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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-16UW]

# Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

Case Investigation of Cervical Cancer (CICC) Study – New – National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Invasive cervical cancer occurs when cervical cancer spreads from the surface of the cervix to deeper cervical tissue or to other parts of the body. In the United States, invasive cervical cancer is largely preventable due to the availability of (1) screening tests, which allow for early detection and treatment of cervical pre-cancers, and (2) a vaccine that prevents infection with types of human papillomavirus (HPV) which are associated with over 80% of cervical cancers. However, one previous study showed that half of the women who developed cervical cancer had not been adequately screened, and a more recent study showed that there were still approximately 8 million women in the U.S. who had not been screened for cervical cancer in the previous five years.

CDC plans to conduct the Case Investigation of Cervical Cancer (CICC) Study to improve understanding of the facilitators and barriers to cervical cancer screening and timely follow-up of abnormal test results. The proposed project will identify women recently diagnosed with invasive cervical cancer (2014-2016) through cancer registries in three states. Each registry will enroll cancer survivors within that state who consent to participate in the study.

Three types of data will be collected. (1) Existing cancer registry data will provide information on tumor characteristics, diagnosis, and stage of cancer. This will be used to describe the characteristics of the sample of survivors and for the identification of the eligible sample. (2) Participants will be asked to complete a survey. The purpose of the survey is to identify self-reported barriers and facilitators to screening and care, and to examine recall of screening tests. (3) Participants will also be asked to complete medical release and healthcare source forms to permit medical chart abstraction. The purpose of the medical chart abstraction is to obtain detailed clinical information about all screening and treatment prior to diagnosis. Together the information from these three sources of data will be used to identify opportunities for intervention to reach women and their providers in order to increase screening and appropriate follow-up care.

Based on preliminary data from three state cancer registries, a total of approximately 1,670 eligible cervical cancer survivors are eligible for participation. CDC estimates a survey response rate of 50% of across the entire sample (N=835) followed by an 80% response rate to the medical release and healthcare source forms (N=668). These estimates yield approximately 668 women with complete data for both surveys and

chart abstraction. The estimated burden per response for completing the mail-in questionnaire is 15 minutes. The estimated burden per response for the medical release and healthcare source forms is five minutes. For each CICC participant, the medical chart abstraction process is expected to require follow-up with 1-5 (average of 3) health care providers (N=2,004). The estimated burden for support activities conducted by office assistants at the health care facilities associated with each medical record abstraction is five minutes.

OMB approval is requested for two years. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 217.

Estimated Annualized Burden Hours

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hrs.) |
|---|---|---|---|---|
| Invasive cervical cancer survivors | Case Investigation of Cervical Cancer Study Survey | 418 | 1 | 15/60 |
| | Medical Release and Healthcare Source Forms | 314 | 1 | 5/60 |
| Health care office assistant | Support for medical record abstraction | 1,002 | 1 | 5/60 |

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Office of the Associate Director for Science
Office of the Director
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