

Information Collection Request  
New  
Supporting Statement Part A

Determining Causes of Sudden, Unexpected Infant Death: A National Survey of U.S. Medical  
Examiners and Coroners

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## **A. Justification**

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

The Centers for Disease Control and Prevention (CDC) requests approval by the Office of Management and Budget (OMB) for a new one-time collection of information to explore how medical examiners and coroners (MECs) interpret and report sudden unexpected and unexplained infant deaths (SUID) and the extent to which interpretation and reporting practices vary by jurisdiction. We will survey a nationally representative sample of 800 MECs using a paper survey instrument distributed by mail. Survey findings will help CDC develop evidence-based educational publications and presentations to support optimal classification and reporting practices in order to accurately monitor cause-specific sudden unexplained infant death (SUID) trends. OMB approval is requested for one year.

### **Background**

Each year in the United States, approximately 4,200 infants die suddenly without any cause that is immediately obvious. Half of these sudden unexpected infant deaths are attributed to Sudden Infant Death Syndrome (SIDS), which accounts for about 25% of all deaths between 1 month and twelve months of age and is the leading cause of postneonatal death (Hauck, 2004). Reducing deaths caused by SIDS and other SUID such as accidental suffocation are important public health priorities and identified as Healthy People 2020 objectives.

Between 1990 and 2001, the rate of SIDS in the U.S. decreased from 1.3 per 1,000 live births to 0.56 deaths per 1,000 live births (Task Force on Sudden Infant Death Syndrome, 2005). The 50% decline in SIDS is attributed to the success of the “Back to Sleep” campaign, launched in 1994, during which prone sleeping for infants decreased from about 75% in 1992 to 12% in 2002 (National Infant Sleep Position Public Access Web Site, 2011). SIDS has continued to decline slightly and in 2009 was estimated to be 0.525 deaths per 1000, while prone position for sleeping infants held steady at 11.4% (Kochanek et al., 2011). Yet as SIDS deaths were declining, post neonatal mortality due to other causes of SUID was on the rise, particularly in 1999-2001. Further examination of the cause-specific age at death and month of death distributions suggested that cases MECs once reported as SIDS were subsequently being reported as accidental suffocation and strangulation in bed or as cause unknown/unspecified (Malloy & MacDorman, 2005; Shapiro-Mendoza et al., 2006). Because SIDS, by definition, is nonspecific, there is substantial variation in how MECs interpret and report these deaths. The difficulty in consistently and accurately classifying these deaths reflects the limitations of investigation and documentation, thereby impacting our knowledge of the causes of infant mortality.

In the U.S., we lack an understanding of the variation in SUID reporting practices by MECs. The data collection effort we propose will fill important gaps in knowledge of variation in the way MECs classify and report SUID.

The purpose of this project is to understand how MECs interpret and report SUID and the extent to which their interpretation and reporting practices vary. This will be the first national, geographically representative survey of MECs to explore SUID diagnostic and reporting practices in depth.

The data collection for which approval is sought supports CDC's mission to promote the coordination of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of humans, authorized by Section 241 of the Public Health Service Act [42 U.S.C. 241] (Attachment 1). This data collection effort also supports the Healthy People 2020 objective of reducing the infant mortality rate to 6 deaths per 1,000 live births (Healthy People 2020 website, 2012). This data collection will complement other activities currently being done as part of CDC's Division of Reproductive Health's SUID Initiative. As part of this initiative, CDC is working to identify best practices and encourage consistent classification and reporting of cause of death. Improvements in data quality may lead to improvements in identifying individuals at risk and interventions to minimize SUID cases. The Sudden Infant Death Investigation Reporting Form (SUIDIRF) and guidelines were designed in collaboration with partners to assist investigative agencies to better understand the circumstances and factors contributing to unexplained deaths in infants. Use of the SUIDIRF and the guidance is voluntary. The materials provide a model for the types of information that if collected, can improve the investigation and classification of SUID cases. Along with the SUIDIRF, the CDC and partners developed training materials and conducted train-the-trainer regional academies for medical examiners, coroners, investigators, and child advocates across the United States. The SUIDIRF and training curriculum have been endorsed by several national organizations representing law enforcement, medical examiners, and coroners.

## **Privacy Impact Assessment**

### *Overview of the Data Collection System*

Two kinds of data will be collected as part of the study : 1) administrative data to identify persons responsible for certifying infant deaths in each county selected for the study, and 2) survey response data to be collected using a paper response instrument (Attachment 3). Information regarding the study and instructions to survey respondents are included on the first page of the survey and at the beginning of each survey section.

The survey data collection system will consist of the following components:

- *Telephone Screener.* During the screening phase, telephone interviewers will use computer assisted telephone interviewing (CATI) technology when they contact MECs' offices to capture the names of individuals who may certify infant deaths in their county (Attachment 4a). Additionally, this application will randomly select the individual(s) selected for participation, and will collect the best address and phone number for each.
- *Tracking Database.* During the data collection process, we will use a tracking data base to track each prospective respondent. This database will include the contact information for each respondent. These data will be automatically populated from the telephone screening script. The tracking data base will be used to track each step of the data collection process, generate personalized mailing labels, FedEx labels, survey identification (ID) labels, and personalized cover letters (Attachment 4b). The system will also facilitate follow-up through targeted postcard reminders (Attachment 4c) and/or telephone reminders (Attachment 4d). When surveys are returned, we will update the tracking system so that all follow-up activities are discontinued, which will result in the least amount of burden to study participants.
- *Data Entry Application.* Data from the paper surveys will be entered in a customized data entry application that will include functionality for double keying of all

surveys. During the second pass of data collection, any variable where there is not a match between the two passes will alert the data entry operator, so that s/he can determine the correct value.

CDC's data collection partner will be Battelle, a not-for-profit contract research organization. Personal information for survey respondents will be maintained for the duration of the study. At the conclusion of the study, Battelle will destroy the link between personal identifiers and respondent information (name, address, telephone number). CDC staff will never have access to respondent identifiers.

### *Items of Information to be Collected*

Administrative data containing the names, affiliations, and mailing information for person(s) responsible for certifying infant deaths in all U.S. counties will be obtained from SafetySource, augmented with information from the National Association of Medical Examiners (NAME)'s database.

The primary data collection effort will involve surveying MECs using a paper survey instrument to be distributed via express mail (Attachment 3). The survey instrument contains questions about respondents' organization/reporting jurisdiction (Section A), classification of death for a series of hypothetical infant death cases (Section B), knowledge and opinion regarding interpretation and reporting of infant deaths (Section C), reporting jurisdiction practices and training (Section D), respondent characteristics and demographics (Sections E and F), and jurisdiction-specific training and resource needs and general comments (Section G). Information collected using the paper survey instrument and stored in the data entry application will be retained according to CDC Records Control Schedule. A copy of this data file will be stored at Battelle for 10 years following the conclusion of Battelle's contract with CDC, per Battelle Records Management Policy.

No individually identifiable information will be collected in conjunction with the survey, although responses will be tracked using a unique respondent identification (ID) code. At the conclusion of the study, Battelle will destroy the link between the code and respondent name/contact information. CDC will never have access to any personally identifying information: The survey data file that will be delivered to CDC at the conclusion of the study will be stripped of all identifiers.

### *Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age*

Not applicable. This data collection effort will not involve website(s) and website content. All participants will be adults. No children under 13 years of age will be involved with the study.

## **2. Purpose and Use of Information Collection**

The U.S. Department of Health and Human Services (HHS) has identified reductions in the rates of SIDS and infant mortality as Healthy People 2020 objectives. In order to design and implement appropriate interventions, accurate information about the causes of infant mortality is needed, including better differentiation between SIDS and other sleep related infant deaths, such as suffocation.

