Economic Analysis of the National Program of Cancer Registries

Application for OMB Clearance

Supporting Statement

Part A—Justification

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Form 83-I

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Division of Cancer Prevention and Control (DCPC) of the Centers for Disease Control and Prevention (CDC) is requesting approval to assess the cost and cost-effectiveness of the operation of central cancer registries funded by the National Program of Cancer Registries (NPCR). Information needed for the analysis of cost and effectiveness will be collected from NPCR registries for the period 7/1/2008~~7~~ to 6/30/2012~~1~~. The current request is for three years of OMB approval, to be followed by a request to collect the final, fourth year of data. Information will be collected electronically using a tailored Cost Assessment Tool (CAT). The proposed information collection is in accordance with CDC's mission to conduct, support, and promote efforts to prevent cancer and to increase early detection of cancer, authorized by Section 301 of the Public Health Service Act [42 USC 241] (**Attachment 1a**).

One of the goals of Healthy People 2010 is to "increase the number of States that have a statewide population-based cancer registry that captures case information on at least 95 percent of the expected number of reportable cancers."[1] In 1992, Congress enacted the Cancer Registries Amendment Act, thereby authorizing CDC to establish the National Program of Cancer Registries (NPCR), a nationwide, comprehensive federally sponsored public health infrastructure (**Attachment 1b**). As of 1998, NPCR collects data on new occurrences of cancer; the type, extent, and location of the cancer; and the type of initial treatment in 45 States and the District of Columbia, covering approximately 96% of the US population.[2] Cancer registries in the remaining five states receive federal support from the National Cancer Institute's (NCI's) Surveillance, Epidemiology, and End Results (SEER) Program. The SEER Program also operates six cancer registries in metropolitan areas and collects data on special populations. SEER metropolitan-area and special-population cancer registries report incidence data to NCI and the NPCR-funded statewide cancer registries in their respective states.

In each state or territory, the medical facilities (including hospitals, physicians' offices, therapeutic radiation facilities, freestanding surgical centers, and pathology laboratories) report these data to a central cancer registry. Before NPCR was established, 10 states had no registry, and most states with registries lacked the resources and legislative support they needed to gather complete data.

NPCR-funded cancer registries are required to collect and report information on all state residents who are diagnosed or treated with in situ or invasive cancer, including residents who are diagnosed and treated outside their state of residence. In 2000, the CDC began to receive, evaluate, and publish data from participating cancer registry programs (OMB clearance # 0920-0469 National Cancer Program Registries: Cancer Surveillance System exp. date 1/31/2010). NPCR registries are required to report their incidence data annually beginning with the reference year, which is the first year in which data was collected with the assistance of NPCR funds. To promote standardization among state programs, cancer registries collect and report data using uniform codes and procedures established by the North American Association of Central Cancer Registries (NAACCR).[3] The SEER Program and the NPCR work closely with the NAACCR to promote the collection and publication of high-quality cancer incidence data; high-quality data

meet national data standards for completeness of case ascertainment, timeliness, and quality[4]. In 2002, in collaboration with the NAACCR, the CDC and the NCI began publishing the *United States Cancer Statistics* surveillance reports.

The proposed data collection effort will provide cost data to perform a systematic economic evaluation of the NPCR.

A.2 Purpose and Use of the Information Collection

In FY08, NPCR received approximately $37 million in a Congressional appropriation to help support cancer registries. Although NPCR has received Congressional funding since 1994, there has been no comprehensive study of the true economic costs incurred by the NPCR. Consequently, information on the cost of operating cancer registries is not known. As a result, a top priority of NPCR is to collect cost data and conduct economic analysis/evaluation of the NPCR.

