Information Collection Request
New
Supporting Statement Part A

Sudden Death in the Young Registry

Project Officer: Lena Camperlengo
Health Scientist, Sudden Unexpected Infant Death Initiative
Division of Reproductive Health
Centers for Disease Control & Prevention
770-488-6322 phone
gtx6@cdc.gov
(770) 488-6283 fax

December 9, 2015

Table of Contents

A. Justification

List of Tables

List of Attachments

1. Applicable Laws
    a. Public Health Service Act, Section 301(a) and Section 317K, 42 USC 241(a), 42 USC 247b-12
    b. Sudden Unexpected Death Data Enhancement and Awareness Act, Public Law Number 113-236 (enacted into law on December 18, 2014)
2. Federal Register Notice
    a. 60-day FRN
    b. Summary of Public Comments
3. NCRPCD Case Reporting System - SDY Module
4. MPHI Security Policy, #06-02
5. NCRPCD Child Death Review – Case Reporting System Security Information
6. SDY grantees and expected number of cases
7. NCRPCD secured login screen
8. SDY Steering Committee members

- Goal of the study: The purpose of the information being compiled is to pilot a new standardized method to evaluate the incidence of SDY in 10 participating states and jurisdictions. The methods piloted in this study will be the first time true population-based incidence will be ascertained, because all SDY deaths will be identified, reviewed, and categorized into types based on a common protocol for case ascertainment and classification. ten

- The subpopulation to be studied: A sub-set of deceased youth in 10 grantee states/jurisdictions whose cause of death remained unexplained, cardiac, or neurologic in nature after an autopsy.

- Data collection methods: Piloted information collection and reporting builds on existing, state-based procedures for Child Death Review (CDR). SDY Registry awardees currently participate in a voluntary, state-based case reporting system (CRS) managed by the National Center for the Review and Prevention of Child Death (NCRPCD). SDY Registry awardees will conduct an advanced clinical review of SDY cases according to a common protocol and enter standardized variables into a new SDY module for the CRS. The new SDY module is the subject of this information collection request.

- How data will be analyzed: The CDC will work with SDY grantees to analyze aggregate data for completeness (including missing and unknown responses), timeliness of completed cases and case ascertainment. Since states own their data, any other data analysis is decided by the state. CDC will not be conducting any general research on the information collected from SDY cases within this pilot evaluation.

- Intended use of the resulting data: CDC will work with SDY Registry awardees to improve classification systems and epidemiology of SDY, and to formulate recommendations and best practices for national surveillance of SDY. Improvements in the classification and reporting of SDY cases are essential for the design and implementation of appropriate interventions. States will use their data to determine targeted prevention strategies to reduce the number of infant and childhood deaths.

Supporting Statement A

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a **new** information collection request, authorized by the Public Health Service Act, as amended, Section 301(a) and Section 317K, 42 USC 241(a), 42 USC 247b-12 (See Attachment 1a). In addition, this new request fulfills the Centers for Disease Control and Prevention's (CDC's) obligation to the Sudden Unexpected Death Data Enhancement and Awareness Act, Public Law Number 113-236 (enacted into law on December 18, 2014). 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 old, and to report these activities to Congress by 2016 (See Attachment 1b).

CDC seeks OMB approval for **three years** for federally sponsored information collection designed to strengthen state-based child death review programs. This request seeks approval for:

- CDC SDY Registry grantees to ***conduct*** an advanced clinical case review for SDY cases, beyond the current multi-disciplinary reviews in state and local Child Death Review programs.
- CDC SDY Registry grantees to ***enter*** new standardized Sudden Death in the Young (SDY) variables into an existing data compilation system called the National Child Death Review and Prevention's Case Reporting System.

The death of an infant, child, or young adult is a tragic event—whether caused by injury, poisoning, illness, or other factors. Depending on the jurisdiction in which the death occurred, the cause of death must be certified by an elected government official (a coroner) or an appointed physician who specializes in forensics or pathology (a medical examiner). The death certificate will then be filed with the State and/or county vital registration office, which maintains official records of births, deaths, and other vital statistics. State and local laws determine whether the jurisdiction relies on coroners or medical examiners; determine the professional qualifications for these positions; establish each jurisdiction's procedures for investigating and reporting deaths; and in some cases, specify the participation of additional officials or consultants in the death scene investigation or the determination of cause of death.

