

Sudden Death in the Young (SDY) Case Registry

OMB No. 0920-1092 04/03/2022

Supporting Statement B

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TABLE OF CONTENTS

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS.....	3
<i>B1. Respondent Universe and Sampling Methods.....</i>	<i>3</i>
<i>B2. Procedures for the Collection of Information.....</i>	<i>3</i>
<i>B3. Methods to Maximize Response Rates and Deal with No Response.....</i>	<i>4</i>
<i>B4. Tests of Procedures or Methods to be Undertaken.....</i>	<i>5</i>
<i>B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....</i>	<i>5</i>

ATTACHMENTS

1. Authorizing Legislation:
 - a. Public Health Service Act [42 U.S.C. 241] Section 301(a) and Section 317K, 42 USC 241(a), 42 USC 247b-12
 - b. Sudden Unexpected Death Data Enhancement and Awareness Act, Public Law Number 113-236 (enacted into law on December 18, 2014)
2. Data Collection Tools
 - a. SDY Module Section I
 - b. Advanced Review Discussion Topics
 - c. SDY Module Section N
3. Federal Register Notice
 - a. 60-day Federal Register Notice
 - b. Response to public comments on the 60-day Federal Register Notice
4. Data Use Agreements
 - a. Agreement between CDC and MPHI
 - b. Agreement between CDC and Awardees
5. MPHI Security Policy, #06-02
6. NCFRP Child Death Review - Case Reporting System Security Information
7. Institutional Request for Determination of Research Status:

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sampling Methods

A revision and extension for surveillance of a census (all) sudden deaths in the young (0-19 years old) within 13 awardee states/local jurisdictions is being sought; thus no sampling methods are employed. Based on entries into the SDY Case Registry from 2015 to 2019, awardees on average compile data for an estimated 720 cases per year. All SDY cases have data entry completed on the SDY Module. Approximately 50% of all SDY cases, or 360 cases, continue to the advanced review process each year.

B2. Procedures for the Collection of Information

Through their existing child death review (CDR) programs, awardees compile data for SDY cases on a defined set of SDY questions and enter them into the existing SDY module that is part of a larger 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. The enhanced SDY modules I and N (**Attachments 2a and 2c**), which contain approximately 70 variables, are completed for each case, yet not every variable applies to every case. Data is abstracted from primary data sources, including medical examiner/coroner reports, death investigation reports, medical records, and child protective services records. For approximately 360 of these cases, awardee states/local jurisdictions also convene an advanced review team with relevant clinical expertise, including state health personnel, pediatric cardiologists, pediatric neurologists or epileptologists, and forensic pathologists. This advanced review team comprehensively reviews information from multiple data sources, discusses the information, guided by the attached list of suggested discussion topics or **Sudden Death in the Young (SDY) Case Registry**

an adaptation of this resource (**Attachment 2b**), and uses the information to classify cases according to a standardized algorithm that differentiates causes. Additional information from these advanced case reviews is added to the SDY module as applicable. Password-controlled access for awardees is administered by the NCFRP per NCFRP's data security policies and user agreements (**Attachments 4 and 5**).

B3. Methods to Maximize Response Rates and Deal with No Response

Efforts are made to maximize the response rate as achieving population-level representativeness and data completeness is the primary purpose of this funding. CDC provides guidance to awardees on strategies to minimize missing or unknown responses to SDY variables. These methods include building partnerships with agencies that collect the primary data and providing feedback to these agencies so they might improve the quality of the data. As outlined in the funding announcement for the cooperative agreement, DP18-1806, CDC and the Data Coordinating Center at MPHI provide awardees with a quarterly Data Quality Summary report that includes the frequency of missing and unknown responses that are considered essential to the case definition and classification protocol. This allows CDC and the awardee to track the outcome of data improvement strategies and to track awardees' progress over time. The goal is for the Registry to capture complete information from data abstracted from primary sources that allows states and local jurisdictions to calculate accurate and reliable SDY incidence.

B4. Tests of Procedures or Methods to be Undertaken

This data collection is a revision of a previously approved information collection (OMB #0920-1092, Expiration 04/30/2022). All the variables in the **Sudden Death in the Young (SDY) Case Registry**

SDY module have been used for the last 5 years. While CDC is not proposing any changes to any of the data collection tools, the SDY module, or the advanced review process, CDC has, with experience, been able to: 1) obtain better estimates of the actual numbers of respondents anticipated; 2) obtain more accurate estimates of the amount of time needed to complete the SDY modules; and 3) better determine the number of cases that will need to continue to advance review and the types of medical experts that are needed.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

There are no statistical aspects related to the SDY Registry.

Many individuals were consulted on the following: availability of data; frequency of collection; the clarity of instruction and record keeping; disclosure; reporting format; and the data elements to be recorded, disclosed, or reported. Experts CDC consulted formed the SDY Steering Committee, as listed in the table below.

Table 1. External Consultations Sudden Death in the Young (SDY) Experts Consulted				
Biorepository				
Years consulted	Name	Occupation	Role	Contact information
2014 - current	Mark Russell	Cardiologist	Director of Biorepository, University of Michigan	mruess@med.umich.edu 734-764-5176
2018 - current	Lindsay Wilkerson	Laboratory Technician	Biorepository Lead, University of Michigan	wilkerli@med.umich.edu 734-615-2429
2015-	Lauren	Laboratory	Biorepositor	n/a

Sudden Death in the Young (SDY) Case Registry

2016	Bieneman n	Technician	y Lead, University of Michigan	
2016- 2018	Alissa Novack	Laboratory Technician	Biorepositor y Lead, University of Michigan	n/a
Data Coordinating Center at Michigan Public Health Institute				
2015 - current	Meghan Faulkner	SDY Data Coordinating Center Director	Data Manager for SDY Case Registry, Technical Assistance	mfaulkne@mphi.org 517-324-6014
2014 - current	Heather MacLeod	SDY Data Coordinating Center Senior Project Manager	Primary contact for SDY; expertise in genetic counseling, Technical Assistance	hmacleodgc@gmail.com 630-432-9918
2014- 2107	Teri Covington	Directions of the National Center for Fatality Review and Prevention	Expert in fatality review protocols and procedures	n/a
National Institutes of Health				
2014 - current	Kristin Burns	Medical Officer, National Heart, Lung, and Blood Institute (NHLBI)	Overall lead for SDY Case Registry Study. Primary contact for questions related to cardiac	kristin.burns@nih.gov 301-594-6859

Sudden Death in the Young (SDY) Case Registry

			conditions	
2014 - current	Jonathan Kaltman	Branch Chief, NHLBI	Overall project guidance	kaltmanj@nhlbi.nih.gov 301-435-0528
2014 - current	Vicky Whittemore	Program Director, National Institute of Neurologic Disorders and Stroke	Sudden Unexpected Death in Epilepsy (SUDEP) and epilepsy	vicky.whittemore@nih.gov 301-496-1917
2014-2016	Ellen Rosenberg	Clinical Trial Specialist, NHLBI	Consent Expert	n/a
Centers for Disease Control and Prevention				
2014-current	Sharyn Parks Brown	Epidemiologist	DRH	svp2@cdc.gov
2014-current	Carrie Shapiro-Mendoza, PhD	Branch Chief	DRH	ayn9@cdc.gov
2014-current	Niu Tian, MD	Medical Officer	DPH	vii9@cdc.gov

Sudden Death in the Young (SDY) Case Registry