Affected Public: Individuals; Business or Other For-Profit Institutions; Not-For-Profit Institutions; State or Local Government.

Estimated Annual Number of Respondents: 45,000.

Projected average burden estimates for the next three years:

Average Expected Annual Number of Activities: 40.

Average Number of Respondents per Activity: 1,125.

Responses per Respondent: 1.

Annual Responses: 45,000.

Average Minutes per Response: 3 minutes.

Annual Burden Hours: 2,250 hours.

Frequency: On occasion.

Request for Comments: Agency and public comment is again invited specifically on the need for and practical utility of this information collection, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). The comments will become a matter of public record.

Approved: July 11, 2018.

David Apol,

General Counsel and Acting Director, U.S. Office of Government Ethics.

[FR Doc. 2018–15411 Filed 7–18–18; 8:45 a.m.]

BILLING CODE 6345–03–P

GULF COAST ECOSYSTEM RESTORATION COUNCIL

[Docket No.: 107162018–1111–03]

Notice of Proposed Subaward Under a Council-Selected Restoration Component Award

AGENCY: Gulf Coast Ecosystem Restoration Council.

ACTION: Notice.

SUMMARY: The Gulf Coast Ecosystem Restoration Council (RESTORE Council) publishes notice of proposed subawards from the Mississippi Department of Environmental Quality (MDEQ) to the Mississippi Wildlife Federation and the Partnership for Gulf Coast Land Conservation, two Mississippi nonprofit organizations, for the purpose of education and outreach in accordance with the Sea Grant Education and Outreach (EOE) Award, as approved in the Initial Funded Priority List.

FOR FURTHER INFORMATION CONTACT: Please send questions by email to *joshua.easton@restorethegulf.gov.*

SUPPLEMENTARY INFORMATION: Section 1321(t)(2)(E)(ii)(III) of the RESTORE Act (33 U.S.C. 1321(t)(2)(E)(ii)(III)) and Treasury's implementing regulation at 31 CFR 34.401(b) require that, for purposes of awards made under the Council-Selected Restoration Component, a State or Federal award recipient may make a grant or subaward to or enter into a cooperative agreement with a nongovernmental entity that equals or exceeds 10 percent of the total amount of the award provided to the State or Federal award recipient only if certain notice requirements are met. Specifically, at least 30 days before the State or Federal award recipient enters into such an agreement, the Council must publish in the **Federal Register** and deliver to specified Congressional Committees the name of the recipient and subrecipient; a brief description of the activity, including its purpose; and the amount of the award. This notice accomplishes the **Federal Register** requirement.

Description of Proposed Action

As specified in the Initial Funded Priority List, which is available on the Council's website at *https://www.restorethegulf.gov/council-selected-restoration-component/funded-priorities-list,* RESTORE Act funds in the amount of $750,000 will support the Sea Grant Education and Outreach (EOE) Award to MDEQ. As part of this project, MDEQ will provide a subaward in the amount of $84,150 to the Mississippi Wildlife Federation for enhancement of the Mississippi Habitat Stewards Program. Through the subaward, the Mississippi Wildlife Federation will expand an existing curriculum that relays the ecosystem benefits of upstream land conservation, habitat restoration and water quality restoration. The expanded curriculum will be offered for three different targeted audiences at different levels: Habitat steward volunteers; youth, ages 9–12; and local high school environmental clubs.

MDEQ will also provide a subaward in the amount of $99,050 to the Partnership for Gulf Coast Land Conservation (PGCLC). The PGCLC will conduct an outreach initiative that includes three components: The development of science-based communication products for use with a general audience that summarize and explain the benefits of land conservation in the Gulf coast region in lay terminology; field visits that bring together stakeholders to illustrate, in the field and by boat, the connectivity that land conservation practices along our coastal streams have to water quality in the northern Gulf of Mexico and to our marine and estuarine living resources; and the development of a short digital film that illustrates the connection between riparian and wetland forests and marine and estuarine living resources in the northern Gulf of Mexico.

Keala J. Hughes,

Director of External Affairs & Tribal Relations, Gulf Coast Ecosystem Restoration Council.

[FR Doc. 2018–15451 Filed 7–18–18; 8:45 am]

BILLING CODE 6560–58–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substance and Disease Registry

[60Day–18–18AJK Docket No. ATSDR–2018–0002]

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 ''Per- or Polyfluoroalkyl Substances (PFAS) Exposure Assessments.'' ATSDR and the CDC National Center for Environmental Health (NCEH) will conduct a minimum of eight exposure assessments (EAs) at current or former military installations with known PFAS contamination in drinking water, groundwater, or another water source.

DATES: ATSDR must receive written comments on or before September 17, 2018.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2018–0002 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 NE, 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 NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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

Per- or Polyfluoroalkyl Substances (PFAS) Exposure Assessments—New—Agency for Toxic Substances and Disease Registry (ATSDR) and the National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Per- and polyfluoroalkyl substances (PFAS) are a large group of man-made chemicals that have been used in industry and consumer products worldwide since the 1950s. Although some PFAS are no longer produced in the United States, they many remain in the environment and may impact people's health. Thus, PFAS are contaminants that have gained national prominence over the last decade.

