Supporting Statement of the Request for OMB Review and Approval of Promotion of the National Amyotrophic Lateral Sclerosis (ALS) Registry to Non-referral Centers

0923-NEW
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(Part A: Justification)

Principal Investigator:
Paul Mehta, MD
Division of Toxicology and Human Health Sciences
Agency for Toxic Substances and Disease Registry
4770 Buford Highway, MS F-57
Atlanta, GA 30341
Phone: 770-488-0556
Fax: 770-488-1537
Email: pum4@cdc.gov

Point of Contact:
Wendy E. Kaye, PhD
Agency for Toxic Substances and Disease Registry
Phone: 770-488-3696; Email: wek1@cdc.gov

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Goal of the study: This study aims to evaluate educational and promotional outreach activities among select non-referral/non-specialty center neurology practices.
Intended use of the resulting data: The proposed data collection is intended to inform neurologists and their staff about the National ALS Registry (Registry), to encourage them to inform their ALS patients about the Registry, and to increase persons with ALS self-enrollment in the Registry's web portal.
Methods to be used to collect: This project will employ an interrupted time series design with a comparison group. Data will be collected through phone calls, faxes, and key informant interviews with neurologists.
The subpopulation to be studied: Neurologists in three groups, with two states in each group, will receive various education and promotional components designed to encourage neurologists to promote the Registry to their patients with ALS.
Data analysis: Descriptive statistics will be used to analyze the changes between groups and resulting changes in Registry enrollment rates. Registry self-enrollment is vital for identifying new and prevalent ALS cases and currently provides the only opportunity for Persons with ALS (PALS) to complete the surveys and be eligible for notification about future research. This endeavor will promote the Registry to providers in direct contact with PALS as well as provide information on strengths and limitations of the current Registry materials and outreach methods. This information can be used to better promote the Registry and increase enrollment.

A. Justification

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a new two-year approval for an information collection request (ICR) titled the "Promotion of the National ALS Registry to Non-referral Centers."

1. Circumstances Making the Collection of Information Necessary

A bill to amend the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis Registry, S. 1382: ALS Registry Act, was signed into law on October 10, 2008 by President Bush and became Public Law 110-373 (**Attachment 1)**. The activities of this project are part of the ongoing effort to maintain the National ALS Registry (Registry, OMB Control No. 0923-0041, expiration date 09/30/2016).

Under the Act, ATSDR is authorized to (1) develop a system to collect data on amyotrophic lateral sclerosis (ALS) and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, or progress to ALS; and (2) establish a national registry for the collection and storage of such data to develop a population-based registry of cases. The primary goal of the surveillance system/national registry is to obtain more complete information on the likely prevalence of ALS and to better describe the demographic characteristics (age, race, sex, and geographic location) of those with ALS. The secondary goal of the national registry is to collect additional information on potential risk factors for ALS including, but not limited to, family history of ALS, smoking history, and military service.[1] The 60-day Federal Register Notice was published on March 24, 2015 and is provided in (**Attachment 2).**

ATSDR implemented the Registry in 2009 using an algorithm applied to national administrative databases from the Centers for Medicare and Medicaid Services, Veterans Health Administration, and Veterans Benefits Administration.[1,2] A self-registration component was launched in October 2010. The

Registry's non-traditional case ascertainment methodology required validation; therefore, ATSDR established State and Metropolitan ALS Surveillance Projects (Surveillance Projects, OMB Control No. 0923-0043, expiration date 04/30/2014). Surveillance Projects were completed in the entire states of Florida[3], New Jersey[4], and Texas, in coordination with the health department in each state, during 2010 and 2011.[5] Eight additional metropolitan area (Atlanta, Baltimore[6], Chicago, Detroit, Las Vegas, Los Angeles[7], Philadelphia[6], and San Francisco[7]) Surveillance Projects were conducted from 2011 to 2013.[5] ATSDR will use the surveillance dataset to evaluate the completeness of the Registry in these specific geographic areas by detecting discrepancies in the patterns of self-registration, as well as gaps in the completeness of administrative databases. In order to avoid biasing results from the Surveillance Projects' evaluation of the Registry's completeness, staff were instructed to not promote the Registry during the Surveillance Period which occurred from 2010 to 2013. This may have resulted in a missed educational and promotional outreach opportunity among neurologists.

