Information Collection Request

Revision

National Program of Cancer Registries Cancer Surveillance System
OMB No. 0920-0469

Supporting Statement: Part A

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Goal: The goal of the project is to continue collection of cancer occurrence and outcomes in the United States under the National Program of Cancer Registries (NPCR).

Intended Use: The data will be used to: track cancer incidence at national and state level; identify disparities in burden of disease; assess success of public health screening and other intervention programs; and assess quality of care.

Data Collection Methods: Data are reported to CDC by NPCR-supported central cancer registries. Reporting to central cancer registries by hospital and other care providers is required by state legislation. The information collection includes all cancers.

Study Population: All persons diagnosed with cancer.

Analysis: Analysis includes cancer incidence rates and Joinpoint trends, using SEERSTAT and other standard epidemiologic methods including logistic regression.

A.1 Circumstances Making the Collection of Information Necessary

In 2012, the most recent year for which complete information is available, more than 580,000 people died of cancer and more than 1.5 million were diagnosed with cancer (1). It is estimated that 13.8 million Americans are currently alive with a history of cancer (2). In the U.S., State cancer registries are the only method for systematically collecting and reporting population-based information about cancer incidence and outcomes such as survival. These data are used to measure the changing incidence and burden of each cancer; identify populations at increased or increasing risk; target preventive measures; and measure the success or failure of cancer control efforts in the U.S.

Cancer registration depends upon Central Cancer Registries (CCRs), funded primarily by CDC's National Program of Cancer Registries (NPCR). NPCR was established in 1992 when Congress enacted the Cancer Registries Amendment Act, Public Law 102-515 **(Attachment 1a**), later incorporated into the Public Health Service (PHS) Act [42 U.S.C. 242k]. Congressional appropriations have been provided for the NPCR since its inception in 1992. In fiscal year 2012, CDC awarded about $37 million through cooperative agreements to assist in funding central cancer registry operations in 45 states, the District of Columbia, Puerto Rico, and the Pacific Island Jurisdictions**.** Information is collected and maintained at CDC under Section 301 of the Public Health Service (PHS) Act [42 U.S.C. 242k] (**Attachment 1b**). NPCR captures cancer in 96% of the U.S population and includes 45 states, the District of Columbia, Puerto Rico, and the Pacific Islands Jurisdictions. State collection is conducted under the authority of state laws in all 50 states which require reporting of cancer data to the CCR. The same is true for the District

of Columbia, the Pacific Islands Jurisdiction and Puerto Rico and all additional references to states include these areas as well.

The state CCR receives data from hospitals, pathology laboratories, and providers who provide cancer diagnosis or treatment. The data are collected on all cancer diagnoses and include type of cancer, stage, age, race, ethnicity, and initial type of treatment received. The CCRs then aggregate the data and use the information for activities such as state and county cancer reports, implementation of screening interventions, and cancer cluster investigations. An overview of data collection and flow is provided in **Attachment 2**.

These same data are collected within the NPCR-funded CCR regardless of the data submission to CDC. Uniform standards for cancer reporting are developed collaboratively by state CCRs, various organizations in the oncology community (e.g., American College of Surgeon's Commission on Cancer, American Joint Committee on Cancer), the National Cancer Institute and CDC. These collaborative standards are operationalized and disseminated by the North American Association of Central Cancer Registries (NAACCR), a professional organization that formalizes and disseminates the data standards for cancer registration across all of North America. Cancer registry standards are regularly reviewed and updated by NAACCR.

Data submission from states to CDC is electronic and requires minimal additional effort from the CCR. All records are de-identified before submission to CDC so that neither CDC nor any researcher is able to identify a cancer patient. Information in identifiable form (IIF) is reported to CDC including: height, weight, date of birth and medical information about the types of cancer that occur (histology, morphology, and behavior), the anatomic location, the extent of disease at the time of diagnosis, the kinds of treatment received by cancer patients, and the outcomes of treatment and clinical management.

