Project Determination

Sudden Unexpected Infant Death (SUID) and Death in the Young (SDY) Case Registry

Project ID:	0900f3eb81fccd1e
Accession #:	NCCDPHP-PIHT-9/8/22-ccd1e
Project Contact:	Carri Cottengim
Organization:	NCCDPHP/DRH/MIHB/PIHT
Status:	Project In Progress
Intended Use:	Project Determination
Estimated Start Date:	04/30/22
Estimated Completion Date:	09/30/30
CDC/ATSDR HRPO/IRB Protocol#:	
OMB Control#:	0920-1092

Description

Priority

Standard

Date Needed

01/09/23

Determination Start Date

09/08/22

Description

The Sudden Unexpected Infant Death (SUID) and Death in the Young (SDY) Case Registry is a CDC Division or Reproductive Health surveillance program. The Case Registry improves and standardizes information about sudden death so recipients can better understand incidence and risk factors. Information collection and reporting builds on existing, state-based procedures for Child Death Review (CDR). Through their existing CDR programs, recipients already conduct surveillance and use the National Fatality Review-Case Reporting System (NFR-CRS). CDC funding provides technical assistance to these programs so they can improve their

case ascertainment, data quality and timeliness of the data. All recipients of the current multi-component NOFO (DP18-1806) compile complete and timely data for an estimated 1000 cases per year, on a defined set of SUID and SDY questions and abstract the data into the NFR-CRS, run through the Michigan Public Health Institute's (MPHI) National Center for Fatality Review and Prevention (NCFRP) program. Data is abstracted into the NFR-CRS by states/jurisdictions using primary data sources, including medical examiner/coroner reports, death investigation reports, medical records, and child protective services records. For approximately 370 of these cases per year, recipient jurisdictions funded for the SDY component conduct activities that are outside of their normal CDR programs. First, they convene an advanced review team with relevant clinical expertise, including state health personnel, pediatric cardiologists, pediatric neurologists or epileptologists, and forensic pathologists. Next, they comprehensively review individual case information from multiple data sources, discuss the information, and use the information to classify cases according to a standardized algorithm that differentiates causes of death. Finally, they report the additional information from these advanced case reviews into an SDY module of the NFR-CRS. These specific SDY activities, which are a subset of the overall program, require OMB approval (OMB No. 0920-1092). In FY2023, a new 5-year multi-component NOFO (DP23-2306) will continue the work and fund new applicants to participate in the SUID and SDY Case Registry. In addition to continuing the SUID and SDY Case Registry activities described above, recipients of the new funding opportunity will improve consistent abstraction of variables related to SDoH (e.g. housing insecurity) and apply a health equity lens to data analysis to inform prevention strategies, including identifying and addressing disproportionately impacted communities. Also, as part of a new component in FY23, some recipients can choose to apply to develop and implement prevention strategies to reduce disparities in incidence of SUID within jurisdictions. This is non-research public health surveillance program to establish the incidence of SUID and SDY in funded jurisdictions, and in FY23 develop and implement prevention activities. CDC will provide technical assistance, receiving de-identified data for quality assurance activities and surveillance reports. OMB approval under the Paperwork Reduction Act has been received (OMB No. 0920-1092) for the additional SDY activities which include a clinical discussion of already available data and data entry from this review into a module that has been added on the NFR-CRS in order to capture information from the advanced review. These activities are outside of regular child death

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

No

IMS Activation Name

Not selected

Select the primary priority of the project

Not selected

Select the secondary priority(s) of the project

Not selected

Select the 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 SUID and SDY Case Registry gathers information to learn more about young people who die suddenly and unexpectedly. Babies, children, and young adults up to age 20 are included in the SUID and SDY Case Registry.

