

# Information Collection Request Reinstatement Supporting Statement Part B

## Sudden Death in the Young Registry

Reinstatement of OMB Number 0920-1092

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## List of Attachments

1. Applicable Laws
  - a. Public Health Service Act, 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. 60 Day Federal Register Notice
3. Data Use Agreements
  - a. Agreement between CDC and MPHI
  - b. Agreement between CDC and state/jurisdiction awardees
4. Data Security Policy documents
  - a. MPHI Security Policy
  - b. NCFRP Child Death Review – Case Reporting System Security Information
5. Institutional Request for Determination of Research Status
6. SDY awardees and expected number of cases
7. Data Collection Tools
  - a. SDY Module Section I
  - b. Advanced Review Discussion Topics
  - c. SDY Module Section N

## Supporting Statement B

### Collection of Information Employing Statistical Methods

#### 1. Respondent Universe and Sampling Methods

Surveillance of a census (all) sudden deaths in the young (0-19 years old) within 14 awardee jurisdictions is being sought; thus no sampling methods will be employed. The anticipated number of SDY cases each year (739) was derived using [CDC Wonder](https://wonder.cdc.gov/)<sup>1</sup> data (2012-16) to calculate the approximate estimated incidence of SDY (**Attachment 6**). CDC Wonder is an online database for the analysis of public health data. An estimated 739 SDY cases will have data entry completed on the SDY Module. Using data from CDC's first SDY Case Registry funding cycle (2015-2018) we also estimated the number of SDY cases that will meet eligibility criteria for advanced review and be required to undergo review at an advanced review meeting. Per our assessment, approximately 50% of all SDY cases, or 370 cases will continue on to the advanced review process each year.

#### 2. Procedures for the Collection of Information

Through their existing child death review (CDR) programs, awardees will compile data for 739 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 7a and 7c**), which contain approximately 70 variables, will be completed for each case, yet not every variable will apply to every case.. Data will be abstracted from primary data sources, including medical examiner/coroner reports, death investigation reports, medical records, and child protective services records. For 370 of these cases, awardee jurisdictions will 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 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 (**Attachments 7b**). Additional information from these advanced case reviews will be 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 3a-b and 4a-b**).

#### 3. Methods to Maximize Response Rates and Deal with Non-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, CDC and the Data Coordinating Center at the Michigan Public Health Institute (MPHI) will provide awardees with a quarterly Data Quality Summary report that will include 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 will allow states and jurisdictions to calculate accurate and reliable SDY incidence.

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<sup>1</sup> <https://wonder.cdc.gov/>

**4. Tests of Procedures or Methods to be Undertaken**

This data collection is a reinstatement of a previously approved information collection (OMB #0920-1092, Expiration 12/31/2018). All of the variables in the SDY module have been used for the last 3 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 completed the SDY modules; 3) better determine the number of cases that will need to continue to advance review and the types of medical experts that are needed.

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

There are no statistical aspects related to the SDY Registry.

A number of 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.

<b>Sudden Death in the Young (SDY) Experts Consulted</b>				
<i>Biorepository</i>				
Years consulted	Name	Occupation	Role	Contact information
2014 - current	Mark Russell	Cardiologist	Director of Biorepository, University of Michigan	mruss@med.umich.edu 734-764-5176
2018 - current	Lindsay Wilkerson	Laboratory Technician	Biorepository Lead, University of Michigan	wilkerli@med.umich.edu 734-615-2429
2015-2016	Lauren Bienemann	Laboratory Technician	Biorepository Lead, University of Michigan	n/a
2016-2018	Alissa Novack	Laboratory Technician	Biorepository Lead, University of Michigan	n/a
<i>Data Coordinating Center at Michigan Public Health Institute</i>				
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
<i>National Institutes of Health</i>				
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 conditions	kristin.burns@nih.gov 301-594-6859
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	Sudden Unexpected Death in Epilepsy (SUDEP) and epilepsy	vicky.whittemore@nih.gov 301-496-1917

		<i>and Stroke</i>		
2014-2016	<i>Ellen Rosenberg</i>	<i>Clinical Trial Specialist, NHLBI</i>	<i>Consent Expert</i>	n/a