Over time, and recognizing the unique circumstances and vulnerabilities experienced by children, states have instituted Child Death Review (CDR) programs to promote thorough, multidisciplinary review of deaths involving infants, children, and youth. Child Death Review (CDR) programs now function in every state, and the program is often mandated by the state. CDR teams often include law enforcement officials, personnel from social services departments, and specialized medical consultants. States have moved toward team-based approaches to CDR because they improve the quality of information reported on individual death certificates and the state's summary reports on vital statistics. In turn, improvements in classification and reporting also strengthen the state's capacity to implement and evaluate strategies for reducing infant and child deaths. Finally, multidisciplinary CDR teams support essential linkages and communications among diverse stakeholders and departments who have responsibilities for maternal and child health.

The term “Sudden Death in the Young” (SDY) is defined as any death of an infant, child, or young adult, investigated by a medical examiner or coroner, except homicides, suicides, overdoses, poisonings, or other obvious external injury deaths. Estimates of the annual incidence of SDY vary broadly due to differences in definitions, inconsistencies in classifying cause of death on death certificates, variable ages and types of study populations, and differing case ascertainment methodologies. Because complete information has not been collected on the incidence, causes, and risk factors for SDY, lack of evidence confounds attempts to implement optimal diagnostic, treatment, and public health prevention approaches for reducing the incidence of SDY.

Some deaths are caused by previously undiagnosed medical conditions and might be prevented with early intervention. Medical conditions that are known to increase the risk of SDY include hypertrophic cardiomyopathy, coronary artery anomalies of wrong sinus origin, arrhythmogenic right ventricular cardiomyopathy, ion channelopathies, and genetic forms of epilepsy such as Dravet Syndrome. Sudden cardiac death in the young (SCDY) has been documented at all ages and may be associated with competitive athletics. However, in up to 30% of cases of SCDY no specific diagnosis is found. Similarly, sudden unexplained death in epilepsy (SUDEP) has been documented at all ages, and several risk factors have been identified, including some cases originating with ion channelopathies. For infants less than one year of age, approximately 10-15% of Sudden Unexpected Infant Death (SUID) cases may also be due to ion channelopathies.

To improve U.S. estimates of SDY incidence and its epidemiology, there is a need for a surveillance system that produces more accurate and timely information about SDY and identifies deaths attributable to SCDY and SUDEP based on uniform case definitions. To address this knowledge gap, the Centers for Disease Control and Prevention (CDC), in collaboration with the National Institutes of Health (NIH) National Heart, Lung, and Blood Institute (NHLBI) and the National Institute of Neurological Disorders and Stroke (NINDS), are working with ten selected states or jurisdictions to implement the Sudden Death in the Young (SDY) Registry through a CDC-based cooperative agreement program (DP14-1403). Eligible applicants included state health offices or their bona fide agents. Applicants were either the state’s Child Death Review (CDR) team, or they worked in tandem with this state-based program. Key activities for each state/jurisdiction participating in the SDY Registry pilot program include:

1. Local and state CDR teams will continue to identify, review and enter information pertaining to infant and childhood deaths up to the age mandated by state law or protocol and following the procedures maintained by the National Center for the Review and Prevention of Child Death (NCRPCD).

2. The state CDR team will set up an advanced review of a sub-set of cases regularly reviewed by the state’s CDR teams. An advanced review team should consist of a pediatric cardiologist, an epileptologist, a neurologist, a forensic pathologist, and a representative from the state health department. Using a standardized algorithm, the advanced review team will determine the category in which each SDY case belongs.

3. The state CDR team will enter SDY-specific information in the web-based NCRPCD Case Reporting System (CRS), already used by state CDR teams. All information is compiled from primary data sources already used by CDR teams and include death investigation and autopsy reports as well as health and social services records as mandated by law in each state. State participation in the SDY Registry does not impose additional burden on primary sources of information such as families, law enforcement, social service records, etc.