Objective

The objectives of the SUID and SDY Case Registry surveillance program are to gather and store information about sudden child deaths to help to 1) count the number and types of sudden deaths in babies, children and young adults up to age 20, 2) try to understand the causes and risk factors for the deaths, 3) see if some children are more at risk of dying than others, and 4) find ways to prevent these deaths. Data is shared with CDC, who uses the data to provide technical assistance to improve completeness (including missing and unknown responses) and timeliness of completed cases. The SUID and SDY Case Registry program improves and standardizes case ascertainment so that funded states/local jurisdictions can improve understanding of the incidence and risk factors for sudden death. SUID and SDY Case Registry data informs our understanding of the epidemiology of SUID and SDY, including the incidence, disparities, and risk factors. These data elements are used to inform prevention strategies as well as develop best practices for surveillance of SUID and SDY. Additionally, the new FY2023 will further address racial/ethnic and socioeconomic disparities by improving abstracted data and understanding of SDoH and the effect on SUID/SDY incidence which will guide prevention in funded jurisdictions. In a subset of recipients this includes the development and implementation of prevention strategies to reduce infant deaths using compiled data and American Academy of Pediatrics recommendations.

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?

Yes

Project does not incorporate elements of health equity science

Not selected

Measuring Disparities

Not selected

Studying Social Determinants of Health (SDOH)

Yes

SDOH Economic Stability

Yes

SDOH Education

Yes

SDOH Health Care Access

Yes

SDOH Neighborhood and Environment

Yes

SDOH Social and Community Context

Yes

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 Population to be Included/Represented

General US Population; Children; American Indian or Alaska Native; Asian; Black or African American; Hispanic or Latino; Native Hawaiian or Other Pacific Islander; White; Female; Male-

Tags/Keywords

Infant Mortality; Child Mortality

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

Methods

Information collection and reporting for the SUID and SDY Case Registry builds on existing state-based procedures for Child Death Review (CDR) who already abstract data into the National Fatality Review-Case Reporting System (NFR-CRS) about each case using existing data sources. CDC funds help recipients improve this process. All data for the Case Registry is shared with CDC, from the NFR-CRS, who uses the data to provide technical assistance to improve completeness (including missing and unknown responses) and timeliness of completed cases. Recipients participating in the SDY component, also compile data on a defined set of SDY questions and enter them into the existing SDY module that is part of the existing NFR-CRS. For approximately 370 SDY cases, recipient jurisdictions convene an advanced review team with relevant clinical expertise. The advanced review team comprehensively reviews information from multiple existing data

sources, discusses the information and uses the information to classify cases according to a standardized algorithm that differentiates causes. All the additional information from these advanced case reviews including the classification of the death is entered into the SDY module. The FY23 NOFO will include these same methods with the addition of a subset of recipients using their existing data to develop and implement prevention strategies to reduce infant deaths and share lessons learned.

Collection of Info, Data, or Bio specimens

Through their existing CDR programs, recipients already conduct surveillance and use the National Fatality Review-Case Reporting System (NFR-CRS). CDC funding provides technical assistance to these programs so they can improve their case ascertainment, data quality and timeliness of the data. Current practice is to abstract data about each death from primary data sources, including medical examiner/coroner reports, death investigation reports, medical records, and child protective services records. It is then entered into the web-based NFR-CRS. For the Case Registry no PII is shared with CDC. De-identified data is shared with CDC who uses the data to provide technical assistance to improve completeness (including missing and unknown responses) and timeliness of completed cases and for surveillance reports. The only new data collection as a result of this project is the specific SDY activities listed above, which are a subset of the overall program, and have OMB approval (OMB No. 0920-1092).

Expected Use of Findings/Results and their impact

CDC shares findings with recipients and works with them by providing technical assistance to improve data over time. Data analyses beyond quality improvement analyses conducted by CDC are determined by the recipients. Recipients use their data to develop targeted prevention strategies to reduce the number of infant and childhood deaths. Data elements are used to establish incidence of SUID and SDY, inform prevention strategies and develop best practices for multi-state surveillance of SUID and SDY. The data is made available externally via request, researchers can request data for analyses. The FY23 NOFO will include developing and disseminating prevention tools and resources that will help other recipients use their own Registry data, findings, and recommendations to identify gaps and barriers in health and social service systems and local policies that propagate racial/ethnic disparities in sleep-related deaths.

Could Individuals potentially be identified based on Information Collected?