As indicated in the Federal Register Notice (**Attachment 2a**), Economic evaluation will provide critical information to reach informed decision-making by assessing the effectiveness of the program in relation to the cost expended on registry activities.[5-7] We will identify all registry activities and collect activity-based costs, which is the approach in which all costs related to performing specific activities are systematically calculated. This activity based data collection will allow CDC to perform in-depth evaluation of the NPCR that has not been possible previously using budget information and federal expenditure.[8] The main advantage of activity-based cost estimation is that the cost of specific NPCR activities can be quantified. Unlike budget or total federal spending, the activity-based data will provide details on all resources expended on the NPCR and provide CDC with an estimation of the "economic cost" incurred by the registries. There are numerous examples in the literature on using activity-based costing methods to obtain detailed costing data to perform economic evaluation of health programs both in the US and internationally. In the US, for instance, there is a long history of using the activity-based costing approach to perform cost-effectiveness evaluation of substance abuse programs.[9-11]

Using activity-based costs will allow CDC to assess the true cost of registry operations, identify factors that impact cost, perform cost-effectiveness analysis and develop a resource allocation tool. Data collected in this study will be used to:

1) Understand cost incurred by the NPCR – The detailed data collected in this study will allow CDC and registries to identify the cost of surveillance activities (case ascertainment, death certificate clearance etc.) and data enhancement and analysis activities (database linkages, research studies etc.). We will collect information on all funding sources including the CDC, other organizations, and in-kind contributions to obtain a comprehensive estimation of the resources used. This will allow CDC to assess the cost of each registry activity in relation to the benefits provided to identify efficient allocation of resources.
2) Explain factors that impact cost - There is wide variation in the cost per case collected by the NPCR programs. The data from the project will be analyzed to understand the factors that impact the program cost. These factors could include registry organizational structure, proportion of time spent on surveillance activities versus data enhancement and analysis activities, cost of living differences, size of state served by registry and presence of rural areas in the state.

3) Assess cost-effectiveness of registry operations – The cost of the registry operations will be assessed in relation to the effectiveness of the registry activities. Registry effectiveness will be assessed based on timeliness, completeness, and quality of the cancer registry data produced.

4) Develop a resource allocation tool - Using the data collected and the factors impacting cost, we will develop a tool that will identify the adjusted dollars (cost of living, size of state etc.) per case. This tool will enable CDC to utilize a systematic method for allocating registries' resources that incorporates the effectiveness and efficiency of registries.

In addition, this cost collection will allow CDC to directly address the recommendations from the Office of Management Budget's (OMB) Program Assessment Rating Tool (PART) evaluation and DCPC external panel review team. The data from this study will enable the implementation of the recommendation: to "develop procedures to measure and achieve efficiencies and cost effectiveness in program execution." The cost data collected will also be used by the programs themselves to achieve efficiencies within their registries. Detailed activity based costs collected using the Cost Allocation Tool can be used by the programs to evaluate their registries and identify areas for improvement.

A.3 Use of Improved Information Technology and Burden Reduction

All data will be collected via a web based tool (currently under development) to reduce respondent burden, data collection errors, and delays in receiving data. The questionnaire was based on standard well-established methods for data collection [12-14] to ensure only the key required data elements are collected. The Excel-based version of this tool (see **Attachment 3a** for the Cost Assessment Tool and **Attachment 3b** for the CAT User's Guide) was pilot tested by seven registries (see **Attachment 4** for listing) to assess ability to provide requested data and identify approaches to minimize burden.

The tool will include several features to specifically reduce burden and collect high quality data. For example, the tool will include automated data checks so that it can be used by the programs to perform self-directed quality checks on the data as they input the information. In addition, the list of NPCR surveillance activities and data enhancement and analysis activities will be provided in drop-down boxes to eliminate the time spent typing in text and the tool will also contain an interactive user's guide that will provide variable definitions and instructions for providing the required data. The tool will also be easily accessible through the web and all programs will be provided with detailed instructions and training to input the required data. RTI International, the contractor for this project, will collect and tabulate the data provided by the programs. Only the minimum information necessary for the purposes of this project will be collected. The tool can be used to collect data retrospectively or prospectively as required. Efforts have been made to design the instrument to be brief, easy to use, and understandable. The study investigators have carefully considered the content, appropriateness, and phrasing of the questions**.**

A.4 Efforts to Identify Duplication and Use of Similar Information

CDC initiated a thorough review of available data sources to assess whether these sources could provide the data required for a systematic economic analysis. We reviewed the Annual

Program Evaluation Instrument (APEI) database (OMB NO: 0920-0706 Expiration Date: 12/31/2008), through which infrastructure data regarding the NPCR-funded programs have been reported to the CDC. Each program submits to the CDC information on staffing, policy and procedures, legislation, computer infrastructure, number of reporting sources, data coding, audits, uses of registry data, infrastructure and processes, data items and formats, and data enhancement and analysis activities. This instrument does not collect information on the cost incurred by the registries and the true economic cost of cancer registry activities is not available at the present time.

The Financial Status Report (FSR) submitted by the programs was also reviewed; this document provides information about total federal dollars spent during the fiscal year but there are no details on activities performed. As a result, component or activity costs cannot be identified or allocated to surveillance activities versus data analysis and enhancement activities. Neither the FSR nor APEI provided details on in-kind contributions which were reported to be a significant proportion of the total outlays of the programs.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be impacted by this data collection.

A.6 Consequences of Collecting the Information Less Frequently

Without this cost data, CDC will not be able to assess the cost of the registry's operations, identify factors that impact the cost, perform cost-effectiveness analysis of the programs, nor develop a resource allocation tool. This information is critical to the overall evaluation of the NPCR and essential for future program planning. CDC will collect four years of cost data from all programs funded by the NPCR to estimate activity-based costs. Funding is received on an annual basis, and budgeting is performed on an annual basis as well. Therefore, the cost data will also be collected annually to be consistent with the budgeting and funding process. Reducing the respondent burden below the estimated levels (that is, reducing the frequency of the data collection) would diminish the utility of the study. It is methodologically desirable to have at least four years of data. There are no legal obstacles to reduce the burden.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This project fully complies with all guidelines of 5 CFR 1320.5. There are no special circumstances required.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A notice for public comments on the proposed data collection activities required by 5 CFR 1320.8(d) was published in the Federal Register on July 24, 2007 (Volume 72, Number 141, pages 40297-40298), (**Attachment 2a**). One comment was received. CDC prepared a response to this letter (**Attachment 2b**).

B. CDC works closely with the NPCR funded registries to evaluate the programs and offer assistance as required. During the 2007 NPCR Program Directors' annual

meeting, the 2007 North American Association of Central Cancer Registries annual meeting and a conference call with NPCR Program Directors, we have discussed the objectives of the data collection effort with the registries and have provided them with an overview of the cost collection tool. In addition, we have pilot tested the instrument with seven registries.

A.9 Explanation of Any Payment or Gift to Respondents

No payment or gift is required for this data collection.

A.10 Assurance of Confidentiality Provided to Respondents

The CDC Information Collection Request Office has reviewed this request and determined that the Privacy Act is not applicable. Respondents are state-based cancer registries providing information on their organizational structure, infrastructure, funding sources, expenditures, case reporting system, and other activities. Although a primary contact person will be identified for each cancer registry, the contact person will be speaking from their role as a representative of the responding registry. The information collection does not involve sensitive or personal information.

Data collection will be conducted via a web-based system managed by a contractor, RTI. Data will be submitted to CDC according to approved Internet-based communication protocols and a written security plan. Access to the web-based system will be controlled by a password-protected login which allows varying degrees of access for CDC personnel, RTI personnel, and project personnel associated with each cancer registry. Site personnel will have access only to the data for their own registry. The systems to be put in place will assure that stored information is accessible to authorized users yet secure.

RTI, the system contractor, oversees compliance with the written security plan developed by the CDC National Center for Chronic Disease Prevention and Health Promotion.

A.11 Justification for Sensitive Questions

We are collecting program level cost data and not individual patient level data. The cost assessment tool does not request sensitive or personally identifiable information.