4. The state CDR team will work with CDC staff to develop, implement and evaluate new strategies to improve data completeness, timeliness of case information and case ascertainment.

The activities and resources offered to grantees under the CDC-funded cooperative agreement thus represent a pilot approach that, if successful in elucidating the characteristics and incidence of some SDY cases, will contribute to both national and state-based efforts for SDY classification, surveillance, and prevention.

The SDY Registry builds on existing collaborations and infrastructure unified by a common purpose: strengthening state-based systems for assessing deaths in infants, children and youth and developing appropriate prevention strategies. CDC has previously provided funding and guidance to state-based CDR teams to strengthen monitoring and classification of sudden unexpected infant deaths (SUID). The SDY project, like the SUID project, is built on a major collaborative effort supported through The National Center for the Review and Prevention of Child Death (NCRPCD) at the Michigan Public Health Institute (http://www.mphi.org). The information needed for the CDC-sponsored SDY variables is appended to the existing NCRPCD infrastructure, since this system is familiar to states and is a likely vehicle for expansion. The NCRPCD support currently covers a broad array of process-oriented CDR issues such as forming multi-disciplinary teams, moving from state to local reviews and strengthening partnerships with the local forensic community. In addition, the NCRPCD provides support to CDR programs that voluntarily participate in the web-based NCRPCD Case Reporting System (CRS). This CRS provides a standardized way to compile infant and child death information, already accessed and reviewed by state and local teams. Local and state teams own their data and identifiable data (if entered at all) is not available to anyone but the state that owns the data. The NCRPCD was developed in part with funding and technical assistance from the federal Health Resources and Services Administration (HRSA).

The NCRPCD web-based CRS version 4.0 launched in May 2015 and includes SDY-specific variables based on the common case ascertainment protocol. CDC funded SDY grantees will receive guidance to improve their data completeness, including these new SDY variables, and are expected to enter new SDY variables and to conduct an advanced review for a sub-set of SDY cases. Version 4.0 is available to all CDR programs that use the Case Reporting System. Therefore, these new SDY-specific variables are available for all CDR programs to use at the discretion of each state. In addition, unfunded local and state CDR teams may wish to conduct specialized advanced clinical reviews and are not prohibited from doing so. However, the CDC-sponsored SDY Registry aims to improve data completeness and timeliness of the data entered by providing consultation and guidance to grantees only. The intended result will be complete and timely grantee-based infant and child death information that can be used to guide program and policy decisions at the state and local levels.

Burden is only assessed for the CDC SDY Registry grantees since this is the only activity that is considered federally sponsored. For the purposes of this ICR, a “respondent” is a SDY Registry grantee funded by CDC. As a grantee for CDC’s cooperative agreement, the respondent agrees to compile a specifically defined set of SDY information about a defined set of deaths of children through the state’s existing CDR program.

2. Purpose and Use of the Information Collection

The purpose of the information being compiled is to implement a pilot methodology to better estimate incidence of SDY in the 10 participating states and jurisdictions. This will be the first time true population-based incidence will be ascertained, because all SDY deaths will be identified, reviewed, and categorized into types based on a common protocol being piloted in this investigation for case ascertainment and classification.

The second purpose will be to increase the amount and consistency of data being measured so that more meaningful future research can be conducted. In 2011, the NIH queried the field of SDY experts to learn what research they would conduct if they had access to SDY surveillance data. In future years, the data compiled in the SDY Registry will be available to researchers, state health departments, and CDR programs that are investigating and promoting reporting, screening, genetic counseling and testing, diagnosis, and treatment of epilepsy and heart conditions to prevent SDY. Access to this data for NIH-funded researchers will be under the protocols set up by the NCRPCD and each participating state or jurisdiction, and will not involve CDC. Although researchers have addressed the underlying causes of many health conditions and deaths, there is insufficient understanding about the incidence and underlying causes of SDY. This project is intended to improve the completeness and quality of data from individual deaths so that states and researchers can ultimately investigate how and why these children die and how their deaths can be prevented. This particular information is not gathered by any other system, so if this request is not granted and the information is not gathered, grantees and researchers, we will remain ignorant about causes, incidence, and risk factors of SDY. This pilot project will inform future research through expansion of existing methodologies to other states participating in child death review.

