Information Collection Request Reinstatement
Supporting Statement Part A

Sudden Death in the Young Case Registry

Reinstatement of OMB Number 0920-1092

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- **Goal of the study**: The goal of the Sudden Death in the Young (SDY) Case Registry is to improve and standardize case ascertainment so that funded jurisdictions can better their understanding of the incidence and risk factors for sudden death in youth.
- **Intended use of the resulting data**: Data will be used to inform the descriptive epidemiology of SDY, including the incidence, and risk factors. These data will be used to inform prevention strategies as well as development of best practices for national surveillance of SDY.
- **Methods:** 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 will 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 will be 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, 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. 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. Additional information from these advanced case reviews will be 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.
- **Subpopulation to be studied:** Youth (0-19 years old) in awardee jurisdictions who died suddenly and unexpectedly, and whose death was not explained by a homicide, suicide, drug overdose

Supporting Statement A

Justification

1. Circumstances Making the Collection of Information Necessary

This Information Collection Request (ICR) is for a reinstatement with changes of a previous ICR (**OMB #0920-1092, Expiration 12/31/2018**). 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 a 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 not proposing any changes to any of the previously approved SDY data collection modules or the advanced review process, however, due to previous experience with the system, burden hours on respondents are reduced.

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 or death of the driver in a motor vehicle accident, which may have been triggered by an underlying cardiac or neurological 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 with 10 awardees through cooperative agreements from 2015-2018. To meet the ongoing need to produce accurate and uniform information, CDC and NIH plan to continue the SDY Case Registry with 14 awardees through a CDC-based cooperative agreement program (DP18-1806). The information gathered will continue 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[1].

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

[1] Burns, Kristin M., Lauren Bienemann, Lena Camperlengo, Carri Cottengim, Theresa M. Covington, Heather Dykstra, Meghan Faulkner et al. "The sudden death in the young case registry: collaborating to understand and reduce mortality." *Pediatrics* (2017): e20162757.

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/jurisdiction participating in the SDY Case Registry include:

1. As part of existing CDR process, awardees will 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 jurisdictions). Information is entered into web-based NFR-CRS including Section I (**Attachment 7a**) of the SDY module SDY Case Registry awardees are required to complete. 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, will apply common CDC protocols and the SDY case definition. Only cases that meet this definition will be sent for advanced review. Based on our knowledge from the previous funding cycle approximately, 50% of all SDY cases initially entered in SDY module will continue on to advanced review.

3. Next, awardees will 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 jurisdiction's CDR team. Advanced review teams 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. (**Attachment 7b**)

4. Following the advanced review meeting, the coordinator will enter additional findings, the results of the classification of the cases, and any other SDY-specific information into Section N (**Attachment 7c**) of the SDY module of the web-based NFR-CRS.

5. CDC receives a quarterly de-identified data set from the NCFRP and will analyze the data to assess data completeness, timeliness of case information, and case ascertainment. CDC will share the findings with awardees; who will, 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 will establish the characteristics and incidence of SDY and contribute to multi-jurisdictional SDY classification, surveillance, and prevention efforts.

2. Purpose and Use of the Information Collection

This project will continue to improve the data on SDY cases so that funded 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 jurisdictions can better understand the incidence and causes of sudden death in youth. The primary purpose of the information being compiled is to accurately and reliably calculate the incidence

of SDY in participating states and jurisdictions. For the past three years, all SDY cases in funded 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 jurisdictions. Additionally, NIH has been analyzing de-identified data that has been aggregated across jurisdictions from two closed death year cohorts (2015-16) 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. 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.

In addition to informing state and local SDY prevention programs, the information compiled in the NFR-CRS can be used by states/jurisdictions to track and report progress toward state and federal public health goals, such as Healthy People 2020 and state-mandated child death review reports. Specifically the NFR-CRS provides information to inform progress toward the following Healthy People 2020 goals:

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

MICH-1 Reduce the rate of fetal and infant deaths

- MICH-1.3 Reduce the rate of all infant deaths (within 1 year)
- MICH-1.4 Reduce the rate of neonatal deaths (within the first 28 days of life)
- MICH-1.5 Reduce the rate of post-neonatal deaths (between 28 days and 1 year)
- MICH-1.7 Reduce the rate of infant deaths related to birth defects (congenital heart defects)
- MICH-1.8 Reduce infant deaths from sudden infant death syndrome (SIDS)

MICH-1.9 Reduce infant deaths from sudden unexpected infant deaths (includes SIDS, Unknown

- Cause, Accidental Suffocation, and Strangulation in Bed)

MICH-3 Reduce the rate of child deaths

- MICH-3.1 Reduce the rate of death among children aged 1 to 4 years
- MICH-3.2 Reduce the rate of death among children aged 5 to 9 years