The specific aims of this project are to understand how MECs interpret and report SUID and the extent to which MECs' diagnostic and reporting practices vary. Key questions to be addressed by this project are:

- What terms do MECs use in their cause-of-death determinations and how are these terms defined?
- What guides MECs' decision-making processes when they determine the cause of death/complete the cause of death statement (specifically, what criteria and evidence do they use)?
- How is cause of death typically classified/reported and how much variation is there in MECs' classification/reporting practices?

To answer these questions, we will conduct a nationally representative survey of approximately 800 MECs. Survey respondents will receive a copy of the survey instrument via express mail. Respondents will answer questions about the characteristics of their reporting jurisdiction, will review hypothetical infant death case descriptions and indicate how they would classify those cases (SIDS, SUID, accidental suffocation), will be asked about their reporting practices and training, will provide their knowledge and opinion about topics related to SUID, will be asked about their personal demographic characteristics, and will be given the opportunity to provide information about jurisdiction-specific training and resource needs as well as general comments.

CDC's overarching goal is to improve data collected at death scene investigations and promote consistent classification and reporting in determining the cause of unexpected infant deaths. Data collected from this survey will allow CDC to:

- Describe knowledge, opinion, and SUID diagnostic and reporting practices among U.S. MECs.
- Describe respondent characteristics.
- Examine the factors that influence MECs' interpretation and reporting practices concerning infant death. Factors to be explored will include MEC characteristics (such as training, education and experience) as well as characteristics of the MECs' reporting jurisdiction/region.
- Explore whether there is variation in knowledge, opinion, SUID diagnostic and reporting practices among U.S. MECs by selected sociodemographic characteristics. If differences exist, survey data will permit CDC to describe differences to target future interventions.
- Develop evidence-based educational publications and presentations to support optimal classification and reporting practices.
- Guide CDC's future training and technical assistance related to SUID Initiative activities.

Without this study, CDC has limited knowledge of the factors influencing MECs' SUID-related reporting and interpretation practices. We also will not have information about the extent to which there may be variation in MECs' SUID-related reporting practices. Without this study, CDC has limited information on which to base evidence-based educational publications and presentations to support optimal classification and reporting practices.

## **2.1 Privacy Impact Assessment**

Findings from this study will be disseminated through the publication of 1-3 manuscripts in peer-reviewed journals. Survey findings will also be used to develop educational publications and

presentations encouraging MECs to apply consistent standardized terms and definitions in determining the cause of unexpected infant deaths. All survey data will be de-identified prior to analysis and findings will be reported in the aggregate. Individual respondents will never be identified by name or reporting jurisdiction in oral or written presentations.

### **3. Use of Information Technology and Burden Reduction**

This study will use information technology to reduce the burden on study respondents during the respondent screening and data collection processes:

During the screening phase, telephone interviewers will use CATI technology when they contact MECs' offices to capture the names of individuals who certify infant deaths (Attachment 4a). Additionally, this application will randomly select the individual(s) selected for participation and will collect the best address and phone number for each. Use of CATI technology will reduce the burden on MEC office staff because responses will be given verbally rather than by completing a paper form.

During the data collection process, we will use a database to track each individual respondent that will include the contact information for each respondent. These data will be automatically populated from the telephone screening script. When surveys are returned, we will update the tracking system so that all follow-up activities (reminder calls, etc.) are discontinued. The system will reduce respondent burden by ensuring MECs are contacted at appropriate intervals and are not sent too many mailings. In addition, the system will track respondents to ensure that those who have responded are not contacted with reminders.

Because mail survey strategies have generally been more successful than have fax or Web-based approaches for achieving high response rates among medical professionals (e.g., Nicholls et al., 2011; VanGeest, Johnson & Welch, 2007), we elected to implement the survey via mail to maximize the response rate.

Finally, we have taken particular care to design the survey instrument to collect the minimum amount of information necessary to achieve the goals of the project. We carefully considered the most important factors to measure with respect to the project goals and designed questions to measure those factors.

