BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substance and Disease Registry

[60Day-19-0041; Docket No. ATSDR-2019-0007]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled *"National Amyotrophic Lateral Sclerosis (ALS) Registry."* The National ALS Registry collects information from persons with ALS to better describe the prevalence and potential risk factors for ALS.

DATES: ATSDR must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2019-0007 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition,

the PRA also requires Federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses.

5. Assess information collection costs.

Proposed Project

The National Amyotrophic Lateral Sclerosis (ALS) Registry (OMB Control No. 0923-0041, Expiration Date 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 the National Amyotrophic Lateral Sclerosis (ALS) Registry (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 5 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)	Total Burden (in hours)
Person with ALS	ALS Case Validation Questions	1,670	1	2/60	56
	ALS Case Registration Form	1,500	1	10/60	250
	Voluntary Survey Modules	750	1	85/60	1,063
	Disease Progression Survey*	750	3	5/60	188
	ALS Biorepository Specimen Processing Form and In-Home Collection	325	1	30/60	163
	ALS Biorepository	350	1	10/60	59

	Saliva Collection				
Researchers	ALS Registry Research Application Form	36	1	30/60	18
	Annual Update	24	1	15/60	6
ALS Service Organization	Chapter/District Outreach Reporting Form	135	12	5/60	135
	National Office Outreach Reporting Form	2	12	20/60	8
Total					1,946

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

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