



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

Print Date: 4/14/22

Title: National Notifiable Diseases Surveillance System

Project Id: 0900f3eb81eee7aa

Accession #: -CSELS-4/14/22-ee7aa

Project Contact: Kim Gadsden-knowles

Organization: CSELS

Status: **Project In Progress**

Intended Use: **Project Determination**

Estimated Start Date: 04/18/2022

Estimated Completion Date: 05/31/2025

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0920-0728

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(l)(2)</i>	4/14/22	Ayers_Tracy (eyk6) CIO HSC
PRA: PRA Applies		4/14/22	Ayers_Tracy (eyk6) OMB/PRA

ICRO: PRA Applies	OMB Approval date: 3/16/21 OMB Expiration date: 3/31/24	4/14/22	Zirger_Jeffrey (wtj5) ICRO Reviewer
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Description & Funding

Description

Priority:	Urgent
Date Needed:	04/18/2022
Priority Justification:	The determination is needed by 4/18/2022 so that it can be attached to the NNDSS PRA Revision that will be submitted to ICRO and OMB.
Determination Start Date:	04/14/22
Description:	The Public Health Services Act (42 U.S.C. 241) authorizes CDC to disseminate nationally notifiable condition information. The National Notifiable Diseases Surveillance System (NNDSS) is based on data collected at the state, territorial and local levels because of legislation and regulations in those jurisdictions that require health care providers, medical laboratories, and other entities to submit health-related data on reportable conditions to public health departments. These reportable conditions, which include infectious and non-infectious diseases, vary by jurisdiction depending upon each jurisdiction's health priorities and needs. Each year, the Council of State and Territorial Epidemiologists (CSTE), supported by CDC, determines which reportable conditions should be designated nationally notifiable or under standardized surveillance. The NNDSS currently facilitates the submission and aggregation of case notification data voluntarily submitted to CDC from 60 jurisdictions: 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). This information is shared across jurisdictional boundaries and both surveillance and prevention and control activities are coordinated at regional and national levels.
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
	To provide the official source of statistics in the United States for nationally notifiable conditions. Data will be used to monitor the

Goals/Purpose	occurrence and spread of nationally notifiable conditions.
Objective:	To collect case notifications (electronically, by email, and by fax) for nationally notifiable conditions from public health departments in every U.S. state, New York City, Washington DC, 5 U.S. territories, and 3 freely associated states for public health surveillance. PRA applies. This data collection is covered by OMB# 0920-0728, National Notifiable Diseases Surveillance System. The NNDSS data collection and use is non-research; it is for public health surveillance / public health practice. The purpose of NNDSS is to prevent or control disease and improve health, or to improve a public health program or service. NNDSS is focused on controlling health problems in the population from which the information is gathered.
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:	Not Selected
Measuring Disparities:	Yes
Studying Social Determinants of Health (SDOH):	Yes
SDOH Economic Stability:	Yes
SDOH Education:	Not Selected
SDOH Health Care Access:	Not Selected
SDOH Neighborhood and Environment:	Not Selected
SDOH Social and Community Context:	Not Selected
SDOH Indices:	Not Selected
Other SDOH Topics:	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:	Other - Case notifications are submitted from 60 jurisdictions. See details in description.
Tags/Keywords:	Public Health Surveillance ; Disease Notification ; Nationally Notifiable Conditions
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 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:	Surveillance Support; Technical Assistance

Methods:	No statistical sampling methods are used. Public health departments review, process and analyze reportable conditions data and voluntarily submit case notification data on nationally notifiable conditions to CDC. The Council of State and Territorial Epidemiologists (CSTE), local, state, and territorial health departments and CDC work jointly to decide which conditions are nationally notifiable and added to NNDSS.
Collection of Info, Data or Biospecimen:	Over 90% of case notifications are sent to CDC by automated electronic Health Level 7 (HL7) or National Electronic Telecommunications System for Surveillance (NETSS) messaging. Some case notification messages are sent to CDC by nonautomated mechanisms including fax, email, secure file upload, and data entry to a secure website. These different mechanisms used to send case notifications to CDC vary by the jurisdiction and disease or condition. All 50 states, all cities (New York City and Washington, D.C.) and one territory (Puerto Rico) submit STD case notifications (STD case notifications account for approximately 87% of all case notifications received by CDC) by automated electronic messaging. Most territories and all freely associated states send STD case notifications by non-automated methods including fax (only quarterly aggregate data are sent by fax), email, secure file upload, and data entry to a secure website.
Expected Use of Findings/Results and their impact:	Data are used by CDC subject matter experts to monitor the occurrence of the conditions, identify populations or geographic areas at high risk, plan prevention and control programs and policies, allocate resources appropriately, and evaluate the effectiveness of programs and policies. The data are also used by CDC to trace cases and their contacts, 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 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 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 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

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #

Council of State and Territorial Epidemiologists					
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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
Kim Gadsden-knowles	02/10 /2024				Project Coordinator		404-498-0355	CENTER FOR SURVEILLANCE EPIDEMIOLOGY AND LABORATORY SERVICES

Data

DMP

Proposed Data Collection Start Date: 4/18/22

Proposed Data Collection End Date: 5/31/25

Proposed Public Access Level: Public

Public Access Justification: For certain nationally notifiable conditions, CDC releases national data to the public through CDC's web-based query system known as CDC WONDER (<http://wonder.cdc.gov/>). NNDSS data are also published on Data.CDC.gov (<https://data.cdc.gov/>) and DATA.GOV (<http://www.data.gov/>).

How Access Will Be Provided for Data: Privacy is protected in a number of ways. CDC WONDER, Data.CDC.gov, and DATA.GOV only provide summary statistics of aggregate data to their users. Data for CDC WONDER are produced by CDC programs, which have already stripped the data of all PII before providing these public-use data sets to CDC WONDER. Furthermore, CDC WONDER dynamically imposes privacy and suppression constraints on all query results sets produced by the CDC WONDER web application, in compliance with each data set's specific data use policy. CDC WONDER and Data.CDC.gov are also subject to and have met CDC's Security Assessment and Authorization (SA&A) process, in which the CDC WONDER constraints are examined and validated by the CDC's Office of the Chief Information Security Officer (OCISO). Only public use, non-PII data in the form of summary statistics are uploaded to Data.CDC.gov per OCISO policy. In addition, NNDSS data published on Data.CDC.gov are also published on DATA.GOV.

Plans for Archival and Long Term Preservation: NNDSS data are kept by the CDC as a 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...									

