Reinstatement Request

OMB No. 0920-0706, exp. 12/30/2011

National Program of Cancer Registries Program Evaluation Instrument (NPCR-PEI)

Supporting Statement Part A

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Netta Apedoe, MPH
Telephone: (770) 488-4570
Fax: (770) 488-4759
Email: ize6@cdc.gov
Division of Cancer Prevention and Control
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
4770 Buford Highway NE, Mail Stop F/69
Atlanta, GA 30341-3724

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ABSTRACT

National Program of Cancer Registries
Program Evaluation Instrument

This is a reinstatement request for a clearance period of three years. Information will be collected on a biennial schedule in odd-numbered years. A regularly scheduled discontinuation occurred in December 2011 after information collection for that year had been completed. In the 83-D, it was noted that there were a number of changes in 2012 that would affect future data collection, including 1) revision of the National Program of Cancer Registries (NPCR) program standards, which could affect the questions in the NPCR program evaluation instrument (PEI), and 2) a new FOA which could change the number of NPCR awardees. This Reinstatement request reflects the anticipated changes in NPCR program standards, minor changes in the content of the PEI, and a slight reduction in the number of NPCR awardees from 49 to 48. In addition, the estimated burden for completing the PEI will increase from 1.5 hours to 2 hours per response, resulting in an overall increase in burden to respondents.

JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting OMB approval for a reinstatement and revision request for the National Program of Cancer Registries – Program Evaluation Instrument (NPCR-PEI) **(Attachment 3A)**. This request is to reinstate the NPCR-PEI process which expired 12/31/2011 and update the survey instrument to measure compliance with revised program standards. Central cancer registries (CCR) in a total of 45 states, the District of Columbia, one Territory, and the Pacific Island Jurisdictions' unified Central Cancer Registry (CCR) are currently funded by NPCR to assist with the operation of central cancer registries that collect and report cancer incidence data to CDC (see **Attachment 4**, List of NPCR Awardees).

Cancer is a substantial public health burden. The American Cancer Society (ACS) estimates that 1,638,910 new cancer cases are expected to be diagnosed in 2012. This estimate does not include carcinoma in situ (noninvasive cancer) of any site except urinary bladder, and does not include basal and squamous cell skin cancers, which are not required to be reported to cancer registries. In 2012, about 577,190 Americans are expected to die of cancer, more than 1,500 people a day. Cancer is the second most common cause of death in the US, exceeded only by heart disease, accounting for nearly one of every four deaths. The National Institutes of Health (NIH) estimates that the over-all costs of cancer in 2007 were $226.8 billion: $103.8 billion for direct medical costs (total of all health expenditures) and $123.0 billion for indirect mortality costs (cost of lost productivity due to premature death.

Within CDC, the Division of Cancer Prevention and Control (DCPC) plans, directs, and supports cancer control efforts through collaboration with prevention partners in state health

agencies, federal agencies, academic institutions, and with national, voluntary, and private-sector organizations. To obtain a firm basis for such programs, state- and territory-based central cancer registries (CCR) are needed to ensure that high-quality and timely cancer surveillance data are available. CDC requires NPCR-funded CCR to report information about their cancer prevention and control activities in order to monitor and support these efforts.

Recognizing the public health value of comprehensive cancer surveillance at the state and national level, Congress mandated the National Program of Cancer Registries (NPCR) in 1992 by enacting the Cancer Registries Amendment Act, Public Law 102-515 (**Attachment 1A**), and further authorizing NPCR and the data collection for this project in Section 301 of the Public Health Service Act [42 U.S.C. 241] **(Attachment 1B)**. This legislation authorizes the CDC to provide funds to states and territories to: 1) improve existing cancer registries; 2) plan and implement registries where none existed; 3) develop model legislation and regulations for states to enhance the viability of registry operations; 4) set standards for data completeness, timeliness, and quality; 5) provide training for registry personnel; and 6) help establish a computerized reporting and data-processing system. The full text of the current law is available online at: http://www.gpo.gov/fdsys/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap6A-subchapII-partM-sec280e.pdf.

The annual collection of performance indicator data from state and territorial programs funded through the National Program of Cancer Registries (NPCR) began 17 years ago and was reduced to biennial collection in 2009. The information collection allows CDC to provide routine feedback to awardees based on their data submissions, to tailor technical assistance as needed, and to support program planning, surveillance and secondary data analysis activities. A three-year extension to collect biennial data was approved by OMB in December 2008 and discontinued at the end of the approval in December 2011, based on expected changes in the number of awardees due to the new FOA to be released in 2012. The current request is to reinstate OMB approval for three years.

