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

Print Date: 6/27/24

Title: Minimal Data Necessary for Case Data During an Emergency Response

Project Id: 0900f3eb823d1eac

Accession #: OPHDST-SO-6/24/24-cfcec

Project Contact: Kim Gadsden-knowles

Organization: OPHDST/SARR/SO

Status: **Pending Regulatory Clearance**

Intended Use: **Project Determination**

Estimated Start Date: 09/30/2024

Estimated Completion Date: 09/30/2027

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #:

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	6/25/24	Broussard_Cheryl S. (gnp2) Human Subjects Coordinator
PRA: **PRA Applies**		6/25/24	Broussard_Cheryl S. (gnp2) OMB/PRA Coordinator

Description & Funding

Description

Priority:	Higher Priority
Date Needed:	07/05/2024
Priority Justification:	The determination is needed by 6/28/2024 so that it can be attached to the new Generic Clearance for the Collection of MDN that will be submitted to ICRO and then to OMB for approval.
CDC Priority Area for this Project:	Readiness and Response
Determination Start Date:	06/25/24
Description:	The Minimal Data Necessary (MDN) for Case Data During an Emergency Response project is specifically designed to collect the MDN and response-specific data as needed, for confirmed, probable, and suspected cases of any disease or condition that is the subject of an emergency response at CDC. During an emergency response, CDC uses case data from State, tribal, local, and territorial (STLT) health departments to inform actions that need to be taken at all levels of public health and by the public. STLT health departments and CDC need to exchange data on confirmed, probable, and suspected cases rapidly. Timely notification of cases from STLT to CDC is critical to provide situational awareness at the federal level to support decision making, particularly for public health threats that escalate quickly and cross jurisdictions. Case data from 60 STLT health departments will be collected for the duration of each emergency response. The 60 STLT jurisdictions include: public health departments in every U.S. state, New York City, Washington DC, 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and 3 freely associated states (Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
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	To allow, state, tribal, local, and territorial (STLT) health departments and CDC to exchange data on confirmed, probable, and suspected cases rapidly during a public health emergency response.

Objective:	To collect the minimum data necessary for confirmed, probable, and suspected cases of any disease or condition that is the subject of an emergency response.
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?:	No
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	No
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	Other - Case data are submitted from 60 STLT jurisdictions. See description
Tags/Keywords:	Public Health Surveillance ; Disease Notification ; readiness and response
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:	Surveillance Support; Technical Assistance
Methods:	No statistical sampling methods are used. Public health departments review, process, analyze and voluntarily submit case data to CDC.
Collection of Info, Data or Biospecimen:	Case data will be sent to CDC by STLT health departments through Data Collation and Integration for Public Health Event Response (DCIPHER). DCIPHER is a secure, scalable tool used to collate, prepare, analyze, and visualize. DCIPHER can connect to virtually any system or data source, enabling data integration agnostic of source or format, and providing near real-time insights into public health problems. While DCIPHER will be the main data collection tool used to collect case data during emergency responses, jurisdictions may use other automated or non-automated mechanisms to send case data to CDC under very limited circumstances. The mechanisms include but are not limited to fax, email, secure file upload, and data entry to a secure website.
Expected Use of Findings/Results and their impact:	Data will be used for ongoing situational awareness and to monitor the occurrence and spread of the disease or condition. Other uses may include identifying populations or geographic areas at high risk; planning prevention and control programs and policies; and allocating resources appropriately. The data may also be used by CDC to obtain travel histories and other information to describe and manage outbreaks and conduct public health follow-up to minimize the spread of disease.
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 (including coded data)?:	Yes
Is this project covered by an Assurance of Confidentiality?	No

Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	No
Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding yet to be added .....

HSC Review

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 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 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
Sarah Rodriguez	02/21/2027				Project Coordinator	xqn3@cdc.gov	703-459-4830	DETECT AND MONITOR DIVISION

Data

DMP

Proposed Data Collection Start Date:	9/30/24
Proposed Data Collection End Date:	9/29/27
Proposed Public Access Level:	Public

Public Access Justification:	Aggregate case data from each emergency response may be available to the public on https://cdc.data.gov and https://data.gov.
How Access Will Be Provided for Data:	Case data will be stored in DCIPHER. DCIPHER is a cloud-based platform used across CDC, by other federal partners, and by STLTbpublic health jurisdictions to collect, collate, share, and link multiple sources of public health, outbreak, and event response data. It is designed to facilitate data interpretation and to inform public health decisions. DCIPHER operates in a FedRAMP-approved cloud environment and receives continuous deployment, upgrades, and patching. Personally identifiable information (PII) is collected, and information can be retrieved by PII. However, information is not retrieved by PII. Jurisdictions remove most PII before data are submitted to CDC, but some data elements (e.g., date of birth, date of diagnosis, county of residence) could potentially be combined with other information to identify individuals. Privacy is protected in several ways. https://cdc.data.gov, and https://data.gov only provide summary statistics of aggregate data to their users. https://cdc.data.gov is also subject to and have met CDC#s Security Assessment and Authorization (SA&A) process through CDC#s Office of the Chief Information Officer (OCIO). Only public use, non-PII data in the form of summary statistics are uploaded to https://cdc.data.gov per OCIO#s policy.
Plans for Archival and Long Term Preservation:	Case data are kept by the CDC as an historical public health record, per CDC's "Scientific and Research Project Records Control Schedule", section 1a ("Authorized Disposition: PERMANENT"). Records Schedule N1-442-09-1.

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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