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

No comparable data are available that meet the needs of the proposed study. Our efforts to identify other data sources examining national patterns in SUID diagnostic practices included systematic searches of the medical and public health literature, CDC research efforts, consultation with MEC experts in the U.S., attendance at professional meetings and national conferences, and informal contacts with staff at other agencies.

Although there is evidence that there are inconsistencies in the way that MECS and pathologists are using diagnostic protocols to classify infant deaths (Camperlengo, Shapiro-Mendoza & Kim, 2011; Graham, Hendrix & Schwalberg, 2009; Laskey, Haberkorn, Applegate & Catellier, 2009; Shapiro-Mendoza et al., 2006; and Walsh, Kryscio, Holsinger & Krous, 2010), previous investigations have not explored in depth the specific criteria that MECs are using to make cause of death determinations nor have they examined regional variation in diagnostic and reporting patterns across the U.S. A U.S. survey of MEC offices conducted by the Department of Justice



(DoJ) focused on collection of administrative and budget data and workload. Although this survey gathered limited information about the diagnostic preferences that MEC offices use, the focus was on total cases handled by the office rather than on infant deaths (Hickman et al., 2007; OMB No. 1121-0296, exp. 7/31/2008).

Based on this current information, it was concluded that no similar data collection effort has been conducted or is currently being conducted.

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

No small businesses will be involved in this data collection.

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

This request is for a one-time study. The data are needed to inform CDC initiatives and recommendations regarding SUID and to promote the Healthy People 2020 objective related to reducing rates of SIDS and infant mortality. This information is essential to guide future CDC efforts to increase consistency in the way MECs are classifying and reporting infant deaths. Without this study, CDC has limited information on which to base publications and presentations to support optimal classification and reporting practices and strategies for SUID prevention.

There are no legal obstacles to reduce the burden.

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

This project 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 of this data collection was published in the Federal Register on November 19, 2012, Volume 77, No. 223, pages 69485-69486 (see Attachment 2a). One public comment was received suggesting that the survey is unnecessary because the information is already available. This is a misperception; CDC has not previously conducted a national survey of U.S. medical examiners and coroners on this topic. CDC provided a courtesy acknowledgement of the public comment (see Attachment 2b).

B. The study protocol including the survey instruments, sampling plan, and data collection procedures were designed in collaboration with researchers at Battelle-Center for Analytics and Public Health.

Staff from the Division of Reproductive Health provided oversight and guidance to the Battelle researchers responsible for the design of the survey instrument, the sampling design, and data collection procedures. The CDC staff were:

<b>Name</b>	<b>Title</b>	<b>Affiliation</b>	<b>Phone Number</b>
Lena Camperlengo, RN, MPH, DrPH	Health Scientist	CDC	(770) 488-6322
Carrie Shapiro-Mendoza, Ph.D.	Senior Scientist	CDC	(770) 488-6263

In addition, four highly regarded U.S. MECs provided expert advice on survey goals, content and format. Two of the the consultants provided the case studies featured in Section B of the survey. Name, title, affiliation(s), and phone numbers are provided for our four MEC consultants are shown below:

<b>Name</b>	<b>Title</b>	<b>Affiliation(s)</b>	<b>Phone Number</b>
Thomas Andrew, MD	Chief Medical Examiner	Office of the Chief Medical Examiner, Concord, NH	(603) 271-1235
John Fudenberg	Assistant Coroner  President Elect/Secretary	Clark County, NV Coroner's Office  Iowa Association of County Medical Examiners (IACME)	(702) 455-3210
Randy Hanzlick, MD	Chief Medical Examiner  Professor of Forensic Pathology Director of Forensic Pathology Training	Fulton County, GA Medical Examiner's Office  Emory University School of Medicine	(404) 730-4400
Gregory Wyatt	Coroner	Sacramento, CA County Coroner's Office	(916) 874-9320

Three of the survey items (A1, D2, and D3) were adapted for use from the DoJ survey (Hickman et al., 2007). Earlier versions of the scenarios included in Section B of the survey were used previously in trainings conducted by two of the project consultants (T. Andrew and R. Hanzlick).

There were no problems with the survey that could not be resolved.

## **9. Explanation of Any Payment or Gift to Respondents**

We plan to provide MECs with a modest incentive of \$10 for participating in this survey.

Obtaining high survey response rates is particularly difficult for busy professionals like MECs. However, there is clear and consistent evidence that monetary incentives significantly increase response rates in most surveys, and experts on survey methods such as Kasprzyk, et al. (2001) and Dillman (2000) recommend their use.

Several studies specifically designed to test the effects of incentives on survey response rates among medical professionals have confirmed the importance of monetary incentives. One study by Everett, et al. (1997), for example, found that response rates were 18% higher among physicians receiving incentives (63% vs. 45%). Another study by Tambor et al. (1993) found significantly more physicians responded when a \$25 incentive was provided compared with a no incentive control group (62.0% vs. 18.3%). A third study by Berk et al. (1993) divided physicians into three groups: Group 1 received a monetary incentive on the initial mailing, Group 2 received a monetary incentive on a second mailing to non-responders, and Group 3 received no incentive. Response rates for the 3 groups were 63%, 50%, and 40%, respectively. Kasprzyk, et al (2001) tested incentives of \$0, \$15 and \$25 and found increased response with higher incentives (27%, 75% and 81% respectively).

The aforementioned studies clearly indicate that respondent incentives should be used to maximize the response rate to the survey. A study of a large sample of physicians found a lower response rate among the promised-incentive group (56%) and a higher response rate (71.5%) among the up-front-incentive group (Delnevo, et al., 2004). Clearly it is best to provide incentives at the time the survey is sent rather than upon return of the completed survey. Therefore, the monetary incentives for this study will be included in the initial survey packet sent to MECs.

In sum, the studies of health care professionals cited above clearly support provision of incentives to be sent with the survey. Achieving a response rate of 80% or higher to the proposed survey is critical to avoid selection bias. The monetary incentive alone is not sufficient to ensure that the study achieves a response rate of at least 80%. Other measures such as sending the surveys by Federal Express, thank you/reminder postcards, and follow-up telephone calls to nonrespondents will also be used to maximize the response rate to the mail survey. If all of these measures are implemented, the study is likely to achieve the targeted response rate.

## **10. Assurance of Confidentiality Provided to Respondents**

NCCDPHP has reviewed this study and has determined that the Privacy Act is not applicable. Although surveys will be mailed to named respondents, respondent names will not be collected on the completed mail survey form.

The data collection contractor (Battelle) will assign a unique ID code to each potential respondent and will maintain a tracking file that links respondent ID codes to respondent names. The tracking file is the only place where ID numbers will be linked with respondent names, and will only be used to track survey completion status and to facilitate follow-up reminders. The tracking file will be stored separately from survey response data and staff responsible for tracking will be different from those who work with the response data (i.e., coders, keyers, programmers, analysts). Hard copies of surveys will be kept in locked file cabinets when not being edited or keyed. Prior to filing and to being sent to data keying, each paper survey will be carefully checked for any identifying information. If any identifying information is found, it will be redacted from the surveys. Data files will be only accessed by the contractor responsible for data collection. Once data quality assurance measures (e.g. checking that all mailings have been sent and accounted for, checking for coding errors, checking that all electronic data have been uploaded) are completed, the tracking file information that would allow linking of individuals to their survey response data will be destroyed.

Statements describing procedures to maintain respondent privacy are included on the survey instrument introduction page (Attachment 3). CDC will receive a de-identified file of response data. All results will be reported in an aggregate manner.

A copy of the contractor's Institutional Review Board (IRB) approval letter is included as Attachment 5.

## **11. Justification for Sensitive Questions**

The survey instrument with introductory information on the cover page is found in Attachment 3. The survey cover letter is included as Attachment 4b. Although race and ethnicity data will be collected, there are no other personal questions on this survey that are generally considered to be personally sensitive, such as sexual behavior, religious beliefs, or alcohol or drug use. Some questions relating to MECs' professional practices are potentially sensitive, in that some respondents could feel anxious about being asked about their attitudes and practices, particularly if they are inconsistent and follow no documented practice guidelines. These questions, however, are essential to the purposes of the data collection. In addition, it has been shown that most physicians view national clinical practice guidelines as recommendations and do not view them as mandated practice standards (Cabana et al., 1999). To reduce potential anxiety about acknowledging practice inconsistent with national guidelines, respondents are reminded on the survey cover page that CDC is seeking information on a variety of practice styles and that there are no right or wrong answers. These issues are addressed in the cover letter that will accompany the survey and the survey instrument introduction.

## **12. Estimates of Annualized Burden Hour and Costs**

### **Estimated Hour Burden**

As shown in Table A. 12-1, the estimated respondent burden includes two components: (1) time for the screening phone call to the jurisdiction to identify the appropriate medical examiner or coroner to complete the mail survey, and (2) time for the selected respondent to review the instructions and complete the mail collection form.

A sample of 800 MECs will be selected for participation in the study. We anticipate that approximately 90% of these individuals will be coroners and 10% will be medical examiners (R. Hanzlick, personal communication, May 18, 2012). Based on the data collection contractor's previous experience with surveys of medical professionals using similar techniques (i.e., distributing surveys by Federal Express, thank you/reminder postcards, and follow-up telephone calls to nonrespondents, we anticipate that 640 respondents (80% of those contacted) will return a completed questionnaire.

We estimate that it will take five minutes for the telephone interviewer to conduct the screening call and to obtain or verify the name and mailing address of the selected medical examiner or coroner. Based upon the results of the pretest, we estimate that it will take respondents 30 minutes to review the instructions for the mail survey, search existing data sources and complete the mail survey. We estimate that approximately 50% of the sample will not respond to the survey within 2 weeks after the thank you/reminder postcard is mailed and will require a follow up call. The results of the pretest are discussed in Section B.4.

**Table A. 12-1. Estimated Annualized****Burden in Hours**

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per response (in hr)	Total Burden (in hr)
Jurisdiction Receptionist or Operator	Telephone screener	800	1	5/60	67
Coroner	National Survey of Medical Examiners and Coroners	576	1	30/60	288
Medical Examiner	National Survey of Medical Examiners and Coroners	64	1	30/60	32
Total					387

As shown in Table A. 12-1, assuming an average of five minutes per screening telephone call and 30 minutes for completion of the mail survey, the estimated annualized hourly burden is 387 hours. This total annual hourly burden represents 67 hours for the jurisdiction’s receptionist to answer the screening call and 288 hours for coroners and 32 hours for medical examiners to complete the mail survey.

### **Estimated Cost to Respondents**

The annualized total cost burden for the study is shown in Table A. 12-2. Assuming an hourly wage rate of \$13.46 for receptionists (based on an annual salary of \$28,000; Indeed.com website, 2012), \$25/hour for a coroner (based on an average annual salary of \$52,072; Buzzle.com website, 2012), and \$47.90/hour for medical examiners (based on an average annual salary of \$99,634 (CBSalary.com website, 2012), we estimate the cost burden to be \$9,630 for this one year study.<sup>0</sup> This represents a cost of \$897 for the jurisdictions’ receptionist or operator for the time spent responding to the telephone screening call and a cost of \$7,200 for the coroners and \$1,533 for the medical examiners for the time spent completing the mail survey.

<sup>0</sup> Assumes a typical employee works 2,080 hours per year.

**Table A. 12-2 Annualized Cost to Respondents**

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Average Hourly Wage Rate	Total Cost
Jurisdiction Receptionist or Operator	Telephone screener	800	1	5/60	\$13.46	\$897
Coroner	National Survey of Medical Examiners and Coroners	576	1	30/60	\$25.00	\$7,200
Medical Examiner	National Survey of Medical Examiners and Coroners	64	1	30/60	\$47.90	\$1,533
<b>Total</b>						<b>\$9,630</b>

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

There is no direct cost to respondents.