NPCR-funded CCRs report specific and standardized data elements to CDC as a function of the National Program of Cancer Registries Cancer Surveillance System (NPCR CSS), OMB No. 0920-0469 which expires: 5/31/2016. NPCR registries have been submitting data to CDC through the NPCR CSS since 2000. Currently there are 48 NPCR registries, which include a sub-set of ten Specialized Registries that submit an expanded set of data items during the November data submission on cancer treatment for breast, colon, and rectal cancers as well as Chronic Myeloid Leukemia all diagnosed in 2011. **Attachment 3a** is a copy of the submission specifications for NPCR registries and contains a list of data items for each of the two planned data submissions – preliminary and final. This table is based on the most recent NAACCR Standards for Cancer Registries, Volume II (3). The ten Specialized Registries report an enhanced set of data items shown in **Attachment 3b**. **Attachment 3c** summarizes the changes to the data elements in either the Standard of Enhanced NPCR CSS Submission Specifications.

CDC requests OMB approval for three years to extend the NPCR CSS information collection, with changes limited to data variable updates as defined by the professional

cancer registry coding standards. There are no changes to the estimated number of respondents, the burden per response, or total estimated annualized burden hours.

A.2 Purpose and Use of the Information Collected

This request includes an update of data definitions that reflect changes in national standards for cancer diagnosis, treatment, and coding. The North American Association of Central Cancer Registries (3) periodically updates the standardized data layout to reflect changes in cancer staging or other changes in data definitions considered necessary to collect accurate data on cancer incidence. These changes will affect the standard reports for all NPCR-funded CCR. **Attachment 3c** summarizes the changes to the NPCR-CSS required data elements.

CDC combines the de-identified data received from the 48 NPCR registries with data from the National Cancer Institute (NCI)-funded Surveillance Epidemiology and End Results (SEER) registries to provide complete National data on cancer. To reduce the nation's cancer burden, behavioral and environmental factors that increase cancer risk must be reduced, and high-quality screening services and evidence-based treatments must be available and accessible, particularly to medically underserved populations (4). The availability of complete and accurate cancer data at the National, state, and local level facilitates identification of disparities in cancer incidence and treatment, which supports targeted interventions such as screening or education to reduce the morbidity and mortality from cancer. The impact of prevention and early detection measures can also be monitored and measured through state cancer registries since they are designed to monitor cancer trends over time, determine cancer patterns in various populations, and guide planning and evaluation of cancer control programs.

Enhanced data from the Specialized Registries are used to assess cancer care, and outcomes in the communities where people are diagnosed and treated. The use of NPCR data for comparison of different interventions to improve cancer prevention and early detection, and to compare the effectiveness cancer treatment, will inform patients, providers, and decision-makers about those that are the most effective. These data will be analyzed by researchers within each state to assess patient centered outcomes and a data set will be established at the National Center for Health Statistics Research Data Center (NCHS RDC) to support research of a combined dataset by all qualified researchers

The public and researchers also have access to this de-identified data via CDC websites and can assess cancer incidence rates overall or for particular cancers, races, or age groups. These public-use data sets are comprised of aggregated data (i.e., not individual case-specific data) that have been modified as needed, according to accepted procedures, to block breaches of confidentiality and prevent disclosure of the patients' confidential information (5-7). More detailed data are also provided through procedures that ensure the privacy and protection of the individuals whose data are included. A copy of CDC's data release policy is provided in **Attachment 4**. CDC's Division of Cancer Prevention

and Control (DCPC) has worked with the NCHS RDC to host the NPCR data and the data from the Specialized Registries (8). The NCHS RDC will allow researchers outside of CDC access to both of these data sets in a secure environment without jeopardizing the confidentiality of the data. Users must have a protocol reviewed and approved and must sign data use agreements. Data users within CDC must also sign data use agreements which require them to meet all privacy requirements necessary to prevent accidental or intentional disclosures.

Numerous scientific publications and informational materials have been produced based on the availability of data on all cancer cases in the U.S. Without this National dataset, public health evaluations and research studies would have to rely on patients in clinical trials or on hospital-based data. The fact that the NPCR data received by CDC are population-based and include National data means that all socio-economic groups are included. These kind of representative data are not produced by hospitals or clinical trials that are limited in the populations they serve. The results of studies from specialized populations or clinical trials can result in erroneous conclusions about cancer incidence and survival. Trends in disparities in the cancer burden, success or failure of screening programs, and improvements in treatment can only be studied in broad-based, population-based data, which are standardized and collected on an ongoing basis. In addition, incidence rates and trends for rare cancers and for special populations such as Native Americans can only be calculated accurately with a National-level dataset, which is available for this purpose because of the NPCR data submission to CDC.

