

that strive to augment the informed consent document and increase a subject's understanding of research participation. The meeting will conclude with a panel of speakers focusing on the regulatory barriers that may be associated with Community Based and Participatory Research. Public comment will be heard on both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business Thursday, October 22, 2009. Information about SACHRP and the draft meeting agenda will be posted on the SACHRP Web site at: <http://www.hhs.gov/ohrp/sachrp/index.html>.

Dated: October 6, 2009.

Jerry Menikoff,

Director, Office for Human Research Protections, Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. E9-24482 Filed 10-9-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood Safety and Availability

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood Safety and Availability (ACBSA) will hold a meeting. The meeting will be open to the public.

DATES: The meeting will take place Thursday, November 19 and Friday, November 20, 2009 from 8:30 a.m. to 5 p.m.

ADDRESSES: The Universities at Shady Grove, 9630 Gudelsky Drive, Rockville, MD 20850, Phone: 301-738-6000.

FOR FURTHER INFORMATION CONTACT: Jerry A. Holmberg, PhD, Executive Secretary,

Advisory Committee on Blood Safety and Availability, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootton Parkway, Suite 250, Rockville, MD 20852, (240) 453-8803, FAX (240) 453-8456, e-mail ACBSA@hhs.gov.

SUPPLEMENTARY INFORMATION: The Advisory Committee on Blood Safety and Availability provides advice to the Secretary and the Assistant Secretary for Health on a range of policy issues that impact (1) Definition of public health parameters around safety and availability of the blood supply and blood products, (2) broad public health, ethical and legal issues related to transfusion and transplantation safety, and (3) the implications for safety and the availability of various economic factors affecting product cost and supply.

In keeping with its established mission, the ACBSA has been asked to review and comment on the current processes and parameters which should be used in the decision-making process for transplantation safety policy. At the November 19 and 20, 2009 meeting, the Committee will be asked to comment and make recommendations on current safety decision making processes within the Department of Health and Human Services while considering those same processes within the Private Sector.

During the meeting, the ACBSA will be provided a briefing on Biovigilance (surveillance of blood, organs, and tissues safety). Specifically, the committee will be asked to comment on the white paper entitled, "Biovigilance in the United States: Efforts to Bridge a Critical Gap in Patient Safety and Donor Health."

The public will have opportunity to present their views to the Committee on both meeting days. A public comment session has been scheduled for November 19 and 20, 2009. Comments will be limited to five minutes per speaker and must be pertinent to the discussion. Pre-registration is required for participation in the public comment session. Any member of the public who would like to participate in this session is encouraged to contact the Executive Secretary at his/her earliest convenience. It is requested that those who wish to have printed material distributed to the Committee provide thirty (30) copies of the document to be distributed to the Executive Secretary, ACBSA, prior to close of business November 16, 2009. If it is not possible to provide 30 copies of the material to be distributed, then individuals are requested to provide at a minimum one (1) copy of the document(s) to be

distributed prior to the close of business November 16, 2009. It also is requested that any member of the public who wishes to provide comments to the Committee utilizing electronic data projection submit the necessary material to the Executive Secretary prior to close of business November 16, 2009.

Dated: September 25, 2009.

Jerry A. Holmberg,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. E9-24483 Filed 10-9-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-10-0612]

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 and send comments to Maryam Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail 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

Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System (OMB #0920-0612, exp. 1/31/2010)—Revision—National Center

for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Cardiovascular disease (CVD), which includes heart disease, myocardial infarction, and stroke, is the leading cause of death for women in the United States, and is largely preventable. The WISEWOMAN program (Well-Integrated Screening and Evaluation for Women Across the Nation), administered by the Centers for Disease Control and Prevention (CDC), was established to examine ways to improve the delivery of services for women who have limited access to health care and elevated risk factors for CVD. The program focuses on reducing CVD risk factors and provides screening services for select risk factors such as elevated blood cholesterol, hypertension and abnormal blood glucose levels. The program also provides lifestyle interventions and medical referrals. On an annual basis, 15 grantees funded through the WISEWOMAN program have provided services to approximately 30,000 women who are already participating in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), also administered by CDC. CDC plans to

increase the reach of the WISEWOMAN program by increasing the number of grantees from 15 to 21.

CDC currently collects information from WISEWOMAN grantees to support continuous program monitoring and improvement activities. CDC seeks to extend OMB approval for three additional years. The total estimated annualized burden will increase due to the increase in the number of funded grantees. However, the burden to each respondent will decrease due to a reduction in the frequency of data collection for items that were previously collected on a quarterly basis. During the next OMB approval period, all information will be collected twice per year.

Information reported to CDC includes baseline and follow-up data (12 months post enrollment) for all women served through the WISEWOMAN program. These data, called the minimum data elements (MDE), include data elements that describe risk factors for the women served in each program and data elements that describe the number and type of intervention sessions attended. Funded grantees compile the data from their existing databases and report the MDE to CDC in April and October of each year. The MDE data provide an assessment of how effective the

WISEWOMAN program is at reducing the burden of cardiovascular disease risk factors among women who utilize program services. The information collected from grantees is also used to assess the cost-effectiveness and impact of the program. The overall program evaluation is designed to demonstrate how WISEWOMAN can obtain more complete health data on vulnerable populations, promote public education about disease incidence and risk-factors, improve the availability of screening and diagnostic services for under-served women, ensure the quality of services provided to under-served women, and develop strategies for improved interventions. The information reported to CDC also includes programmatic information related to grantee management, public education and outreach, professional education, service delivery, cost, and progress toward meeting stated programmatic objectives.

All MDE information will be submitted to CDC electronically. Progress reports will be submitted in hardcopy format. Because certain demographic information has already been collected as part of NBCCEDP, the additional burden on grantees will be modest. There is no cost to the 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 (in hours)
WISEWOMAN Grantees	WISEWOMAN MDEs	21	2	40	1,680
	Progress Report	21	2	16	672
Total					2,352

Dated: October 5, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9-24522 Filed 10-9-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0484]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

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 guidance on reagents for detection of specific novel influenza A viruses.

DATES: Submit written or electronic comments on the collection of information by December 14, 2009.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget