Keith A. Tucker,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–New]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60-days.

Proposed Project: Evaluation of the Consumer Education Campaign ''Make the Call—Don't Miss a Beat'' for the Office on Women's Health (OWH), U.S. Department of Health and Human Services (HHS) (New)—OMB No. 0990–NEW.

Abstract: The ''Make the Call. Don't Miss a Beat'' campaign is a national Public Service Announcement (PSA) campaign that aims to educate, engage and empower women and their families to learn the seven most common symptoms of a heart attack and to call 911 as soon as those symptoms arise. The campaign launched in February, 2011 and includes TV, radio, print and social media PSA. This study will collect information on awareness of the Make the Call—Don't Miss a Beat campaign, knowledge about heart disease, risk status, and likelihood of calling 911 as the first response to the symptoms of a heart attack. Information will also be collected on demographic variables including age, sex, race, education, income, primary language, and marital status. Information will be collected through the use of a probability sample, Random Digit Dial telephone survey. The respondent base will be surveyed only once, as this is a single-wave survey. The sampling plan is to include a minimum of 1200 women from the United States general population, with at least 600 of these women 50 years or older.

ESTIMATED ANNUALIZED BURDEN TABLE

Form	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Screener	General Population, Adult Women, 25+.	4300	1	5/60	358
Main instrument	General Population, Adult Women, 25+.	1200	1	15/60	300
Total					658

Keith A. Tucker,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day-12–12BO]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call (404) 639–5960 or send comments to Daniel Holcomb, CDC Reports Clearance Officer, 1600 Clifton Road, MS D–74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

Monitoring and Reporting System for Community Transformation Grant Awardees—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Chronic diseases, including heart disease, cancer, stroke, diabetes, arthritis, are the leading causes of death and disability in the United States, accounting for seven of every ten deaths and affecting the quality of life of 90 million Americans. Reducing death and disability through the prevention and control of these conditions, and related risk factors such as tobacco use,

physical inactivity, poor diet, and obesity, has critical importance for public health.

The Prevention and Public Health Fund (PPHF) of the Patient Protection and Affordable Care Act of 2010 (ACA) provides an important opportunity for states, counties, territories and tribes to advance public health across the lifespan and to reduce health disparities. The PPHF authorizes Community Transformation Grants (CTG) for the implementation, evaluation, and dissemination of evidence-based community preventive health activities. The CTG program will create healthier communities by building capacity to implement broad evidence and practice-based policy, environmental, programmatic and infrastructure changes, and supporting implementation of such interventions. The CTG program emphasizes five strategic areas: Tobacco-free living, active living and healthy eating, high impact evidence-based clinical and other preventive services, social and emotional wellness, and a healthy and safe physical environment. The CTG program is administered by the Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP).

CDC awarded 68 CTG cooperative agreements to state and local governmental agencies, tribes and territories, state or local non-profit organizations, and national networks of community-based organizations. Fifty-four awardees were from state, local and tribal government, and 14 awardees were from the private, non-profit sector. Each awardee is charged with implementing a community-or awardee-specific work plan that will lead to specific, measurable health outcomes in its jurisdiction (or service area) among an entire population or a specific population subgroup. Each CTG awardee is required to provide semi-annual reports to CDC describing its work plan, objectives, activities, partnerships, resources, and progress.

CDC plans to collect the required progress report information using an electronic management information system (MIS), which has a number of advantages when compared to the collection of narrative reports. First, the MIS will help awardees formulate objectives that are specific, measurable, achievable, relevant and time-framed (SMART), as required by CDC's evaluation strategy. Second, awardees will have the capacity to enter updates on an ongoing basis. This capacity is expected to improve respondent satisfaction and result in more complete enumeration of CTG-funded efforts. In addition, this feature will facilitate communications with CDC and prompt, data-driven technical assistance. Third, information stored in the MIS can be used to satisfy routine, semi-annual reporting requirements while minimizing data re-entry for information that has not changed. Finally, the electronic MIS will allow CDC to formulate ad hoc analyses and reports that would be impracticable using paper-based information sources. Information collected through the MIS will be used to monitor awardee progress, identify and support CDC technical assistance to awardees, and respond to inquiries from the Department of Health and Human Services (HHS), the White House, Congress and other sources. NCCDPHP has successfully implemented similar MIS-based information collections with other chronic disease prevention and control programs.

OMB approval is requested for three years. Awardees will report information to CDC twice per year. The average burden per response is estimated to be three hours. CDC's collection of this information is authorized by section and sections 311 and 317(k)(2) of the Public Health Service Act, 42 U.S. Code 243 and 247b(k)2. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Community Transformation Grant Awardees (state, local and tribal government sector)	54	2	3	324
CTG Awardees (private sector)	14	2	3	84
Total				408

Dated: November 29, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0464]

Draft Guidance for Industry and Food and Drug Administration Staff; the Content of Investigational Device Exemption and Premarket Approval Applications for Artificial Pancreas Device Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Draft Guidance for Industry and FDA Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems.'' This draft guidance document provides industry and the Agency staff with guidelines for developing premarket submissions for artificial pancreas device systems, in particular, the Control-to-Range (CTR) and Control-to-Target (CTT) device systems. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the