



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

Print Date: 7/18/22

Title: National Environmental Assessment Reporting System (NEARS) OMB Package

Project Id: 0900f3eb81ecc76a

Accession #: NCEH-FT-1/25/22-72adc

Project Contact: Erin D Moritz

Organization: NCEH/ATSDR/DEHSP/WFEHSB/FT

Status: Pending Regulatory Clearance

Intended Use: Project Determination

Estimated Start Date: 09/01/2022

Estimated Completion Date: 08/31/2025

CDC/ATSDR HRPO/IRB Protocol #: N/A

OMB Control #: 0920-0980

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other <i>45 CFR 46.102(1)</i> Quality Assurance / Improvement	3/25/22	Abel_Jason A. (jza5) CIO HSC
PRA:			

Description & Funding

Description

Priority: Standard

Date Needed: 04/08/2022

Determination Start Date: 03/25/22

Description: This package requests a three-year Paperwork Reduction Act (PRA) clearance for the National Environmental Assessment Reporting System (NEARS), OMB Control No. 0920-0980, Expiration Date: 08/31/2022. This includes revision of a previously approved information collection request (ICR).

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 The goal of NEARS is to continue to improve public health practice by providing a standardized, detailed reporting system for food safety programs, to collect foodborne outbreak environmental assessment data, and to establish a sound epidemiological basis for disease prevention activities.

Objective: The foodborne outbreak environmental assessment data reported to NEARS will be used to characterize data on food vehicles and monitor trends; identify contributing factors and their environmental antecedents; generate hypotheses, guide planning, and implementation; evaluate food safety programs; and ultimately assist to prevent future outbreaks.

Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?: No

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: Businesses

Tags/Keywords: Foodborne Diseases ; Outbreak investigation ; Public Health Surveillance

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 will participate as co-authors in presentation(s) or publication(s) ; CDC employees will provide substantial technical assistance or oversight ; CDC is providing funding

Method Categories: Individual Interviews (Qualitative); Observation; Outbreak Investigation; Technical Assistance

Methods: During foodborne illness outbreak investigations, environmental health specialists collect detailed environmental data by conducting environmental assessments. These data identify how and why the food became contaminated with pathogens, and how and why these pathogens were not eliminated before ingestion. When reported to CDC via NEARS, this information provides an opportunity to systematically monitor and evaluate environmental factors, which can then be used to develop effective foodborne illness outbreak response and preventative controls.

Collection of Info, Data or Biospecimen: Data from foodborne outbreak environmental assessments are collected by environmental health professionals responding to foodborne outbreaks at retail food establishments. Data are collected through direct observations at the establishment, and through manager interviews or pen-and-paper at the establishment. Participating food safety programs then enter their data into a secured web-based system designed to make data entry easy for respondents.

Expected Use of Findings/Results and their impact: The information collected through NEARS is primarily used by the CDC to identify and understand environmental factors (contributing factors and environmental antecedents) associated with foodborne illness outbreaks. Data collected through NEARS will also be used to describe outbreaks and outbreak responses, describe environmental factors associated with outbreaks, and describe the associations between environmental antecedents and specific contributing factors.

Could Individuals potentially be identified based on Information Collected? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Environmental Health Specialists Network	RFA-EH-20-001	2020	5	1540700.00

HSC Review

HSC Attributes

Quality Assurance / Improvement 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 wavers

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 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

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
Adam Kramer	04/05 /2025		12/31/2022		Co-Investigator		404-498-1228	FOOD
Beth Wittry	12/29 /2023		12/19/2021		Co-Investigator		770-488-7333	FOOD
Erin Mortiz	12/27 /2024		12/31/2021		Co-Investigator	nrj8@cdc.gov	404-498-2756	FOOD
Laura Brown	01/25 /2025		12/20/2021		Principal Investigator		770-488-2	WATER FOOD AND ENVIRONMENTAL HEALTH SERVICES BRANCH

Data

DMP

Proposed Data Collection Start Date: 9/1/22

Proposed Data Collection End Date: 8/31/25

Proposed Public Access Level: Public

Public Access Justification: Data will be released publicly with each publication.

How Access Will Be Provided for Data: Datasets will be release on the CDC Stacks Public Health Publications website. The sites of the food safety program will be de-identified and free text reviewed to ensure it contains no identifying information available for the restaurant or program. All data are stored behind the CDC firewall.

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

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Moritz_Erin (nrj8) PRA Reviewer	07/15/2022	Zip file containing the revised 30 day FRN and ICR and supporting documents.	Paperwork Reduction Act Form	NEARS OMB Submitted 7-15-22.zip
	Davis_Stephanie I. (sgd8) PRA Reviewer	07/12/2022	Zipfile of NEARS 30D FRN and Revision ICR. Please address comments and revisions. Add attachments marked PLACEHOLDER. I have edited the burden table to include NEARS	Paperwork Reduction Act Form	NEARS 30D FRN ICR rev OS.zip

			registration to match the NCEZID DFVED OES PIA system description.		
	Moritz_Erin (nrj8) PRA Reviewer	07/07/2022	Zip file containing the 30 day FRN and ICR for the NEARS surveillance system.	Paperwork Reduction Act Form	NEARS OMB Submitted 7722.zip
	Davis_Stephanie I. (sgd8) PRA Reviewer	06/24/2022	Zipfile of 30D FRN and ICR reviewed with comments from OS	Paperwork Reduction Act Form	Files rev OS.zip
	Moritz_Erin (nrj8) PRA Reviewer	06/22/2022	Compressed file includes supporting statements A and B, relevant attachments, the 30-day FRN, and burden worksheets.	Paperwork Reduction Act Form	NEARS OMB Submitted 06222022.zip
	Davis_Stephanie I. (sgd8) PRA Reviewer	05/09/2022	30D FRN publication request and revision ICR files with OS comments to address.	Paperwork Reduction Act Form	Files rev OS.zip
Current	Moritz_Erin (nrj8) Project Contact	04/27/2022	The updated compressed file contains: Supporting Statement A, Supporting Statement B, attachments and appendix documents, the 30 day FRN, and the 30 day FRN Publication Request Form.	Paperwork Reduction Act Form	Submit to STARS 04272022.zip
	Moritz_Erin (nrj8) Project Contact	03/17/2022	Compressed file contains: Supporting Statement A, Supporting Statement B, 10 attachments (including the 60 day FRN [Attachment 3]), and the 60 day FRN Publication Request Form.	Paperwork Reduction Act Form	NEARS OMB Package.zip