Specific examples of data use are provided below.

- **Cancer Surveillance:** The CDC and the states face the challenge of reducing cancer morbidity and mortality through prevention and early detection. Effective cancer control requires the regular, ongoing collection and analysis of health-related data to monitor the frequency and distribution the disease in the population. The NPCR CSS helps CDC continue to meet its public health responsibilities by providing routine surveillance reports on the national cancer burden by demographic characteristics, tumor characteristics, survival time, and other items of interest to the public health agencies responsible for the design, implementation, and evaluation of cancer prevention and control activities. CDC's prevention efforts are enhanced by the ability to target areas with high rates of cancer with appropriate screening such as mammography, Pap smears, and colorectal cancer screening. The Agency for Healthcare Research and Quality (AHRQ includes measures for effectiveness of care in cancer (http://www.ahrq.gov/research/findings/nhqrdr/nhqrdr13/measurespec/breast-cancer.html).The AHRQ *Healthcare Quality Report* includes rates of advanced stage female breast and colorectal cancer and all invasive cervical cancer by state.

  Since 2002, CDC and the NCI, in collaboration with the North American Association of Central Cancer Registries (NAACCR) have published the *United States Cancer Statistics* (USCS) (http://www.cdc.gov/cancer/uscs). The *USCS* report contains a set of official federal cancer incidence statistics from each state that had high quality registry data. For cancer cases diagnosed in 2012, the most recent year for which

federal data is available, 49 statewide population based cancer registries and District of Columbia met USCS publication criteria resulting in 99% population coverage. Data for selected cancer sites are also available as pre-calculated counts and rates on the NCI/CDC State Cancer Profiles Website (http://statecancerprofiles.cancer.gov/) and on the CDC's WONDER Website (http://wonder.cdc.gov/CancerIncidence.html).

The Council of State and Territorial Epidemiologists (CSTE) has voted to include cancer as part of the chronic disease indicators of the National Public Health Surveillance System (NPHSS) (9). The NPCR CSS continues to work to make timely data available for the NPHSS and publication in the *Morbidity and Mortality Weekly Report*.

- **Program Planning and Evaluation:** CDC sponsors and supports a wide variety of public health programs in the U.S. designed to monitor and reduce morbidity and mortality from cancer such as the National Comprehensive Cancer Control Program, National Tobacco Control Program, the National Breast and Cervical Cancer Early Detection Program, the National Colorectal Cancer Roundtable, prostate cancer control initiatives, and the National Skin Cancer Prevention Education Program. 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).

  Cancer information collected under NPCR CSS is very important to evaluate the success and remaining challenges in meeting CDC program goals and objectives, as well as to identify areas that can benefit from education and training, technical assistance, and other resources.

A.3 Use of Improved Information Technology and Burden Reduction

All NPCR registries submit their data to CDC electronically in a standardized format established by the NAACCR and used by all cancer registry systems in North America. Because the formats and definitions have been well established for many years, the electronic submission of de-identified data to CDC requires minimal effort by the NPCR CCR. Data submission is via a secure socket layer (SSL) encryption and each NPCR registry is provided a one month time period for completion of their data submission. Software and statistical programs are provided to create the data set for submission. This process includes removal of identifiers such as name, address, Social Security Number (SSN), and exact date of birth.

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

Limited cancer incidence data are available through the NCI's Surveillance Epidemiology and End Results (SEER) Program, which represents 9%-26% of the population of the U.S. (http://seer.cancer.gov). Five states receive joint funding from the

two federal programs and report their data to both federal agencies. SEER data are of high quality and are used to analyze long term trends in cancer incidence, patient survival, and for many other research purposes. While the SEER data are appropriate for some analyses, these data are not representative of the U.S. population and are often not adequate for analysis of U.S. regions, racial/ethnic populations, and rare cancer analyses. These data are also not useful for the 45 states without a SEER registry for program planning and evaluation. NPCR-funded registries cover 96% of the United States population and complement the SEER data to provide 100% coverage of the U.S. population. In the states where the SEER program covers a part of the state (Alaska, California, Michigan, Washington) and the state participates in the NPCR, there is no duplication of effort. The SEER program reports data from its catchment area to the NPCR-funded state central cancer registry. Five additional states (California, Kentucky, Louisiana, Georgia and New Jersey) receive funding from NCI to enhance the representativeness of the SEER program.

