs in using CDC's new clinical heat guidance.

Objective:

The objective of this project is to gain an understanding of the perceived effectiveness and utility of CDC's clinical heat guidance and support the development and improvement of future clinical heat guidance materials and products.

Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?: Yes

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: Programmatic Work

Target Populations to be Included/Represented: Healthcare Provider

Tags/Keywords: Extreme Heat ; Anticipatory Guidance

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 ; CDC employees or agents will obtain data by intervening or interacting with participants ; CDC is NOT a recipient or provider of private data, specimens, materials or services ; CDC is providing funding

Method Categories: Survey

Methods:

CDC/NCEH will work with the National Center for Farmworker Health (NCFH) and the National Association of Community Health Centers (NACHC) to survey the nation's 1,496 Community Health Centers on their use of CDC's heat guidance released April 2024 designed for help clinicians reduce the impact of heat in the health of their patients. CDC, in partnership with NCFH and NACHC, will administer a 37-question CDC and NCFH-designed survey to clinicians and non-clinicians at CHCs for content and usability testing of CDC's Clinical Heat Guidance. This evaluation will use qualitative and quantitative data collection methods to assess the design and use of CDC's web-based heat guidance materials. Additionally, the survey will gather audience knowledge, attitudes, and beliefs (KABs), perceptions of campaign asset products, and clinic and clinician specialty characteristics. NCFH/CDC will deploy the electronic survey over a three-week period to capture responses about CDC's heat and health guidance. A target sample size of 1000 of the total 1,496 CHCs was informed by the parameters required to achieve a margin of error of 5% or less at a 95% confidence interval for 33 percent of the overall sample. The estimated proportion of survey respondents who are familiar with the materials being tested is one in three (33%). With a sample size of 1,000, 330 respondents are estimated to be familiar with the CDC materials. Among these 330 respondents, the margin of error is 4.76%, given an overall sample size of 1,000 and a universe of 1,496 health centers. G*Power was used to calculate an a priori sample size for additional power analysis needed to assess the message effects and variances in scores within each of two groups: those familiar with the resources and those unfamiliar with the resources. To conduct t-tests to detect a moderate effect size ($\eta^2=0.2$), with 95% confidence ($\alpha=0.05$), a minimum sample size of 262 (for the familiar group) or approximately 845 survey participants will be needed. Due to the likelihood of having some missing data on some questions, this number was rounded up to 1,000 participants needed. Each participant will acknowledge consent prior to beginning the survey response.

Collection of Info, Data or Biospecimen:

Feedback on the guidance will be collected via a survey to clinicians and non-clinician clinic staff at the nation's 1,496 CHCs, targeting a sample size of 1,000.

Expected Use of Findings/Results and their impact:

Information obtained will be used to gain an understanding of the perceived effectiveness and utility of CDC's clinical heat guidance and support the development and improvement of future clinical heat guidance materials and products.

Could Individuals potentially be identified based on Information Collected?

No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Contract	Project Management for Environmental Issues	GS00F045DA	2021	1	135000.00

HSC Review

HSC Attributes

Quality Assurance / Improvement

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 wavers

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 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

Will you be working with an outside Organization or Institution? Yes

Institution	FWA #	FWA Exp Date	Funding	Funding Restriction Amount
Guidehouse LLP	FWA00028885	08/28/28	GS00F045DA - GS00F045DA	

Institution	Funding Restriction Percentage	Funding Restriction Reason	Funding Restriction has been Lifted
Guidehouse LLP			

Institution	Institution Role(s)	Institution Project Title	Institution Project Tracking #	Prime Institution
Guidehouse LLP	Intervening or Interacting with Human Subjects; Providing Technical Assistance; Obtaining, Storing or Transferring Non-Identifiable Private Information or Non-Identifiable Biospecimens; Recruiting Subjects			

Institution	Regulatory Coverage	IRB Review Status
Guidehouse LLP	IRB Review is Not Required	

Institution	Registered IRB	IRB Registration Exp. Date	IRB Approval Status
Guidehouse LLP			

Institution	IRB Approval Date	IRB Approval Exp. Date	Relying Institution IRB
Guidehouse LLP			

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
Ambarish Vaidyanathan	08/28 /2026	12/30/2022	12/30/2022	12/30/2022		Project Coordinator	dvq3@cdc.gov	770-488-3997	CLIMATE AND HEALTH BRANCH
Laura Seeff	08/31 /2026					Project Coordinator	lvs3@cdc.gov	404-639-7063	OD
Paul Schramm	08/02 /2026					Project Coordinator	imw3@cdc.gov	770-488-6	DIVISION OF ENVIRONMENTAL HEALTH SCIENCE AND PRACTICE
Shubhayu Saha	04/17 /2026	11/26/2021	11/28/2021			Project Coordinator	hsf5@cdc.gov	770-488-0783	CLIMATE AND HEALTH BRANCH

Data

DMP

Proposed Data Collection Start Date: 1/6/25

Proposed Data Collection End Date: 1/24/25

Proposed Public Access Level: Public, Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - Since the survey is collecting information to inform program evaluation, and not public health outcomes, the raw data themselves are #non-public#

Public Access Justification:

Data will be both public and non-public. The survey collecting program evaluation data that will help us improve customer service for heat guidance users. De-identified aggregate level data from the data collection will be shared publicly in reports and publications in an effort to highlight lessons learned, barriers to use of guidance, and best practices.