The SDY Registry fits into the broader CDC research agenda in that it furthers 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

Public health goals like Healthy People 2020 are also tracked by states. In addition to informing state and local SDY prevention programs, the information compiled in the Case Reporting System can be used by states to track and report progress towards state and federal public health goals, such as Healthy People 2020 (listed above) as well as state-mandated Child Death Review Reports.

The data compiled by the grantees are also intended for use by the jurisdictions in which they were entered. For example, County X should use its data for information about how children in County X are dying. Similarly, a state CDR program can use statewide SDY data to inform its decisions about prevention recommendations and activities.

Grantees will compile the information through the CDR program in their state and through advanced clinical review of children whose death is defined as a SDY. How frequently they enter the information will be dependent on how many cases are identified in a CDR team's catchment area. It is anticipated that approximately 900 SDY deaths will be reviewed by participating states' CDR teams and advanced clinical review teams each year and entered into the Case Reporting System.

In this pilot evaluation, MPHI will provide de-identified data to the CDC quarterly. CDC and the Data Coordinating Center (MPHI) will use the data compiled through the methodology piloted in this project to assist the states with data quality improvement strategies. From guidance and consultation with CDC, grantees will test common case definitions and protocols, developing best practices and recommendations to improve data that can be adopted by jurisdictions that are not a part of the CDC-funded pilot program. Ultimately, the data compiled via the improved process will be used to better understand the incidence of SDY and the characteristics associated with these deaths in forthcoming research not included in the scope of this specific request.

3. Use of Improved Information Technology and Burden Reduction
All responses will be entered electronically into the new SDY module in the existing NCRPCD Case Reporting System, a web-based system stored on Michigan Public Health Institute (MPHI) servers.

The NCRPCD Case Reporting System is designed with extensive gatekeeper questions and responding skip patterns so "users" complete only relevant variables. This function is designed for maximum user ease and reduces the time burden for entering new SDY variables.

4. Efforts to Identify Duplication and Use of Similar Information
The NCRPCD Case Reporting System was developed with state CDR teams and has been functioning since 2005. No similar database exists. By building on an existing and familiar system, CDC is avoiding duplication of efforts and minimizing burden.

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. Local and state CDR teams will only compile information on an SDY case when a case occurs. Advanced clinical review teams will only review a sub-set of cases. Some grantee states have so few cases that they predict only yearly meetings while larger states may

have monthly or quarterly advanced clinical 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 Notice was published in the Federal Register on November 3, 2014 (Vol. 79, No. 212, pp. 65217-65218; see Attachment 2a). One public comment was received and acknowledged (Attachment 2b).

B. Consultation with persons outside the agency about the availability of data, frequency of collection, the clarity of instruction and record keeping, disclosure, or reporting format, and on the data elements to be recorded, disclosed, or reported.

In 2012, the National Heart, Lung and Blood Institute at the National Institutes of Health began collaborating with CDC to plan and create the SDY Registry. An SDY Steering Committee formed from this collaboration and was expanded to include a contracted Data Coordinating Center at Michigan Public Health Institute. Since its formation, the Steering Committee has met regularly via teleconference to discuss pertinent issues.

In addition, CDC and NIH convened the SDY Advisory Committee, which met twice in Atlanta in early 2014 for technical consultation and to develop the new SDY variables. The SDY Advisory Committee is composed of experts including leaders in forensic and cardiac pathology, epileptologists, cardiologists, public health, genetics, child death review, and advocacy. Many of the expert panel members are active researchers and clinicians. They were selected and invited to participate on the SDY Advisory Committee by the SDY Steering Committee based on level of expertise, clinical and research contributions, and interest in better characterizing and preventing SDY.

The SDY Advisory Committee will stay intact for technical consultation throughout the SDY Registry project. The new SDY variables represent a consensus list of questions recommended by leading experts for characterizing SDY and identifying methods for prevention.

In version 4.0 (launch date June 2015) of the NCRPCD Case Reporting System, new SDY variables will be available to all CDR teams- those funded for the SDY Registry as well as those not funded. Unfunded states will not receive CDC technical assistance to improve the information already compiled, reviewed and discussed at state and local CDR programs.

9. Explanation of Any Payment or Gift to Respondents
No remuneration will be provided to respondents (i.e., grantees) other than the CDC's cooperative agreement (DP14-1403) funds to participating state health departments.

10. Assurance of Confidentiality Provided to Respondents
As stated above, "respondents" are grantees consisting of the 10 sites evaluated in this pilot study. The CDC will be monitoring grantee data completeness, timeliness and case ascertainment levels compiled via the new methodology piloted in this project. The CDC safeguards individual grantee information and grantee-level information is not shared with other grantees in an attempt to keep data quality

information confidential. Since grantees are funded with federal dollars, they do not assume that their contact information will be confidential. The CDC shreds their original applications to ensure confidentiality. Once awarded, grantees do share program information with no assurances of confidentiality.

Privacy Impact Assessment
For purposes of the Privacy Impact Assessment, a "respondent" or "individual" is considered the SDY grantee. The "data collection system" refers to the CDC DRH-sponsored SDY variables, which are a part of a larger web-based data collection system maintained by the National Center for the Review and Prevention of Child Death.

Overview of the data collection system
The CDC-sponsored SDY variables are being added to an existing web-based Case Reporting System, managed by the NCRPCD. This Case Reporting System is voluntarily used by state and local Child Death Review programs.

The Case Reporting System was built by NCRPCD's programmers and has been in place since 2005. It is a voluntary central database for use by state CDR programs, into which they enter data about the circumstances of each child death they review. Forty-three states now use the Case Reporting System. The data is entered into the online database by a person designated by the state CDR coordinator and that data entry person is granted restricted access to enter CDR and SDY data. The job description of the person who enters data varies from jurisdiction to jurisdiction, depending on how the jurisdiction's CDR team is structured.

Access to the secured NCRPCD Case Reporting System is password protected and NCRPCD controls and monitors access and provides training for users. All users are subject to their state laws related to the CDR process and the privacy of the data being collected. All users are also subject to the terms of a data use agreement between the NCRPCD and each participating grantee.

Users have access only to the information they enter. In other words, the system does not allow one local team to see information entered by another local team. The NCRPCD has no access to certain identifiable data fields either.

All information compiled in the Case Reporting System is on deceased infants, children and adolescents. The upper age limit is determined by state laws. CDR programs are functioning in all U.S. states as well as Guam, the Department of Defense and Navajo Nation. States use the web-based NCRPCD Case Reporting System to compile standardized information on these infant and child deaths in order to produce state mandated reports and target prevention strategies.

The users who will enter the SDY data in the participating states are the same users who currently enter CDR data into the system. The proposed change from current operations for users is that they will enter answers to new variables specifically related to SDY. States that are not funded by CDC through this cooperative agreement will also be able to enter the new dataset of SDY variables if they so choose, but they will not receive technical assistance to improve their data quality.

Description of the information to be collected

The CDC-sponsored SDY variables added to the NCRPCD Case Reporting System represent information needed to determine incidence of SDY, such as sudden cardiac death and sudden death in epilepsy. New data variables specifically related to SDY that will be compiled from primary data sources is attached as Attachment 3 (note: Attachment 3 only includes new SDY variables and not the entire Case Report). This project does not include primary data collection. Grantees will compile data from previously collected data sources such as autopsy reports and medical records for the decedent, as they do for all CDR cases.

Description of how the information will be shared and for what purpose
The information compiled is owned and used by states to inform policies and evaluate infant and child death prevention programs. Since states own their data, any sharing is determined by their own policies. In addition, the NCRPCD has formalized protocols for potential investigators to request very specific, de-identified, aggregated information for research purposes. Any data shared beyond the users (i.e., the team entering the data) is stripped of identifiers using HIPAA guidelines. These stipulations are detailed in the data use agreement each participating state has with NCRPCD.

The CDC uses aggregated grantee data to monitor timelines and completeness of data as well as case ascertainment. The CDC enters into a data sharing agreement with each grantee. The CDC does not have access to identifiable information per the data sharing agreement.

