ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Women-Screening interview	55	1	10/60	10
Women-Focus groups	32	1	2	64
Women-individual interviews	20	1	2	40
Community leaders-Focus groups	32	1	2	64
Total				178

Dated: July 21, 2006.

Joan F. Karr,

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

[FR Doc. E6–12023 Filed 7–26–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–06–06BM]

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 Seleda Perryman, CDC Assistant 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

Randomized Controlled Trial of Routine Screening for Intimate Partner Violence—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Intimate partner violence (IPV) is a prevalent problem with serious health consequences that include death, physical injury, increased rates of physical illness, posttraumatic stress, increased psychological distress, depression, substance abuse, and suicide. Some studies suggest that abuse perpetrated by intimate partners tends to be repetitive and escalates in severity over time. This research has been the basis for promoting early diagnosis and intervention.

Health care providers appear to be well situated to identify IPV. Women come into contact with health care services routinely for a number of reasons such as prenatal care, family planning, cancer screening, and well baby care. Women experiencing IPV make more visits to emergency departments, primary care facilities, and mental health agencies than non-abused women. Considering the magnitude and severity of IPV, and the potential role health care providers could play in reducing its serious consequences, numerous professional and health care organizations have recommended routine screening of women for IPV in primary care settings. However, various systematic reviews of the literature have not found evidence for the effectiveness of screening to improve outcomes for women exposed to IPV.

A recent expert panel recommended that a randomized controlled trial (RCT) be conducted to establish the effectiveness of screening on women's health. In order to appropriately design a RCT, estimates of health change are required to calculate the sample size for the RCT, and consequently, establish its cost. In addition, the feasibility, acceptability, and impact of different approaches to screening and the concordance of different data collection methods need to be assessed to adequately design the RCT.

CDC has a contract to pilot test measures and procedures that are being proposed for a RCT of routine screening of IPV. This pilot test will recruit 175 women from OBGYN and family planning services in Cook County Hospital in Chicago. Women who agree to participate will be asked to complete a baseline computer-assisted and one week follow-up telephone questionnaire that will include overall health, physical and mental health, disability, health care utilization, and quality of life (QOL). Based on this pilot test, the measure will be revised and used in a RCT with 3000 women to test the impact of screening on health and QOL. There are no costs to respondents other than their time to participate in the survey.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Number of respondents	Number of responses per respondents	Avg. burden/ response (in hours)	Total burden (hours)
Screener for Pilot	210	1	1/60	4
Pilot Health and QOL questionnaire	175	2	20/60	117
Screener for Final Pilot	3750	1	1/60	63

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form	Number of respondents	Number of responses per respondents	Avg. burden/ response (in hours)	Total burden (hours)
Health and QOL questionnaire Final	3000	2	20/60	2000
Total				2184

Dated: July 21, 2006.

Joan F. Karr,

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

[FR Doc. E6–12025 Filed 7–26–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): CDC Public Health Research: Health Protection Research Initiative Graduate Training Program Grant, Request for Applications (RFA) CD07–001

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 the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): CDC Public Health Research: Health Protection Research Initiative Graduate Training Program Grant, Request for Applications (RFA) CD07–001.

Time and Date: 12 p.m.–4 p.m., September 14, 2006 (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 To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to RFA CD07–001, ''CDC Public Health Research: Health Protection Research Initiative Graduate Training Program Grant.''

Contact Person For More Information: Christine Morrison, PhD., Scientific Review Administrator, Office of Extramural Research, CDC, 1600 Clifton Road, NE., Mailstop D72, Atlanta, GA 30333, Telephone 404.639.3098.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 20, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6–12015 Filed 7–26–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0275]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems.'' This guidance document describes a means by which fecal calprotectin immunological test systems may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify fecal calprotectin immunological test systems into class II (special controls). This guidance document is immediately in effect as the special control for fecal calprotectin immunological test systems, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Class II Special Controls Guidance Document: Fecal Calprotectin, Immunological Test Systems'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Deborah Moore, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0493.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying fecal calprotectin immunological test systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This notice announces the guidance document that will serve as the special control for fecal calprotectin immunological test systems.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register**