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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day-19-0041]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled "National Amyotrophic Lateral Sclerosis (ALS) Registry" to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on May 24, 2019 to obtain comments from the public and affected agencies. ATSDR did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Amyotrophic Lateral Sclerosis (ALS) Registry – (OMB Control No. 0923-0041, Exp. 11/30/2019) – Revision – Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year Paperwork Reduction Act (PRA) clearance for a revision information collection request (ICR) entitled "The National Amyotrophic Lateral Sclerosis (ALS) Registry." (OMB Control No. 0923-0041, Expiration Date 11/30/2019). The current request is a revision designed to strengthen the usefulness of the National ALS Registry for researchers. The changes to the ICR include:

(1) Addition of an organized sports participation survey to capture history and current participation in physical activities. This additional survey will take approximately five minutes to complete and will add an additional 63 total burden hours for respondents;

(2) Two additional questions to capture race and ethnicity upon registration with other basic demographic information will be added to ALS Case Registration Form prior to Persons with ALS (PALS) completing more detailed surveys.

On October 10, 2008, President Bush signed S.1382: ALS Registry Act which amended the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis (ALS) Registry. The activities described are part of the ongoing effort to maintain the National ALS Registry.

First approved in 2010 for self-registration, the primary goal of the surveillance system/registry remains to obtain reliable information on the incidence and prevalence of ALS and to better describe the demographic characteristics (age, race, sex, and geographic location) of persons with ALS. Those interested in participating in the National ALS Registry must answer a series of validation questions and if determined to be eligible, they can register.

The secondary goal of the surveillance system/registry is to collect additional information on potential risk factors for ALS, including, but not limited to, family history of ALS, smoking history, military service, residential history, lifetime occupational exposure, home pesticide use, hobbies, participation in sports, hormonal and reproductive history (women only), caffeine use, trauma, health insurance, open-ended supplemental questions, and clinical signs and symptoms. After registration, participants complete as many as 17 voluntary survey modules, each taking up to five minutes. In addition, in Year 1, a disease progression survey for new registrants is completed at zero, three, and six months. In Year 2 and Year 3, the disease progression survey is repeated at the yearly anniversary, and at six months. For burden estimation, the number of disease progression survey responses per year has been rounded up to three times.

A biorepository component was added in 2016 to increase the value of the National ALS Registry to researchers. As part of registration the participant can request additional information about the biorepository and provide additional contact information. A geographically representative sample is selected to provide specimens. There are two types of specimen collections, in-home and postmortem. The in-home collection includes blood, urine, and saliva. The postmortem collection includes the brain, spinal cord, cerebral spinal fluid (CSF), bone, muscle, and skin.

In addition to fulfilling the two-part Congressional mandate, the Registry is designed to be a tool for ALS researchers. Now that the Registry has matured, ATSDR has made data and specimens available to approved researchers and has added a respondent type. Researchers can request access to specimens, data, or both collected by the National ALS Registry for their research projects. ATSDR will review applications for scientific validity and human subjects' protection and make data/specimens available to approved researchers. ATSDR is collaborating with ALS service organizations to conduct outreach activities through their local chapters and districts as well as on a national level. They provide ATSDR with information on their outreach efforts in support of the Registry on a monthly basis.

There are no costs to the respondents other than their time. Participation in this proposed information collection is completely voluntary. The total number of burden hours requested is 1,946 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Person with ALS	ALS Case Validation Questions	1,670	1	2/60
	ALS Case Registration Form	1,500	1	10/60
	Voluntary Survey Modules	750	1	85/60
	Disease Progression Survey*	750	3	5/60
	ALS Biorepository Specimen Processing Form and In-Home Collection	325	1	30/60
	ALS Biorepository Saliva Collection	350	1	10/60
Researchers	ALS Registry Research Application Form	36	1	30/60
	Annual Update	24	1	15/60
ALS Service Organization	Chapter/District Outreach Reporting Form	135	12	5/60
	National Office Outreach Reporting Form	2	12	20/60

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