**14. Estimates of Annualized Cost to the Federal Government**

It will take one year to conduct this project. The total cost to the government will be \$302,000, which includes \$281,000 in contract costs to Battelle and \$21,000 in other costs to the Federal government. The other federal costs include salary, fringe, travel, and supply expenses related to the involvement of two federal employees: Carrie Shapiro-Mendoza and Lena Camperlengo. Carrie Shapiro-Mendoza is the principal investigator and the CDC technical monitor and will devote 5% FTE to the project. Lena Camperlengo will devote 2% FTE.

The resulting annualized cost to the government is \$312,000, which includes costs for survey planning and the 8 month period when the survey data will be collected, cleaned, and analyzed and the final report will be written.

**Table A. 14-1 Annualized Cost to the Federal Government**

Item	Annualized Cost
Contractor	\$302,000
Technical Monitor @ 5% and 2% Time	\$ 10,500
Total	\$312,500

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

This is a new study.

## 16. Plans for Tabulation and Publication and Project Time Schedule

### Time Schedule

The time schedule for remaining project activities is shown in Table A.16-1. Within the first month after receiving OMB approval, we will select the sample of MECs to be surveyed. Once the telephone interviewers have been trained, we will begin making the telephone screening calls to determine the names and addresses of the MECs to be surveyed. Surveys will be mailed in batches shortly after the telephone screening calls are made. Data collection will be completed within approximately five months of receiving OMB approval.

Data coding, entry and cleaning will begin as soon as completed surveys are returned and will be completed within approximately six months of receiving OMB approval, at which time an analytic dataset and codebook will be developed. Data analysis and report writing will be completed eight months after receiving OMB approval.

**Table A. 16-1 Project Time Schedule**

<b>Activity</b>	<b>Schedule (months after OMB clearance)</b>
Select sample of MECs	Month 1
Conduct screening telephone calls	Months 1-2
Conduct mail survey	Months 1-5
Data coding, entry, and cleaning	Months 1-6
Develop analytic data sets and codebook	Month 6
Data analysis	Month 6-7
Final report	Month 8

### Publication Plan

Findings from this study will be disseminated through the publication of 1-3 manuscripts in peer-reviewed journals. Survey findings will also be used to develop educational publications and presentations aimed at ensuring that MECs apply consistent standardized terms and definitions in determining the cause of unexpected infant deaths.

### Analysis Plan

After the survey data are entered and cleaned, the data file will be prepared for analysis and survey weights will be assigned. The analysis of the survey data will include univariate and bivariate analyses. Table shells illustrating the analyses to be performed are included as Attachment 6. The plans for weighting of the survey data and both types of analyses are described below.

### *Weighting of Survey Data*

In order to make quantitative estimates of any quantities or proportions estimated in the survey (i.e., the proportion of MECs who respond in a certain way to a specific survey question), survey weights will be employed to calculate appropriate confidence intervals on those estimates. If we performed a simple random survey of individuals from an infinitely large population, then 800 respondents would yield 95% confidence intervals of  $\pm 3.5\%$  on an estimated proportion of 50%. If the proportion were closer to 0% or 100% then the confidence interval would be more narrow. The structure of this survey is complex with the possibility of clustering within counties, so the correct number is not likely to be 3.5%. It will thus be necessary to employ the survey weights to estimate quantitative summaries and their associated confidence intervals.

### *Univariate Analysis*

Univariate distributions and descriptive statistics (means and frequencies) will first be obtained for all variables in the survey. Weighted total and percentage distributions will be generated for categorical variables, and weighted means will be generated for continuous variables.

### *Bivariate Analyses*

Bivariate analyses will next be conducted to examine differences in how MECs classify infant deaths by region, urban/rural, training and education, and other respondent characteristics.

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

Display of OMB expiration date is appropriate for this study.

### **18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exemptions being requested for this clearance.



## Bibliography

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