Reinstatement Request

OMB No. 0920-0706

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

Supporting Statement Part A

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SUMMARY TABLE

- Goal of the study: Information will be collected from awardees funded under FOA DP17-1701 cooperative agreement to evaluate the National Program of Cancer Registries (NPCR) cancer registries' use of funds, progress towards meeting program goals and objectives, and operational attributes; to collect information about advanced activities; and to highlight ways registry data is used.

- Intended use of the resulting data: Information collected will be used to monitor and evaluate the awardees' performance, improve the program standards, and provide CDC with information to respond to requests from within CDC, HHS, White House, Congress, and others about the program.

- Methods to be used to collect: Information will be collected electronically from awardees using a web-based survey, the NPCR-PEI Survey.

- The subpopulation to be studied: All central cancer registries funded by FOA DP17-1701.

- How data will be analyzed: The data will be analyzed using descriptive and summary statistics.

A. JUSTIFICATION

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 May 2016 after information collection for 2015 had been completed. This reinstatement request reflects the anticipated changes in NPCR program standards, changes in the PEI content, and a

slight increase in the number of NPCR awardees from 48 to 50. The estimated burden for completing the PEI will remain at 2 hours per response, resulting in an overall increase in burden to respondents.

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting OMB approval for a reinstatement with change 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 05/31/2016 and update the survey instrument based on feedback from stakeholders and revisions to NPCR Program Standards. Minor changes to the NPCR-PEI include removing questions determined to be outdated or inappropriate for this survey, rewording questions for clarity and consolidating a few questions. In addition, some questions that were asked in previous collections and continually showed 100% compliance were deleted. These changes are noted in **Attachment 3C.**

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.

CDC established standards to indicate the optimum achievement of specific functions and/or activities to be carried out by the Central Cancer Registry (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 pertaining to program collaboration, external partnerships, cancer data and surveillance, community level interventions and patient support, health systems change, and program monitoring and evaluation **(Attachment 5)**.

The annual collection of performance indicator data from state and territorial programs funded through the National Program of Cancer Registries (NPCR) began 24 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.

The NPCR is one of a number of CDC-sponsored public health programs, within the Division of Cancer Prevention and Control (DCPC), designed to monitor and reduce morbidity and mortality in the United States from cancer, which is a substantial public health burden. Cancer is the second most common cause of death in the US, exceeded only by heart disease.

CDC 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 CCRs to report information about their cancer prevention and control activities in order to monitor and support these efforts.

A2. Purpose and Use of Information Collection

The NPCR-PEI data are a complement to existing mechanisms that evaluate the completeness, timeliness, and quality of population-based CCR data (OMB no. 0920-0469, exp. 6/30/2019). To assist NPCR in its determination of funded CCRs' progress towards established program standards, the NPCR-PEI is designed to evaluate NPCR-funded registries' use of funds, progress towards meeting program goals and objectives, and operational attributes; 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. 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 2017 and 2019 and **Attachment 3C** for a list of changes that will be implemented in 2017 since the previous approval in 2013-2016.

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., Cancer Tumor Registrar (CTR) Quality Control, CTR Education/Training, Epidemiologist); 2) revision to cancer reporting legislation; 3) various data quality control activities; 4) data collection activities as they relate to achieving NPCR program standards for data completeness; 5) whether 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 NPCR-PEI are based on the NPCR Program Standards (see **Attachment 5**), which are revised every five years. The 2017 revisions were driven by feedback from stakeholders and updates to NPCR Program Standards. As noted above, some questions have been removed, some have been reworded, and a few were added to consolidate removed questions. In addition, some questions that were asked in previous collections and continually showed 100% compliance were deleted. These changes are noted in **Attachment 3C.**

In order to continue the current program evaluation process, a contractor will be retained to administer the web-based NPCR-PEI (see **Attachment 3C**) and respond to web-based technical assistance requests by the CCRs. Based on NPCR-PEI submissions, standardized descriptive reports will be generated by the contractor for the CCRs and the CDC. These reports will allow CDC to provide feedback to the CCRs by identifying areas in which they may benefit from education and training, technical assistance, and other resources, as well as evaluating the status of other activities in which the CCRs are involved (e.g., independent and collaborative research, improvements in electronic reporting), and assisting them with the implementation of changes in the NPCR.

DCPC regularly receives Congressional and public inquiry for federal agency documentation and accountability of achievement of program objectives and outcomes (e.g., the Government Performance and Results Act of 1993). NPCR-PEI data are used to report results to CDC officials, Congress, and the Office of Management and Budget. The continuation of data collection is imperative for future monitoring and evaluation of the NPCR.

Finally, subsets of NPCR-PEI data are available to internal and external investigators, on a

limited basis and with appropriate security controls, for research purposes.

CDC reviews the quality of data in each NPCR-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. If incomplete or implausible information is identified, the CDC program consultants will contact awardees to discuss the errors. The survey will be re-opened for the awardee to make corrections if the awardee confirms the findings were erroneous.

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. The NPCR-PEI allows electronic transmission of the data, which increases efficiency and reporting.

Respondents have consistently submitted their NPCR-PEI responses electronically at a rate of 100% and we anticipate this trend for future submissions. However, since we offer awardees the option to submit the NPCR-PEI via mail courier we expect no more than 10% paper submissions and at least a 90% electronic response rate.

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. 6/30/2019) activity by evaluating attributes that are not otherwise evaluated, such as hospital and pathology laboratory reporting and industrial or occupational history data. 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.

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

Biennial data collection 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 within a five-year FOA. 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 evaluation. The CDC is also obligated to provide status reports on the NPCR to Congress and other CDC officials.

