

Supporting Statement A

Extension: OMB No. 0920-1092 9/30/2025

Supporting Statement A

Program Official/Contact

Renata Thompson

Public Health Advisor

National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention

P: 770-488-5380

F: 770-488-6283

Zns4@cdc.gov

[Click here to enter submission date Month day, 20##]

TABLE OF CONTENTS

A. JUSTIFICATION.....	4
A1. Circumstances Making the Collection of Information Necessary.....	4
A3. Use of Improved Information Technology and Burden Reduction.....	8
A4. Efforts to Identify Duplication and Use of Similar Information.....	9
A5. Impact on Small Businesses or Other Small Entities.....	9
The information compiled will have no impact on small businesses or other small entities.....	9
A6. Consequences of Collecting the Information Less Frequently.....	9
A7. Special Circumstances Relating to the Guidelines of 5 CRF 1320.5.....	9
A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency.....	9
A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent..	11
A11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	13
A12. Estimates of Annualized Burden Hours and Costs.....	13
A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers.....	15
A14. Annualized Cost to the Federal Government.....	15
A15. Explanation for Program Changes or Adjustments.....	16
A16. Plans for Tabulation and Publication and Project Time Schedule.....	16
A17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	17
A18. Exceptions to Certification for Paperwork Reduction Act Submission.....	17
REFERENCES.....	18

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. Screenshots of web-based data collection pages: 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 package

4. Agreement between CDC and recipients MPHI Security Policy, #06-02

5. NCFRP Child Death Review – Case Reporting System Security Information

6. Institutional Determination of Research Status: non-research determination

7. Privacy Narrative

JUSTIFICATION SUMMARY

Goal of the project: The goal of the Sudden Death in the Young (SDY) component of the Sudden Unexpected Infant Death (SUID) and SDY Case Registry (hereafter referred to as the “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 inform our understanding of the epidemiology of SDY, including the incidence, and risk factors. These elements are used to inform prevention strategies as well as development of best practices for multi-state 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 606 cases, recipients 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 303 of these cases, recipients 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 recipient jurisdictions who die suddenly and unexpectedly, and whose deaths are not explained by a homicide, suicide, drug overdose, terminal illness, or an external cause that is the only and obvious reason for the fatal injury (e.g., driver in a single-motor vehicle crash).

How data will be analyzed: CDC analyzes previously compiled, aggregated data and assesses the completeness (including missing and unknown responses), timeliness, and case ascertainment of the data set. CDC shares findings and works with SDY recipients to provide technical assistance to improve the data quality and utility over time. Data analyses beyond quality improvement analyses conducted by CDC are determined by the recipients. Recipients 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 an extension of a previous ICR (OMB #0920-1092, Expiration 9/30/25). 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 three 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 and therefore only needs an extension.

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 Sudden Death in the Young (SDY) vary broadly due to differences in case 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.

To meet the ongoing need to produce accurate and uniform information, CDC, and NIH continued the SDY Case Registry in 2018 with 13 recipients through a CDC-based cooperative agreement program (DP18-1806). In 2023, a new cooperative agreement program with 12 recipients (DP23-0006) was launched by CDC with continued support from NIH. The current revision seeks to revise burden hour estimates, modify responses for data elements collected, and to extend OMB approval for a period of three years. The information gathered 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.

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/jurisdiction participating in the SDY Case Registry include:

1. As part of existing CDR process, recipients 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 of the SDY module SDY Case Registry recipients 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, recipients, 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, recipients 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 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.
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 recipients; 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 recipients 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.

A2. 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 calculate the incidence of SDY accurately and reliably 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 recipients 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 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
- MICH-03 Reduce the rate of deaths in children and adolescents aged 1 to 19 years
- MICH-14 Increase the proportion of infants who are put to sleep on their backs
- MICH D03 Increase the proportion of infants who are put to sleep in a safe sleep environment

The data compiled by the recipients 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. 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.

Data from the system are made publicly available through a data request directly to MPHI. States always have access to their own data.

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 recipients. 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 recipients 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.

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 June 16, 2025, vol. 090 No. 114, pp. 25287-25288 (see Att 3).

CDC did not receive public comments related to this notice.

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.

Table 1. External Consultations

<i>Sudden Death in the Young (SDY) Experts Consulted</i>			
Biorepository			
Name	Title and Affiliation	Contact information	Role

