instruments are needed to gather, process, aggregate, evaluate, and disseminate information describing the program's processes and outcomes. The information will be used by CDC to document progress toward meeting established program goals and objectives, to evaluate outcomes generated by the Ready CDC Personal Preparedness Workshops and to respond to data inquiries made by other agencies of the federal government.

Survey instrument questions will gather perceptions about personal and regional preparedness from the perspective of the participant. Each participant will be surveyed three times, once before and twice after their participation in the Personal Preparedness Workshop.

It is estimated that there will be a total of 600 respondents/year with an estimated time for data collection of 20 minutes each on the pre-workshop survey, 5 minutes each on the Ready CDC Workshop Evaluation, and 10 minutes each on the Follow Up Survey.

Instruments will be administered electronically (by including a link to the survey Web site with the email invitation) with an option for paper copy administration. The Follow Up Survey will be used to document changes in the categories of questions dealing with preparedness from the initial pre-workshop survey.

The estimated total time for data collection is 35 minutes, resulting in an annualized estimated burden of 350 hours.

There are no costs to respondents except 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 (in hours)
Federal Employee, Contractor, or other external governmental and non-governmental organizations.	Pre-Workshop Survey ..	600	1	20/60	200
Federal Employee, Contractor, or other external governmental and non-governmental organizations.	Ready CDC Workshop evaluation.	600	1	5/60	50
Federal Employee, Contractor, or other external governmental and non-governmental organizations.	Follow Up Survey	600	1	10/60	100
Total	.....	.....	.....	.....	350

LeRoy 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

[30Day–14–13ZC]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Case Studies to Explore Interventions that Support, Build, and Provide Legacy Awareness for Young Breast Cancer Survivors—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Young breast cancer survivors (YBCS, defined as women diagnosed with breast cancer under 45 years old) may have a more difficult time coping with breast cancer treatment and aftercare when compared to older breast cancer survivors. As a result of the Young Women's Breast Health Education and Awareness Requires Learning Young (EARLY) Act, CDC established Funding Opportunity Announcement, DP11–1111, *Developing Support and Educational Awareness for Young (< 45 years of age) Breast Cancer Survivors in the United States.* Subsequently, CDC awarded a three-year cooperative agreement to seven organizations that demonstrated a capacity to (1) reach YBCS, health care providers, and caregivers/families, (2) implement interventions that seek to provide support services, and (3) develop educational communication and awareness resources to support YBCS.

Other establishments within the U.S., such as local and national not-for-profit organizations and academic institutions, implement similar YBCS-focused interventions without funding from CDC's DP11–1111 cooperative agreement. Although these entities are not funded through CDC, they plan, develop, and employ similar tools, strategies, and interventions to reach or benefit these targeted young cancer-survivor populations.

CDC proposes to conduct exploratory case studies of organizations that provide support services and/or educational resources to YBCS, health care providers, and/or caregivers/families. Each selected organization will serve as a unique case and the unit of analysis. Information will be collected from up to 12 organizations: seven case studies will be conducted with organizations that receive funding through CDC's DP11–1111 cooperative agreement, and up to five case studies will be conducted with other organizations that are implementing similar YBCS-focused activities and interventions but do not receive funding under DP11–1111.

Case studies are intended to serve as an exploration of implementation activities, as well as to provide the context for implementation. Information

will be collected during a single site visit to each selected organization to conduct on-site observations and in-depth interviews (IDI) with each organization's key informants, such as Principal Investigators, Program Managers, Program Staff, and Program Partners. IDIs will last 1–2 hours each. Case study findings will help CDC to identify areas in which CDC can build upon existing and emerging efforts to provide support services and educational resources to YBCS, highlight barriers and facilitating factors to implementing interventions targeting YBCS, determine the added value of providing the DP11–1111 cooperative agreement (e.g., funding, technical assistance) to various entities, identify lessons learned that can be applied to future implementation of YBCS interventions, and better understand the sustainability of YBCS interventions following/in the absence of CDC funding.

Case study selection is based on a purposeful selection of CDC-funded and non-CDC funded organizations that support YBCS populations through educational or service programs. Potential organizations for this project may be funded through state, local, or Tribal government, or the private sector. Information will be collected approximately two years after initiation of CDC's cooperative agreement. OMB approval is requested for one year.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 168.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)
Private Sector Organizations	Worksheet for Identifying Site Visit Interviews	7	1	1
	Worksheet for Scheduling Site Visit Interviews	7	1	2
	IDI Guide for Program Directors/Principal Investigators.	7	1	2
	IDI Guide for Program Managers	7	1	1
	IDI Guide for Program Staff Members	35	1	1
	IDI Guide for Program Partners	21	1	1
State, Local, and Tribal Government Organizations.	Worksheet for Identifying Site Visit Interviews.	5	1	1
	Worksheet for Scheduling Site Visit Interviews	5	1	2
	IDI Guide for Program Directors/Principal Investigators.	5	1	2
	IDI Guide for Program Managers	5	1	1
	IDI Guide for Program Staff Members	25	1	1
	IDI Guide for Program Partners	15	1	1

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–2014–N–0001]

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 20, 2014, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301–948–8900.

Contact Person: Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993–0002, *Avena.Russell@fda.hhs.gov,* 301–796–3805, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On March 20, 2014, the committee will discuss, make recommendations, and vote on information regarding the humanitarian device exemption (HDE) application for the XVIVO Perfusion System (XPS™) sponsored by XVIVO Perfusion, Inc. The proposed Indication for Use for the XVIVO Perfusion System, as stated in the HDE, is as follows:

The XPS™ is intended to be used with STEEN Solution for flushing and temporary continuous normothermic machine perfusion of initially unacceptable excised donor lungs during which time the function of the lungs can be reassessed for transplantation.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/*