

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)
State Education Agency	Exemplary Sexual Health Education Measures	19	2	4
	Sexual Health Services Measures	19	2	3
	Safe and Supportive Environments Measures	19	2	1
Local Education Agency	Exemplary Sexual Health Education Measures	17	2	6
	Sexual Health Services Measures	17	2	3
	Safe and Supportive Environments Measures	17	2	6
Non-governmental organization.	Exemplary Sexual Health Education Measures	2	2	30/60
	Sexual Health Services Measures	2	2	30/60
	Safe and Supportive Environments Measures	2	2	30/60

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.*

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 BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND
 HUMAN SERVICES**

**Centers for Disease Control and
 Prevention**

[60Day-14-14AVQ]

**Proposed Data Collections Submitted
 for Public Comment and
 Recommendations**

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov*.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to

minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Returning Our Veterans to Employment and Reintegration (ROVER): Work Stress and Assistance Animals—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Veterans with chronic posttraumatic stress disorder (PTSD) face barriers that prevent many of them from successfully reintegrating into society and returning to the work force. Various reports claim that higher unemployment rates and increased healthcare costs and utilization are associated with PTSD.

Symptoms associated with PTSD include diminished interest or participation in significant activities, feelings of detachment or estrangement from others, difficulty falling or staying

asleep, hyper vigilance, exaggerated startle response, difficulty with concentration or attention, and a restricted range of affect. Amelioration of PTSD symptoms is necessary to facilitate reintegration of veterans into society and the workforce; these benefits may also contribute positively to veterans' overall physical and psychological health.

A review of mostly anecdotal evidence suggests that animal-assisted interventions may have general therapeutic benefits for individuals with PTSD. Although a few reports tout the benefits of human-animal companionship, no studies have focused specifically on investigating the elements of human-animal interactions that might be therapeutic for individuals with PTSD or other stress-related disorders. Furthermore, there is scant evidence supporting the notion that service dogs or therapy dogs may directly improve functioning and, thereby, ease an individual's reintegration into society and employment.

NIOSH is seeking a 3-year approval from OMB on a research study aimed at understanding the benefits of human-animal interactions for the purpose of facilitating the reintegration and employment of veterans with PTSD. The efficacy of using service dogs or other types of assistance dogs to help veterans with disabilities return to work has not been established in well-controlled scientific studies, and fundamental empirical evidence is scant. As a step toward a greater understanding, a laboratory-based work-simulation study will be conducted to investigate the influence of the presence of and interactions with a dog on the reactivity and performance of veterans with and without PTSD to work-related and startle stressors. Results of the laboratory-based study will complement the findings of another project (OMB No. 09200985), which is gathering information about veterans perceptions

of the barriers and facilitators to reintegration through two national Web-based surveys. There is no duplication of effort or burden because the research objectives and research methods are substantial different.

This study will be conducted at the NIOSH research facility in Morgantown, WV, which includes state-of-the-art laboratories and equipment to simulate work-related stress under controlled conditions and will use a small-n experimental design with multiple, repeated assessments over time to measure the behavioral (work performance), psychological, and physiological responses of participants. The role of dogs in potentially moderating the effects of the stressors will be investigated with either the absence or presence of a dog in some conditions and a dog that is either familiar or unfamiliar to the veteran in other conditions. The general working hypothesis is that the presence of, and/or interaction with, a familiar dog reduces stress and enhances work performance for both veterans with and

without PTSD, with a greater benefit to veterans with PTSD.