According to the recently published Morbidity and Mortality Weekly Report (MMWR), the proportion of cases identified via self-enrollment was lower than those identified in the administrative data for the period October 2010 through December 2011; that is 15.8% of cases were identified through self-enrollment only, 14.7% were identified both through self-enrollment and the national administrative databases, and 69.5% were identified through the national administrative databases only.[8] Further, self-registered individuals are more likely to be younger in age and White.[8] On-going self-registration is critical because not all persons with ALS can be identified through the algorithm, and only self-registering persons with ALS can complete the risk-factor surveys. ATSDR has partnered with stakeholders at two large ALS service organizations to promote the Registry to persons with ALS and much of their work is conducted at the major ALS referral/specialty centers in the US. Therefore, efforts to increase Registry awareness among non-referral center neurology practices and to increase self-enrollment of persons with ALS through neurologists at non-referral center neurology practices are needed.

This request addresses the need to promote the Registry among neurologists who do not work at major ALS referral centers. This is a minimal risk study with no potential risks to the participants. The objectives of this project are to 1) implement a pilot project to conduct educational and promotional outreach activities at non-referral center neurology practices in the US, to inform neurologists and their staff about the Registry, to encourage them to inform their patients about the Registry, and to increase persons with ALS self-enrollment in the Registry through the web portal via the use of existing Registry brochures, pamphlets, and factsheets; and 2) examine the effectiveness of educational and promotional outreach activities by reviewing persons with ALS self-enrollment rates before, during, and after the project period. By increasing self-enrollment rates of a more diverse group of persons with ALS, ATSDR will be able to produce more accurate estimates of prevalence of ALS in the US, and collect risk-factor survey data from a more representative sample of persons with ALS nationwide. These activities will allow ATSDR to fulfill its congressional mandate under the ALS Registry Act (**Attachment 1**) and improve the overall Registry representativeness and usefulness.

To achieve these objectives, a four group educational and promotional outreach project has been designed (**Attachment 5**). Three groups (Group 1, Group 2, and Group 3), with two states in each group, will receive various educational and promotional components, and a fourth group (Group 4) consisting of the remaining 44 states will serve as a comparison. The two states selected for Group 1 previously participated in the Surveillance Projects (OMB 0093-0043, expiration date 4/30/2014), while the four states selected for Groups 2 and 3 did not host a Surveillance Project site. This project will implement a methodology similar to that used during the Surveillance Projects to identify non-referral center

neurologists in Groups 1, 2, and 3 (**Attachment 5**). Further, methods that were employed in the Surveillance Projects to discern whether neurologists do or would diagnose and/or care for ALS patients will be replicated in Groups 1 and 2.

2. Purpose and Use of Information Collection

The purpose of this information collection is to gather information from non-referral center neurologists and their neurology practices to better promote the National ALS Registry, and increase self-enrollment thereby increasing the representativeness of the Registry.

To meet the objectives defined in section A.1, a contract has been awarded by ATSDR to conduct this pilot project. This project will employ an interrupted time series design with a comparison group as described below. Data will be collected and analyzed with technical oversight from ATSDR over a two year period and results will be shared with the scientific community.

Educational and promotional outreach components, will include mailings, phone calls, and in-person communication. Identified neurologists in Group 1 [Florida (FL) and New Jersey (NJ)] will receive phone calls to determine if they diagnose/care for patients with ALS, a targeting mailing, follow-up phone calls, faxes as needed, key informant interviews, and train-the-trainer site visits. Identified neurologists in Group 2 [New York (NY) and Virginia (VA)], will receive phone calls to determine if they diagnose/care for patients with ALS, a targeted mailing, follow-up phone calls, and faxes as needed. Identified neurologists in Group 3 [Washington (WA) and Ohio (OH)] will receive only a mailing. Group 4 (remaining 44 states) will not receive any educational and promotional outreach components. Neurologists will be identified through public access information channels such as Medical Marketing Services, which gathers physician contact information from the American Medical Association, state licensing websites, and other publically available websites such as Health Grades.

