in accordance with the Freedom of Information Act and, if deemed appropriate, will redact such information. Disclosures of information concerning third party medical information will be redacted.

Contact person for more information: Paul J. Middendorf, Ph.D., Designated Federal Officer, NIOSH, CDC, 2400 Century Parkway NE., Mail Stop E–20, Atlanta, Georgia 30345, telephone 1 (888) 982–4748; email: *wtc-stac@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–25039 Filed 10–14–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–17–16PA]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (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, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Study to Explore Early Development (SEED) Phase 3—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Autism spectrum disorders (ASD) are a group of neurodevelopmental disorders characterized by qualitative impairments in social interaction and communication and stereotyped behaviors and interests. Recent systematic population surveys and routine monitoring systems in the U.S. and other countries indicate the prevalence to be 1–2%. Apart from the identification of some rare genetic conditions that are commonly associated with autism, causal mechanisms for the disorder largely remain unknown.

The Children's Health Act of 2000 mandated CDC to establish autism surveillance and research programs to address the number, incidence, and causes of autism and related developmental disabilities. Under the provisions of this act, NCBDDD funded five Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) through program announcements in FY2001 and FY2002; CDC's NCBDDD served as the sixth CADDRE site.

For the first funding cycle (2001–2006), each CADDRE grantee had three core objectives: To develop a protocol for a multi-site collaborative epidemiologic study focused on autism (which was eventually named the Study to Explore Early Development [SEED]); to conduct surveillance of autism and other developmental disabilities; and to conduct site-specific investigator-initiated studies on autism. In FY 2006, through a second CADDRE funding cycle, five grantees were awarded. The CADDRE activities for the second funding cycle (2006–2011) were limited to implementation of the first phase of SEED (subsequently known as SEED 1). CDC served as the sixth CADDRE SEED 1 site during this period. A second phase of SEED (SEED 2) was funded under a third funding cycle (2011–2016). Five CADDRE grantees received the awards. Again, CDC served as the sixth SEED 2 site.

A third phase of SEED (SEED 3) was funded in July 2016. Five extramural sites were funded. Together with the CDC, they will implement the SEED 3 collaborative protocol. The SEED 3 protocol for identification of study participants, recruitment, and study data collection flow will be similar to the protocols for SEED 1 and 2.

However, while all SEED phases have the same research goals and the same basic study design, data collection has been greatly streamlined and revised between SEED 1, SEED 2, and SEED 3. Many study instruments and data collection components included in the SEED 1 protocol are not included in the SEED 3 protocol; two instruments included in the SEED 3 protocol were developed subsequent to SEED 1 to capture an abbreviated version of information that had been included on some of the discontinued SEED 1 forms and to capture some additional information overlooked in the SEED 1 protocol; and instruments included in all phases of SEED underwent review and minor revision subsequent to SEED 1 to address ambiguities and difficulties experienced during SEED 1 data collection. Implementing this phase of SEED will increase the total SEED pooled sample size for investigation of high priority hypotheses. Maintaining the same basic study design and general protocol integrity will ensure that data pooling can be achieved across SEED phases.

Families will be identified from each of the 3 groups: Autism Spectrum Disorder (ASD), other developmental delay or disorder comparison group (DD), and a second comparison group of children randomly drawn from the entire study cohort population (POP). It is expected that the 6 SEED 3 study sites will have a total of 2,106 children enroll and complete the study protocol. The data collection process will take approximately 9 hours 10 minutes (ASD group); 5 hours 30 minutes (POP group); 2 hours 45 minutes (DD group) to complete, which includes (1) maternal telephone interview with questions about maternal reproductive history and

pregnancy with the index child, (2) parent-completed questionnaires about parental and child health and child development, (3) in-person child developmental evaluation, (4) maternal and child anthropometry measurements, and (5) biosampling from biological parents and child.

There are no costs to participants other than their time. The total estimated annual burden hours are 7,118.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)
Mother All potential participants sent mailing	Invitation Packet/Response Card	1,718	1	10/60
Mother Potentially eligible with contact by study staff	Invitation Call Script and Social Communication Questionnaire.	859	1	30/60
Mother Eligible, consented, and enrolled; assigned to the ASD workflow based on enrollment intake.	Enrollment Packet	469	1	20/60
Mother Completed this study step	Follow-up Phone Call Script and Pregnancy Reference Form.	422	1	15/60
	Maternal Interview Call	422	1	1
	Self-Administered Forms	375	1	105/60
	Follow-up Call 2	375	1	20/60
	Clinic/Home Visit—Developmental Assessment.	328	1	225/60
Father Completed this study step	Clinic/Home Visit—Saliva Collection (optional—on own).	164	1	15/60
Child Completed this study step	Clinic/Home Visit—Developmental Assessment.	328	1	135/60
Mother All potential participants sent mailing	Invitation Packet/Response Card	1,466	1	10/60
Mother Potentially eligible with contact by study staff	Invitation Call Script and Social Communication Questionnaire.	733	1	30/60
Mother Eligible, consented, and enrolled; assigned to the POP workflow based on enrollment intake.	Enrollment Packet	334	1	20/60
Mother Completed this study step	Follow-up Phone Call Script and Pregnancy Reference Form.	301	1	15/60
	Maternal Interview Call	301	1	1
	Self-Administered Forms	267	1	105/60
	Follow-up Call 2	267	1	20/60
	Clinic/Home Visit—Developmental Assessment.	234	1	50/60
Father Completed this study step	Clinic/Home Visit—Saliva Collection (optional—on own).	117	1	15/60
Child Completed this study step	Clinic/Home Visit—Developmental Assessment.	234	1	90/60
Mother All potential participants sent mailing	Invitation Packet/Response Card	641	1	10/60
Mother Potentially eligible with contact by study staff	Invitation Call Script and Social Communication Questionnaire.	321	1	30/60
Mother Eligible, consented, and enrolled; assigned to the DD workflow based on enrollment intake.	Enrollment Packet	175	1	20/60
Mother Completed this study step	Follow-up Phone Call Script and Pregnancy Reference Form.	158	1	15/60
	Maternal Interview Call	158	1	1
	Self-Administered Forms	140	1	55/60
	Follow-up Call 2	140	1	20/60

Leroy A. Richardson,

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. 2016–25061 Filed 10–14–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0037]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fee Act Waivers and Reductions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the paperwork burden of requesting a waiver or reduction of fees under Animal Drug User Fee Act (ADUFA).