The NPCR is one of a number of CDC-sponsored public health programs designed to monitor and reduce morbidity and mortality in the United States from cancer. Related programs include the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), the National Colorectal Cancer Roundtable, prostate cancer control initiatives, and skin cancer prevention and education initiatives.

Privacy Impact Assessment

The NPCR Program Evaluation Instrument (PEI) was assessed in the previous clearance period (2008-2011). An overview of the data collection system and a listing of the items of information to be collected are provided in the subsequent sections.

Overview of the Data Collection System

NPCR-funded awardees are state and territorial governments or bona-fide agents. The cooperative agreement for NPCR funding requires awardees to complete and submit an annual program evaluation to CDC. In lieu of this annual evaluation, it is intended that once every other year, occurring in odd years, NPCR will deploy the web-based NPCR-PEI for approximately a 4-6 week period at which time awardees will complete the instrument (**Attachment 3A**). The NPCR-PEI is a user-friendly, web-based instrument. Each awardee is provided a secure login and a secure archive location for their data.

Each awardee will receive an electronic letter providing information about the procedures for accessing the NPCR-PEI, obtaining technical assistance, and regarding secure PEI login information (**Attachment 3B**). For years in which the NPCR-PEI is not deployed, a secure web-based data aggregation display system will be deployed to display national results from the previous year's instrument (**Attachment 6**).

The information that is collected relates to registry operations and procedures, such as staffing patterns and data linkages, not personal information. Awardees maintain data in local data management systems used to administer their programs and can use any software system that meets their needs.

The data provided to the contractor is archived on secure network servers with user ID and password restricted access at the location of the data contractor. Access rights and restrictions to network resources are determined by user ID. Networked systems are maintained in a secure room with access strictly limited to essential employees. Information is archived indefinitely. The contractor aggregates and validates the data for quality and completeness and prepares a SAS analysis file and a set of feedback reports to CDC and awardees within 60 days of the submission.

Items of information to be collected

To assist NPCR in its determination of funded CCRs' progress towards established program standards, the NPCR-PEI is designed to collect information from the following categories of registry operations: 1) staffing, 2) legislation, 3) administration, 4) reporting completeness, 5) data exchange, 6) data content and format, 7) data quality assurance, 8) data use, 9) collaborative relationships, 10) advanced activities, and 11) survey feedback. See **Attachment 3A** instrument to be used in 2013 and 2015 and **Attachment 3C** for a list of changes that will be implemented in 2013 since the previous approval in 2009-2011.

Examples of information that can be obtained from various questions include, but are not limited to: 1) number of filled staff full-time positions by position responsibility (e.g., CTR Quality Control, CTR Education/Training, Epidemiologist); 2) legislation protecting the confidentiality of CCR data; 3) various data quality control activities; 4) data collection activities as they relate to achieving NPCR program standards for data completeness; 5) whether

or not registry data is being used for comprehensive cancer control programs, needs assessment/program planning, clinical studies, or incidence and mortality estimates.

The majority of the questions on the PEI are based on the NPCR Program Standards (see **Attachment 5**) which are revised every five years. The 2012 revisions were necessitated by the changes in technology (e.g. increased access to electronic medical records), changes in terms, and changes in national and international standards. Therefore some questions have been deleted, some have been reworded, and a few will be added to measure adherence to requirements in the new FOA 1205. In addition, questions that showed 100% compliance in 2011 will be deleted.

Identification of Websites and Website Content Directed at Children under 13 Years of Age

PEI data compiled at the awardee level are transmitted to the contractor via a password-protected secure website (**Attachment 3B**) and are encrypted during transmission. The encryption is accomplished via Secure Sockets Layer (SSL) strong encryption, the same level of protection used by e-commerce sites to protect financial transactions.

The PEI website does not have content directed at children under 13 years of age.

A2. Purpose and Use of Information Collection

Increasingly, there is Congressional and public demand for federal agency documentation and accountability of achievement of program objectives and outcomes (e.g., the Government Performance and Results Act of 1993). The NPCR-PEI is designed to evaluate NPCR-funded registries' use of funds, progress towards meeting program goals and objectives, operational attributes, and computer infrastructure; to collect information about advanced activities (e.g., data linkages, geographic information system usage, collection of additional data items); and to highlight ways registry data is used.