By increasing self-enrollment rates, ATSDR will be able to produce more accurate estimates of the prevalence of ALS, and collect risk factor survey data from a more representative sample of persons with ALS nationwide. These activities will enhance the Registry and will allow ATSDR to fulfill its congressional mandate under the ALS Registry Act. ATSDR has begun analyzing the risk factor survey data[6], and has noted that self-enrolled individuals are more likely to be younger in age and White. The proposed project aims to increase Registry self-enrollment rates through promotion of Registry mentioned above to Non-referral Center neurologists, which should increase completion rates of the risk factor surveys, making the survey findings more generalizable to the US population. Further, the risk factor survey data may be used to generate hypotheses which could become the subject of future research studies. Stakeholders and neurologists use the Registry to recruit for their research projects, such as clinical trials. Increasing the number of people who are registered will provide a more representative self-enrolled population from which to sample for their projects. This potentially allows for their research findings to be generalizable to the US population. The key informant interview (KII) findings may help ATSDR make enhancements to the Registry and the Registry promotional materials.

3. Use of Improved Information Technology and Burden Reduction

Information collection for the project Promotion of the National ALS Registry to Non-referral Centers will be carried out through activities such as screening/initial phone calls, follow-up phone calls, train-the-trainer (TTT) and Key Informant Interviews (KIIs).

The Train-the-trainer (TTT) site visits will be conducted in-person using a presentation (**Appendix L1**). The TTT sessions will be shown on laptops and/or iPads. The provision of paper copies of materials will be kept to a minimum. TTT participants will not fill out any data collection instruments during the session. No information will be gathered at the TTT site visit, digital or otherwise.

The KIIs (**Appendix R**) will be conducted face-to-face. Respondents will not fill out any data collection instruments during the KIIs. Interviews will be tape recorded but recordings will be used to supplement field notes taken during the KII. Once the interview notes are completed, the tapes will be destroyed. After transcription the data will be given to ATSDR.

All participation is voluntary. The questions have been held to the absolute minimum required for the intended use of the data.

4. Efforts to Identify Duplication and Use of Similar Information

Because ATSDR staff is in communication with The Council of State and Territorial Epidemiologists, advocacy groups, and ALS researchers, it is clear that no other nationwide collection exists in this field of study. ATSDR has partnered with stakeholders at two large ALS service organizations to promote the Registry to persons with ALS and their work is conducted at the major ALS referral/specialty centers in the US. Therefore, efforts to increase Registry awareness among non-referral center neurology practices and to increase self-enrollment of persons with ALS through neurologists at non-referral/non-specialty center neurology practices are needed. Communications with experts in ALS also did not bring to light any similar data collection efforts.

5. Impact on Small Businesses or Other Small Entities

Every effort will be made to minimize the burden on small businesses. Some of the neurology practices in the project may be considered small businesses or small entities. According to the Survey of American Physician estimates in 2012 and 2014[9,10], approximately 33% of physicians practice in a small business; therefore approximately 227 burden hours will be placed on small businesses over the two year period (33% of the total burden hours). The questions have been held to the absolute minimum required for the intended use of the data. Contract project staff will be in contact with physician's offices and will be available to assist with all activities. We estimate that up to 33 percent of the total burden hours will be incurred by small businesses over the next two years.

6. Consequences of Collecting the Information Less Frequently

The negative consequences of not having the information will lead to failure to carry out the following activities: gather more accurate prevalence estimates on ALS; promote awareness about ALS; increase Registry's self-enrollment to collect critical risk factor data, and consequently lead to lack of fulfillment of congressional mandate under the ALS Registry Act.

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

There are no other special circumstances associated with this data collection. The request fully complies with the regulation 5 CFR 1320.5.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on March 24, 2015, vol. 80, No. 56, pp. 15614-15616 (**Attachment 2**). One non-substantive comment was received (**Attachment 3**).

B. The following individuals were consulted to obtain their views on the availability of data, the clarity of instructions, disclosure, and on the data elements to be recorded and reported.

Jerald Fagliano, PhD, MPH
Project Manager
Environmental and Occupational Health Surveillance Program
New Jersey Department of Health
135 East State Street
P.O. Box 369
Trenton, NJ 08625-0369
Phone: 609-826-4945
Fax: 609-826-4983
Email: jerald.fagliano@doh.state.nj,us

Wendy Kaye, PhD
Senior Epidemiologist
McKing Consulting Corporation
4770 Buford Highway, MS F-57
Atlanta, GA 30341
Phone: 770-488-3699
Email: wek1@cdc.gov

