U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 1/4/21

Title:	National Program of Cancer Registries-Cancer Surveillance System (NPCR-CSS)
Project Id:	0900f3eb81c2e837
Accession #:	NCCDPHP-SRT-11/10/20-2e837
Project Contact:	Wilson_Reda J. (dfo8)
Organization:	NCCDPHP/DCPC/CSB/SRT
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	10/20/2020
Estimated Completion Date:	10/20/2050
CDC/ATSDR HRPO/IRB Protocol #:	2594
OMB Control #:	0920-0469

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	12/29/20	Redmond Leonard_Joan (jrl3) CIO HSC
PRA: **PRA Applies**		12/29/20	Still-LeMelle_Terri (cse6) OMB / PRA

ICRO: **Returned with No Decision**		12/30/20	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Determination Start Date:	11/10/20
Description:	The National Program of Cancer Registries (NPCR) is legislatively mandated under 42 USC 280e-280e-4 to improve cancer registries; to plan and implement registries where none exist; to set standards for data completeness, timeliness, and quality; to provide data collection and analytic training; and to help establish a computerized reporting and data-processing system. This project is the means through which the Federal government's official cancer statistics are produced and published in the United States Cancer Statistics (USCS), https://www.cdc.gov/cancer/uscs/index.htm, an annual web-based report on cancer incidence, mortality, and survival. Overall, the data contained in USCS is used to monitor cancer trends over time, determine cancer patterns in various populations, and guide planning and evaluation of cancer control programs. This report can be used for public health action, program planning and evaluation, and study question formulation. The NPCR-CSS system is a public health surveillance project for cancer incidence (>1.7 million cases diagnosed each year), mortality (~600,000 deaths each year), and survival and is not intended to be a research project. The NPCR-CSS has a current IRB approval under Protocol #2594. This is a new determination request to reclassify the project as public health surveillance to align with the current Assurance of Confidentiality criteria; the AoC for NPCR-CSS is active (expiration date: 05/30/2025). The existing NPCR-CSS is a system to receive data files from NPCR awardees for data evaluation, evaluation of compliance with NPCR Program Standards, and creation of analytic data sets including the U.S. Cancer Statistics database, public use data sets, and restricted access data sets. NPCR-CSS has existing approval from the Office of Management and Budget for an information collection request (OMB #0920-0469). NPCR's mission includes using high quality cancer surveillance data for public health surveillance and to monitor trends in cancer risk factors, incidence, mortality, and survival for cancer prevention and control. NPCR-CSS#s objective is to provide integrated and comprehensive cancer information systems to facilitate these activities in order to meet national cancer prevention and control objectives, fulfill agency responsibilities for public health surveillance, comply with Congressional mandates, and better meet the needs of state public health departments. This project is considered public health surveillance practice for the dissemination of important facts about the burden of cancer in the U.S. and as the foundation for providing education and information about cancer incidence, mortality and survival.
IMS/CIO/Epi-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected

Goals/Purpose	NPCR-CSS is an ongoing project with a previously approved DMP and determination reviews and operates under IRB Protocol #2594. This entry is for the reclassification of the project as public health surveillance to align with the Assurance of Confidentiality reclassification based on recent changes to the Common Rule. NPCR-CSS's goal is to make datasets available that address public health surveillance activities (e.g., publishing routine surveillance reports, tracking national health objectives for special populations, over time, and by geographic boundaries), evaluate cancer initiatives and guide program planning (e.g., identifying patterns of cancer diagnosis and treatment, identifying regions with higher proportions of late-stage cancer), and secondary analyses of the NPCR-CSS datasets that assist the cancer surveillance community to address specific cancer-related research questions that support the purpose of this public health surveillance program (e.g., monitoring the frequency and distribution of disease, evaluating cancer prevention and control activities, program planning and evaluation). NPCR#s mission is to monitor trends in cancer risk factors, incidence, mortality, and survival for cancer prevention and control and includes providing cancer surveillance data for epidemiologic research. The purpose of the NPCR-CSS is to provide a system to receive data files from NPCR-funded programs for data evaluation, to determine compliance with NPCR Program Standards, and to create an aggregated data file from which analytic data sets are created including the US Cancer Statistics database, public use datasets, and restricted access data sets. The data contained in the NPCR-CSS system does not have direct identifiable information, individuals cannot be directly identified, and there is no interaction with human subjects or specimen collection. However, the data does contain potentially identifiable information (county, ZIP code, age, date of birth, etc.). The potentially identifiable information is recoded to further protect confidentiality; e.g., individual age recoded to 10-year age groups.
Objective:	This project does not require nonfederal people or institutions to respond or disclose information to a third party or the public. The project does require NPCR-funded programs, 50 programs are currently funded, to create and submit a de-identified data file of cancer incidence in their respective geographic coverage area. NPCR-CSS has existing approval from the Office of Management and Budget for an information collection request (OMB #0920-0469). This de-identified file is submitted to CDC's contractor according to specifications developed by NPCR using a nationally recognized standard record layout. The data collected by the NPCR-funded programs is initially reported by healthcare facilities (e.g., hospitals) and providers (e.g., physicians and laboratories) based on information recorded in the medical record. CDC may provide technical assistance to the NPCR-funded programs as it relates to preparing a de-identified data file, assuring high data quality, uploading the file to a secure document server hosted by CDC#s contractor. This project does not involve research conducted by NIH.
Activities or Tasks:	Secondary Data or Specimen Analysis, Purchase, Use, or Transfer of Information, Data, Biospecimens or Materials
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Public Health Surveillance
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided, CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens, CDC employees will participate as co-authors in presentation(s) or publication(s), CDC employees will provide substantial technical assistance or oversight
Method Categories:	Analytic Services (can be data/specimen TA for non-research,research,investigations); QA/QI; Secondary Data Analysis; Surveillance Support; Technical Assistance
Methods:	NPCR-funded central cancer registries submit de-identified data to CDC on an annual basis where the data are edited, standardized, and aggregated into the NPCR-CSS. This Public Health Surveillance protocol covers the analysis and dissemination of these data for 1) surveillance activities, 2) program planning and evaluation, 3) secondary data analysis, and 4) creation of public use datasets. The design of the specific analysis and dissemination activities depend on the specific activity. NPCR-funded central cancer registries continuously receive cancer incidence data, including information on diagnosis, treatment, and outcomes, on individuals residing, diagnosed, or treated within their geographic boundaries. Cases available in the NPCR-CSS dataset are defined as all invasive and in situ cancers (with the exception of basal and squamous carcinoma of the skin and

Collection of Info, Data or Biospecimen:	carcinoma in situ of the cervix) and benign and borderline tumors of the brain and central nervous system. Central cancer registries must report to CDC data items specified in 42 USC 280e-280e-4 and those needed for NPCR surveillance and program planning and evaluation. More data items are collected at the central cancer registry level than are reported to CDC. Mandated data elements that are available for analysis and dissemination include: 1) demographic data (e.g. age groups, race, sex, residence at diagnosis); 2) cancer data (e.g., primary site, morphology, date of diagnosis, diagnostic confirmation, stage at diagnosis); and 3) treatment data. Patient follow-up status (e.g., vital status, cause of death) is also reported though it is not mandated by 42 USC 280e-280e-4. All variables are defined by the Uniform Data Standards Committee of the North American Association of Central Cancer Registries (NAACCR), a standard setting organization for cancer registries. Changes to data items or conversion issues are handled by this committee and disseminated to the NAACCR membership. NPCR#s commitment to standards for data quality includes requiring central cancer registries to conform to standard definitions so that data are comparable across geographic boundaries. Data quality evaluations assure the validity and reliability of the reported information.
Expected Use of Findings/Results:	When standards of completeness and quality have been met for the NPCR-CSS final submission, CDC aggregates state data and makes them available in non-confidential, pre-calculated rates on the Internet in a format that facilitates obtaining data by sex, race, age, geographic area, and other common factors of interest. Any data published from NPCR-CSS in surveillance reports, either in printed copy or on the Internet, are scrutinized to assure that the confidentiality of the individual is protected. Current users of the NPCR-CSS data must sign a data release agreement as outlined in a data release policy that is updated annually. Restricted-access data sets are available with appropriate processes in place to protect confidentiality and security. 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 tests, and colorectal cancer screening. The Agency for Healthcare Research and Quality (AHRQ) includes measures for effectiveness of care in cancer. Since 2002, CDC and the NCI, have published the United States Cancer Statistics (USCS) containing a set of official federal cancer incidence statistics for the entire US population. 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.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers?	Yes
Is an assurance of confidentiality in place or planned?	Yes
Is a certificate of confidentiality in place or planned?	No
Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award
CDC Contract	National Program of Cancer Registries Cancer Surveillance System (NPCR-CSS)	200-2010-37215-0022	2017	4

HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	No
Estimated number of study participants	
Population - Children	N/A
Population - Minors	N/A
Population - Prisoners	N/A
Population - Pregnant Women	N/A
Population - Emancipated Minors	N/A

Suggested level of risk to subjects Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection

Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Institutions yet to be added .....