Specific knowledge about operational activities in which NPCR registries are engaged, their use of requested funds, and CDC-recommended activities in which the registries report are not involved, and `are all examples of NPCR-PEI data used to examine NPCR registry operations and their success. The NPCR-PEI data are a complement to existing mechanisms that evaluate the completeness, timeliness, and quality of population-based central cancer registry (CCR) data. CDC encourages CCRs to continue increasing the ways their data is used.

As authorized under the Public Health Service Act, and its subsequent amendments, CDC established standards to indicate the optimum achievement of specific functions and/or activities to be carried out by the CCR. The purposes of these standards are to guide priorities and activities of funded programs, provide objective measures of program progress, and to improve program processes that ultimately affect outcomes. NPCR Program Standards set measurable outcomes for CCR legislative authority, program administration, electronic data exchange, data content and format, data completeness, timeliness, and quality, data use, and collaborative relationships **(Attachment 5)**.

In order to continue the current program evaluation process, a contractor, ICF International (ICFI), will be retained to administer the web-based NPCR-PEI and respond to web-based technical assistance requests by the CCRs. Based on NPCR-PEI submissions, standardized descriptive reports will be generated by ICFI for the CCRs and the CDC. These reports will allow the program to monitor and evaluate the awardees' performance with NPCR program standards and with various attributes of registry operations. NPCR-PEI data will be used by CDC for program planning and improvement and monitoring NPCR's progress toward meeting its own goals and objectives. CDC will provide regular feedback to awardees based on their NPCR-PEI responses, tailoring technical assistance as indicated.

NPCR cancer registry operations information collected by the NPCR-PEI is essential to identify areas in which registries may benefit from education and training, technical assistance, and other resources, as well as to evaluate the status of other activities in which the CCRs are involved (e.g., independent and collaborative research, improvements in electronic reporting), and to effectively assist the CCRs with the implementation of changes in the NPCR.

The CDC reviews the quality of data in each PEI submission to ensure data are appropriate to monitor and evaluate the program. Data accuracy and management are critical for the data to be useful. CDC program consultants review the submissions upon receipt to identify incomplete or implausible information for follow-up.

PEI data are used to report results to CDC officials, Congress, and the Office of Management and Budget. CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) has developed performance measures for the Program Rating Assessment Tool (PART) that use PEI data to evaluate NBCCEDP program outcomes in annual reports to the Office of Management and Budget (OMB). PART measures require credible data sources. The NPCR PART evaluates trends in electronic reporting for which the data collection methodology has been successful with no problems reported by the NPCR awardees. The continuation of data collection is imperative for future monitoring and evaluation of the NPCR. Finally, subsets of PEI data are available to internal and external investigators, on a limited basis and with appropriate security controls, for research purposes.

Privacy Impact Assessment Information

There are no plans for a public-use dataset. Awardees are provided access to reports comparing their program operations with the averages of regional and national program operations. DCPC investigators will have restricted access to an analytical dataset of program results to use for analysis and publication in peer-review journals and presentations to cancer control organizations. Program participation and results will be reported in aggregate to describe program operations and compliance with NPCR standards. Any data published in program reports, either in printed copy or on the Internet, will be scrutinized to assure that small cell counts are masked and the privacy of the state is protected.

A3. Use of Improved Information Technology and Burden Reduction

The NPCR-PEI is made available to the CCRs on the internet as a user-friendly, web-based instrument. The web-based system facilitates data entry by allowing awardees secure access to the system at any location with an internet connection. Each CCR Program Director is provided a secure login and a secure archive location for their data. The system eliminates software installation and upgrades by respondents, as the questions are formatted so that only one question (top five local laboratory names) requires a text response. The NPCR-PEI allows electronic transmission of the data, an efficient mechanism that minimizes the reporting burden on the states. The burden has also been reduced since 2009 when submissions were reduced from annual to biennial submissions.

A4. Efforts to Identify Duplication and Use of Similar Information

No other program evaluation of NPCR registry operations and data use is currently performed.

The NPCR-PEI data collection is unique to national cancer surveillance in providing a national data set that assists the CDC in evaluating the NPCR, implementing improvements and increasing efficiency of cancer registry operations, and complements the existing NPCR-Cancer Surveillance System (NPCR-CSS) (OMB no. 0920-0469, exp. 1/31/2013; reinstatement in process) activity by evaluating attributes that are not otherwise evaluated. Although the NPCR-PEI places some burden on the CCRs, it also is poised to serve as a program evaluation tool for the CCRs. CCRs usually do not have the means or expertise to evaluate their own programs, and thus are not able to supply CDC with an evaluation of their cancer registry operations.