Data will be collected via an online survey (see Attachment 1 # Survey Instrument and Attachment 2 # Programmed Survey) in a Qualtrics platform Fedramp approved and hosted by the National Association for Community Health Centers, a subcontractor to the CoAg recipient. Respondents will be recruited through a notification (see Attachment 3 # Recruitment Email) to the respondent

universe (see Attachment 6 # Respondent Universe) via email. The email notification will explain: # The purpose of the data collection, and why their participation is important; # Instructions for participating; # Method to safeguard their responses; # That participation is voluntary; # The expected time to complete the instrument; # Contact information for the project team; and # Information on how to receive token of appreciation with email address. The email notification will include a survey link, where each participant will submit responses. The survey will be fielded for up to 3 weeks to ensure respondents have sufficient time to respond. Participants will receive up to one reminder email each week (i.e., up to three emails in total) (see Attachments 4 and 5). Survey invites will be sent to all CHCs to either the CMO or the CEO, who will be instructed to identify the staff person most knowledgeable or familiar with the topic (which could be the initial CMO or CEO recipient themselves) with guidance to complete the survey if relevant to the recipient and to send the survey to complete and distribute to any other relevant staff to complete. Survey responses will be tracked by census region towards a total response of 1,000 surveys. Regions will be closed before the 3-week period if necessary if responses reach 1,000. Survey respondents will receive an electronic gift card in compensation for their time to complete the survey. Emails for recipients to receive the e-gift will be provided by respondents will be encrypted, stored in a separate data base from the survey results, and destroyed as soon as e-gift cards are sent. After the raw survey data are downloaded from the Qualtrics platform, the project team will use MS Excel software for data processing and cleaning, and SPSS statistical software for the analysis. Each variable will be clearly named and labeled, and each will be properly identified by type (e.g., Likert-type variables designated as interval variables). The data set cleaning procedures will include independent review of data set creation to ensure accuracy. The data will be password protected and stored in a secure environment maintained by the contractor.

How Access Will Be Provided for Data:

An encrypted and de-identified data set will be made available to CDC after the initial data analysis is conducted in early 2025 by the cooperative agreement recipient, so that CDC may be able to link survey results on use of CDC heat guidance to weather data (looking at hottest months of the year) and use of the CDC-NOAA HeatRisk tool. Once available, a link to the archived data with a description of when, how and by whom the data can be accessed will be shared, in compliance with all laws, regulations, and rights regarding data storage, privacy, and long-term preservation.

Plans for Archival and Long Term Preservation:

Spatiality

Country	State/Province	County/Region
United States		

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	12/12/2024	NOA 0920-1154 (2023)	Notice of Action	NOA 0920-1154_2023.pdf
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	Recruitment flyer	Participant Information Form	Attachment 7. Recruitment Flyer.png
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	Recruitment and reminder emails	Participant Information Form	Attachments 4-6 - Recruitment, Reminder and Final Reminder Emails_11.18.24.docx
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	participant worksheet for non physicians	Other	Att 11 Worksheet non-physician users.pdf
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	participant worksheet - physicians	Other	Att 10 Worksheet physician users.pdf
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	Survey Instrument	Data Collection Form	Attachment 1. CDC Clinical Heat Guidance Survey Instrument, Heat Eval for GenIC 1154 - 11.15.24.docx
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	example of programmed survey	Data Collection Form	Attachement 3. Example of Programmed Survey Heat and Health Eval - for GenIC 1154 -11.18.24.PNG
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	Programmed Survey	Data Collection Form	Attachment 2. Programmed CDC-Heat_Guidance Survey Flow - for Heat Eval GenIC 1154 - 11.18,24.docx
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	SSB for Eval of CDCs Clinical Heat Guidance - GenIC1154	Paperwork Reduction Act Form	SSB - for CDC Clinical Heat Guidance Eval - GenIC 1154 -11.18.24.docx
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	SSA for Eval of CDCs Clinical Heat Guidance - GenIC 1154	Paperwork Reduction Act Form	SSA - for CDC Clinical Heat Guidance Eval - GenIC 1154 - 11.18.24.docx
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	Recruitment flyer	Participant Information Form	Attachment 7. Recruitment Flyer.png
	Seeff_Laura C.				Attachments 4-6 - Recruitment, Reminder and Final

	(lvs3) Project Contact	12/06/2024	Recruitment and reminder emails	Participant Information Form	Reminder Emails_11.18.24.docx
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	participant worksheet for non physicians	Other	Att 11 Worksheet non-physician users.pdf
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	participant worksheet - physicians	Other	Att 10 Worksheet physician users.pdf
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	Survey Instrument	Data Collection Form	Attachment 1. CDC Clinical Heat Guidance Survey Instrument, Heat Eval for GenIC 1154 - 11.15.24.docx
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	example of programmed survey	Data Collection Form	Attachement 3. Example of Programmed Survey Heat and Health Eval - for GenIC 1154 -11.18.24.PNG
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	Programmed Survey	Data Collection Form	Attachment 2. Programmed CDC-Heat_Guidance Survey Flow - for Heat Eval GenIC 1154 - 11.18,24.docx
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	SSB for Eval of CDCs Clinical Heat Guidance - GenIC1154	Paperwork Reduction Act Form	SSB - for CDC Clinical Heat Guidance Eval - GenIC 1154 -11.18.24.docx
	Seeff_Laura C. (lvs3) Project Contact	12/06/2024	SSA for Eval of CDCs Clinical Heat Guidance - GenIC 1154	Paperwork Reduction Act Form	SSA - for CDC Clinical Heat Guidance Eval - GenIC 1154 - 11.18.24.docx
Current	Seeff_Laura C. (lvs3) Project Contact	11/19/2024	SSA	Paperwork Reduction Act Form, 0.1260 Request to End Review of Human Research Studies	SSA - for CDC Clinical Heat Guidance Eval - GenIC 1154 - 11.18.24.docx
	Seeff_Laura C. (lvs3) Project Contact	11/19/2024	Recruitment flyer	Participant Information Form	Attachment 7. Recruitment Flyer.png
	Seeff_Laura C. (lvs3) Project Contact	11/19/2024	Recruitment and reminder emails	Participant Information Form	Attachments 4-6 - Recruitment, Reminder and Final Reminder Emails_11.18.24.docx
	Seeff_Laura C. (lvs3) Project Contact	11/19/2024	participant worksheet for non physicians	Other	Att 11 Worksheet non-physician users.pdf
	Seeff_Laura C. (lvs3) Project Contact	11/19/2024	participant worksheet - physicians	Other	Att 10 Worksheet physician users.pdf

	Seeff_Laura C. (lvs3) Project Contact	11/19/2024	Survey Instrument	Data Collection Form	Attachment 1. CDC Clinical Heat Guidance Survey Instrument, Heat Eval for GenIC 1154 - 11.15.24.docx
	Seeff_Laura C. (lvs3) Project Contact	11/19/2024	example of programmed survey	Data Collection Form	Attachement 3. Example of Programmed Survey Heat and Health Eval - for GenIC 1154 -11.18.24.PNG
	Seeff_Laura C. (lvs3) Project Contact	11/19/2024	Programmed Survey	Data Collection Form	Attachment 2. Programmed CDC-Heat_Guidance Survey Flow - for Heat Eval GenIC 1154 - 11.18,24.docx
	Seeff_Laura C. (lvs3) Project Contact	11/19/2024	SSB for Eval of CDCs Clinical Heat Guidance - GenIC1154	Paperwork Reduction Act Form	SSB - for CDC Clinical Heat Guidance Eval - GenIC 1154 -11.18.24.docx
	Seeff_Laura C. (lvs3) Project Contact	11/19/2024	SSA for Eval of CDCs Clinical Heat Guidance - GenIC 1154	Paperwork Reduction Act Form	SSA - for CDC Clinical Heat Guidance Eval - GenIC 1154 - 11.18.24.docx
	Green_Donata (dqg7) Project Contact	02/14/2024	Draft Heat and Health pregnant people guidance	Other	DRAFT Heat and Health Pregnant People Guidance.docx
	Green_Donata (dqg7) Project Contact	02/14/2024	Draft moderators guide	Other	Draft Moderators Discussion Guide Heat_Health.docx
	Green_Donata (dqg7) Project Contact	02/14/2024	Draft Heat and Health Asthma guidance	Other	DRAFT Heat and Health Asthma Guidance.docx
	Green_Donata (dqg7) Project Contact	02/14/2024	Draft Heat and Health CVD guidance	Other	DRAFT Heat and Health CVD Guidance.docx
	Green_Donata (dqg7) Project Contact	02/14/2024	One pager description of the moderators guide and the discussion session format.	Other	Pilot Heat and Health Initiative One Pager (Description of Guide and Session Format).docx
	Green_Donata (dqg7) Project Contact	02/14/2024	One pager of the description of the moderators guide and the discussion group format.	Other	Pilot Heat and Health Initiative Project Determination Consent Form.docx



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