A.12 Estimated Annualized Burden Hours and Cost to Respondents

A.12.A Estimated Annualized Burden Hours

Each of the 46 NPCR registries (see **Attachment 5** for listing) will be asked to complete one set of data annually for four years for their program via the web based Cost Assessment Tool. While several people at the registry may contribute to the completion of a single costing questionnaire, this completion effort will result in a single completed questionnaire, with one staff member at each registry serving as the key personnel responsible for completing the questionnaire for submission. As discussed earlier, based on the feedback provided from the seven programs during the pilot phase of this project, we estimate that the registries will require approximately 22 hours to attend training sessions, gather the required data and enter the

information into the web based system. We estimate that although the Data Manager will serve as the key contact and have overall responsibility to complete the questionnaire, both the Registry Director and Business Manager will also be required to offer some support. Based on the pilot testing, the registry director and the business manager will be required to spend 4 hours each while the Data Manager will spend 14 hours, for a total of 22 hours. The number of respondents and the estimated burden hours are provided in Table A.12-A.

Table A.12-A Estimated Annualized Burden Hours

Types of Respondents	Form Name	Number of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total burden (in hours)
NPCR Funded Registry	Cost Allocation Tool (CAT)	46	1	22	1,012

A.12-B Estimated Annualized Cost to Respondents

The average cost to respondents is estimated at $22,993, as shown in Table A.12-B. The annualized cost to respondents is based on the average wages provided to us during pilot testing of our data collection questionnaire with the seven programs. On average, the director, the business manager and data manager earned $30, $25 and $20 an hour, respectively. The average hourly wage rate is a weighted average based on the program director contributing 4 hours to data collection with an hourly wage of $30, the business manager contributing 4 hours with an hourly wage of $25, and a data manager contributing 14 hours with a wage of $20.

Table A.12-B Annualized Cost to Respondents

Type of Respondent	Number of Respondents	No. of Responses per Respondent	Average Burden per Respondent (in hours)	Weighted Average Hourly Wage Rate	Respondent cost
NPCR Funded Registry	46	1	22	$22.72	$22,993

A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

No cost other than those described in A.12 will be incurred by the respondents to complete this data collection.

A.14 Annualized Cost to the Federal Government

The total annualized cost to the government is $137,204, as summarized in Table A.14-A. Two types of government costs will be incurred: 1) contracted data collection and analysis, and 2) government personnel.

The data collection contractor will be RTI International. The contract is for a total of $221,584 for Year 1, $85,027 for Year 2 and $85,027 for Year 3. The average annualized expenditure for the first three years of data collection is $130,546.

The Technical Monitor and co-technical monitor are assigned for 5% and 2% of their time, respectively. Using the average annual salary of $95,122 (GS-14) for the both Technical- and Co-technical Monitors, the total annualized expenditure for government personnel is $6,659. The Technical Monitor and Co-Technical Monitor have overall responsibility for overseeing the design and administration of the survey and will be responsible for analyzing the survey data, sharing results with the programs, presenting findings at the CDC and at national and international professional meetings, preparing summaries, reports and manuscripts for publication in peer reviewed journals.

TableA.14-A. Estimated Annualized Cost to the Federal Government

	Activity/Personnel	Total Cost
Data Collection Contractor (RTI)		
▪ Build Data Collection Tool	$25,621	
▪ Pilot Test Tool	$8,300	
▪ Train Programs	$7,360	
▪ Collect Data/Create Analytic File	$44,857	
▪ Data Analysis and Reporting	$36,715	
▪ Development/Other	$7,693	
Subtotal, RTI		**$130,546**
CDC Personnel		
• Technical Monitor at 5% FTE	$4,756	
• Co-Technical Monitor at 2% FTE	$1,902	
Subtotal, Federal Personnel		**$6,658**
Grand Total		**$137,204**

A.15 Explanation for Program Changes or Adjustments

This is a request for a new data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Using the data collected in the Cost Assessment Tool we will generate activity-based cost estimates. The questionnaire requests expenditure details in the following areas:

1) Total Expenditure by Funding Source;

2) In-kind contributions;

3) Personnel expenditures;

4) Personnel activities;
5) Consultant expenditures;
6) Costs associated with computers, travel, and training;
7) Software licensing costs;
8) Administrative costs;
9) And other factors affecting costs, effectiveness, and data collection.