MICH-4 Reduce the rate of adolescent and young adult deaths

- MICH-4.1 Reduce the rate of death among adolescents aged 10 to 14 years
- MICH-4.2 Reduce the rate of death among adolescents aged 15 to 19 years
- MICH-4.3 Reduce the rate of death among adolescents aged 20 to 24 years

Injury and Violence Prevention

- IVP-5 Increase the number of States and the District of Columbia where 90 percent of sudden and unexpected deaths to infants are reviewed by a child fatality review team
- IVP-24 Reduce unintentional suffocation deaths
- IVP-24.2 Reduce unintentional suffocation deaths to infants 0-12 months

The data compiled by the awardees will continue to be used by the 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. Ultimately, the data will be used to better understand the

etiology and incidence of SDY and the characteristics associated with these deaths; both critical in targeting prevention efforts.

3. 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.

4. 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.

5. Impact on Small Businesses or Other Small Entities
The information compiled will have no impact on small businesses or other small entities.

6. 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 will only compile information on an SDY case when a case occurs. Advanced review teams will 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 jurisdiction.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Notice was published in the Federal Register on November 6, 2018, vol. 83, No. 215, pp. 55547-55548 with the title "Sudden Death in Young Registry)" (**Attachment 2**). No public comments were received.

B. 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.

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*	*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*
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 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*	*Program*	*Sudden Unexpected*	*vicky.whittemore@nih.go*

	Whittemore	*Director, National Institute of Neurologic Disorders and Stroke*	*Death in Epilepsy (SUDEP) and epilepsy*	v *301-496-1917*
2014-2016	*Ellen Rosenberg*	*Clinical Trial Specialist, NHLBI*	*Consent Expert*	n/a

9. Explanation of Any Payment or Gift to Respondents
No remuneration will be provided to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
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. 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 come in contact with.

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/jurisdiction who is granted restricted access. All PII collected as a part of case reporting is managed and maintained by individual states and jurisdictions. Only state and jurisdiction personnel are granted this restricted access and only for their own state/jurisdiction so that they are unable to access and enter PII for other 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 jurisdictions subject to the terms in the data use agreement between (**Attachment 3a**). . 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 states (**Attachment 3b**).

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 4a**)
- NCFRP Child Death Review – Case Reporting System Security Information (**Attachment 4b**).

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.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The SDY Registry has been determined by CDC to be public health practice surveillance and does not require IRB review **(Attachment 5)**.

States participating in the SDY Case Registry follow ethical review rules for their own state 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.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

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 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 jurisdiction’s/state’s existing CDR program.

Estimates of the anticipated number of SDY each year were derived using CDC Wonder[2] data (2012-16) (**Attachment 6**). CDC Wonder is an online database for the analysis of public health data. Estimates were obtained for each of the 14 awardees funded under the cooperative agreement and totaled 739 cases.

For the SDY Case Registry, each of the 14 federally funded state/jurisdiction awardees will, on average, have 53 of the 739 cases each year. Burden is assessed for each awardee's state health personnel's time to enter the information into the SDY modules, contained within the larger Case Reporting System. It is estimated it will take 10 minutes to enter data on each case into Module I (**Attachment 7a**).

Additionally, using data from our first SDY Case Registry funding cycle (2014-2018) we estimated the portion of SDY cases that require an advanced review. Per our assessment, approximately, 50% or an estimated 370 cases, will require advanced review each year. Burden is assessed for the advanced review team's time to review each of the estimated 370 cases (average 26 cases per awardee) that are predicted to require advanced review. The team for each awardee consists of medical experts, typically: 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 will be 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 (**Attachment 7b**). The estimated burden is 15 minutes per case. Since each of the 14 awardees are required to include 3 medical expert respondents, we estimate 42 medical expert respondents in total, each reviewing an average of 26 cases for a burden of 273 hours.

Following the advanced case review, each of the 14 federally funded state/jurisdiction awardees will complete SDY module N (**Attachment 7c**). Burden is assessed for each awardee's state health personnel's time to enter the information into the SDY modules, contained within the larger Case Reporting System. It is estimated it will take 10 minutes to enter data on each case. The module is completed for each of the 739 cases each year, averaging 53 cases per grantee.

The total estimated burden is **521** hours (Table 1, below).

[2] https://wonder.cdc.gov/

Table 1 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 health personnel	SDY Module I	14	53	10/60	124
Medical Expert	Advanced Review	42	26	15/60	273
State Health Personnel	SDY Module N	14	53	10/60	124
Total hours					**521 hours**

B. Estimated Annualized Costs to Respondents

The table below summarizes the estimated annualized costs. The estimates of hourly wages were obtained from the Department of Labor. The total estimated annualized cost to respondents is $19,897.29.