Impact the proposed collection will have on the respondent's privacy
Since a "respondent" is the SDY grantee, the privacy issue becomes pertinent to the grantee (often a state or state agency). State and local teams collect and own their data, so they control access to their data.

In the process of providing technical assistance to grantees, CDC is careful to protect the identity of grantees when comparing meta-information on data completeness, timeliness of data and case ascertainment. Grantees are provided quarterly Data Summary Sheets that track their data quality over time and compare their statistics to the sum of all grantee cases.

If CDC were to publish any meta-information (e.g., in a process evaluation of data quality improvements), grantees would need to consent to use of their state name in the final manuscript, but there are no plans to publish information at the grantee level.

Informing individuals that providing the information is voluntary
"Individuals" are defined as funded grantees, so by nature of their proposal submission to become a SDY grantee, they are informed that they are voluntarily participating in technical assistance to improve their current CDR practices by improving data quality and compiling new SDY variables that will allow them to determine the incidence of SDY in their state or jurisdiction.

In addition, CDC procures a data sharing agreement between grantees and CDC so that CDC can access meta-information for purposes of providing technical assistance to improve grantee data quality.

Opportunities to consent to sharing and submission of information
"Individuals" are defined as funded grantees, so by nature of their proposal submission to become a SDY grantee, they are consenting to enter new SDY variables and convene the advanced review teams. Since

grantees own their SDY variable data, they are in control of providing or declining consent to any entity who wishes to receive that data.

The CDC enters into a data sharing agreement to receive meta-information on a grantee's aggregate cases. No identifiers are shared with CDC and CDC uses this information to conduct technical assistance activities.

How the information will be secured
All data compiled will be entered by the state assigned grantee users into the NCRPCD Case Reporting System and stored on Michigan Public Health Institute (MPHI) servers. All involved MPHI staff comply with institutional standard operating procedures related to subject confidentiality, information security, safe data collection practices, etc. Only users authorized by SDY sites will be assigned a password to access the system, and the password must be changed every 6 months. Web entry users will be trained on privacy sensitive data.

MPHI has the following formal policies pertaining to security of data: Building Facilities Management (includes building security), Policy # 04-05; Secure Transport and Receipt of HIPAA Regulated Protected Health Information, #08-02-.12; Breach Notification Policy, # 08-02.9; De-identified Data, # 08-02.5; Accounting for Disclosures of PHI, #08-02.3; Authorizations for Use and Disclosure of PHI, #08.02-2; Privacy Training, #08-02.11; MPHI Security Policy, #06-02 (Attachment 4); Server Security & Management Policy, #04-13; MPHI Child Death Review – Case Reporting System Security Information (Attachment 5).

Whether a system of records is being created under the Privacy Act
No. There are no records created under the Privacy Act.

IRB Approval
The SDY Registry (DP14-1403) has been determined a non-research cooperative agreement and thus is not considered for IRB approval.

Grantees participating in the SDY Registry follow IRB rules for their state and agency. IRB is not usually considered necessary for CDR programs because the cases reviewed represent deceased individuals and no identifiable information is shared outside of the confidential review process.

11. Justification for Sensitive Questions
As stated above, "respondents" are grantees. The CDC will be monitoring grantee data completeness, timeliness and case ascertainment levels. These are not considered sensitive questions, yet CDC safeguards individual grantee information and grantee-level information is not shared with other grantees in an attempt to keep data quality information confidential.

12. Estimates of Annualized Burden Hours and Costs
A. Estimated Annualized Burden Hours
Estimates are based on an estimate of 900 cases annually (Attachment 6). SDY information will be entered into a new module of the existing NCRPCD Case Reporting System (Attachment 3). Burden is assessed only for the new SDY module being piloted in this project.

Burden is assessed for the state health office's time to enter the information into the NCRPCD Case Reporting System SDY module as well as time required to work on data quality improvement activities with CDC's contractor. The estimated burden for the state health office is 30 minutes per case.

Burden is also assessed for the advanced review team's time to review each case. Each team consists of medical experts such as a cardiologist, a neurologist or epileptologist and a forensic pathologist. The estimated burden is five minutes per specialist per case. The 900 cases annually will be distributed among the 10 grantees. The table reflects an even distribution among grantees. See Attachment 6 for per grantee estimates.

