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

Print Date: 3/11/21

Title:	NCEHATSDR Service Delivery (Generic Clearance)
Project Id:	0900f3eb81cc43d8
Accession #:	-NCEH-3/10/21-c43d8
Project Contact:	Abel_Jason A. (jza5)
Organization:	NCEH/ATSDR
Status:	**Pending Regulatory Clearance**
Intended Use:	**Project Determination**
Estimated Start Date:	02/01/2022
Estimated Completion Date:	01/31/2025
CDC/ATSDR HRPO/IRB Protocol #:	NA
OMB Control #:	0923-0047

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Program Evaluation Quality Assurance / Improvement Other - Service Delivery and Program Improvement	3/11/21	Davis_Stephanie I. (sgd8) CIO HSC

PRA: **PRA Applies**		3/11/21	Davis_Stephanie I. (sgd8) CIO OMB / PRA

Description & Funding

Description

Priority:	Standard
Determination Start Date:	03/10/21
Description:	This is a request to publish the 60-day Federal Register Notice for ATSDR #Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery# (OMB Control No. 0923-0047; expiration date 01/31/2022). The information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Federal government#s commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study.
IMS/CIO/Epi-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
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.
Objective:	The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency#s services will be unavailable.
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Feedback

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 employees or agents will obtain or use anonymous or unlinked data or biological specimens, CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens, CDC employees will participate as co-authors in presentation(s) or publication(s), CDC employees will provide substantial technical assistance or oversight
Method Categories:	Discussion Group; Focus Group; Individual Interviews (Qualitative); Needs Assessment; QA/QI
Methods:	ATSDR will only submit a collection for approval under this generic clearance if it meets the following conditions: # The collections are voluntary; # The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government; # The collections are noncontroversial and do not raise issues of concern to other Federal agencies; # Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; # Personally identifiable information (PII) is collected only to the extent necessary and is not retained; # Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency (if released, the agency must indicate the qualitative nature of the information); # Information gathered will not be used for the purpose of substantially informing influential policy decisions; and # Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.
Collection of Info, Data or Biospecimen:	The types of collections that this generic clearance covers include, but are not limited to: # Customer comment cards/complaint forms # Small discussion groups # Focus Groups of customers, potential customers, delivery partners, or other stakeholders # Cognitive laboratory studies, such as those used to refine questions or assess usability of a website; # Qualitative customer satisfaction surveys (e.g., post-transaction surveys; opt-out web surveys) # In-person observation testing (e.g., website or software usability tests)
Expected Use of Findings/Results:	The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency#s services will be unavailable.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers?	Yes
Is an assurance of confidentiality in place or planned?	No
Is a certificate of confidentiality in place or planned?	No
Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award
Other-Staff time only - $0	Staff time only - $0			

HSC Review

HSC Attributes

Program Evaluation Yes

Quality Assurance / Improvement Yes

Other - Service Delivery and Program Improvement Yes

Additional Ethical Considerations

Resulting data collected are not published but will be used to improve agency products.

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children

Population - Minors

Population - Prisoners

Population - Pregnant Women

Population - Emancipated Minors

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
Stephanie Davis	02/22 /2024	10/24/2021	08/03/2021	08/15/2014	Data Use Contact	sgd8@cdc.gov	770-488-3676	NATIONAL CENTER FOR ENVIRONMENTAL HEALTH

Data

DMP

Proposed Data Collection Start Date:	2/1/22
Proposed Data Collection End Date:	1/31/25
Proposed Public Access Level:	Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - Quality improvement for ATSDR services

Public Access Justification: This is a generic IC request to allow gathering of feedback on services provided by ATSDR for the purposes of quality improvement.

How Access Will Be Provided for Data: Data will be used by ATSDR to evaluate and improve services.

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...									