NAACCR plays a leadership role in setting standards for the collection of cancer data and currently publishes population-based state cancer incidence data and aggregated state data yearly in *Cancer Incidence in North America* (CINA) (10). The submission of data to NAACCR is voluntary and varies from year to year. No public use data set is available to meet both public health surveillance needs and NPCR needs for program planning and evaluation.

The National Cancer Data Base (NCDB) from the American College of Surgeons (ACoS) contains data items required by the Commission on Cancer Approvals Program. NCDB is based on approximately 1,400 participating hospitals. The program was started in 1989 and approximately 70% of all U.S. cancer cases are collected annually. The data are not population-based since NCDB does not collect all cancer cases in a defined geographic area and cannot be used to calculate incidence rates. In addition, the NCDB cannot identify multiple cancer reports for the same individual that may arise from a surgical hospital, pathology lab, and treatment facilities. This means that a single case may be reported multiple times in the database.

While there are a number of cancer registration activities in the U.S., it is clear that the resulting data do not meet the public health need for a national cancer surveillance system. The NPCR CSS is unique in meeting the national need for a population-based dataset with adequate numbers of rare cancers, representation of racial/ethnic populations, and state-based data for program planning and evaluation. With the addition of data items that will be collected by the Specialized central cancer registries the NPCR CSS will be able to address the diagnosis and treatment components of the cancer continuum using cancer registry data for breast, colon, and rectum cancer and for Chronic Myeloid Leukemia. The comparison of different interventions and strategies to diagnose and treat cancer would inform patients, providers, and decision-makers about those that are the most effective.

A5. Impact on Small Businesses or Other Small Entities

Respondents are state-based central cancer registries. No small businesses will be involved in this information collection.

A6. Consequences of Collecting the Information Less Frequently

Because of the time needed to collect and aggregate data from a large number of cancer cases each year, NPCR registries report to CDC final data that is already 2 years old and typical data analyses from these data are three years behind the current diagnosis year. Delaying these data reports any further would jeopardize the ability of the national cancer system to reflect cancer trends of current importance. Instead, the emphasis has been to try and provide more recent data from surveillance systems.

It is important to provide annual information on the national cancer burden to CDC officials, Congress, constituents, and other Federal, State, and local agencies. The data are also used to evaluate the success over time of prevention (tobacco control) or screening (breast, colorectal, cervical) efforts at the state and National level. The report of the enhanced variables will allow for patient-centered outcomes research that could impact treatment recommendations and assessments of treatment efficacy.

In addition, the ability of CDC to monitor and improve program effectiveness will be compromised if data is collected less frequently. It is essential that CDC and State program managers evaluate program strengths and weaknesses on an annual basis and make adjustments. Because of staff changes or other issues, a central registry that has performed well in the past may yet have problems with data quality or completeness. It is critical to identify these registries as soon as possible so that needed technical assistance or guidance can be provided.

During this extension period CDC will support two submissions per year. The additional preliminary submission in January will allow CDC to prepare to produce early estimates of cancer incidence and other statistics, in advance of the detailed data validation steps required for the November. Also, the assessment of data quality will allow for earlier technical assistance to central registries that are having difficulties. As electronic reporting continues to grow, this earlier submission provides a foundation for reporting final data earlier for public health purposes. Without this initial work to evaluate and improve the quality of this earlier data, progress cannot be made toward this goal.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A Notice was published in the Federal Register on February 1, 2016, Volume 81, No. 20, pp. 5123-5124 **(Attachment 6).** No public comments were received.

DCPC/NPCR staff have established a NPCR Central Cancer Registry Council which has regular monthly conference calls with CDC staff to provide feedback and input into NPCR operations including data collection requirements and procedures. These calls occur monthly including during 2015. The Council consists of Program Directors which serve on the group on a rotating basis (**Attachment 7**).

In addition, CDC works closely with NCI SEER staff to share information about data collection requirements and methods to ensure consistent National data and to provide guidance to states that are co-funded in operational procedures. In addition to regular calls (during 2015) with NCI staff, CDC and NCI staff serve together on numerous committees and workgroups including NAACCR work groups where standards are set for data collection and reporting throughout North America. These workgroups are ongoing.

