Information Collection Request

REINSTATEMENT WITH CHANGE

National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Monitoring Activities

Formerly Titled, "Annual Survey of the National Breast and Cervical Cancer Early Detection Program Grantees' Program Implementation."

OMB Control No. 0920-1046

Supporting Statement: Part A

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- **Goal of the study**: The goal of this data collection is to systematically collect information about the implementation and outcomes of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), which funds 70 grantees.
- **Intended use of the resulting data:** CDC will use resulting data to monitor the implementation of NBCCEDP activities, and evaluate outcomes achieved across all grantees.
- **Methods to be used to collect:** CDC will conduct an annual grantee survey and collect clinic-level information from grantees' health system partners.
- **The subpopulation to be studied:** The subpopulation for the grantee survey is the 70 NBCCEDP program directors/program managers. Clinic-level information, including breast and cervical screening rates, represents clients ages 50-74 for breast cancer screenings and 21-65 for cervical cancer screenings within partner health systems.
- **How data will be analyzed:** CDC will use descriptive statistics to produce reports for CDC program management and NBCCEDP grantees, with a particular focus on the primary outcome of interest – changes in clinic-level breast and cervical screening rates.

ABSTRACT

CDC is requesting a reinstatement with change of the information collection with the OMB control number 0920-1046, formerly entitled "Annual Survey of the National Breast and Cervical Cancer Early Detection Program Grantees' Program Implementation" (exp. date 1/31/2018). We are proposing a new title, "National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Monitoring Activities." In 2017, CDC significantly redesigned the NBCCEDP to have a stronger focus on grantees partnering with health system clinics to implement evidence-based interventions (EBIs). The NBCCEDP currently provides funding to 70 grantees under "Cancer Prevention and Control Programs for State, Territorial, and Tribal Organizations (DP17-1701)." Consistent with programmatic changes, the information collection plan has also been redesigned. Changes include a redesigned survey and a new clinic-level data collection. The information collection will allow CDC to provide routine monitoring feedback to grantees based on their data submissions, tailor technical assistance as needed, support program planning, and assess program outcomes. The estimated annualized burden is 683 hours. OMB

approval is requested by November 15, 2018, in preparation for information collection beginning in Fall 2018. OMB approval is requested for three years.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

CDC is requesting a reinstatement with change of OMB No. 0920-1046. The number of respondents will increase from 67 to 70. In the previous OMB approval period, information collection consisted of an annual grantee survey. In the next cycle, information collection will consist of a redesigned survey and a new clinic-level data collection. Total estimated annualized burden will increase. OMB approval is requested for three years.

Cancer is the second leading cause of death in the U.S.[1] In 2014, approximately 1.6 million people were diagnosed with cancer, and more than 591,000 people died from cancer.[2] Both breast and cervical cancers are prevalent among U.S. women – in 2014, more than 236,000 women were diagnosed with breast cancer, and more than 12,000 women were diagnosed with cervical cancer.[3] Evidence shows that deaths from both breast and cervical cancers can be avoided by increasing screening services – mammography and pap tests – among women. However, screening is typically underutilized among women who are under- or uninsured, have no regular source of healthcare, or who recently immigrated to the U.S.[4] As a longstanding priority within chronic disease prevention, CDC focuses on increasing access to these cancer screenings, particularly among women who may be at increased risk.

To improve access to cancer screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354, **Attachment 2 - Breast and Cervical Cancer Mortality Prevention Act of 1990**) which directed CDC to create the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and to conduct program monitoring and evaluation activities. The NBCCEDP currently funds 70 grantees including states and the District of Columbia; U.S. territories; and tribes and tribal organizations. As a comprehensive, organized screening program, the NBCCEDP supports several key strategies to achieve program

[1] *United States Cancer Statistics: 1999–2013 Incidence and Mortality Web-based Report*https://nccd.cdc.gov/uscs/
[2] *United States Cancer Statistics: 1999–2013 Incidence and Mortality Web-based Report*https://nccd.cdc.gov/uscs/
[3] Centers for Disease Control and Prevention (2017). *Cancer*. Retrieved on 28 March 2017 from https://www.cdc.gov/cancer/index.htm.
[4] Centers for Disease Control and Prevention. Cancer Screening Test Use—United States, 2015. *MMWR* 2017;66(8):201-206.

outcomes, including program collaboration, partnership development, use of cancer surveillance data, environmental approaches, community-clinical linkages, health systems change, and ongoing program monitoring and evaluation (**Attachment 3 – NBCCEDP Logic Model**).