There are no existing, comparable data sources available for the collection of this information. The Economic Analysis of the NPCR (OMB No. 0920-0776, exp. 3/31/2011) collected activity-based cost information from NPCR awardees to support analysis of the costs and cost-effectiveness of the NPCR. That information has been used to assess the costs of various program components, identify factors that impact average cost, perform cost-effectiveness analysis, and to develop a resource allocation tool for ensuring the most appropriate use of limited program resources. The PEI data complement the cost data collection by providing the effectiveness measure for the cost-effectiveness analyses of the program. The economic analysis collection has been discontinued and the economic analysis is in progress.

A5. Impact on Small Businesses or Other Small Entities

No small businesses are involved in this study.

A6. Consequences of Collecting the Information Less Frequently

Initially, the CDC collected PEI data annually. The data collection was reduced to biennial in 2009. This allows the CDC to regularly evaluate the overall performance of the NPCR, to make adjustments toward improved effectiveness and to identify new goals as part of on-going planning efforts. It also allows the CDC to effectively monitor awardee performance and provide constructive guidance to them on a consistent basis. The collection of these data less frequently would compromise the ability of the CDC to perform this surveillance. The CDC is also obligated to provide status reports on the NPCR to Congress and other CDC officials. There are no legal obstacles to reduce the burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

These data are collected in a manner consistent with the guidelines in 5 CFR 1320.5. There are no special circumstances contained within this application.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Notice of this study was published in the Federal Register on November 5, 2012, Vol. 77, No. 214, pages 66467-66468 (**Attachment 2**). No public comments were received.

B. The Division of Cancer Prevention and Control (DCPC) consulted with staff at ICFI regarding various components of the NPCR-PEI. ICFI provided consultation regarding implementation and testing of the NPCR-PEI web-based system, and all processes involved in receiving, processing, evaluating, aggregating, and disseminating data from the NPCR-PEI. A list of ICFI staff consulted by DCPC is provided in **Attachment 7**.

In addition to consultation with ICFI, NPCR program evaluation staff members participated in national conferences, trainings, seminars, and evaluation forums for program evaluation professionals. These activities provided an extended forum for the direct discussion of program evaluation issues and an opportunity for the CDC to engage in consultation with other program evaluation professionals. The meetings and trainings have also provided excellent networking opportunities for NPCR-PEI key staff to share their experiences and ideas.

The CDC maintains a regular forum of awardee Program Directors that conference quarterly to discuss such topics as the NPCR-PEI. This mechanism allows input from funded programs to determine the questions appropriate for this type of evaluation.

A9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be made to respondents (awardees) to complete the web-based NPCR-PEI and submit responses to CDC.

A10. Assurance of Confidentiality Provided to Respondents

Protecting privacy is of paramount concern to the NPCR. No data is collected that has the potential for direct or deductive identification of an individual respondent.

Privacy Impact Assessment Information

A. This submission has been reviewed by CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), which determined that the Privacy Act does not apply. Respondents are institutional awardees (central cancer registries), not individuals. The information collected pertains to each cancer registry's activities and attributes. No personal information is collected.

B. The PEI data are secured by technical, physical and administrative safeguards as outlined below.

Technical

- Data are maintained in a secure location on a dedicated server at ICFI. The server resides on ICFI's local area network (LAN) behind the firewall. Access to the NPCR-PEI server is limited to authorized ICFI staff and is password protected on its own security domain. All of the contractor's project staff is required to sign a confidentiality agreement.
- NPCR-PEI data are encrypted and submitted electronically from the awardees and arrive on a document server behind ICFI's firewall. The data are moved automatically from the document server to the NPCR-PEI server. Each CCR has its own directory location so no CCR has access to another CCR's data.

Physical

- The contractor's server is housed in a secure facility with restricted access.
- Receipt and processing logs are maintained to document data receipt, file processing and report production. All reports and electronic storage media containing PEI data are stored under lock and key when not in use and will be destroyed when no longer needed.

Administrative

- CDC and contract staff have developed and implemented an information system security plan to ensure that the data are kept secure. Periodic review and update of the data contractor's security processes is conducted to adjust for needed changes and will be amended as needed to maintain the continued security of the data.
- The contractual agreement between CDC and the contractor includes non-disclosure terms. The contractor's project security team oversees operations to prevent unauthorized disclosure of the CCDE data.

C. The NPCR-PEI information collection is not considered research with human subjects. No consent process is required.

D. NPCR awardees are required to participate in the PEI information collection as a condition of cooperative agreement funding.