Mark Russell	Cardiologist	mruess@med.umich.edu 734-764-5176	Director of Biorepository, University of Michigan (UMI)
Sarah Geisler	Laboratory Technician	ssutter@med.umich.edu 734-615-2429	Biorepository Lead Tech, UMI
Data Coordinating Center (DCC) at Michigan Public Health Institute			
Meghan Faulkner	SDY Data Coordinating Center (DCC) Director	mfaulkne@mphi.org 517-324-6014	Technical Assistance
Heather MacLeod	SDY DCC Senior Project Manager	hmacleod@mphi.org 630-432-9918	Primary contact for SDY; expertise in genetic counseling, Technical Assistance
Krishna Felzke	SDY DCC Project Coordinator	kfelzke@mphi.org 517-324-8339	Technical Assistance
Erik Buczowski	SDY DCC Data Manager	ebuczko@mphi.org 517-324-6061	Data Manager for SDY Case Registry, Technical Assistance
National Institutes of Health			
Kristin Burns	Medical Officer, National Heart, Lung, and Blood Institute (NHLBI)	kristin.burns@nih.gov 301-594-6859	Overall lead for SDY Case Registry Study and cardiac expertise
Bryanna Schwartz	Medical Officer, NHLBI	Bryanna.Schwartz@nih.gov 301-594-8868	Secondary lead for questions related to cardiac conditions
Vicky Whittemore	Program Director, National Institute of Neurologic Disorders and Stroke (NINDS)	vicky.whittemore@nih.gov 301-496-1917	Sudden Unexpected Death in Epilepsy (SUDEP) and epilepsy

Table 2. Consultations within CDC

Name	Title	Affiliation	Email	Role
Tiffany Colarusso, MD	Team Lead	DRH	tja4@cdc.gov	project guidance
Sharyn Parks Brown	Epidemiologist	DRH	svp2@cdc.gov	Lead Epidemiologist and Data support
Alexa Erck-Lambert	Epidemiologist/ Program Manager	DRH	Xwp5@cdc.gov v 847-651-3119	Data Support and Technical Support

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 7**). 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 of their contract with CDC. 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.

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 4**). 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 5**)

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

This project determined that this project does not constitute research with human subjects as defined by the US Code of Federal Regulations (45 CFR 46.102). (**See Att. 7.**)

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 recipients since, unlike ongoing routine CDR programs, recipients 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, recipients (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.

Recipients on average compile data for an estimated 606 cases per year. For the SDY Case Registry, each of the 12 federally funded state/jurisdiction recipients, on average, have 51 of the 606 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 takes, on average, 10 minutes to enter data on each case into Module I (**Attachment 2a**).

Additionally, using data from previous work we estimated the portion of SDY cases that require an advanced review. Per our assessment, approximately, 50% or an estimated 303 cases, require advanced review each year. Burden is assessed for the advanced review team’s time to review each of the estimated 303 cases (average 51 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 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 (**Attachment 2a**). The estimated burden is 15 minutes per case. Since each of the 12 recipients are required to include 3 medical expert respondents, we estimate 36 medical expert respondents in total, each reviewing an average of 26 cases for a burden of 234 hours.

Following the advanced case review, each of the 12 federally funded state/jurisdiction recipients complete SDY module N (**Attachment 2c**). 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 takes approximately 10 minutes to enter data on each case. The module is completed for each of the 606 cases each year, averaging 51 cases per recipient.

Table A12A: Estimated Annualized Burden (Hours)

Type of respondent	Form name	No. of respondent	No. Responses	Average burden per	Total burden
--------------------	-----------	-------------------	---------------	--------------------	--------------

		s	per respondent	response (in hours)	hours
State health personnel	SDY Module I	12	51	10/60	102
Medical Expert	Advanced Review	36	26	15/60	234
State Health Personnel	SDY Module N	12	51	10/60	102
Total hours					438 hours

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 Health Personnel	SDY Module I	12	51	10/60	102	\$20.61	\$2,102.22
Medical Expert	Advanced Review	36	26	15/60	234	\$157.82	\$36,929.88
State Health Personnel	SDY Module N	12	51	10/60	102	\$20.61	\$2,102.22
Total							\$41,134.32

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 recipients 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 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 total annual cost to the government for these tasks is \$120,000 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 (\$1,008,330 total) between CDC and the 12 state and jurisdictional recipients are allocated to cover the time devoted to SDY module data entry and advanced clinical review. In addition, \$9,380 is needed for CDC personnel salaries.

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

Expense Type	Expense Explanation	Annual Costs (dollars)
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"> Centers for Disease Control and Prevention (\$33,628) National Heart Lung Blood Institute (NHLBI) (\$86,372) 	\$120,000
Cooperative Agreement	Cooperative Agreement DP18-1806 with 12 SDY Registry Recipients: 5% of time devoted to advanced review, SDY module and quality assurance measures.	\$50,416
CDC Personnel	Health Scientist GS-12, 2% of FTE	\$2,124
	Epidemiologist GS-13, 2% of FTE	\$2,526
	Team Lead, Medical Officer GS-14, 1% of FTE	\$2,000
	Health Scientist GS-14, 1% of FTE	\$1,492
	Public Health Advisor GS-13, 1% of FTE	\$1,238

	Subtotal, CDC Personnel	\$9,380
	TOTAL COST TO THE GOVERNMENT	\$179,796

A15. Explanation for Program Changes or Adjustments

This request is for an extension.

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 recipients' timeliness of data, data completeness on SDY variables and case ascertainment. Data analyses beyond quality improvement analyses conducted by CDC are determined by the recipients. Recipients use their data to develop targeted prevention strategies to reduce the number of infant and childhood 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.

REFERENCES

1. 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

2. 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>)