Historically, the NBCCEDP has focused on clinical service delivery, whereby grantees partner with health systems and their clinics to deliver breast and cervical cancer screening, diagnostic evaluation, and treatment referrals for women diagnosed with cancer. Priority populations for NBCCEDP screening services include women residing within defined geographical locations (as determined by the funded program) who are (1) at or below 250% of the federal poverty level, (2) aged 40-64 years for breast cancer services, and aged 21-64 years for cervical cancer services, and (3) under- or uninsured.

In 2017, CDC significantly redesigned the NBCCEDP and issued a new Funding Opportunity Announcement to support a 5-year cooperative agreement for the NBCCEDP (CDC-RFA-DP17-1701). The new FOA expands the NBCCEDP's focus on direct service provision to include implementation of EBIs within health systems intended to increase breast and cervical cancer screening among clinic populations ages 21-74. Grantees partner with health systems to implement EBIs in health system clinics, with increases in clinic-level breast and cervical screening rates as the primary outcome of interest. Priority populations for these clinic-based interventions include disparate populations ages 50-74 for breast cancer screening and 21-64 for cervical cancer screening. By implementing health systems changes using EBIs, the NBCCEDP can have greater impact on improving breast and cervical cancer screening rates.

Consistent with programmatic changes, the information collection plan has also been redesigned. CDC is authorized to collect information by the Public Health Service Act **(see Attachment 1 – Authorizing Legislation)**.

2. Purpose and Use of the Information Collection

CDC is required to monitor and evaluate processes and outcomes related to the NBCCEDP. Based on the redesigned NBCCEDP, CDC developed a logic model to illustrate the strategies and expected outcomes associated with the NBCCEDP over time (**Attachment 3 – NBCCEDP Logic Model**). As illustrated in the logic model, CDC anticipates that grantees' implementation

of the eight strategies and activities described will result in several desired short-, intermediate-, and long-term outcomes, including increased breast and cervical screening rates.

As mentioned, beyond supporting screening service delivery, the current NBCCEDP has a focus on grantees partnering with health system clinics to implement EBIs (**Attachment 4 – EBI Logic Models**). Implementation of these EBIs have been shown to be effective in contributing to many short-term outcomes of interest at the provider and patient levels, ultimately supporting increases in breast and cervical screening rates. Health systems (e.g., FQHCs) are typically comprised of multiple primary care clinics. These clinics may opt to implement differing EBIs to meet the specific needs of their population, and will experience differing outcomes related to program reach and changes in screening rates. Therefore, clinic-level data collection is essential to monitor EBI implementation and monitor changes in screening rates, an important program outcome. This represents greater emphasis on health systems change as a means to strengthen the impact of the NBCCEDP.

The NBCCEDP logic model guided the development of evaluation questions and sub-questions designed to monitor grantees implementation of strategies and activities, and evaluate program outcomes (**Attachment 5 – NBCCEDP Evaluation Question Matrix**). Each information collection is intended to directly inform one or more evaluation questions or sub-questions. Two forms of data collection are proposed to assess program implementation (i.e., processes) and outcomes – a revised grantee survey and clinic-level data collection.

Grantee Survey

While a survey was used to monitor implementation of the previous iteration of the NBCCEDP, the instrument was entirely reconstructed to reflect the focus of the redesigned program under DP17-1701. The proposed grantee survey focuses on the following areas: (1) management, program, and evaluation challenges, (2) program resources, (3) partnerships, (4) health systems change for screening delivery, (5) EBI implementation for health systems change, and (6) other strategies for sustainable cancer control (**Attachment 6 – NBCCEDP Grantee Survey (screenshots)**). CDC will conduct the NBCCEDP grantee survey among all 70 grantees following the end of each program year.

Clinic-Level Data Collection

Given that grantees are required to implement EBIs in partner health system clinics, CDC proposes to collect new data at the clinic level. These data will allow assessment of EBI implementation and the NBCCEDP's primary outcome of interest – breast and cervical cancer screening rates within partner health system clinics. Grantees will report aggregate baseline data for each of their partner health system clinics (an average of six clinics per grantee) that are recruited to participate, including health system, clinic, and patient population characteristics, as well as baseline screening rates. In program years 2-5, grantees will report aggregate annual data for each partner clinic, including monitoring and quality improvement activities, EBI implementation, and an annual screening rate. NBCCEDP grantees will collect and report NBCCEDP clinic-level (not patient) data for all health system partners' primary care clinic sites. Information will be collected separately for breast and cervical cancer activities **(**see **Attachment 7a – NBCCEDP Clinic-Level Data Dictionary, Breast** and **Attachment 7b - NBCCEDP Clinic-Level Data Dictionary, Cervical)**. Clinics typically already collect these data elements for ongoing monitoring of their own clinical activities. These data will help CDC to describe program reach, the clinic settings, characteristics of the population being served, program activities implemented at the clinic-level, and changes in breast and cervical cancer screening rates over time.

