

# Sudden Death in the Young

OMB No. 0920-1092 04/30/2022

## Supporting Statement A

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## **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. Agreement between CDC and awardees MPHI Security Policy, #06-02
6. NCFRP Child Death Review - Case Reporting System Security Information
7. Institutional Determination of Research Status: non-research determination
8. Privacy Narrative

## JUSTIFICATION SUMMARY

**Goal of the project:** The goal of the Sudden Death in the Young (SDY) Case Registry is to improve and standardize case ascertainment so that funded states/local jurisdictions can better their understanding of the incidence and risk factors for sudden death in youth.

**Intended use of the resulting data:** Data is be used to inform the descriptive epidemiology of SDY, including the incidence, and risk factors. These data are used to inform prevention strategies as well as development of best practices for national surveillance of SDY.

**Methods to be used to collect:** 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 Michigan Public Health Institute's (MPHI) National Center for Fatality Review and Prevention (NCFRP) program. Data is abstracted 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, awardees also 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 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. Additional information from these advanced case reviews is entered into the SDY module. 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.

**The subpopulation to be studied:** Youth (0-19 years old) in awardee states/local jurisdictions who died suddenly and unexpectedly, and whose death was not explained by a homicide, suicide, drug overdose, terminal illness, or an external cause that was the only and obvious reason for the fatal injury (e.g., driver in a single-motor vehicle crash).

**How the data will be analyzed:** CDC analyzes aggregated data and assess the completeness (including missing and unknown responses), timeliness, and case ascertainment of the data set. CDC shares findings and works with SDY awardees to provide technical assistance to improve the 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.

## **A. JUSTIFICATION**

### ***A1. Circumstances Making the Collection of Information Necessary***

This Information Collection Request (ICR) is for a revision of a previous ICR (OMB #0920-1092, Expiration 4/30/22). Authorization for this information collection comes from the Public Health Service Act, as amended, Section 301(a) and Section 317K, 42 USC 241(a), 42 USC 247b-12 (**Attachment 1a**). In addition, this request fulfills the Centers for Disease Control and Prevention's (CDC) obligation to the Sudden Unexpected Death Data Enhancement and Awareness Act, Public Law Number 113-236 (enacted into law on December 18, 2014) (**Attachment 1b**). This Bill directs CDC and the National Institutes of Health (NIH) to carry out surveillance activities related to sudden death in children less than 19 years of age.

CDC seeks OMB approval for 3 years for a federally sponsored information collection designed to improve the understanding of Sudden Death in Young (SDY) by standardizing and enhancing the data collected through state-based child death reviews (CDR) programs. CDC is seeking a revision due to minor changes that result in an eleven-hour reduction in the burden compared to the prior ICR.

Establishing reliable estimates of incidence of SDY is a critical step in prevention efforts. SDY is defined as any sudden and unexpected death of an infant, child, or young adult, investigated by a medical examiner or coroner, not explained by homicides, suicides, overdoses, poisonings, other obvious external injury deaths, or terminal illnesses. Some injury deaths where there may have been an inciting natural cause (e.g., drowning triggered by an underlying cardiac condition) are also included in the definition.

Estimates of the annual incidence of SDY vary broadly due to differences in definitions, inconsistencies in classifying cause of death on death certificates,

study populations, and case ascertainment. To address the need for improved estimates of SDY incidence and its epidemiology based on uniform cases definitions, CDC, in collaboration with NIH's National Heart, Lung, and Blood Institute (NHLBI) and National Institute of Neurological Disorders and Stroke (NINDS), implemented the SDY Case Registry in 2015.

## ***A2. Purpose and Use of the Information Collection***

This project will continue to improve the data on SDY cases so that funded states/local jurisdictions and researchers can better determine how and why these children die and, most importantly, how their deaths may be prevented. The goal of the SDY Case Registry is to improve and standardize case ascertainment so that funded states/local jurisdictions can better understand the incidence and causes of sudden death in youth. The primary purpose of the information being compiled is to calculate the incidence of SDY accurately and reliably in participating states/local jurisdictions.

To meet the ongoing need to produce accurate and uniform information, CDC, and NIH continued the SDY Case Registry in 2018 with 13 awardees through a CDC-based cooperative agreement program (DP18-1806). Awardees include states as well as local jurisdictions such as counties or regions of a single state. The information gathered continues to inform the implementation of optimal diagnostic, treatment, and public health prevention approaches for reducing the incidence of SDY. The SDY Case Registry also creates NIH infrastructure for future research about previously unknown or unrecognized risk factors for, or causes of, these deaths.

The SDY Case Registry builds on ongoing collaborations involving state-based CDR teams, CDC, NIH, the Health Resources and Services Administration (HRSA) and the National Center for Fatality Review and Prevention (NCFRP) at the Michigan Public Health Institute (MPHI). The NCFRP supports a web-based National Fatality Review Case Reporting System (NFR-CRS) that states can use on a voluntary basis to manage their state-specific CDR data. Due to variability in case definitions and

reporting procedures, the system does not produce national estimates, but serves as a vital repository of information to facilitate state-based surveillance and public health activities.

Key activities for each state/local jurisdiction participating in the SDY Case Registry include:

1. As part of existing CDR process, awardees follow procedures defined by the NCFRP to identify, review, and enter information pertaining to all infant and childhood deaths up to the age mandated by state law or protocol (often 18 years of age, but may be up to 20 in some states/local jurisdictions). Information is entered into web-based NFR-CRS including Section I of the SDY module SDY Case Registry awardees are required to complete. (**Attachment 2a**) All information entered has been compiled from primary data sources already used by CDR teams (e.g., medical records, death investigation and autopsy reports, health, and social services records).
2. After initial CDR review, awardees, apply common CDC protocols and the SDY case definition. Only cases that meet this definition are sent for advanced review. Based on our knowledge from the previous work approximately, 50% of all SDY cases initially entered in SDY module continue to an advanced review meeting.
3. Next, awardees conduct an advanced review for SDY cases identified in step 2. The advanced review includes convening clinicians with varying expertise (pediatric cardiology; pediatric neurology or epileptology; and forensic pathology) to participate in a more technical and medical review of information already compiled. These advanced reviews are more intensive than the typical reviews conducted by the state and local jurisdiction's CDR team. Advanced review teams 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 (**Attachment 2b**).
4. Following the advanced review meeting, the coordinator enters additional findings, the results of the classification of the cases, and any

other SDY-specific information into Section N (**Attachment 2c**) of the SDY module of the web-based NFR-CRS.

5. CDC receives a quarterly de-identified data set from the NCFRP and analyzes the data to assess data completeness, timeliness of case information, and case ascertainment. CDC shares the findings with awardees; who, in turn, work with CDC staff to develop, implement, and evaluate strategies to improve the quality of their data.

The guidance and resources offered to awardees under the cooperative agreement for conducting advanced reviews and entering data in the SDY module establish the characteristics and incidence of SDY and contribute to multi-jurisdictional SDY classification, surveillance, and prevention efforts.

For the past three years, all SDY cases in funded states/ local jurisdictions have been identified, reviewed, and categorized into SDY types (e.g., explained cardiovascular, explained neurological) based on common protocols. Data have been used by awardees to understand the population of youth dying suddenly and unexpectedly in the funded states/local jurisdictions. Additionally, NIH has been analyzing de-identified data that has been aggregated across states/local jurisdictions from five closed death year cohorts (2015-19) to establish incidence and better understand SDY characteristics. Data has been used to inform the descriptive epidemiology of SDY, including the incidence, and risk factors.<sup>1,2</sup> These data are also used to inform prevention strategies and development of best practices for national surveillance of SDY. Finally, de-identified data from the SDY Registry will continue to be available to researchers, state health departments, and CDR programs that are investigating and promoting reporting, screening, genetic counseling and testing, diagnosis, and treatment to prevent SDY.

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<sup>1</sup> Kristin M. Burns, Lauren Bienemann, Lena Camperlengo, Carri Cottengim, Theresa M. Covington, Heather Dykstra, Meghan Faulkner, Rosemarie Kobau, Alexa B. Erck Lambert, Heather MacLeod, Sharyn E. Parks, Ellen Rosenberg, Mark W. Russell, Carrie K. Shapiro-Mendoza, Esther Shaw, Niu Tian, Vicky Whittemore, Jonathan R. Kaltman, Sudden Death in the Young Case Registry Steering Committee; The Sudden Death in the Young Case Registry: Collaborating to Understand and Reduce Mortality. *Pediatrics* March 2017; 139 (3): e20162757. [10.1542/peds.2016-2757](https://doi.org/10.1542/peds.2016-2757)

<sup>2</sup> Kristin M. Burns, Carri Cottengim, Heather Dykstra, Meghan Faulkner, Alexa B. Erck Lambert, Heather MacLeod, Alissa Novak, Sharyn E. Parks, Mark W. Russell, Carrie K. Shapiro-Mendoza, Esther Shaw, Niu Tian, Vicky Whittemore, Jonathan R. Kaltman, Epidemiology of Sudden Death in a Population-Based Study of Infants and Children, *The Journal of Pediatrics: X*, Volume 2, 2020, 100023, ISSN 2590-0420, <https://doi.org/10.1016/j.ympdx.2020.100023>. (<https://www.sciencedirect.com/science/article/pii/S2590042020300045>)

In addition to informing state and local SDY prevention programs, the information compiled in the NFR-CRS can be used by states/local jurisdictions to track and report progress toward state and federal public health goals, such as Healthy People 2030 and state-mandated child death review reports. Specifically, the NFR-CRS provides information to inform progress toward the following Healthy People 2030 goals:

Maternal, Infant and Child Health Maternal, Infant and Child Health:

- MICH-02 Reduce the rate of infant deaths within 1 year of age
- MICH-03 Reduce the rate of deaths in children and adolescents aged 1 to 19 years
- MICH-14 Increase the portion of infants who are put to sleep on their backs
- TU-18 Increase the proportion of smoke-free homes
- IVP-D01 Increase the number of states where a child fatality review team reviews external causes of death in children
- IVP-D02 Increase the number of states where a child fatality review team reviews sudden and unexpected deaths in infants

The data compiled by the awardees will continue to be used by the states/local jurisdictions in which they were entered. Similarly, a state CDR program may use statewide SDY data to inform decisions about prevention recommendations and activities. The CDC provides technical assistance to assist the states with data quality improvement strategies. The data will continue to be used to better understand the etiology and incidence of SDY, and the characteristics associated with these deaths; both critical in targeting prevention efforts.

### ***A3. Use of Improved Information Technology and Burden Reduction***

All case-related information is entered electronically into the SDY data module in the existing NFR-CRS, a web-based system stored on the MPHI's secured servers.

The NFR-CRS has always been designed with extensive questions that guide responses using skip patterns so "users" complete only relevant variables. This function is designed for maximum user-friendliness and reduces the time burden for entering SDY case information.

#### ***A4. Efforts to Identify Duplication and Use of Similar Information***

The NFR-CRS was developed with input from state CDR programs and has been in existence since 2005. No similar database exists. By building on an existing system that is familiar to the end users, CDC avoided duplication of efforts and minimizes burden of awardees. The SDY modules were developed in conjunction with multiple partners who are all vested in the SDY Case Registry.

#### ***A5. Impact on Small Businesses or Other Small Entities***

The information compiled will have no impact on small businesses or other small entities.

#### ***A6. Consequences of Collecting the Information Less Frequently***

SDY cases are rare and are not predictable, thus timing of data collection is guided by this reality. Local and state CDR teams only compile information on an SDY case when a case occurs. Advanced review teams only review and classify SDY cases that are identified by awardees as meeting the SDY case definition. Some states have so few cases that they predict only one yearly meeting while larger states may have monthly or quarterly advanced review team meetings, depending on the number of SDY cases in that state/local jurisdiction.

#### ***A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5***

This request fully complies with the regulation 5 CFR 1320.5.

#### ***A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency***

Part A: PUBLIC NOTICE

A 60-day Federal Register Notice was published in the Federal Register on September 7, 2021, vol. 86 No. 170, pp. 50124-50125 (**see Attachment 3a**).