No

Funding

Funding Type	Funding Title	Funding #	Original Fiscal Year	# of Years of Award	Budget Amount
CDC Cooperative Agreement	SUID and SDY Case Registry (new)	DP23-2306	2023	5	3600000.00
CDC Cooperative Agreement	SUID and SDY Case Registry	DP18-1806	2018	5	2200000.00

HSC Review

Regulation and Policy

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

Institutions

Institution	FWA #	FWA Exp. Date	IRB Title	IRB Exp. Date	Funding #

Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
Work Sfty Hlth Tm 2 EOC	10/25/2025				Project Officer	eocwsh2@cdc.gov		EMERGENCY OPERATIONS CENTER

DMP

Proposed Data Collection Start Date	09/29/18
Proposed Data Collection End Date	09/30/30
Proposed Public Access Level	Restricted
Data Use Type	Research Data Center
Data Use Type Data Use Type URL	www.keepingkidsalive.org
Data Use Contact	acollier@mphi.org
Public Access justification	A public use data set is not generated because the data is governed by data use agreements between NCFRP and individual states and these agreements allow only for data sharing to researchers who apply to use the data.
How Access Will Be Provided for Data	Data can be requested using the following link https://www.ncfrp.org/resources/data-dissemination/ Researchers must be affiliated with eligible Receiving Institutions (i.e., an institution of higher education, research organization, non-profit agency or government agency that either

	employs or contracts with the Investigator). The Institution must be registered with the U.S. Office for Human Research Protections. Any release of data will be subject to a signed Contract for Access to and Use of Data (Contract for Data) between NCFRP and an authorized representative of the Receiving Institution. An Application for De-identified Dataset must identify a principal investigator (PI). The PI serves as the primary point of contact for all communications involving the Contract for Data. The PI must sign the Contract for Data, by which the PI assumes responsibility for compliance with all terms of the Contract for Data by employees of the Receiving Institution, including the day-to-day security of the electronic data and all printed output derived from the files. Each additional researcher who will have access to the NCFRP dataset must be identified on the Application for Data and must sign a Confidentiality Agreement. The applicants may not release or permit others to release the dataset in whole or in part to any persons other than those identified in the Application for Data. No data file that includes HIPAA-defined personally identifiable elements is available to researchers. The complete Case Report tool contains more than 300 questions (approximately 2,600 data elements) about an individual fatality. (The Case Report form can be viewed and downloaded at www.ncfrp.org.) Although states often enter HIPPA-defined personally identifiable data elements (child's name, address, date of birth, date of death, date of incident, and incident county) into the NFR-CRS, all personally identifiable data elements will be removed from any dataset made available to researchers. The data elements that will be removed from the dataset are listed in the Application for Access to De-identified Dataset and in the DUA between NCFRP and the state. Due to the potentially large size of the data set and the labor involved in assuring that identifiers are not inadvertently put into the narrative section. The "Narrative" field contained in Section O of the Case Report form will only be released to researchers under special circumstances (i.e. smaller data sets).
Plans for archival and long-term preservation of the data	All data submitted via the Internet using the NFR-CRS are stored on a server located within the MPHI Data Center. Data are stored on this server indefinitely unless a state terminates the data use agreement. Per the Data Use Agreement, if a state terminates its agreement, at their request, MPHI will remove all of the case data from its server. However, state data stored on back up tapes cannot be removed, but it will never be reported or disseminated by MPHI. MPHI will maintain all data in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS/CDC policies and shall not dispose of any records unless authorized by HHS/CDC. De-identified data sets submitted to CDC are also stored indefinitely. They are housed on CDC servers and managed by the CDC data steward. Currently there are no anticipated storage concerns for this data. These data are considered official public records and are preserved according to The Federal Records Act of 1950 (amended to 44 U.S.C. Chapter 31). Retention of such records will follow the Scientific and

	Research Project Retention Schedule available at: http://intranet.cdc.gov/ocoo/docs/sbiu/records-management/bb-scientific-research.docx.

Spatiality (Geographic Location)

Country	State/Province	County/Region

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	09/15/22	Redmond Leonard_Joan (jrl3) CIO HSC
PRA: **PRA Applies**		09/15/22	Still-LeMelle_Terri (cse6) OMB / PRA
ICRO: **PRA Applies**	OMB Approval date: 09/09/22 OMB Expiration date: 09/30/25	09/16/22	Zirger_Jeffrey (wtj5) ICRO Reviewer