CDC also confers on an ongoing basis with other partners including the American Joint Committee on Cancer which establishes staging criteria in the U.S. and the Commission on Cancer which certifies hospitals in cancer care and operates most of the hospital-based cancer registries.

A9. Explanation of Any Payment or Gifts to Respondents

No payment will be made to respondents (grantees) to submit NPCR data to CDC.

A10. Protection of the Privacy and Confidentiality of Information Provided to Respondents

This submission has been reviewed by OCISO at CDC which determined that the Privacy Act does not apply. Data are submitted by State health organizations and do not contain names, social security numbers or addresses.

CDC does not receive patient names, exact dates of birth, addresses, or Social Security Numbers. Confidentiality and privacy are of paramount concern to the NPCR because of the confidentiality concerns of the grantees, the private nature of medical data in a cancer surveillance database, and the potential for direct and deductive identification of an individual in the NPCR CSS. After extensive discussions with the CDC Privacy Officer, CDC obtained an Assurance of Confidentiality (308(d)) on June 7, 2000, with multiple renewals, the most recent in 2015 **(Attachment 5**). This approval was updated and

approved November 10, 2010 to include the specific data items that are submitted by the Specialized Registries that collected enhanced data.

The risk of direct identification of an individual in NPCR CSS data is remote because personal identifying data (name, SSN, and street address) are not reported to the CDC. However, a unique identifier assigned by the state and received by CDC for each individual cancer patient is reported to CDC. CDC does not have access to the link between this identifier and the identity of the patient. The state CCR's maintain the linkage information between the unique codes and the personal identities in their database in order to respond and follow-up on data queries from CDC. Since multiple primary cancers are a matter of research interest, the public use files must also contain a unique identifier for each patient so that patients with multiple primaries can be assessed.

Geographical data (e.g., county and census tract) pose some risk of identification for rare cancers within small rural populations, particularly if they can be linked with other datasets in some way. Because surveillance and analysis of cancer by county are of public health interest, CDC makes these data available via the National Center for Health Statistics Research Data Center (NCHS RDC), which requires a signed data release agreement and provides guidelines for data use. CDC creates and maintains multiple datasets of increasing sensitivity with respect to geographic data**.** In the first tier of data (the least confidential), state is the smallest geographic unit released. A more sensitive dataset would contain county-level data. The user will have to describe the need for county-level data. In data tiers one and two, other potential identifiers include date (month and year) and place of birth, race, vital status, date of last contact and cancers that are so uncommon that they are not included in USCS.. These data will be examined prior to release, and if necessary recoded to protect small population subsets. For example, only the month and year will be provided for potentially identifying dates such as date of birth, diagnosis, and death. Once tier one and two data have been examined and recoded, we believe that they will not pose a significant risk to confidentiality.

A third and most sensitive dataset may contain census tract in addition to the variables in the first and second datasets. This dataset is the most likely to create opportunities for deductive identification and as such, CDC intends to limit use of this dataset to those times this detail is needed to address the research questions. To provide data, CDC will require a research protocol, local IRB approval, and a plan to assure confidentiality. Data will be provided to meet specific needs and data items will be collapsed when necessary to protect confidentiality. Only a limited number of tier three analyses will be approved each year. The NPCR CSS data use agreement is based on the NCHS model.

To address the issue of deductive identification of an individual because of small numbers (e.g., in a census tract), guidelines from the NCHS Staff Manual on Confidentiality are used (19). NCHS has guidelines for published data and one for micro-data files or public-use files. The guidelines for published data include: 1) In no table should all cases of any line or column be found in a single cell, 2) In no case should the total figure for a line or column of a cross-tabulation be less than five unweighted cases, and 3) In no case should a quantity figure be based upon fewer than five

unweighted cases. The guidance for avoiding inadvertent disclosures through the release of micro data tapes includes: 1) "tape must not contain any detailed information about the subject that could facilitate identification and that is not essential for research purposes (e.g., exact date of the subject's birth) and 2) Geographic places that have fewer than 100,000 people are not to be identified on the tape. These guidelines from NCHS serve as a model for NPCR CSS as confidentiality procedures. In addition, the program will need to be attentive to changes in the environment that may impact efforts to maintain confidentiality.

Additional information on privacy safeguards applicable to data collection, de-identification, coding, transmission, storage, and reporting appears below.