Under Section 8006 of the Consolidated Appropriations Act, 2018, the Agency for Toxic Substances and Disease Registry and CDC National Center for Environmental Health (ATSDR/NCEH) are requesting a three-year Paperwork Reduction Act clearance for a new information collection request (ICR). ATSDR/NCEH will conduct EAs at current or former domestic military installations known to have PFAS in drinking water, groundwater, or any other sources of water. The annualized number of EAs assumes the following. ATSDR/NCEH will conduct a minimum of eight EAs, but ATSDR/NCEH may complete an additional seven for a total of 15 EAs. Therefore, ATSDR/NCEH anticipates conducting five PFAS EAs each year for three years.

All eligible respondents will be consented before being included in each EA. The consent forms will include adult consent, and parental permission and child assent forms, as appropriate. Each consented respondent will provide a serum and a urine sample. In addition, heads of households from ten percent of households using tap water for their drinking water will consent to provide tap water and indoor dust samples. The consent forms will include permission to store some biospecimens and environmental samples for future analysis and will include permission to recontact respondents for potential investigations or studies in the future. ATSDR will also collect contact information to provide respondents with their individual sampling results.

Household Eligibility Screener: ATSDR/NCEH will conduct the PFAS EAs in communities with populations living on or near current or former military installations. ATSDR/NCEH will recruit a desired sample size of 379 respondents per EA (1,895 total per year) using statistical household sampling methods. Eligibility criteria for individuals include specific age intervals (*i.e.,* children older than three years given the lack of NHANES comparison data for younger children), lack of bleeding disorders that would prevent a blood draw, and time of residency (*i.e.,* at least one year in the home).

Applying an average U.S. household size of 2.5 members, per EA, ATSDR/NCEH will enroll respondents from 152 eligible households (379/2.5). To identify the 152 eligible households, we further assume a 65 percent household eligibility rate. This will require administering a 5-minute eligibility screener to 234 heads-of-households per EA (152*100/65), or to 1,170 heads-of-households per year (234 × 5). The annual time burden requested for eligibility screening is 98 hours.

Exposure Assessment Questionnaire for Biological and Environmental Testing for Adults, Parents, or Children: ATSDR/NCEH will administer an exposure questionnaire to all consented respondents that includes questions associated with potential exposure to PFAS both inside and outside the home (*e.g.,* work or school). In addition, the adult questionnaire also includes several questions associated with water use and flooring type while the child questionnaire includes questions regarding playing in soil; these questions are intended to evaluate potential exposure and to support the environmental testing. The time associated with administering the questionnaire and completing the biological sampling is approximately 30 minutes for 1,440 adults (720 hours). The time associated is 15 minutes for 264 parents responding for their children, 3–11 years old (66 hours), and for 191 children, 12–17 years old, who respond for themselves (48 hours). ATSDR/NCEH will use the questionnaire and laboratory results to identify likely exposure scenarios.

Household Recruitment Script for Environmental Sampling: The households providing environmental samples will be randomly selected from households that report using tap water for drinking water. ATSDR/NCEH will recruit 10 percent subset of these eligible households to collect tap water and indoor dust samples. Assuming a 65 percent response rate, ATSDR/NCEH will administer a 5-minute recruitment script to 23 heads-of households who are eligible to take part in each EA (152/10*100/65). The time required to administer the recruitment script is 5 minutes. This will result in annual recruitment from 117 heads-of-households and 10 hours for five EAs.

Environmental Sample Collection Form: Again, assuming a 65 percent response rate, to meet our sample size

goal of 10 percent of eligible households, ATSDR/NCEH will consent and collect samples from approximately 15 households per EA or households annually (152*10/100*5). The average time burden is estimated as 15 minutes per response, or 19 hours annually.

ATSDR estimates the total annualized time burden is 961 hours. Participation is voluntary, and there are no costs to respondents other than their time.

Public health professionals, environmental risk managers, and other decision makers can use EA results to make informed decisions about the sources and impact of PFAS contamination in environmental media within their own community and jurisdiction. The data will support their recommendations for public health actions to reduce or eliminate harmful levels of PFAS in the local environment. These EAs are not intended to yield information about PFAS exposure that will be generalized beyond the defined boundaries of each investigation; however, ATSDR/NCEH will use these EA findings to inform a future national PFAS health study.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Potential EA Heads-of-Households	Household Eligibility Screener	1,170	1	5/60	98
EA Adults	*Exposure Questionnaire for Biological and Environmental Testing (Adults).*	1,440	1	30/60	720
EA Parents	EA Questionnaire for Biological Testing (Child).	264	1	15/60	66
EA Children	EA Questionnaire for Biological Testing (Child).	191	1	15/60	48
EA Heads-of-Households	*Household Recruitment Script for Environmental Sampling.*	117	1	5/60	10
	Environmental Sample Collection Form.	76	1	15/60	19
Total					961

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–15437 Filed 7–18–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1224]

Use of Electronic Health Record Data in Clinical Investigations; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Use of Electronic Health Record Data in Clinical Investigations.'' The guidance provides recommendations for sponsors, clinical investigators, contract research organizations (CROs), institutional review boards (IRBs), and other interested parties on the use of electronic health record (EHR) data in FDA-regulated clinical investigations. The guidance finalizes the draft guidance issued in May 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on July 19, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1224 for ''Use of Electronic Health Record Data in Clinical Investigations; Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be