

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)	Total burden (in hrs)
Local Health Department Representative.	Interview Guide for Local Health Department Representative.	15	1	30/60	8
Older Adult—Screened Out	Senior Village Survey	1,431	1	1/60	24
Older Adult—Participant	Senior Village Survey	1,550	1	20/60	517
Total	580

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

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to (FOA) DP15-001, Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and its Complications.

Time And Date: 11 a.m.–6 p.m., May 5–6, 2015 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters For Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to “Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and its Complications, DP15-001, initial review.”

Contact Person For More Information: Brenda Colley Gilbert, Ph.D., M.S.P.H., Director, Extramural Research Program Operations and Services, CDC, 4770 Buford Highway NE., Mailstop F-80, Atlanta, Georgia 30341, Telephone: (770) 488-6295, BJC4@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.

Catherine Ramadei,
Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-1005; Docket No. CDC-2015-0018]

Proposed Data Collection Submitted for Public Comment and Recommendations

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

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, 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. This notice invites comment on the information collection request for reinstatement with change of the collection previously approved under OMB control number 0920-1005—“*Conduct an Older Adult Mobility Assessment Tool Impact Evaluation and Develop a Dissemination Plan*”. This collection will help evaluate whether the Mobility Planning Tool is effective for promoting

readiness to adopt mobility-protective behaviors in older adults.

DATES: Written comments must be received on or before June 8, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0018 by any of the following methods: Federal eRulemaking Portal:

Regulation.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, 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. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted 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 the 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 OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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.

Proposed Project

Conduct an Older Adult Mobility Assessment Tool Impact Evaluation and

Develop a Dissemination Plan (OMB Control No. 0920–1005)—Reinstatement with Change—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC's National Center for Injury Prevention and Control (NCIPC) requests approval for 3 years, from the Office of Management and Budget (OMB) for a reinstatement with change for the previously approved OMB No. 0920–1005 (Exp. Date: 12–31–2014) designed to evaluate whether the Mobility Planning Tool is effective for promoting readiness to adopt mobility-protective behaviors in older adults and assess potential strategies for dissemination of the Mobility Planning Tool. With this reinstatement, NCIPC requests a change of title from “*Older Adult Safe Mobility Assessment Tool*” to “*Conduct an Older Adult Mobility Assessment Tool Impact Evaluation and Develop a Dissemination Plan.*”

The population of older adults in the U.S. is growing rapidly. By 2030, this segment of the population will increase to an estimated 72 million (20% of the U.S. population). A critical public health issue for the older adult population is mobility—how well people are able to get to places they need to go. The goals of this study are to evaluate (1) whether the Mobility Planning Tool (MPT) is effective for promoting readiness to adopt mobility-protective behaviors in older adults and (2) assess potential strategies for dissemination of the MPT.

NCIPC will collect study data using telephone interviews. The study population is community-living older

adults ages 60–74 with no known mobility limitations. A total of 1,000 individuals will participate in the study. Prospective respondents will answer a series of screening questions. Individuals who meet the screening criteria and are willing to participate will complete a baseline and follow-up interview each lasting approximately 10 minutes.

NCIPC will analyzed the collected data using descriptive statistics and a series of t-tests, chi-square analyses, and Mann-Whitney U-tests. Multivariate analyses will include a series of repeated measures Analysis of Variance (ANOVA), and logistic regressions.

The data collected from this study will help CDC identify what further revisions to the MPT might be necessary before it is disseminated publicly. Selected study findings may eventually be presented in oral and poster presentations and published in a peer-reviewed journal. Without this information collection, CDC will not know whether the MPT is an effective tool for promoting readiness to adopt mobility-protective behaviors in older adults and will not know whether additional revisions to the tool are necessary before the MPT is disseminated publicly. Without this study, CDC will have limited information about what strategies are most likely to be effective for disseminating the MPT publicly to the target audience.