A11. Justification for Sensitive Questions

Respondents are institutions (central cancer registries) and not individuals. Therefore, no information of a sensitive nature such as race/ethnicity, religious beliefs, or sexual preference will be collected.

A12. Estimates of Annualized Burden Hours and Costs

These data are either already collected by or are readily available to the respondents (Central Cancer Registries (CCRs) funded by the National Program of Cancer Registries, n=48). Thus, the only burden on the CCRs involves the time it takes to enter responses on the web-based NPCR-PEI every other year. **Attachment 3A** represents the web-based data collection instrument, which will be updated with the new expiration date upon receipt of OMB approval. Respondents receive an announcement concerning data collection and instructions via letter (see **Attachment 3B**).

The burden estimate for completing the NPCR-PEI was determined in consultation with three potential respondents (see **Attachment 6**), who estimated burden ranging from 1.5 to 2.5 hours. Their experience served as the basis for the average burden estimate of two hours per respondent. The burden to respondents should not increase from year to year, and may even decrease as technological advances are implemented in deployment of the NPCR-PEI. Table 12-A appears to indicate a decrease in the number of respondents. This is due to annualization of responses over the requested three-year clearance period. Data collection will actually occur in two of the three years approved for this project, 2013 and 2015. This translates into 96 total respondents, combining years 1 (2013) and 3 (2015) (48 respondents/year*2 years), divided by the three year clearance period (96/3). In year 2 (2014), respondents will receive an analysis and display of results.

Table 12-A. 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)
NPCR Awardees	PEI	32	1	2	64

A12B. The total annualized cost to respondents is estimated to be $1,920. NPCR Program

Directors respond on behalf of their cancer registries. Utilizing information from NPCR Continuation Applications, the hourly wage rate was determined for each central cancer registry Program Director funded by NPCR. Due to the wide variation in salaries, the median wage was determined rather than the average, and represents the hourly wage rate shown in Table 12-B.

Table 12-B. Annualized Cost to Respondents.

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden per Response	Average Hourly Wage Rate	Total Cost
Program Directors for NPCR Awardees	32	1	2	$30	$1,920

Source: CDC-RFA-DP07-703 Funding Applications

A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

No additional computer hardware or software other than that which is already available to the CCRs (awardees) is needed to enter responses on the web-based NPCR-PEI, hence no capital or maintenance costs are anticipated.

A14. Annualized Cost to the Government

The estimated annual cost for the contractor for consultation services, technical assistance, and hosting of the NPCR-PEI web application and database is $26,166 per year. The contractor costs are estimated as follows: hourly wage for project staff, approximately 200 hours, average of $42/hour for a total of approximately $8,400; fringe benefits (34% of total wages) for a total of approximately $2,856; labor overhead (38% of total wages) of approximately $3,192; approximately $4,000 in supplies; $2,000 for travel; facilities and administration at 15% for an approximate total of $3,220; miscellaneous $1,017, and fee at 6% for an approximate total of $1,481.

Additional annual costs include personnel costs for federal employees involved in oversight and analysis. The annual staff cost is estimated at $23,000 (25% of a GS-13 public health advisor FTE).

Table A14. Estimated Annualized Cost to the Federal Government.

	Annualized Cost
Contractor	$26,166

CDC Personnel	$23,000
Total	$49,166

A15. Explanation for Program Changes or Adjustments

In comparison to the previous OMB clearance period (2009-2011), the number of reporting entities is being reduced from 49 to 48. Content of the NPCR PEI instrument is being updated to reflect updates in the NPCR program standards.

A16. Plans for Tabulation and Publication and Project Time Schedule

CDC requests a three-year clearance for the proposed program evaluation instrument. Responses to the evaluation instrument will be received every other year from awardees. The same procedure for completing the instrument and submitting response data will be repeated for each deployment. Transmitted data reflect the CCRs' status at the point in time as of December 31 each year, and this information is transmitted to CDC approximately 90 days later. The schedule for 2013 (Table 16) is anticipated to be:

Table A16. Time Schedule for Instrument Availability, Responding to the Instrument, Generating Data Files, and Creating Descriptive Reports.

Tasks	Schedule
NPCR-PEI awardees' status	December 31 each year 1 and 3
NPCR-PEI completed by awardees	March each year 1 and 3
Data files generated	July 31 each year 1 and 3
Descriptive Reports and data display made available to awardees	April 30 year 2

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

There is no request for a date display exemption.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.