Together, the proposed information collection activities are expected to contribute to a more effective NBCCEDP and strengthen CDC's ability to demonstrate program results. These monitoring efforts will also help to identify successful activities that need to be maintained, replicated, or expanded, as well as provide insight into areas needing improvement.

The scope of information collection is limited to monitoring the public health activities and experiences of NBCCEDP grantees acting in their official capacity. Personal identifying information will not be collected, and the information collection will not yield information that can be generalized. CDC will use this information to better understand the range of experiences among grantees and as one of many inputs into decision-making and/or program management. In addition, the findings will be reported back to the grantees to help them identify successful implementation models and focus networking for shared experiences, lessons learned, and best practices.

3. Use of Improved Information Technology and Burden Reduction

Grantee survey data will be collected annually via a web-based questionnaire allowing respondents to complete and submit their responses electronically. Clinic-level data will be collected annually through a web-based template **(Attachment 7 - NBCCEDP Clinic-Level Data Collection Instrument (screenshots)).** Both methods use pre-existing web infrastructure and tools already in place for the NBCCEDP grantees. These methods were chosen to reduce the overall burden on respondents.

4. Efforts to Identify Duplication and Use of Similar Information

The information to be collected from the NBCCEDP grantees are unique to the current program and, therefore, not duplicative of other efforts. The grantee survey collects some information with which previously funded grantee programs will be familiar; these, along with new items, are essential for program monitoring and to answer CDC's evaluation questions. All clinic-level data elements are new and unique. There is an existing, complementary information collection to monitor breast and cervical screening service delivery, the Minimum Data Elements (MDEs; OMB No: 0920-0571 exp. 12/31/2018).

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

The purpose of this request is to ensure collection of information that is not otherwise available in a current, time sensitive, or standardized format to specific or emergent priorities of HHS and CDC. Information collection plans, including the frequency of collection, are informed by previous funding cycles, approved information collection for other DCPC screening programs (i.e., the Colorectal Cancer Control Program), and feedback from stakeholders (e.g., grantee programs, subject matter experts in the field). Without this information collection, there would be:

- No systematic information collection regarding the implementation of NBCCEDP program activities and outcomes, as required in the current FOA.
- No systematic assessment of grantees' training and technical assistance needs.

- No systematic assessment of monitoring and evaluation efforts at the grantee and clinic levels.
- Less effective and less timely assessment of implementation partners and their program activities.
- Fewer resources from which to make data-driven decisions that are often required of CDC as well as required of its grantees.

OMB approval is requested for three years. There are no legal obstacles to reduce the burden.

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

There are no special circumstances with this information collection request. This request fully complies with the regulation 5 CFR 1320.5. Participation in the cooperative agreement program is voluntary. Participation in the information collection is required for funded awardees.

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

A. PUBLIC NOTICE

Notice of this project was published in the Federal Register on January 26, 2018, in Vol. 83, No. 18, pages 3711-3712 (see **Attachment 8 –** 60-Day Federal Register Notice). No public comments were received.

B. CONSULTATION

The individuals listed below, including CDC contractors and external partner organizations, provided expert consultation on the development of data collection tools and protocols.

Table A.8.1. Individuals Who Have Provided Consultation on the Project					
Consultant	**Title**	**Affiliation**	**Email**	**Phone**	**Year of Consult**
Bill Helsel	Project Manager	Information Management Services, Inc. (IMS)	helselb@imsweb.com	301-680-9770	2017
Bill Kammerer	Project Manager	Information Management Services, Inc. (IMS)	kammererb@imsweb.com	301-680-9770	2017
Peggy Hannon	Director, Associate Professor	University of Washington School of Public Health	peggyh@uw.edu	206-616-7859	2017
Heather Brandt	Associate Professor	University of South Carolina	hbrandt@sc.edu	803-576-5649	2017
Christen Lara	Data Quality and Analytics Manager	University of Colorado	Christen.Lara@state.co.us	303-692-2531	2017
Steven Leadbetter	Consultant	DB Consulting Group, Inc.	szl1@cdc.gov	727-623-0074	2017

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by CDC's Privacy Office who determined that the Privacy Act does not apply. Activities do not involve the collection of individually identifiable information, and all data are programmatic in nature. A completed Privacy Impact Assessment Form is Attached (**Attachment 10**).