Table 2 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 respond-dent costs
State Health Personnel	SDY Module I	14	53	10/60	124	$18.90	$2,343.60
Medical Expert	Advanced Review	42	26	15/60	273	$47.13	$12,866.49
State Health Personnel	SDY Module N	14	53	10/60	124	$18.90	$2,343.60
Total							**$17,553.69**

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

a) Total capital and start-up cost component:

There are no capital or start-up costs for awardees and the NFR-CRS is available to all CDR teams at no cost.

b) Total operation, maintenance and purchase of services component:

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 health departments.

14. 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 total annual cost to the government for these tasks will be $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 14 state and jurisdictional 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.

Table 3 Annualized Cost to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Contract	Contract No. 200-2013-57324 Michigan Public Health Institute (MPHI) with Data Coordinating Center Contract: 10% of contract time devoted to SDY activities: • Centers for Disease Control and Prevention ($16,650) • National Heart Lung Blood Institute (NHLBI) ($56,420)	**$73,070**
Cooperative Agreement	Cooperative Agreement DP18-1806 with 14 SDY Registry Awardees: 5% of time devoted to advanced review, SDY module and quality assurance measures.	**$24,896**
CDC Personnel	Health Scientist GS-12, 2% of FTE	$2,112
	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
	Subtotal, CDC Personnel	**$8,475**
	TOTAL COST TO THE GOVERNMENT	**$106,441**

15. Explanation for Program Changes or Adjustments

This Information Collection Request (ICR) is filed as a reinstatement of OMB Number 0920-1092. 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.

Although the number of SDY Registry awardees has increased from 10 to 14, our estimated net burden is lower because of changes in the method used to calculate of the average number cases anticipated per awardee. Previous experience has also revealed that it takes a shorter time to complete the SDY modules than originally estimated and that a lower proportion of cases will need to have an advanced review.

Estimate of the number of respondents:

To estimate the number of SDY cases for the current information collection request, we used a process which looked at the average number of SDY cases each of our awardee jurisdictions had over a 5-year period based on available CDC Wonder data. The average we found for the current set of awardees was 53 cases (**Attachment 6**). The average number of cases per awardee is lower than the previous average because of changes in individual awardees and because of differences in the expected cases to be reported among continuing awardees.

Estimated time to complete the SDY modules:

In addition, program experience has allowed us to modify the amount of time it takes to complete the SDY modules. It was previously estimated that the time for state health personnel to enter data for cases was 30 minutes per case. Communication with grantees has allowed us to reduce that time to an average of 20 minutes (10 minutes per case, per module). Each module is now reported separately so that the statement reporting the burden can be displayed at the beginning of the module (i.e., not at the beginning of the larger case reporting system). In this manner, the burden is displayed only to those who are completing the module, and more directly describes what the burden of the added information collection entails.

Cases needing advance review, and medical experts needed for review:

CDC has also learned through experience that approximately only half of the identified SDY cases go to advanced review each year -- many of these cases either end up as incomplete cases or have an explained cause of death, making the advanced review unnecessary. This allowed us to use a program-based process to estimate the proportion of cases going through advanced review. In addition, CDC has learned through experience that review from either, and not both, a pediatric neurologist or epileptologist, is sufficient. Hence our burden has been reduced by moving to an advanced review by three, rather than four, medical experts (i.e., a pediatric cardiologists, a forensic pathologist, and either a pediatric neurologist or an epileptologist). Because the questions structuring the review for each type

of specialist are the same, the calculation of the burden uses one data collection guideline (**Attachment 7b**), and has been collapsed into a single burden estimate for all medical experts.

As a result of these changes, the annualized burden estimate has been reduced from previous estimates of 750 hours to 521 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

Table 4 Project Time Schedule

Activity	Time Schedule
Selection of awardees through objective review	July 2018
Beginning of project performance year	September 31, 2018
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

Time schedule for entire project: The project will begin September 30, 2018 and will end September 29, 2023. It may be re-competed and/or expanded in 2023.

Length of time requested for OMB clearance: 3 years

Plans for tabulation and publication: Data will be publically reported in periodic manuscripts that describe the SDY cases in the Registry.

Complex analytical techniques that will be used: No complex analysis is planned; only descriptive data analyses are planned.

Analysis plan: Aggregated (i.e., not on individual cases level) information entered into the NFR-CRS will be analyzed by CDC on a quarterly basis for quality improvement purposes only. The Data Coordinating Center will also use 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 will use their data to develop targeted prevention strategies to reduce the number of infant and childhood deaths.

17. Reason(s) Display of OMB Expiration Date is Inappropriate
The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions
There are no exceptions to the certification.