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 01/05/2017, Vol. 82, No. 03, pages 1339-1340 (**Attachment 2**). No public comments were received.

B. The Division of Cancer Prevention and Control (DCPC) received input from 8 NPCR awardees who volunteered to participate in the development of the 2017 NPCR-PEI following the completion of the 2015 NPCR-PEI. The awardees were given 9 days to review the survey for clear, comprehensive, and concise questions. Responses were considered and incorporated as appropriate. A list of registries that volunteered to provide input is provided in **Attachment 7.**

C. The contractor will provide 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.

The CDC maintains a regular forum of awardee Program Directors that convene 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. Protection of the Privacy and Confidentiality of Information Provided by Respondents

Overview of the Data Collection System

NPCR-funded awardees are state and territorial governments (including the District of Columbia) or their bona-fide agents. The cooperative agreement for NPCR funding requires awardees to complete the web-based biennial NPCR-PEI program evaluation for submission to CDC. Awardees are given approximately 4-6 weeks to complete the instrument (**Attachment3A**). 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.

A CDC appointed contractor will oversee the web-based development and release of the NPCR-PEI to respondents and ensure the integrity of the data collection and analysis. The contractor will send an electronic letter including information pertaining to secure NPCR-PEI login information, procedures for accessing the NPCR-PEI, and obtaining technical assistance (**Attachment 3B**) to each awardee. For years in which the NPCR-PEI is not collected, 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 correlates to registry operations and procedures, such as staffing patterns and data linkages, but does not include 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

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.

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. There is no potential for direct or deductive identification of an individual respondent.

B. The NPCR-PEI data will be secured by technical, physical and administrative safeguards as outlined below.

Technical

- Data will be maintained in a secure location on a dedicated server by the contractor. The server will have firewall protection. Access to the NPCR-PEI server will be limited to authorized contracting staff and is password protected on its own security domain. All of the contractor's project staff will be required to sign a confidentiality agreement.
- NPCR-PEI data will be encrypted and submitted electronically from the awardees and arrive on a document server behind the contractor's firewall. The data will be 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 will be housed in a secure facility with restricted access.
- Receipt and processing logs will be maintained to document data receipt, file processing and report production. All reports and electronic storage media containing NPCR-PEI data will be stored under lock and key when not in use and will be destroyed when no longer needed.

Administrative

- CDC will work with the contract staff to develop and implement an information system security plan to ensure that the data are kept secure. Periodic review and update of the contractor's security processes will be 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 will include non-disclosure terms. The contractor will have a project security team to oversee operations to prevent unauthorized disclosure of the NPCR-PEI 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 NPCR-PEI information collection as a condition of cooperative agreement funding.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The NPCR Program, and subsequent NPCR-PEI survey, is considered public health practice for the entire project period, by the National Center for Chronic Disease Prevention and Health Promotion's IRB coordinator. Please see the attached Research Determination form (**Attachment 8**).

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

A new FOA (DP17-1701) was released December 15, 2016 and closed March 24, 2017. A new project period will begin July 1, 2017. DP17-1701 allowed previously unfunded states to apply for NPCR funding. DP17-1701 NPCR eligibility will include the 48 awardees funded under the DP12-1205 FOA and potentially 2 previously unfunded State health departments or their Bona Fide Agents, and US territories (see **Attachment 4**, List of current NPCR Awardees and projected DP17-1701 awardees).

The burden estimate for completing the NPCR-PEI was determined in consultation with eight projected respondents (see **Attachment 7**), 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. Table 12-A indicates the number of annualized respondents over the requested three-year clearance period. Data collection will occur in two of the three years approved for this project, 2017 and 2019. This translates into 100 total respondents, combining years 1 (2017) and 3 (2019) (50 respondents/year*2 years), divided by the three year clearance period (100/3). In year 2 (2018), 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 (Online)	30	1	2	60
NPCR Awardees	PEI (Paper)	3	1	2	6
Total		33	1	2	66

A12B. The total annualized cost to respondents is estimated to be $2,046. 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	Number of	Number of	Average	Average	Total Cost

Respondents	Respondents	Responses per Respondent	Burden per Response	Hourly Wage Rate	
Program Directors for NPCR Awardees	30	1	2	$31	$1860
Program Directors for NPCR Awardees	3	1	2	$31	$186
Total					$2,046

Source: CDC-RFA-DP12-1205 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, therefore 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 $23,550 (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	$23,550
Total	$49,716

A15. Explanation for Program Changes or Adjustments

In comparison to the previous OMB clearance period (2013-2016), the number of reporting entities is being increased from 48 to 50. Survey instrument fielding will coincide with the release of a new FOA (DP17-1701) and project period (2017-2022). DP17-1701 will allow previously unfunded states to apply.

In the current FOA (DP12-1205), NPCR eligibility was limited to grantees who were funded under the previous FOA (DP07-703).

DP17-1701 NPCR eligibility includes the 48 awardees funded under the DP12-1205 FOA and potentially 2 previously unfunded State health departments or their Bona Fide Agents, and US territories (UT and the Virgin Islands) who applied for funding. Expanded DP17-1701 eligibility is the reason for the slight burden increase from 64 to 66 annualized hours (See **attachment 4** List of current NPCR Awardees and projected DP17-1701 awardees).

Content of the NPCR PEI instrument is being updated based on feedback from stakeholders and updates to 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 (2017 and 2019). 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 2017 (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 of year 1 and year 3
NPCR-PEI completed by awardees	March 1 and year 3
Data files generated	July 31 of year 1 and year 3
Descriptive Reports and data display made available to awardees	April 30 of 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.