Statement of impact on the respondent's privacy

The grantee survey includes programmatic information and does not contain direct personal identifiers. As such, the information collection will have little or no effect on the respondent's privacy.

The clinic-level data collection identifies the partner health system and clinic by name and includes the clinic address – both of which are publicly available. The name, in addition to an assigned ID, are used to ensure accurate identification of the clinic when reporting longitudinal (annual) information, and to compare clinic implementation activities with grantee work plans. With the exception of feedback reports to grantees, CDC will not identify the name of the health system or clinic partner. Information is treated in a secure manner, and will not be disclosed unless otherwise compelled by law.

Opportunities to consent to sharing and submission of information

Respondents will be notified that their information will be maintained in a secure manner and that they will receive individualized feedback reports for their use. There is no impact on the respondent's privacy.

How information is secured

Both information collections are secured by technical, physical, and administrative safeguards as outlined below.

Technical

- All data reside on a dedicated server on the contractor's local area network behind the contractor's firewall, and is password protected on its own security domain. Access to the server is limited to the contractor's authorized project staff. Non-project staff will not have access to the data. All of the contractor's project staff are required to sign a non-disclosure agreement before passwords and keys are assigned.
- Access to the NBCCEDP program website is restricted via a password-protected secure website. Access to grantee-specific reports and clinic-level data entry systems **(Attachment 7 - NBCCEDP Clinic-Level Collection Instrument (screenshots))** are further restricted within the website. Each grantee has its own directory location, so no grantee has access to another grantee's information. The NBCCEDP website utilizes the Hypertext Transfer Protocol Secure (HTTPS) method to ensure secure connections. In

addition, the website will enable Strict Transport Security (HSTS), which is in compliance with OMB memorandum M-15-13, Policy to Require Secure Connections across Federal Websites and Web Services.

- Once information has been compiled by the contractor and delivered to CDC via a secure website, all data are maintained with restricted access on CDC's secure LAN server with access permission granted by the CDC NBCCEDP data manager.

Physical

- The contractor's server is housed in a secure facility with restricted access.
- Receipt and processing logs are maintained to document data receipt, file processing and report production. All reports and electronic storage media containing grantee information are stored under lock and key when not in use and will be destroyed when no longer needed.
- Once data have been compiled by the contractor and delivered to CDC, all 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 and contract staff have developed and implemented an information system security plan to ensure that the information is kept secure. Periodic review and update of the contractor's security processes is conducted to adjust for needed changes and will be amended as needed to maintain the continued security of the information.
- The contractual agreement between CDC and the contractor includes non-disclosure terms. The contractor's project security team oversees operations to prevent unauthorized disclosure of the NBCCEDP data.
- Once the information have been delivered to CDC, data are housed on CDC's secure LAN server and restricted access is controlled by the NBCCEDP data manager.

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

No information will be collected that are of personal or sensitive nature, and collected information will not yield information that can be generalized. As such, this information collection will not require IRB review.

12. Estimates of Annualized Burden Hours and Costs

The NBCCEDP funds a total of 70 grantee programs (see **Attachment 11**, DP17-1701 Awardee Program List). Estimated burden hours are described below.

- The estimated burden hours for the NBCCEDP grantee survey is based on a pilot by 5 public health professionals. In the pilot test, the average time to complete the instrument including reviewing instructions and completing the instrument was approximately 45 minutes. The total estimated burden for the grantee survey is 53 hours.
- The estimated burden hours for the NBCCEDP clinic-level information collection tool is based on a pilot by 4 public health professionals. In the pilot test, the average time to complete the instrument was approximately 45 minutes. We estimate an average of 6 responses per grantee annually for breast cancer activities, and 6 responses per grantee annually for cervical cancer activities, to correspond with the number of health system partners. There is no additional burden for clinics as they typically collect these data elements to monitor their day-to-day clinic activities. The time required by grantees to gather these data from their partner clinics is included in the burden estimate. The total estimated burden for clinic-level data collection is 630 hours.