Daniel Lefkowitz, PhD, MS
Research Scientist II
Environmental & Occupational Health Surveillance Program
New Jersey Department of Health
135 East State Street
P.O. Box 369
Trenton, NJ 08625-0369
Phone: 609-292-0274
Fax: 609-826-4983
Email: daniel.lefkowitz@doh.state.nj.us

Maggie Ritsick, MPH
Vice President/Project Manager
McKing Consulting Corporation
2900 Chamblee Tucker Road
Building 10, Suite 100
Atlanta, GA 30341
Phone: 770-220-0608
Fax:770-220-0670

Email: mritsick@mcking.com

Laurie Wagner, MPH
Study Coordinator
National ALS Biorepository Pilot Study
McKing Consulting Corporation
2900 Chamblee Tucker Road
Building 10, Suite 100
Atlanta, Georgia 30341
Phone: 1-855-874-6912
Fax: 1-855-598-7485
Email: lwagner@secure.mcking.com

9. Explanation of Any Payment or Gift to Respondents

Neurologists will receive $100 for completing a KII. No other participants will receive any payment or gift. The decision to include $100 for completing the KII was based on the successful reporting in the Surveillance Projects (OMB No. 0923-0043, expiration date 04/30/14). Very few neurologists declined compensation for a form that averaged 15 minutes to complete during the Surveillance Projects. Finally, the typical hourly salary for a neurologist is $105.22 and we are asking for 60 minutes of their time to complete the KII. Providing monetary incentives is standard practice in qualitative research. We anticipate 25% of neurologists selected will agree to participate in the KII, and 90% of those who agree will complete the KII. The methodology used to identify KII participants includes selecting replacement neurologists for those who do not agree to participate.

10. Assurance of Confidentiality Provided to Respondents

10.1 Privacy Impact Assessment Information

No IIF is being collected. Data cannot be retrieved by name.

ATSDR's pilot project on Promoting ALS Registry to non-referral providers will employ an interrupted time series design. To achieve the objectives described in section A.1, a four group educational and promotional outreach project has been designed (**Attachment 5**). Three groups (Group 1, Group 2, and Group 3), with two states in each group, will receive various educational and promotional components, and a fourth group (Group 4) consisting of the remaining 44 states will serve as a comparison.

Educational and promotional outreach components, as further described below, include mailings, phone calls, and in-person communication. Identified neurologists in Group 1 [Florida (FL) and New Jersey (NJ)] will receive phone calls to determine if they diagnose/care for patients with ALS, a targeting mailing, follow-up phone calls, faxes as needed, KIIs, and TTT site visits. Identified neurologists in Group 2 [New York (NY) and Virginia (VA)], will receive phone calls to determine if they diagnose/care for patients with ALS, a targeted mailing, follow-up phone calls, and faxes as needed. Identified neurologists in Group 3 [Washington (WA) and Ohio (OH)] will receive a mailing. Group 4 (remaining 44 states) will not receive any educational and promotional outreach components.

For Groups 1 and 2, non-referral center neurologists or their staff will be asked if the practice

diagnoses/cares for ALS patients via a phone call. For Group 1, a sample of neurologists that currently or would diagnose and/or care for ALS patients in FL and NJ will be eligible for a TTT session (**Appendix L1**) and KIIs (**Appendix R**).

For Groups 1 and 2, neurologists or their staff will be asked if the practice diagnoses/treats ALS patients via telephone conversation.

Information to be collected includes: full name and work address of providers/neurology practices will be identified from publicly available sources. Names will not be associated with completed TTTs and KIIs.

For the KIIs, we will collect neurologists' knowledge, attitudes, and beliefs about the Registry (**Appendix R**).

Phone calls to Groups 1 and 2 will be conducted to determine which neurologists do or would diagnose and/or care for ALS patients, to determine how many ALS patients are seen on an annual basis, and to confirm contact information for neurologists **(Appendix A**). Targeted mailings to Groups 1, 2, and 3 will not collect any data (**Appendix C1 and C2**). Follow-up phone calls (**Appendices D and G**) will be conducted to neurologists in Group 1 to confirm if the mailing was received, if the Registry poster was hung in the neurology office, if the neurologists saw any ALS patients in the last three months, and if the neurologist completed the CME module. No data will be collected during the TTT session (**Appendix 1**). During the KIIs, neurologists will be asked questions to better understand their knowledge, attitudes, and beliefs about the Registry, and to gather additional information about the currently deployed Registry materials (**Appendix R**). The aggregate information will be shared with ATSDR for purposes of enhancing the Registry. No individual information will be shared with individuals outside of the project team.

