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

Print Date: 2/23/22

Title:	Sudden Death in the Young
Project Id:	0900f3eb81e89294
Accession #:	NCCDPHP-PIHT-2/9/22-89294
Project Contact:	Carri Cottengim
Organization:	NCCDPHP/DRH/MIHB/PIHT
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	04/30/2022
Estimated Completion Date:	09/30/2030
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-1092

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	2/17/22	Redmond Leonard_Joan (jrl3) CIO HSC
PRA: **PRA Applies**		2/18/22	Still-LeMelle_Terri (cse6) OMB / PRA

ICRO: **PRA Applies**	OMB Approval date: 4/9/19 OMB Expiration date: 4/30/22	2/22/22	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Determination Start Date:	02/09/22
Description:	The Sudden Death in the Young (SDY) Case Registry improves and standardizes case ascertainment so that funded jurisdictions can better understand the incidence and risk factors for sudden death in youth. Information collection and reporting builds on existing, state-based procedures for Child Death Review (CDR). Through their existing CDR programs, awardees compile data for an estimated 739 cases per year, on a defined set of SDY questions and enter it into the existing SDY module that is part of the existing National Fatality Review-Case Reporting System (NFR-CRS) run through the Michigan Public Health Institute#s (MPHI) National Center for Fatality Review and Prevention (NCFRP) program. Data is abstracted by states/jurisdictions from 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, awardee jurisdictions also convene an advanced review team with relevant clinical expertise, including state health personnel, pediatric cardiologists, pediatric neurologists or epileptologists, and forensic pathologists. Awardees funded under DP18#1806 for SDY surveillance comprehensively review individual cases 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. Additional information from these advanced case reviews is entered into the SDY module. This is non-research public health surveillance to establish the incidence of SDY in funded jurisdictions. CDC will provide technical assistance, receiving de-identified data for quality assurance activities and surveillance reports.
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 Sudden Death in the Young (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 SDY Case Registry. The objectives of the SDY Case Registry are to gather and store information about sudden child deaths to help to 1)count the

Objective:	number and types of sudden deaths in babies, children and young adults up to age 20, 2)try to understand the causes 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, which uses the data to provide technical assistance to improve completeness (including missing and unknown responses) and timeliness of completed cases.
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:	Not Selected
Studying Social Determinants of Health (SDOH):	Yes
SDOH Economic Stability:	Yes
SDOH Education:	Yes
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:	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 ; CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens ; CDC employees will provide substantial technical assistance or oversight
Method Categories:	Surveillance Support
	Information collection and reporting builds on existing state-based procedures for Child Death Review (CDR). Through their existing CDR programs, for an estimated 739 cases, awardees compile data on a defined set of SDY questions and enter them into the existing SDY module that is part of the existing National Fatality Review-Case Reporting System (NFR-CRS) run through the

Methods:	Michigan Public Health Institute#s (MPHI) National Center for Fatality Review and Prevention (NCFRP) program. For approximately 370 SDY cases, awardee jurisdictions will convene an advanced review team with relevant clinical expertise, including state health personnel, pediatric cardiologists, pediatric neurologists or epileptologists, and forensic pathologists. The advanced review team will comprehensively review information from multiple data sources, discuss the information and use 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. 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.
Collection of Info, Data or Biospecimen:	Data about the death is abstracted 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 SDY module.
Expected Use of Findings/Results and their impact:	CDC shares findings with awardees 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 awardees. Awardees use their data to develop targeted prevention strategies to reduce the number of infant and childhood deaths. The data will be made available via request only, and researchers can request data for analyses. These data inform our understanding of the epidemiology of SDY, including the incidence, and risk factors. These data elements are used to establish incidence of SDY, inform prevention strategies and develop best practices for multi-state surveillance of SDY.
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	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
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 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
Carri Cottengim	01/14/2023				Project Officer		770-488-4290	PERINATAL INFANT HEALTH TEAM

Data

DMP

Proposed Data Collection Start Date:	9/30/18
Proposed Data Collection End Date:	9/30/23
Proposed Public Access Level:	Restricted

Restricted Details:

Data Use Type:	Research Data Center
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). 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

Plans for Archival and Long Term Preservation:	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

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...									