U.S. Veterans, with and without PTSD, and veterans with service dogs will be recruited with the assistance of various veterans' organizations to participate in this research study. During the initial recruitment phase, veterans who receive and respond to the recruitment announcements will complete several Web-based prescreening questionnaires, and eligible veterans, who are enrolled into the research study, will complete additional questionnaires and tasks in multi-day assessment sessions at the NIOSH Morgantown facility. An estimated 400 persons in various veterans' agencies will receive email announcements of the research study and follow-up phone calls. The work activity associated with reading the email, answering the phone calls, and distributing a study announcement/flyer to additional individuals is estimated to take up to 10 minutes for each occurrence. Approximately 200 veterans are expected to see the recruitment

flyers and complete the initial Web-based contact form and several prescreening forms, including the Pet Attitude Scale, the Combat Exposure Scale, PTSD Checklist, Medication List, Drug Abuse Screening Test, Center for Epidemiological Studies Depression Scale, Short Michigan Alcoholism Screening Tool, and the World Health Organization Quality of Life Index Brief. A total of 64 eligible veterans from this pool are expected to be enrolled in the laboratory portion of the study, including at least 16 veterans who own a service dog. Upon entering the study, all enrolled veterans will complete the Positive and Negative Affect Scale on site, and veterans with service dogs will complete the Big Five Inventory (BFI), the Canine Behavioral Assessment and Research Questionnaire (CBARQ), the Pet Attachment and Life Impact Scale (PALS), Dog Personality Scale (DPQ), and the Social Style-Self and the Social Style-Service Dog questionnaires.

There are no costs to respondents other than their time.

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
Representatives of veterans organizations.	Veterans Study Announcement Email/Phone Contact.	400	1	10/60	67
Veterans	Recruitment Flyer	200	1	10/60	33
Veterans	Contact Form	64	1	10/60	11
Veterans	Pre-Screening Pet Attitude Scale	64	1	5/60	5
Veterans	Pre-Screening Combat Exposure Scale.	64	1	5/60	5
Veterans	Pre-Screening PTSD Checklist	64	1	5/60	5
Veterans	Pre-Screening Medication List	64	1	5/60	5
Veterans	Pre-Screening Drug Abuse Screening Test.	64	1	5/60	5
Veterans	Pre-Screening Center for Epidemiological Studies Depression Scale.	64	1	5/60	5
Veterans	Pre-Screening Short Michigan Alcoholism Screening Tool.	64	1	5/60	5
Veterans	Pre-Screening World Health Organization Quality of Life Index Brief.	64	1	10/60	11
Enrolled Veterans without Service Dogs.	Positive and Negative Affect Scale (PANAS).	48	3	2/60	5
Enrolled Veterans with Service Dogs	PANAS	16	6	2/60	3
Enrolled Veterans without Service Dogs.	NASA Task Load Index (NASA TLX)	48	2	2/60	5
Enrolled Veterans with Service Dogs	NASA TLX	16	4	2/60	2
Enrolled Veterans with Service Dogs	Big Five Inventory (BFI)	16	1	10/60	3
Enrolled Veterans with Service Dogs	Canine Behavioral Assessment and Research Questionnaire (CBARQ).	16	1	10/60	3
Enrolled Veterans with Service Dogs	Pet Attachment and Life Impact Scale (PALS).	16	1	10/60	3
Enrolled Veterans with Service Dogs	Dog Personality Scale (DPQ)	16	1	10/60	3
Enrolled Veterans with Service Dogs	Social Style-Self	16	1	10/60	3
Enrolled Veterans with Service Dogs	Social Style-Service Dog	16	1	10/60	3
Total	190

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.*

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**DEPARTMENT OF HEALTH AND
 HUMAN SERVICES**

**Centers for Disease Control and
 Prevention**

**Georgia Tuberculosis Outbreak Among
 Homeless**

AGENCY: Centers for Disease Control and
 Prevention (CDC), Department of Health
 and Human Services (HHS).

ACTION: Notice of award.

SUMMARY: The Centers for Disease
 Control and Prevention (CDC) located
 within the United States Department of
 Health and Human Services (HHS)
 announces a notice of award to the
 Georgia Department of Public Health,
 Tuberculosis (TB) Program. This award
 will be in the amount of \$419,095.00.

The purpose of this award is to halt
 the further spread of a drug-resistant
 strain of tuberculosis associated with
 multiple homeless shelters in Fulton
 County, Georgia.

DATES: It is expected the notice of award
 will begin on or about September 3,
 2014. The project period will be for one
 year.