Project results will be shared in two main ways: monthly reports to ATSDR and a manuscript. Reports will only present responses in aggregate form and there is no way to identify individual neurologist's responses during the KIIs. The project results will be shared with ATSDR in order to prompt recommendations for future Registry promotion to future increase persons with ALS self-enrollment and thus the representativeness of enrollees to the entire U.S. population.

We intend to share project findings by publishing a manuscript in peer-reviewed journal, which is a common practice in public health and for the National ALS Registry.

The key informant interview data collection will be collected without identifiers thus there will be no potential impact on the respondent's privacy. The initial and follow-up phone calls will confirm publically available information as well as if the practice diagnoses/treats ALS patients.

Individuals participating in the phone calls, TTT and KII will be informed that their participation is voluntary and they are not mandated to provide the information requested. Neurologists who are selected and volunteer to participate in the KII will be mailed a consent form (**Appendix O**) prior to the scheduled site visit. During the KII site visit, the consent form will be reviewed and all questions will be answered prior to conducting the interview. Neurologists will provide verbal consent to participate in the KIIs. However, we will not ask that the consent from be signed. Individuals who provide their verbal informed

consent will be able to participate in the key informant interview (**Appendix R, page 2**).

Contractors will be responsible for data collection and maintaining lists of neurologists and neurology practices in the six intervention states. McKing Consulting Corporation will own the neurologist contact information data. Neurologists' names, practices names, and practice contact information will be used to deliver the project components. Information collected from the initial and follow-up phone calls will be only accessible to project staff. Tape information from the KIIs will be recorded without names or identifiers. Recorded KIIs will not contain personal identifiers. The tape recordings will be used to supplement field notes taken while conducting the KIIs. Transcripts of the KIIs will be transmitted to ATSDR. No identifying data will be transmitted to ATSDR. Federal employees will participate in the analysis of collected data.

This submission has been reviewed by the Information Collection Review Office which has determined that the Privacy Act does not apply to this information collection. PII is never stored or retained by the CDC, and a System of Records is not required for this clearance.

CDC/ATSDR Office of Human Subjects Protection determined that this project is exempt from IRB review on December 5, 2014 (**Attachment 4).**

11. Justification for Sensitive Questions

Neurologists will be asked about their knowledge, beliefs, and behaviors related to the National ALS Registry. We do not believe these questions collect sensitive information.

12. Estimates of Annualized Burden Hours and Costs

A. Burden hours are included in Table 1. During the 2 year project period, approximately 3800 neurologist support staff will receive initial phone calls, approximately 760 neurologist support staff will complete Faxes to Determine Provider Status, 1900 neurologist support staff will receive follow-up phone calls, approximately 380 neurologist support staff will complete Faxes to determine if the mailing was received, approximately 120 neurologists will receive invitation phone calls for TTT sessions, approximately 128 neurologists will receive invitation phone calls for KIIs, approximately 30 neurologists will participate in the TTT sessions, and approximately 32 neurologists will participate in the KIIs. Neurologists will have the option to include a support staff member in the TTT session, but it is not required that one participate.

1900 neurologist support staff will receive an initial phone call will take approximately 6 minutes.

380 neurologist support staff will receive a fax to determine provider status will take approximately 1 minute.

950 neurologist support staff will receive a follow-up phone call #1 (one-week post mailing) will take approximately 3 minutes.

950 neurologist support staff will receive a follow-up phone call #2 (three months post mailing) will take

approximately 3 minutes.

190 neurologist support staff will receive a fax to determine if the mailing was received will take approximately 1 minute.

60 neurologists or their support staff will receive a phone call to determine interest in participating in the TTT will take approximately 6 minutes. It is anticipated that approximately 25% of contacted neurologists will agree to participate in the TTT.

64 neurologists or their support staff will receive phone calls to determine interest in participating in the KII will take approximately 6 minutes. It is anticipated that approximately 25% of contacted neurologists will agree to participate in the KII.

15 neurologists or their support staff will participate in the TTT session will take approximately 60 minutes. We anticipate that 40 percent of the fifteen participating neurologists will be accompanied by an additional staff person; therefore twenty-one respondents will attend the TTT session.

16 neurologists will participate in the KII will take approximately 60 minutes.