The estimate of the time burden is based on the experience with the existing NCRPCD Case Reporting System. With respect to data entry, even though there will be new SDY variables, not every case will be SDY and not every question will pertain to each case. For instance, one asks whether the child had a history of any of 38 conditions; no one child will have had every condition, so the respondent need only fill in applicable ones. The module also has a number of gatekeeper questions and extensive skip patterns so that respondents will not see inapplicable questions.

Another factor in estimating burden of data entry is that the respondents are already familiar with the current NCRPCD Case Reporting System, which they complete in their usual and customary business. It is the experience of the NCRPCD that questions will be an easy addition to the current task. The burden for data entry will be on state health office personnel. This burden will result in additional time as compared to the rest of the advanced review committee members. The burden on the clinical members of the advanced review team will only be their time to discuss the compiled primary data on each death. Each person listed below will only contribute brief points on each case and categorize the case. This is represented in Table 1 below.

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	10	90	30/60	450
Pediatric cardiologists	SDY Module	10	90	5/60	75
Epileptologists	SDY Module	10	90	5/60	75
Neurologists	SDY Module	10	90	5/60	75
Forensic pathologists	SDY Module	10	90	5/60	75
Total hours					**750 hours**

B. Estimated Annualized Costs to Respondents

Table 2 Estimated Annualized Burden Costs

Type of respondents	No. of respondents	No. Cases	Avg. Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respon-dent Costs
State health personnel	10	90	30/60	450	$18.90	$8,505
Pediatric cardiologists	10	90	5/60	75	$47.13	$3,535
Epileptologists	10	90	5/60	75	$47.13	$3,535
Neurologists	10	90	5/60	75	$47.13	$3,535
Forensic pathologists	10	90	5/60	75	$47.13	$3,535
Total						**$22,645**

Source: Department of Labor Medium Weekly Earnings of full-time wage and salary workers by detailed occupation and sex. http://www.bls.gov/cps/cpsaat39.htm.

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 grantees and the NCRPCD Case Reporting System 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 has been funded to plan and provide technical assistance and monitor the SDY Registry, including the two new grantee tasks of entering SDY variables and conducting advanced reviews. The total annual cost to the government for these new tasks will be $125,423 per year, which includes contract costs to the Data Coordinating Center, and ten grantee cooperative agreements costs to cover the entering of new SDY variables and convening an advanced review.

Table 3 Annualized Cost to the Federal Government

Item	Annualized Cost
$831,283 Data Coordinating Center Contract @ 10% of time spent on planning, implementing and monitoring two new tasks	83,128
$635,875 cooperative agreement with 10 grantees @ 5% of time spent on planning, implementing and monitoring two new tasks	31,795

Technical Monitors @ 5% and 2% of time spent on planning, implementing and monitoring two new tasks	10,500
Total	**$ 125,423**

15. Explanation for Program Changes or Adjustments
N/A. This is a new information collection request.

16. Plans for Tabulation and Publication and Project Time Schedule

Table 4 Project Time Schedule

Activity	Time Schedule
Selection of grantees through objective review	July 2014
Beginning of project performance year	September 1, 2014
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
Advanced review of cases that meet SDY Registry definition	Within 90 days of CDR team meeting
Collect and enter all SDY Registry data into NCRPCD Case Reporting System	Within 30 days of review team meetings
Analyze and disseminate data	Quarterly
Utilize SDY Registry Data	Quarterly for summary reports on data quality
Participate in grantee meetings	Annually

Time schedule for entire project: The project will begin September 1, 2014, and will end August 31, 2018. It may be re-competed and/or expanded at that time.

Length of time requested for OMB clearance: 3 years

Plans for tabulation and publication: There are no specific plans for publication of the data.

Complex analytical techniques that will be used: No complex analysis is planned.

Analysis plan: Information entered into the NCRPCD Case Reporting System will be analyzed quarterly on an aggregated level (i.e., not on individual cases level) for quality improvement purposes only. The Data Coordinating Center will track grantees' timeliness of data, data completeness on SDY variables and case ascertainment.

17. Reason(s) Display of OMB Expiration Date is Inappropriate
N/A

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.