Under personnel expenditure, for instance, all program staff will be asked to provide the proportion of time spent on each of the surveillance activities and data enhancement and analysis activities. Surveillance activities specified include:

10) Management;
11) Administration;
12) Training of registry staff;
13) Training of others by registry staff;
14) Database management;
15) IT support;
16) Case ascertainment;
17) Death certificated clearance;
18) Data collection/abstraction;
19) Quality assurance and improvement;
20) Developing analytic files;
21) Analyzing and generating reports;
22) Sharing cases;
23) Electronic case reporting and data encryption;
24) Reporting requirements to CDC, NAACCR, and state.
25) Automatic casefinding using electronic linkage
26) Geocoding cancer cases;

Data enhancement and analysis include:

27) Linking records to other state-wide or national databases;
28) Implementing a cancer inquiry response system;
29) Research studies and advanced analysis using registry data;
30) Publication of research studies using registry data;
31) Active follow-up.

The cost generated at the activity level will be assessed to ensure that these costs sum to the total expenditure reported by the programs as a validation check. Detailed assessment of these activity-based costs will be performed and summary statistics will be generated for cost associated with each NPCR activity. We will show the possible range of values and generate univariate statistics (e.g., mean, standard deviation, median, interquartile range). We will also

report the cost associated with surveillance activities and data enhancement and analysis activities separately. Total cost and cost for the individual surveillance activities and data enhancement and analysis activities, as applicable, will be compared among the registries. We will develop histograms to compare the distribution of costs across the activities for each registry (see **Attachment 6** for examples from pilot testing). All analysis will be performed in Microsoft Excel or SAS.

Variation in these costs by registry organizational structure (private organization, health department, or health department with a contractor) and size of the program (by total number of cases ascertained) will be assessed. We will generate univariate statistics stratified by structure and program size to identify potential differences. In order to assess potential economies of scale (projected cost for future programs with differing case volume), costs that are fixed versus variable will be identified for each registry. Fixed costs when amortized across large number of cases ascertained could decrease cost and make the program more efficient. It will also be important to consider diseconomies of scale as potentially larger registries may result in reduced quality of case abstracts provided. In addition, the factors that impact average cost per case collected will be evaluated using regression analysis.[15,16] We will perform multivariate analysis to identify the key factors that impact average cost (for example, the number of cases ascertained, registry organizational structure, proportion of time spent on surveillance activities versus data enhancement and analysis activities, price differences as indicated by regional Consumer Price Index (CPI), and presence of rural areas in the regions served by the registries). For instance, the regression can be specifies as follows:

$$\text{Log } Y_i = \beta 0 + \beta 1 \text{ Cases}_i + \beta 2 \text{ Price}_i + \beta x \text{ Other Factors}_i + e_i$$

where

Y = Cost per Case Ascertained

β = coefficient values

Cases = total volume of cases reported by the registry (annual period)

Price = geographical differences input prices

Other factors = variables hypothesized to impact cost per case (eg. presence of rural areas)

Using log transformation of cost helps to correct for skewness that is generally present in cost estimates. Also, in addition, we could also estimate log-log models to assess the elasticity of the average cost with respect to the key factors (regressors such as the ones listed above), i.e., provide the percentage change in average cost given a percentage change in a key factor. We will perform these analyses both including and excluding in-kind contributions to identify the impact of these contributions to program operation.

We will use the information gained from the multivariate assessment to create a resource allocation model that will guide future program funding decisions and provide incentives to operate the programs more efficiently.[17] This allocation model will be based on the factors that impact cost of individual programs, adjustment for program past performance and the findings from the activity-based cost assessment regarding approaches to improve overall program efficiency.

We will also perform a systematic cost-effectiveness assessment and identify incremental cost-effectiveness based on registry organizational structure.[5-7] The effectiveness measures used will include the number of cases, and the cases adjusted for quality of data reported. We will calculate the cost per case ascertained and the cost per quality adjusted case. For example, the cost per case ascertained will be obtained using the following calculation.