The total annualized burden for all activities is 344 hours.

TABLE 1: ESTIMATED ANNUALIZED BURDEN OF HOURS

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden of Response (in hours)	Total Burden Hours
Neurologist Support Staff	Initial Phone Call	1,900	1	6/60	190
Neurologist Support Staff	Fax to Determine Provider Status	380	1	1/60	6
Neurologist Support Staff	Follow-up Phone Call 1 (One-Week Post Mailing)	950	1	3/60	48
Neurologist Support Staff	Follow-up Phone Call 2 (Three Months Post Mailing)	950	1	3/60	48
Neurologist Support Staff	Fax to Determine if Mailing was Received	190	1	1/60	3
Neurologist/Neurologist Support Staff	Train-the-trainer Invitation Phone Call	60	1	6/60	6

Neurologist/Neurologist Support Staff	Key Informant Interview Invitation Phone Call	64	1	6/60	6
Neurologist/Neurologist Support Staff	Train-the-trainer	21	1	1	21
Neurologist	Key Informant Interview	16	1	1	16
				Total	344

B. Neurologist support staff such as medical secretaries will likely respond to the Initial Phone Call and follow Up Phone Calls 1 and 2. Neurologist support staff of selected neurologists may answer the phone for the TTT invitation and KII invitation, but we anticipate speaking directly with the selected neurologists. Neurologist support staff of selected neurologists will have the option of participating in the TTT sessions, but this is not required. The hourly wage of $15.48 for office support staff is based on Payscale.com for Medical Secretaries and the US Department of Labor, Bureau of Labor Statistics 2013 National Occupation Employment and Wage Estimates using category 43-6013 Medical Secretaries working in offices of Physicians. http://www.bls.gov/oes/current/oes436013.htm

C. Burden costs are included in Table 2. Neurologists will participate in the TTT sessions and KIIs. The hourly wage rate of $105.22 for neurologists is based on PayScale.com for neurologists and the US Department of Labor, Bureau of Labor Statistics 2013 National Occupation Employment and Wage Estimates using category 29-1069 Physicians and Surgeons, All Others practicing in offices, because neurologists are not listed separately. (http://www.bls.gov/oes/current/oes291069.htm).

TABLE 2: ESTIMATED ANNUALIZED BURDEN OF HOURS

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Burden Costs
Neurologist Support Staff	Initial Phone Call	190	$15.48	$2,941
Neurologist Support Staff	Fax to Determine Provider Status	6	$15.48	$93
Neurologist Support Staff	Follow up Phone Call 1 (One Week Post-Mailing)	48	$15.48	$743
Neurologist Support Staff	Follow up Phone Call 2 (Three Months Post-Mailing)	48	$15.48	$743
Neurologist Support Staff	Fax to Determine if Mailing was Received	3	$15.48	$46
Neurologist	Train-the-trainer Invitation Phone Call	6	$105.22	$631
Neurologist	Key Informant	6	$105.22	$631

	Interview Invitation Phone Call			
Neurologist	Train-the-trainer	21	$79.58	$1,671
Neurologist	Key Informant Interview	16	$105.22	$1,684
			Total	$9,183

* The rate of $79.58 was calculated as a weighted for the participation of 15 neurologists at the previously established rate of $105.22/hour and 6 support staff at $15.48/hour.

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

There are no capital or maintenance costs incurred by respondents because the information will be collected in paper format by the project coordinators.

14. Annualized Cost to the Government

The annual cost to the Government is $458,251.49.

TABLE 3: ESTIMATED COST TO THE GOVERNMENT			
	Year 1	Year 2	Two Years Combined
ATSDR Personnel Time	$25.511.00	$25,511.00	$51,022.00
Contract	$432,740.49	$432,740.49	$865,480,98
Total	$458,251.49	$458,251.49	$916,502.98

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will begin immediately following OMB approval and will last approximately 6 months. At the conclusion of data collection a two month data analysis period will begin. Following data analysis a manuscript will be prepared for publication. We also plan to publish selected summary reports on CDC's website during the second year of this project.

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

We will be displaying the OMB expiration date on all documents created for this project. We are requesting an exemption from the display of OMB Expiration Date on the documents listed in Appendices C4, C5, C6, C7, C8 and C9 as they belong to another approved OMB Project (OMB No. 0923-0041, Expiration Date 09/30/16).

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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