B. The NPCR CSS data are secured by technical, physical, and administrative safeguards. A data contractor, ICF Macro, has been retained to assist with data management and analysis. The safeguards are outlined below:

Technical

- The NPCR CSS project has completed the required Security Certification and Accreditation renewal process managed by CDC's Chief Information Security Officer.
- CDC uses a contractor for the data submission process. The NPCR CSS project data reside on a dedicated server that resides on ICF Macro's local area network (LAN) behind the contractor's firewall and is password protected on its own security domain. Access to the NPCR CSS server is limited to the contractor's authorized project staff. No other non-project staff are allowed access to the NPCR CSS. All of the contractor's project staff are required to sign a confidentiality agreement before passwords and keys are assigned. All staff must pass background checks appropriate to their responsibilities for holding a public trust position.
- NPCR CSS data that are submitted electronically are encrypted during transmission from the states. They arrive on a document server behind the data collection contractor's firewall. Each State has its own directory location so no State has access to another State's data. The data are moved automatically from the document server to the NPCR CSS server.
- Once the data have been compiled by the contractor and delivered to CDC via the document server behind the firewall, all NPCR CSS datasets are maintained for restricted access on CDC's secure LAN server.

Physical

- The contractor's NPCR CSS server is housed in a secure, guarded facility. All contractor staff are issued identification badges. Elevator and stairwell access is controlled by key cards.
- Receipt and processing logs are maintained to document data receipt, file processing, and report production. All reports and electronic storage media containing NPCR

CSS data are stored under lock and key when not in use and will be destroyed when no longer needed.

- Once the data is compiled by the data collection contractor and delivered to CDC, all NPCR CSS datasets are maintained for restricted access on a secure LAN server, which is housed in a secure facility. All CDC staff are issued identification badges and access to the building is controlled by key cards.

Administrative

- CDC staff and the contract staff have developed a security plan to ensure that the data are kept secure and confidential. Periodic review and update of the data collection contractor's security processes is conducted to adjust for rapid changes in computer technology and to incorporate advances in security approaches. The security plan will be amended as needed to maintain the continued security and confidentiality of NPCR CSS data.
- All project staff receive annual security awareness training covering security procedures. The contractor's project security team oversees operations to prevent unauthorized disclosure of the NPCR CSS data.
- Once the data is delivered to CDC, access to these datasets is only granted when appropriate confidentiality release forms have been signed and returned to the NPCR CSS Data Security Steward.

A11. Institutional Review Board and Justification for Sensitive Questions

Collection of incidence data for surveillance is considered public health surveillance rather than research. However, epidemiologic analysis of the NPCR data for research is covered by a protocol submitted to Institutional Review at CDC. The study protocol (#2594) for analysis of data from NPCR-CSS has been reviewed and approved by a CDC Institutional Review Board (IRB). The most current notice of approval (October 1, 2015) is attached **(Attachment 8).** The DCPC maintains IRB approval through the annual continuation process. Analysis of the enhanced data collected through the 10 Specialized Registries was incorporated into the IRB protocol for NPCR-CSS.

There are no sensitive questions asked directly of the central cancer registry (i.e., the respondent); however, some of the patient-level data received from the central cancer registry are of a sensitive nature. This data include sensitive information about cancer diagnosis and treatment, which is central to the purposes of the project. In addition, race and ethnicity data are collected per HHS guidelines, and for use in epidemiologic analyses. The information is required to meet cancer surveillance objectives. Information regarding weight, height, co-morbid conditions, specific treatment regimens, and biomarkers are central to patient centered outcomes research. The information is required to allow for appropriate comparison of the different interventions and strategies to diagnose and treat cancer.

A12. Estimates of Annualized Burden Hours and Costs

A. Respondents are the 48 NPCR central cancer registries (45 states, the District of Columbia, Puerto Rico, and the Pacific Islands Jurisdiction). CDC is requesting two submissions per year. Each of these submissions will include 38 registries reporting standard data items listed in **Attachment 3a**. Ten Specialized Registries funded central cancer registries will report the same variables plus additional data items that will support patient centered outcomes research (variables are listed in **Attachment 3b).**

The estimated burden per response is 2 hours. All information is reported to CDC electronically. The total estimated annualized burden is 192 hours. States prepare their data files and send them electronically to CDC. The web page displays the OMB control number, the expiration date and a burden statement **(Attachment 9).** This information appears on the log in page of the website that the states use to transfer their files electronically.

Table A12-A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Central Cancer Registries in States, Territories, and the District of Columbia	Standard NPCR CSS Report	38	2	2	152
	Enhanced NPCR CSS Report	10	2	2	40
				Total	192

B. The annualized cost to respondents of reporting data to CDC is estimated to be $6,912. It is estimated that the following state cancer registry personnel will be required to help prepare and submit data electronically to CDC: data managers, information technology staff and program directors. However, it should be noted that the specific nature of the work in the central cancer registries does not correlate with the employment categories as outlined by the Department of Labor. The categories listed below are similar in job description to those in central cancer registries.

Table A12-B. Annualized Cost to Respondents

Type of Respondents	Form Name	No. of Respondents	Total Burden (in hours)	Average Hourly Wage	Total Cost
Central Cancer Registries in States, Territories, and the District of Columbia	Standard NPCR CSS Report	38	152	$36	$5,472
	Enhanced NPCR CSS Report	10	40	$36	$1,440
				Total	$6,912

*Based upon U.S. Bureau of Labor Statistics. *Occupational Employment Statistics. May 2009 National Occupational Employment and Wage Estimates.* Washington, DC: U.S. Bureau of Labor Statistics. Available at: http://www.bls.gov/oes/current/oes_nat.htm#00-0000 [accessed October16, 2015.]

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

The computer hardware and software needed for an electronic data submission to CDC are readily available to grantees since they already utilize these resources to collect and distribute cancer incidence data for state purposes; hence no capital or maintenance costs are anticipated.

A14. Annualized Cost to the Federal Government

The average annual cost for the contractor for NPCR CSS data collection is $1,600,955 per year for a five-year total of $8,004,777. Additional annual costs include personnel costs of federal employees involved in oversight and analysis. The annual staff cost is estimated at $120,000 (1.0 epidemiologist FTE, 0.2 public health advisor FTE, and miscellaneous expenses include travel, etc.).

Table A14-A. Estimated Annualized Federal Government Cost Distribution

A15. Explanation for Program Changes or Adjustments

CDC requests OMB approval for three years to extend the NPCR CSS information collection, with changes limited to data variable updates as defined by the professional cancer registry coding standards. There are no changes to the estimated number of respondents, the burden per response, or total estimated annualized burden hours.

A16. Plans for Tabulations and Publication and Project Time Schedule

CDC is requesting that Preliminary data (referred to as 12 month data) be submitted in January. These data will consist of one year of data for the most recent year of available cancer data. These data will be evaluated for completeness and quality and reports will be provided back to each registry and to CDC. Additional technical assistance will be provided as needed. These data may also be used to provide early reports of cancer incidence.

CDC is requesting that NPCR registries report Final Data (24 month data) each year in November. These data include diagnoses for each year the registry has been funded by NPCR to report data (1995 forward in many cases). Corrections and additions are added each year by the central cancer registries. Consequently each year the process of data submission, data editing, data enhancement, and creation of public use datasets will be repeated (Table A16). The schedule each year will be similar to what is found here:

Table A16. Time Schedule for Preliminary and Final Data Reporting, Analysis and Publication

Preliminary (12 month data)	
	Jan 2017
	March 2017

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.

References:

1 U.S. Cancer Statistics Working Group. *United States Cancer Statistics: 1999–2012 Incidence and Mortality Web-based Report*. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2015. Available at: www.cdc.gov/uscs.

2 Howlader N, Noone AM, Krapcho M, Garshell J, Miller D, Altekruse SF, Kosary CL, Yu M, Ruhl J, Tatalovich Z,Mariotto A, Lewis DR, Chen HS, Feuer EJ, Cronin KA (eds). SEER Cancer Statistics Review, 1975-2012, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2012/, based on November 2014 SEER data submission, posted to the SEER web site, April 2015.

3 Havener L and Thornton M (editors). Standards for Cancer Registries, Vol II: Data Standards and Data Dictionary, 13th ed. Springfield, Ill: North American Association of Central for Cancer Registries; 2008.

4 Haynes MA, Smedley BD. *The Unequal Burden of Cancer: An Assessment of NIH Research and Programs for Ethnic Minorities and the Medically Underserved*. Washington (DC): The National Academies Press; 1999.

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