Cost per case ascertained = Annual total program cost / number of cases ascertained

The two ratios described above will be derived for all registries. We will perform nonparametric bootstrapping to evaluate the uncertainty of the results from the cost effectiveness calculations to generate 95% confidence intervals.

Finally, the analysis that will be performed will address specific questions including the following:

1) What is the additional cost of geocoding? Does this vary among the programs?

2) What is the total IT/software cost for registries that use CDC versus commercial software?

3) What is the impact of electronic data reporting from laboratory on overall cost of registry operations?

4) Is there variation in cost of specific activities, such as case ascertainment, across the registries?

Results of the study will be disseminated to various programs and other stakeholders through reports, web conferences, presentations at professional meetings, and publication of manuscripts in peer-reviewed journals. It is anticipated that the results of this project will be developed into several scientific and non-scientific reports. These reports include:

Economic analysis of the National Program of Cancer Registries

The data collected via activity-based costing will be used to perform a systematic economic evaluation of the NPCR. We will report the total cost associated with specific activities of the program, the average cost per case ascertained and the incremental cost-effectiveness of the programs as appropriate. The assessment will also be stratified by both registry organizational structure and by volume of cases ascertained to identify potential areas for improving registry efficiency.

Explaining State variations in the average cost per case ascertained in the National Program of Cancer Registries—United States

We will perform an evaluation of factors that impact registry operating costs. We will identify the magnitude and direction of the impact for factors that are statistically significant. The factors to be studied include the number of cases ascertained, registry organizational structure, proportion of time spent on surveillance activities versus data enhancement and analysis, price differences as indicated by regional CPI, and presence of rural areas in the region served by the registry.

Cost-effectiveness analysis of the National Program of Cancer Registries

Using the activity based cost data collected and the effectiveness measures reported by the registries, such as timeliness, completeness and quality of data submission, we will develop cost-effectiveness ratios for individual registries funded by the NPCR. We will also use the data quality indicators to develop composite measures to include in the cost-effectiveness calculation. We will asses whether cost-effectiveness of registry operations differ by registry characteristics including, volume of cases, organization structure, and other factors.

The funding cycle for NPCR funded registries begins July 1 and ends June 30 of the following calendar year. Financial status reports (FSR), currently reported to CDC under the 0920-0706 clearance, are due 90 days after the end of the funding cycle (October 1). In order to assure that new information to be reported for economic analysis is consistent with the fully reconciled financial information reported in the FSR, we propose the following schedule (Table A.16-A) for collection of economic cost data. We plan to train the NPCR awardees in the first month after OMB approval and to collect data for the first funding cycle by October 30, 200~~8~~9. We plan to complete all data collection and analysis by July 31, 201~~2~~3.

Table A.16-A.Project Time Schedule

Funding Cycle for NPCR Funded Registries	Target Date for Transmitting Data to CDC	Data Analysis Period
July 1, 200~~7~~8 – June 30, 200~~8~~9	Oct 30, 200~~8~~9	Nov 1, 200~~8~~9 - March 31, 201~~0~~0
July 1, 200~~8~~9 – June 30, 201~~0~~0	Oct 30, 201~~0~~0	Nov 1, 201~~0~~0 - March 31, 2011~~0~~
July 1, 201~~0~~0 – June 30, 201~~0~~1	Oct 30, 2011~~0~~	Nov 1, 2011~~0~~ - March 31, 2012~~1~~

Target dates for data collection and analysis will be adjusted if OMB approval is not received by October 1, 200~~8~~9. CDC plans to seek an extension of OMB approval to collect information on NPCR awardees' activities during the fourth funding cycle (July 1, 2011~~0~~ – June 30, 2012~~1~~). Final reports and manuscripts will be prepared during the period April 1 – July 31, 201~~2~~3.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

No request for an exemption from displaying the expiration date for OMB approval is being sought.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

These data will be collected in a manner consistent with the certification statement identified in Item 19 “Certification for Paperwork Reduction Act Submissions” of OMB Form 83-I. No exceptions are requested.

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