CDC received 1 comment and did not provide a response because the comment fell outside the scope of this information collection. (**Attachment 3b**).

Part B: CONSULTATION

CDC sought consultation outside of the agency from individuals listed in the below table on the: availability of data; frequency of collection; clarity of instruction and record keeping; disclosure; reporting format; and data elements to be recorded, disclosed, or reported. No major unresolved problems were highlighted during consultation.

Experts CDC consulted formed the SDY Steering Committee. This committee remains intact for technical consultation throughout the SDY Registry project and holds monthly calls to discuss project progress and strategies to address challenges.

<b>Table 1. External Consultations Sudden Death in the Young (SDY) Experts Consulted</b>				
<b>Biorepository</b>				
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
<b>Data Coordinating Center at Michigan Public Health Institute</b>				
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	hmacleodgc@gmail.com 630-432-9918

			Assistance	
2014-2107	Teri Covington	Directions of the National Center for Fatality Review and Prevention	Expert in fatality review protocols and procedures	n/a
<b>National Institutes of Health</b>				
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 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
<b>Centers for Disease Control and Prevention</b>				
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

**A9. Explanation of Any Payment or Gift to Respondents**

Respondents do not receive an incentive.

## ***A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent***

This submission has been reviewed by staff in CDC's National Center for Chronic Disease Prevention and Health Promotion who determined that the Privacy Act does not apply (**Attachment 8**). The Privacy Act does not apply because CDC does not collect or receive any information in identifiable form (IIF).

De-identified data are transmitted to CDC on a quarterly basis, via a secure file transfer protocol (SFTP) site. The CDC stores all electronic data in a secure and confidential location that only CDC's SUID/SDY Case Registry team members have access to. Electronic data is backed up on a secure server per CDC protocol.

While the Privacy Act is not applicable, the appropriate security controls and rules of behavior will be incorporated to protect the confidentiality of information, proprietary, sensitive, and personally identifiable information (PII) the awardee may encounter.

As part of the regular child death review process, respondents enter extensive information about individual cases, including PII, into the NFR-CRS, a web-based system stored on the MPHI's secured servers. However, while this information is stored on MPHI servers using infrastructure managed by NCFRP, this information is entered by a designated person for each state/local jurisdiction who is granted restricted access. All PII collected as a part of case reporting is managed and maintained by individual states/local jurisdictions. Only state and jurisdiction personnel are granted this restricted access and only for their own state/local jurisdiction so that they are unable to access and enter PII for other states/local jurisdictions. The NCFRP assigns a unique and auto-generated identifier to reference individual cases and creates de-identified data sets that do not contain any PII (i.e., no dates, locations, and names are included). All PII is stripped from any NCFRP data download received by CDC.

The NCFRP provides CDC and NIH with a de-identified data set for funded states/local jurisdictions subject to the terms in the data use agreement between listed parties (**Attachment 4a**). The CDC agrees that it will not release nor permit others to release the data set or any part of it to any person other than the members of the CDC who have completed a data usage agreement form. CDC is also subject to the terms of a data use agreement with state/local jurisdiction awardees (**Attachment 4b**). The attached data use agreement is the newest version of the document which was signed shortly after funding was awarded and applies to all work conducted under that funding (i.e., for five years).

MPHI, the parent organization of NCFRP and the entity responsible for security and privacy, has formal policies, which are relevant specifically to security of all data in the case reporting system, including the SDY modules:

- MPHI Security Policy, #06-02 (**Attachment 5**). The attached agreement is the newest version available. MPHI is currently working on an update to the agreement.
- NCFRP Child Death Review – Case Reporting System Security Information (**Attachment 6**)

All involved MPHI staff comply with institutional standard operating procedures related to subject confidentiality, information security, and safe data collection practices. Access to the secured NFR-CRS is password-protected and NCFRP controls and monitors access and provides training for users. Only authorized users will be assigned a password to access the system, and the password must be changed every 6 months. All web data entry users will be trained on privacy and sensitive data.