The total estimated annual burden hours are 734.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Individuals Responding to Initial Phone Call Who Refuse to be Screened.	Screening Interview Guide	2,500	1	1/60	42
Individuals Responding to Initial Phone Call Responding to Screening Questions.	Screening Interview Guide	1,500	1	5/60	125
Study Participants	Baseline Interview Guide	1,000	1	10/60	167
Study Participants	MPT	500	1	30/60	250
Study Participants	Follow-up Interview Guide	900	1	10/60	150
Total	734

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**

Food and Drug Administration

[Docket No. FDA-2015-N-0986]

**Center for Devices and Radiological
 Health: Experiential Learning Program**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH or Center) is announcing the 2015 Experiential Learning Program (ELP). This training component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. The purpose of this document is to invite medical device industry, academia, and health care facilities to apply to participate in this formal training program for FDA's medical device review staff, or to contact CDRH for more information regarding the ELP.

DATES: Submit either an electronic or written request for participation in the ELP by May 8, 2015. The proposal should include a description of your facility relative to focus areas described in tables 1 or 2). Please include the Area of Interest (see tables 1 or 2) that the site visit will demonstrate to CDRH staff, a

contact person, site visit location(s), length of site visit, proposed dates, and maximum number of CDRH staff that can be accommodated during a site visit. Proposals submitted without this minimum information will not be considered. In addition, please include an agenda outlining the proposed training for the site visit. A sample request and agenda are available on the ELP Web site at <http://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392988.pdf> and <http://www.fda.gov/scienceresearch/sciencereeropportunities/ucm380676.htm>.

ADDRESSES: Submit either electronic requests to <http://www.regulations.gov> or written requests to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify proposals with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Latonya Powell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5232, Silver Spring, MD 20993-0002, 301-796-6965, FAX: 301-827-3079, Latonya.powell@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is responsible for ensuring the safety and effectiveness of medical devices marketed in the United States. Furthermore, CDRH assures that patients and providers have timely and continued access to high-quality, safe, and effective medical devices. In support of this mission, the Center launched various training and development initiatives to enhance

performance of its staff involved in regulatory review and in the premarket review process. One of these initiatives, the ELP Pilot, was launched in 2012 and fully implemented on April 2, 2013 (78 FR 19711). CDRH is committed to advancing regulatory science; providing industry with predictable, consistent, transparent, and efficient regulatory pathways; and helping to ensure consumer confidence in medical devices marketed in the United States and throughout the world. The ELP is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. This is a collaborative effort to enhance communication and facilitate the premarket review process. Furthermore, CDRH is committed to understanding current industry practices, innovative technologies, regulatory impacts, and regulatory needs.

These formal training visits are not intended for FDA to inspect, assess, judge, or perform a regulatory function (e.g., compliance inspection), but rather, they are an opportunity to provide CDRH review staff a better understanding of the products they review. Through this notice, CDRH is formally requesting participation from companies, academia, and clinical facilities, including those that have previously participated in the ELP or other FDA site visit programs.

II. ELP

A. ELP Training Component

In this training program, groups of CDRH staff will observe operations at research, manufacturing, academia, and health care facilities. The focus areas and specific areas of interest for visits may include the following:

TABLE 1—AREAS OF INTEREST—MEDICAL DEVICES/TECHNOLOGY

Focus area	Specific areas of interest
Failure analysis of orthopedic devices.	Methods for retrieval and preservation of failed implants for analysis; understanding how retrieved implants may be analyzed; methods for identifying failure modes; understanding how analysis of failed implants influences device design modifications.
Radiologic analysis of orthopedic devices.	Methods of radiologic analysis and associated data analyses; radiologic imaging core laboratories.
Automated external defibrillators (AEDs).	Manufacturing process; incoming component inspection; design verification testing; human factors testing; returned product testing (as available).
Diagnostic imaging catheters for cardiovascular diseases.	Manufacturing process; design verification testing; returned product testing (as available); ultrasound, optical coherence tomography (OCT), and near infrared spectroscopy (NIS) catheters.
Endovascular grafts for treatment of aortic aneurysms.	Physician-sponsored clinical studies; observation of endovascular grafting surgical procedure; surgical planning process; factors that influence device modifications (e.g., patient anatomy, patient pathology).
Animal models for evaluation of hemostatic devices.	Models of traumatic injury and severe hemorrhage; limitations of the model; understanding the relevance of the data generated from these models in evaluating hemostatic devices.
Hyaluronic acid in dermal tissue fillers.	Manufacturing process; source materials; performance testing (e.g., material characterization, biocompatibility, residence time).
Minimally invasive glaucoma surgery (MIGS) devices.	Observation of a MIGS procedure; surgical planning; surgical challenges.