FOR FURTHER INFORMATION CONTACT: Gail
 Burns-Grant, Division of Tuberculosis
 Elimination, Field Services and
 Evaluation Branch, Centers for Disease
 Control and Prevention, 1600 Clifton
 Road NE., MS E-10, Atlanta, GA 30333;
 phone: 404-639-5344; email: *GAB2@
 cdc.gov*.

SUPPLEMENTARY INFORMATION: Currently,
 the state of Georgia is experiencing a
 public health emergency in Fulton
 County where there has been extensive
 transmission of a drug-resistant strain of
 tuberculosis (TB) associated with
 multiple homeless shelters in the
 county. The Georgia Department of
 Public Health asked CDC to provide
 emergency funding for the immediate
 implementation of CDC
 recommendations provided as a result
 of a May 2014 outbreak investigation to
 prevent further transmission of this
 drug-resistant strain of tuberculosis and
 to prevent further deaths associated
 with this outbreak. Project number is
 CDC-RFA-PS14-1416.

Dated: September 4, 2014.

Ron A. Otten,
*Acting Deputy Associate Director for Science,
 Centers for Disease Control and Prevention.*

[FR Doc. 2014-21455 Filed 9-4-14; 4:15 pm]

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**DEPARTMENT OF HEALTH AND
 HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

**Advisory Committee Renewals;
 Correction**

AGENCY: Food and Drug Administration,
 HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug
 Administration (FDA) is correcting a
 notice entitled “Advisory Committee
 Renewals” that appeared in the **Federal
 Register** of August 25, 2014 (79 FR
 50658). The document announced the
 renewal of certain FDA advisory
 committees by the Commissioner of
 Food and Drugs. The table in the
 document contained several errors. This
 document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Lisa
 Granger, Office of Policy, Food and Drug
 Administration, 10903 New Hampshire
 Ave., Bldg. 32, rm. 3330, Silver Spring,
 MD 20993-0002, 301-796-9115.

SUPPLEMENTARY INFORMATION: In the
Federal Register of Monday, August 25,
 2014, in FR Doc. 2014-20017, on page
 50659 the table is corrected to read:

Name of committee	Date of expiration
Advisory Committee for Pharmaceutical Science and Clinical Pharmacology	January 22, 2016.
Gastrointestinal Drugs Advisory Committee	March 3, 2016.
Bone, Reproductive and Urologic Drugs Advisory Committee (formerly Reproductive Health Drugs Advisory Committee)	March 23, 2016.
Arthritis Advisory Committee	April 5, 2016.
Pharmacy Compounding Advisory Committee	April 25, 2016.
Anesthetic and Analgesic Drugs Advisory Committee	May 1, 2016.
Blood Products Advisory Committee	May 13, 2016.
Pulmonary-Allergy Drugs Advisory Committee	May 30, 2016.
Drug Safety and Risk Management Advisory Committee	May 31, 2016.
Science Advisory Board to the National Center for Toxicological Research	June 2, 2016.
Peripheral and Central Nervous System Drugs Advisory Committee	June 4, 2016.
Psychopharmacologic Drugs Advisory Committee	June 4, 2016.
Transmissible and Spongiform Encephalopathies Advisory Committee	June 9, 2016.
Science Board to the Food and Drug Administration	June 26, 2016.
Allergenic Products Advisory Committee	July 9, 2016.

Dated: September 3, 2014.

Jill Hartzler Warner,
*Associate Commissioner for Special Medical
 Programs.*

[FR Doc. 2014-21369 Filed 9-8-14; 8:45 am]

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**DEPARTMENT OF HEALTH AND
 HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2014-N-1049]

**Exploring the Expansion of
 Conditional Approval to Appropriate
 Categories of New Animal Drugs**

AGENCY: Food and Drug Administration,
 HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
 Administration (FDA) is announcing
 that it is beginning the exploration
 process described in a stated
 performance goal in the Animal Drug
 User Fee Amendments of 2013 (ADUFA
 III) goals letter. Consistent with the
 performance goal, the FDA is inviting
 comments in regard to the Agency
 exploring the use of statutory changes to
 expand the use of conditional approval