### ***A11. Institutional Review Board (IRB) and Justification for Sensitive Questions***

CDC’s Institutional Review Board determined that this project is public health practice surveillance and does not constitute research with human subjects as defined by the US Code of Federal Regulations (45 CFR 46.102). (**See Attachment 7.**)

States/local jurisdictions participating in the SDY Case Registry follow ethical review rules for their own state/local jurisdiction and agency.

#### *Sensitive Questions*

CDC only receives de-identified data. Ongoing, routine child death reviews are vital state based public health functions for which sensitive data may be collected. However, the data received by CDC as part of sponsored SDY Case Registry activities are de-identified before being reported to CDC, and therefore no sensitive questions are a part of this information collection request.

## **A12. Estimates of Annualized Burden Hours and Costs**

Burden is only assessed for the CDC SDY Case Registry awardees since, unlike ongoing routine CDR programs, they are the only respondents involved in this federally sponsored project. For the purposes of this ICR, a “respondent” is an SDY Registry awardee who represents a state or local jurisdiction. As stated in CDC’s cooperative agreement, awardees (respondents) agree to compile a defined set of SDY information about a defined subset of child deaths through the state or local jurisdiction’s existing CDR program.

Based on entries into the SDY Case Registry from 2015 to 2019, awardees on average compile data for an estimated 720 cases per year. Each of the 13 federally funded awardees, on average, have 55 of the 720 cases each year. Burden is assessed for each awardee’s state or local health department personnel’s time to enter the information into the SDY modules, contained within the larger Case Reporting System. It takes, on average, 10 minutes to enter data on each case into Module I (**Attachment 2a**).

Additionally, using data from the previous years of the Registry we estimated the portion of SDY cases that require an advanced review. Per our assessment, approximately, 50% or an estimated 360 cases, require advanced review each year. Burden is assessed for the advanced review team’s time to review each of the estimated 360 cases (average 28 cases per awardee) that are predicted to require advanced review. The team for each awardee consists of medical experts, including: 1) a pediatric cardiologist, 2) a pediatric neurologist or epileptologist, and 3) a forensic pathologist. The burden on the members of the advanced review team is for their time to discuss the compiled primary data (e.g., medical records, autopsy reports, ancillary testing) on each of the cases, categorize the case using the classification algorithm and discuss any additional data that needs to be entered following the review. Advanced review teams meetings are guided by the attached list of suggested discussion topics or an adaptation of this resource (**Attachment 2b**). The estimated burden is 15 minutes per case. Since each of the 13 awardees are required to include 3 medical expert respondents, we

estimate 39 medical expert respondents in total, each reviewing an average of 28 cases for a burden of 273 hours/year.

Following the case review, each of the 13 federally funded awardees complete SDY Module N (**Attachment 2c**). Burden is assessed for each awardee’s state or local health department personnel’s time to enter the information into the SDY modules, contained within the larger Case Reporting System. It takes approximately 10 minutes to enter data on each case. The module is completed for each of the 720 cases each year, averaging 53 cases per grantee. To estimate annualized burden costs, the Bureau of Labor Statistics Wage Data by occupation was consulted.

**Table A12A: Estimated Annualized Burden (Hours)**

Type of respondent	Form name	No. of respondents	No. Responses per respondent	Average burden per response (in hours)	Total burden hours
State/ Local Health Department Personnel	SDY Module I	13	55	10/60	119
Medical Expert	Advanced Review	39	28	15/60	273
State/ Local Health Department Personnel	SDY Module N	13	55	10/60	119
<b>Total hours</b>					<b>511 hours</b>

**Table A12B: Estimated Annualized Burden Costs**

Type of respondent	Form Name	No. of respondents	No. Responses per respondent	Average burden per response (in hours)	Total burden hours	Hourly wage rate	Total respondent costs

State/ Local Health Dept Personnel	SDY Module I	13	55	10/60	119	\$18.90	\$2,249.10
Medical Expert	Advance d Review	39	28	15/60	273	\$47.13	\$12,866.4 9
State/ Local Health Dept Personnel	SDY Module N	13	55	10/60	119	\$18.90	\$2,249.10
<b>Total cost</b>							<b>\$17,364. 69</b>

***A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers***

There are no other costs. There are no capital or start-up costs for awardees and the NFR-CRS is available to all CDR teams at no cost. There is no purchase of services components, and there is no operation and maintenance cost that can be separated from the usual and customary cost of the current work of the state and local health departments.

***A14. Annualized Cost to the Federal Government***

The Data Coordinating Center at NCFRP is contracted to provide technical assistance for Child Death Review activities data collection activities, including oversight for the two awardee tasks of entering data into the SDY module and conducting advanced reviews. The annual cost to the government for these tasks is \$73,070 per year, which includes contract costs covered by funds from The National Heart, Lung, and Blood Institute (NHLBI) and the Centers for Disease Control and Prevention. Additionally, approximately 5% of the cooperative agreement funds awarded for SDY registry activities (\$497,917 total) between CDC and the 13 awardees are allocated to cover the time devoted to SDY module data entry and advanced clinical review. In addition, \$8,475 is needed for CDC personnel salaries. The resulting total annual cost to the government is \$115,803.

**Table A14.-A.** Estimated Annualized Federal Government Cost Distribution

<b>Expense Type</b>	<b>Expense Explanation</b>	<b>Annual Costs (dollars)</b>
Contract	Contract No. 75D30118C03074 Michigan Public Health Institute (MPHI) with Data Coordinating Center Contract: 10% of contract time devoted to SDY activities: <ul style="list-style-type: none"> <li>Centers for Disease Control and Prevention (\$14,605.39)</li> <li>National Heart Lung Blood Institute (NHLBI) (\$59,306.30)</li> </ul>	\$73,912
Cooperative Agreement	Cooperative Agreement DP18-1806 with 13 SDY Registry Awardees: 5% of time devoted to advanced review, SDY module and quality assurance measures.	\$24,896
CDC Personnel	Health Scientist GS-13, 2% of FTE	\$2,157
	Epidemiologist GS-13, 2% of FTE	\$2,468
	Team Lead, Medical Officer GS-14, 1% of FTE	\$1,500
	Health Scientist GS-14, 1% of FTE	\$1,234
	Public Health Advisor GS-13, 1% of FTE	\$1,161
	<b>Subtotal, CDC Personnel</b>	\$8,475
	<b>TOTAL COST TO THE GOVERNMENT</b>	<b>\$115,803</b>

**A15. Explanation for Program Changes or Adjustments**

This request is for a revision. The change was a 10-hour reduction in burden hours. There has been a decrease from 14 to 13 awardees. Additionally, estimates from the most recent data suggest a likely average of 55 cases per state/local jurisdiction, an increase from an average of 53 cases per state/local jurisdiction estimated in the previous ICR. As a result of the slight decrease in the number of awardees and a slight increase in the average number of cases per state/local jurisdiction, we estimate an overall reduction in burden of 10 hours.

**A16. Plans for Tabulation and Publication and Project Time Schedule**

Aggregated (i.e., not on individual cases level) information entered into the NFR-CRS is analyzed by CDC on a quarterly basis for quality improvement purposes only. The Data Coordinating Center also uses the data to track awardees' timeliness of data, data completeness on SDY variables and case ascertainment. 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, child and adolescent deaths.

Data will be publicly reported in periodic manuscripts that describe the SDY cases in the Registry. No complex analysis is planned; only descriptive data analyses are planned. We are requesting 3 years of OMB approval for this recurring data collection effort.

**Table A.16.** Estimated Time Schedule for Project Activities

Activity	Time Schedule
Identify individual cases for CDR review	Within 24 hours for autopsy and within 30 days for CDR
CDR held for each death	Within 90 days of case identification
Compile and enter data into NCFRP Case Reporting System including the required SDY Module	Within 30 days of review team meetings
Advanced review of cases that meet SDY Registry definition	Within 90 days of CDR team meeting
Additional data entry into the SDY module	Within 30 days of the advanced review meeting
Analyze and disseminate data	Quarterly
Utilize SDY Registry Data	Quarterly for summary reports on data quality
Participate in awardee meetings	Annually

**A17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The display of the OMB expiration date is appropriate.

**A18. Exceptions to Certification for Paperwork Reduction Act Submission**

There are no exceptions to the certification.