Table 12.A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hrs)	Total Burden Hours
NBCCEDP Grantees	NBCCEDP Grantee Survey	70	1	45/60	53

	NBCCEDP Clinic-level Information Collection Instrument - Breast	70	6	45/60	315
	NBCCEDP Clinic-level Information Collection Instrument – Cervical	70	6	45/60	315
Total					683

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf). Based on DOL data, an average hourly wage of $57.11 is estimated for all respondents.

Table 12.B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Number of Respondents	Total Burden Hours	Average Hourly Wage	Total Cost
NBCCEDP Grantees	NBCCEDP Grantee Survey	70	53	$57.11	$3,027

	NBCCEDP Clinic-level Information Collection Instrument - Breast	70	315	$57.11	$17,990
	NBCCEDP Clinic-level Information Collection Instrument - Cervical	70	315	$57.11	$17,990
Total					$39,007

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

There will be no direct costs to the respondents other than their time to participate in each information collection.

14. Annualized Cost to the Government

Total operations and maintenance costs includes work performed by both the contractor and CDC personnel. Salary cost of CDC staff include an FTE (GS-13) to lead the project and coordinate all related activities of each information collection as well as another FTE (GS-13) to help with data management, analysis and report preparation. Four hundred and eighty hours of staff time was estimated for each FTE annually for this information collection. Cost of the contractor represents an estimated 35% ($463,152) of total annual contract funds ($1,323,293) allocated for NBCCEDP data management activities. The estimated annualized cost to the federal government is $507,284. Table A.14-A describes how the cost estimate was calculated.

Table A14-A. Estimated Annualized Federal Government Cost Distribution

Staff (FTE)	Average Hours per	Average Hourly Rate	Average Cost

	Collection		
Health Scientist (GS-13) Lead health scientist to prepare OMB package; overall coordination; and consult on information collection, analysis, report preparation	480	$45.97	$22,066
Health Scientist (GS-13) Data management support, analysis, report preparation	480	$45.97	$22,066
Contractor Costs			
Annualized Cost of Contract with Information Management Services Responsible for building web-based application, information collection, coding and entry, quality control, analysis, report preparation			$463,152
Estimated Total Cost of Information Collection			$507,284

Table A14-B. Estimated Annualized Federal Government Operational and Maintenance Costs

The majority of data collection and management tasks will be the responsibility of the CDC contractor, and will not require additional operational or maintenance costs to the Federal government. CDC personnel will oversee the project, and provide leadership and coordination which will not require additional costs beyond individual employees' salaries. Therefore, there are no additional operational or maintenance costs associated with this information collection.

Table A14-B. Total Cost to the Federal Government

Operational and Maintenance Costs	**Estimated Annualized Federal Government Costs**	**Total Cost**
$0.00	$507,284	$507,284

15. Explanation for Program Changes or Adjustments

This is a request for reinstatement with change to OMB No. 0920-1046. For the NBCCEDP annual grantee survey, the number of respondents increase from 67 to 70 and the total burden increases from 45 hours to 53 hours, a net increase of 8 hours. The NBCCEDP clinic-level data collection is new and involves all 70 respondents and 630 estimated burden hours. The overall burden has increased from 45 hours to 683 hours, a net increase of 638 hours.

Table A15. Changes in Information Collection

	Previous Approval		Proposed Changes for Current Reinstatement			
Information Collection Instrument	**No. Respondents**	**No. Burden Hrs.**	**No. Respondents**	**No. Burden Hrs.**	**Change in Respondents**	**Change in Burden Hrs.**
NBCCEDP Grantee Survey	67	45	70	53	+3	+8
NBCCEDP Clinic-level Data Collection Instrument - Breast			70	315	+70	+315
NBCCEDP Clinic-level Data Collection Instrument - Cervical			70	315	+70	+315
						+638

16. Plans for Tabulation and Publication and Project Time Schedule

The NBCCEDP Grantee Survey will be completed annually within 2 months after the end of each program year (in July or August). Data validation, analysis, and report preparation and dissemination will follow. A summary timeline is provided below:

Table A.16-A. Project Time Schedule

Activity	**Time Schedule**
Introductory emails for NBCCEDP Grantee Survey sent to respondents with link to survey, information collection begins. NBCCEDP Clinic-Level Data Instrument available for reporting, information collection begins.	Begin 1-3 months after end of program year, information collection continued for up to 6 weeks
Survey reminder emails sent to non-responders (survey only)	10 days after introductory letters sent
Data Validation	Completed 1 month after end of information collection
Data Analyses	Completed 4 months after end of information collection
Report Preparation	Completed 6 months after end of information collection

Report Dissemination	Completed 7 months after end of information collection

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.