

office in processing your request, or fax your request to 301-402-2071. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document. Submit written comments to GINA GUIDANCE COMMENTS, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail to [ohrp@hhs.gov](mailto:ohrp@hhs.gov) or via facsimile at 240-453-6909. Comments received, including any personal information, will be made available to the public upon request.

**FOR FURTHER INFORMATION CONTACT:**

Michael A. Carome, M.D., Captain, U.S. Public Health Service, OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240-453-6900; e-mail [Michael.Carome@hhs.gov](mailto:Michael.Carome@hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

OHRP, Office of Public Health and Science, is announcing the availability of a guidance document entitled, "Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards." The guidance document provides OHRP's first formal guidance on this topic. The document applies to non-exempt human subjects research conducted or supported by HHS and is intended primarily for investigators who conduct, and IRBs that review, genetic research.

The guidance document provides some general background information regarding GINA and discusses some of the implications of GINA with respect to the criteria for IRB approval of research and the requirements for obtaining informed consent under the HHS regulations for the protection of human subjects (45 CFR part 46).

**II. Electronic Access**

Persons with access to the Internet may obtain the guidance document on OHRP's Web site at <http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html> and <http://www.hhs.gov/ohrp/humansubjects/guidance/gina.pdf>.

**III. Request for Comments**

Interested persons may submit comments regarding this guidance document to OHRP at any time. Please see the **ADDRESSES** section for information on where to submit written comments.

Dated: April 1, 2009.

**Jerry Menikoff,**

*Director, Office for Human Research Protections.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

**Proposed Projects**

*Title:* Cross-Site Evaluation of the Infant Adoption Awareness Training Program for Projects Initially Funded in Fiscal Year 2006.

*OMB No.:* New Collection.

*Description:* The Administration for Children and Families (ACF), Children's Bureau (CB), will conduct the Cross-Site Evaluation of the Infant Adoption Awareness Training Program (IAATP). Title XII, Subtitle A, of the Children's Health Act of 2000 (CHA) authorizes the Department of Health and Human Services to make Infant Adoption Awareness Training grants available to national, regional, and local adoption organizations for the purposes of developing and implementing programs that train the staff of public and non-profit private health service organizations to provide adoption information and referrals to pregnant women on an equal basis with all other courses of action included in non-directive counseling of pregnant women. Participants in the training include individuals who provide pregnancy or adoption information and those who will provide such services after receiving the training, with Title X (relating to voluntary family planning projects), Section 330 (relating to community health centers, migrant health centers, and centers serving homeless individuals and residents of public housing), and CHA-funded school-based health centers, receiving priority to receive the training. A total of six organizations were awarded IAATP funding in 2006.

Section 1201(a)(2)(A) of the IAATP legislation requires grantees to develop and deliver trainings that are consistent with the Best Practice Guidelines for Infant Adoption Awareness Training. The IAATP guidelines address training goals, basic skills, curriculum and

training structure. A complete description of the guidelines is available at [http://www.acf.hhs.gov/programs/cb/programs\\_fund/discretionary/iaatp.htm](http://www.acf.hhs.gov/programs/cb/programs_fund/discretionary/iaatp.htm).

In addition, grantees are required to conduct local evaluation of program outcomes and participate in the national evaluation of the extent to which IAATP training objectives are met. The Infant Adoption Awareness Training Program: Trainee Survey is the primary data collection instrument for the national cross-site evaluation. Respondents will complete the survey prior to receiving training and approximately 90 days after the training to assess the extent to which trainees demonstrate sustained gains in their knowledge about adoption, and to determine the impact of the training on their subsequent work with pregnant women.

1. Do health care workers who participate in the IAATP training: Demonstrate enhanced knowledge, attitudes, skills, and behaviors with respect to adoption counseling following completion of the program? Provide adoption information to pregnant women on an equal basis with other pregnancy planning options? Demonstrate enhanced awareness of community adoption-related resources and refer expectant mothers to them as needed?

2. Are trainees more confident about discussing all three pregnancy planning options (parenting, abortion, and adoption) in a non-directive counseling style than they were prior to participating in the training? Cross-site evaluation data will be collected on an annual basis throughout the five-year funding period. Pre-test and follow-up versions of the survey are expected to require approximately 10 to 15 minutes to complete. Estimated response time for the follow-up survey includes time for respondents to access the Web-based survey, complete the survey online, and electronically submit the survey. Respondents will not need to implement a recordkeeping system or compile source data in order to complete the survey. Where possible, fields in the follow-up version of the survey will be pre-filled with static data from the respondents pre-test (e.g., demographics, agency type) in order to further expedite completion of the survey and minimize respondent burden.

*Respondents:* Infant Adoption Awareness Program Trainees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
IAATP: Trainee Survey Pre-Test Administration .....	1,200	1	0.15	180
IAATP: Trainee Survey Follow-Up Administration .....	1,200	1	0.10	120

*Estimated Total Annual Burden Hours: 300.*

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

*The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 2, 2009.

**Janean Chambers,**  
*Reports Clearance Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30Day-09-08BJ]**

**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 the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

**Proposed Project**

A Study of Primary and Secondary Prevention Behaviors Practiced Among Five-Year Survivors of Colorectal Cancer—New—National Center for Chronic Disease Prevention and Control (NCCDPHP), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

Colorectal cancer (CRC) is the third most prevalent cancer and the second leading cause of cancer death in both men and women in the United States. In 2004, there were an estimated 145,083 new cases of colorectal cancer diagnosed and 53,580 deaths. However, the five-year relative survival rates of patients diagnosed with CRC have been steadily increasing since 1975 and there are now over one million CRC survivors in the U.S.

Despite improved survival rates, CRC survivors are at an elevated risk for cancer recurrence, second primary

cancers, and other health problems after being treated for cancer. Research evidence suggests that these elevated risks can be mitigated by healthy lifestyle practices and by undergoing regular medical follow-up and cancer screenings, however, little is known about the factors that motivate or hinder the adoption of recommended cancer prevention and screening behaviors in this population.

CDC proposes to conduct a survey of five-year CRC survivors to collect information about knowledge, attitudes, psychosocial factors, health status and behaviors, and utilization of health care services including screening services. Potential survey respondents will be identified through California Cancer Registry records. Each physician associated with one or more CRC patients will be responsible for reviewing a customized list of names to identify patients who should not be contacted for recruitment into the study. Following receipt of physician permission to contact potential participants, and receipt of participant consent, 1,000 respondents will complete a survey of health behaviors. Approximately 900 respondents are expected to complete a self-administered survey that will be delivered and returned by mail, and 100 respondents are expected to complete the survey by computer-assisted telephone interview, in response to a follow-up call from study staff. OMB clearance is being requested for one year of data collection.

Findings from this study will help guide future policies, programs, and interventions developed to enhance and improve the long-term health and well being of cancer survivors.

There are no costs to respondents except the time to complete the survey. The total estimated burden hours are 1,095.

**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)
Physicians .....	List of Potential Study Participants ..	1,950	1	13/60	423