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Jessica King	09/20/2022		09/05/2021		Co-Investigator	gzk3@cdc.gov	770-488-4279	DATA ANALYSIS SUPPORT TEAM
Manxia Wu	09/19/2022		11/20/2021		Co-Investigator	ilb8@cdc.gov	770-488-3189	CANCER SURVEILLANCE BRANCH
Mary O'neil	09/23/2022	12/04/2021			Co-Investigator	dbi8@cdc.gov	770-488-8247	SURVEILLANCE RESEARCH TEAM
Simple Singh	09/19/2022		11/09/2021		Co-Investigator	hjv3@cdc.gov	770-488-2	SURVEILLANCE RESEARCH TEAM

Data

DMP

Proposed Data Collection Start Date: 9/20/17

Proposed Data Collection End Date: 9/19/50

Proposed Public Access Level: Public, Non-Public, Restricted

Non-Public Details:

Reason For Not Releasing Data: Other - Dataset includes indirection identifiable information that, in combination with other information, reduces data confidentiality

Restricted Details:

Data Use Type: Research Data Center

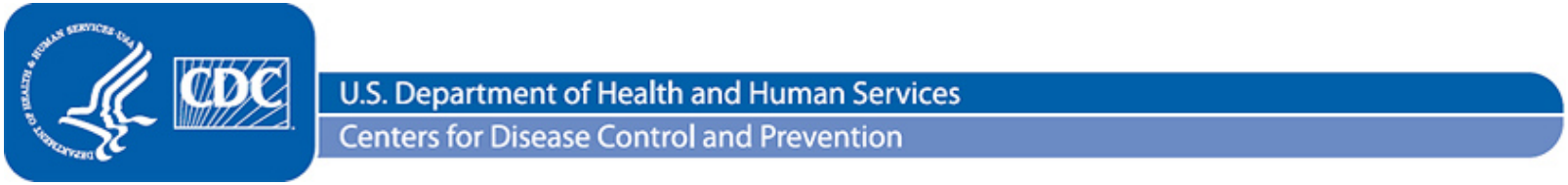
Data Use Type URL:	https://www.cdc.gov/rdc/B1DataType/Dt131.htm
Data Use Contact:	Reda Wilson
Public Access Justification:	NPCR#s mission is to monitor trends in cancer risk factors, incidence, mortality, and survival for cancer prevention and control and includes providing cancer surveillance data for epidemiologic research. Providing a public access dataset facilitates analyses outside the CDC.
How Access Will Be Provided for Data:	NPCR defines public web-based query systems as datasets that are comprised of aggregated data (i.e., not individual case-specific data or microdata) that have been modified according to accepted procedures to block breaches of confidentiality and prevent disclosure of the patient#s identity or confidential information and have a database behind a CDC firewall that is either case-specific microdata or pre-analyzed data tables. These public web-based systems can be accessed at https://www.cdc.gov/cancer/uscs and https://wonder.cdc.gov/cancer.html. There are no restrictions on access to public web-based query systems. A public release disclosure statement cautions users against inappropriate use of the data or inappropriate disclosure of information. In addition to the web-based systems, the NPCR/SEER USCS Incidence Public-Use Research Dataset (PUD) is available. The PUD is defined as the version of the full NPCR/SEER USCS microdata (i.e., individual case-specific data) that have been modified as needed to minimize the potential for disclosure of confidential information. It consists of a subset of data items published in USCS. This dataset does not contain personal identifiers such as a patient#s name, street address, or Social Security number as this information is not transmitted by central cancer registries to CDC as part of their annual data submission. Certain data items, such as date of birth, and reporting-source (death certificate only and autopsy) cases have also been removed from this research dataset to minimize the potential identification of individuals with the occurrence of rare cancer in a person of certain age or racial or ethnic group or living in a specific county. The dataset is available publicly through SEER*Stat software after signing an NPCR and SEER # U.S. Cancer Statistics Research Data Use Agreement. A Public Release Disclosure Statement cautions users against inappropriate use of the data or inappropriate disclosure of information. Cell suppression of <16 cases is automatic and the SEER*Stat case listing function is disabled as additional data protection measures.
Plans for Archival and Long Term Preservation:	Data for the public web-based query systems are archived at https://www.cdc.gov/cancer/uscs/dataviz/archive.htm. Older versions of the Public-Use Research Dataset continue to be maintained within the SEER*Stat software.

Spatiality

Country	State/Province	County/Region
United States		

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									


CDC
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention