Supporting Statement A: Social and Economic Barriers to Receiving Optimal Services Along the Cancer Care Continuum

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Supporting Statement A

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JUSTIFICATION SUMMARY

Goal of the project: This research study will help CDC examine the social and economic barriers that individuals who are newly diagnosed with colorectal, breast, and cervical cancer face at each stage of the cancer care continuum, from screening through survivorship. We are also interested in learning about caregivers' experiences including the barriers they faced as well as the barriers they perceived their care recipients faced. This project will improve our understanding of the cancer care experience, and how experiences may vary across cancer care continuum and for different populations.

Intended use of the resulting data: The results will produce data-driven evidence that inform efforts aimed at increasing access to cancer care services, reducing the burden of cancers and closing the disparities gap.

Methods to be used to collect: We will use a mixed methods data collection approach. We will survey cancer survivors and then administer a follow-up survey to respondents. We will administer a survey to caregivers of individuals who went through cancer treatment. All survivors and caregivers will initially be invited to complete an online survey; the final reminder will be accompanied with a paper survey. We will conduct interviews with selected survivors and caregivers who completed a survey. Finally, we will conduct focus groups with representatives from various patient/survivor advocacy organizations to hear their perspectives on the barriers cancer survivors face.

The subpopulation to be studied: Our research focuses on breast, cervical, and colorectal cancer survivors and their caregivers. We will also collect data from representatives of cancer patient/survivor advocacy organizations.

How data will be analyzed: We will link each survivor's survey data to their cancer registry data, creating a linked analytical data file. All quantitative (survey) data will be analyzed using statistical analysis software (e.g., SAS, R). We will conduct descriptive analysis and use regression analysis to assess associations between individual- and community-level barriers to care and cancer-related outcomes across the cancer care continuum.

For qualitative data analysis, we will use an inductive–deductive approach. Interview and focus group data will be coded in qualitative analysis software or Excel. We will conduct a thematic analysis to identify common themes from focus group and interview participants.

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a three-year OMB approval for a new collection to collect data about the social and economic barriers faced by individuals diagnosed with cancer and their caregivers from individuals diagnosed with cancer, their caregivers, and representatives from cancer advocacy organizations. CDC is authorized to collect the information under the Public Health Service Act, Title 42, Section 301 (**Attachment 1**).

Cancer Overview

Cancer is the second leading cause of death in the United States (NCCDPHP, 2022). One in three people will get cancer in their lifetime (National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), 2022, June 7). An estimated 1.9 million new cases of cancer and approximately 600,000 deaths are expected in 2023 (Siegel, Miller, Wagle, & Jemal, 2023). Cancer prevalence is expected to continue rising due to an aging population and lifestyle factors such as obesity, physical inactivity, and smoking (Siegel et al., 2023).

Breast cancer is the most common type of cancer in the United States (U.S.) (National Cancer Institute (NCI), 2023, March 7). Colorectal cancer is the fourth most common cancer in the U.S (United States Cancer Statistics (USCS) Working Group, 2023). While female breast cancer has a 90.8% five-year relative survival, colorectal cancer has only a 65.0% five-year relative survival which is comparable to cervical cancer (67.2%) (Surveillance Epidemiology and End Results Program (SEER), n.d.-a, n.d.-b, n.d.-c). Cervical cancer is preventable due to HPV vaccination. Cervical cancer screening can help detect pre-cancers when they are treatable and prevent cervical cancer from developing (Hartman, 2023, January 24). Colorectal cancer screening can also be preventative (Division of Cancer Prevention and Control, 2023; U.S. Preventive Services Task Force, 2021, May 18).

Cancer Disparities

The burden of cancer is not evenly distributed across populations, and inequities in cancer incidence and outcomes are well-documented (Zavala et al., 2021). For example, African American women have a higher incidence of breast cancer than White women under age 45, but much lower incidence than White women between the ages of 60-84; however Black women are more likely to die of breast cancer than White women at every age (Copeland, Lake, & Firth, 2013; Howlader et al., 2014). Additionally, non-Hispanic African American women have the third-highest incidence of cervical cancer (after Hispanic women and non-Hispanic American Indian and Alaskan Native women) and “are more likely to die from the disease than women of any other race or ethnicity” (O'Hara, 2022;

United States Cancer Statistics (USCS) Working Group, 2023, June). As another example, African Americans have the highest incidence and mortality rates of colorectal cancer compared to all other racial and ethnic groups in the U.S. (Augustus & Ellis, 2018). These health inequities are driven by a combination of social, economic, and environmental factors such as lack of access to health care, poverty, and systemic and structural racism (Division of Cancer Prevention and Control, 2021).

Growing research suggests that disparities in cancer morbidity and mortality are often a result of gaps or failures in receiving guideline-recommended health care services along the cancer care continuum, from screening and diagnosis through treatment and survivorship (Zapka, Taplin, Ganz, Grunfeld, & Sterba, 2012). These health care failures result in low levels of screening, lack of timely follow-up, and delays in receiving care (Pruitt, Shim, Mullen, Vernon, & Amick, 2009). Racial minorities, residents of rural areas, and low-income individuals are among those who experience these failures and thus disparities in cancer outcomes (Singh & Jemal, 2017). There is growing evidence that socioeconomic barriers are a major driver of these health care failures (Hall et al., 2018; Kurani et al., 2020; Subramanian & Keating, 2017; Tangka et al., 2020).

A.2. Purpose and Use of the Information Collection

This research study will help CDC examine the social and economic barriers that individuals who were recently diagnosed with colorectal, breast, and cervical cancer face at each stage of the cancer care continuum, from screening through survivorship. We are also interested in learning about caregivers' experiences including the barriers they faced as well as the barriers they perceived their care recipients faced. This project will improve our understanding of the cancer care experience, and how experiences may vary across cancer care continuum and for different populations. CDC may use the findings from this research to inform efforts aimed at increasing access to cancer care services, reducing the burden of cancers and closing the disparities gap.

Details of the data collection activities are provided below:

Survey Data Collection

Individuals previously diagnosed with cancer will be randomly sampled from three state cancer registries (California, North Carolina, and Texas). We will begin by inviting all survey participants (Wave 1 Survivor, Wave 2 Survivor, and Caregiver) to complete the web-based version of the instrument (**Attachment 2a** [English] and **Attachment 2c** [Spanish] for Wave 1 Survivor Survey; **Attachment 3a** [English] and **Attachment 3c [Spanish]** for Wave 2 Survivor Survey; and **Attachment 4a** [English] and **Attachment 4c** [Spanish] for Caregiver Survey) and will provide the

print version (**Attachment 2b** [English] and **Attachment 2d** [Spanish] for Wave 1 Survivor Survey; **Attachment 3b** [English] and **Attachment 3d [Spanish]** for Wave 2 Survivor Survey; and **Attachment 4b** [English] and **Attachment 4d** [Spanish] for Caregiver Survey) to non-respondents of the web-based version. All communications related to the Wave 1 Survivor Survey can be found in **Attachments 2g** (English) and **2h** (Spanish). During Wave 1, survivors will be asked if they had a caregiver that provided them with support during their cancer journey. If so, they could choose to provide the caregiver's contact information. Once we have their contact information, caregivers will be invited to complete the web-based version of the Caregiver instrument and will provide the print version to non-respondents of the web-based version. All communications related to the Caregiver Survey can be found in **Attachments 4g** (English) and **4h** (Spanish). All communications related to the Wave 2 Survivor Survey can be found in **Attachments 3g** (English) and **3h** (Spanish).

We will use Voxco Online survey software to develop the web-based instruments. Voxco's customized user interface will provide a clean, simple, and professional appearance, facilitating ease of use. We will ensure that the Web design meets CDC requirements, minimizes respondent burden, and maximizes data quality. We will mail paper surveys to participants as well, to overcome barriers including limited digital literacy and unreliable internet access, which is intended to improve the response rates. With these methods in place, we expect to achieve a sufficient sample size for robust statistical analyses.

We will provide CDC with a clean, de-identified final SAS dataset of survey responses from the Wave 1 Survivor Survey, Wave 2 Survivor Survey, and Caregiver Survey. The data will be used by CDC and its contractors, during the last 12 months of the study, to assess barriers and facilitators to care along the cancer continuum and whether any patterns exist within specific subpopulations (e.g., by race, sex, geographic location, rurality).

Survivor and Caregiver Interviews

In our survivor and caregiver surveys, we will provide an option to volunteer (as no incentive will be provided) for a 1-hour online interview 1-7 months later. From among those who volunteer, we will select 20 survivors and 20 caregivers to interview, focusing on variation in race and ethnicity and geographic residence. All communications related to the Survivor Interviews and Caregiver Interviews can be found in **Attachments 5c** and **6c**, respectively. The interviews will be conducted in English and will provide an opportunity for survivors and caregivers to provide more detail on their respective experiences as a cancer patient/survivor and caregiver, including their primary barriers to accessing care and specifically how social determinants of health (e.g., transportation, housing, employment

status) impacted their experiences (see **Attachment 5a** for Survivor Interview Guide and **Attachment 6a** for Caregiver Interview Guide). The contractors will triangulate these qualitative data with survey findings to provide additional context for quantitative findings and also identify potential extenuating circumstances for consideration.

Involvement of Cancer Patient/Survivor Advocacy Organizations

We will partner with cancer survivor and caregiver groups (e.g., local affiliates of the Komen Foundation and the American Cancer Society) in each of the three states to develop and implement a communication strategy to ensure cancer survivors, their caregivers, and providers receive information about the project before the initial survey mailings. We have developed an Email Blast Ad (**Attachment 2i**) and a One-Page Flyer (**Attachment 11**) to provide general information about the planned surveys. This communication strategy is intended to increase survey response rate during data collection.

We will recruit advocacy group representatives from the advocacy groups we have prioritized based on the type of cancer they address as well as their reach (e.g., national, within NC, CA or TX). We will conduct two virtual focus groups with about eight representatives in each. Each focus group will be 1 hour.

Use of Study Findings

This study is intended to contribute to generalizable knowledge. One limitation of our approach is recall bias; respondents will be asked to recall events, experiences, and demographics from a point-in-time approximately 3-4 years prior to the data collection efforts. However, the experiences of being diagnosed with and undergoing cancer treatment as well as taking on the caregiver role for a cancer patient – during the SARS-CoV-2 pandemic – are likely indelible memories that participants will be able to recall with greater accuracy than other types of events/experiences from several years ago. Another limitation is that we will have participants from 3 states, versus the entire country, in our sampling frame. However, our sample size calculations were targeted to achieve adequate precision withing various demographic groups (e.g., Black, rural residence). There is thus enough number of individuals within each demographic group to accurately capture potential variation across populations who experience disparities.

A.3. Use of Improved Information Technology and Burden Reduction

We will administer: the Wave 1 Survivor Survey to approximately 3,000 individuals (**Attachment 2a** [English] and **Attachment 2c** [Spanish] for Wave 1 [Online] Survivor Survey;

Attachment 2b [English] and **Attachment 2d** [Spanish] for Wave 1 [Paper] Survivor Survey); the Wave 2 Survivor Survey to approximately 1,200 individuals (**Attachment 3a** [English] and **Attachment 3c** [Spanish] for Wave 2 [Online] Survivor Survey; **Attachment 3b** [English] and **Attachment 3d** [Spanish] for Wave 2 [Paper] Survivor Survey); and the Caregiver Survey to approximately 900 individuals (**Attachment 4a** [English] and **Attachment 4c** [Spanish] for Caregiver [Online] Survey; **Attachment 4b** [English] and **Attachment 4d** [Spanish] for Caregiver [Paper] Survey). We will administer all these surveys via a web-based survey platform, Voxco. This electronic survey platform is accessible via the Internet without downloading or installing specialized software, making it easy and efficient for individuals (e.g., cancer patients/survivors and their caregivers) to complete the survey and for CDC and its contractors to track responses and seamlessly merge into our data analysis software program. Respondents will not be required to own any computer equipment outside of the minimum needed for web browsing. Completing the survey online will eliminate the burden of completing a paper survey; only non-respondents, after 2 mail reminder attempts, will be mailed a paper survey. The survey will be programmed with skip patterns to further reduce respondent burden (i.e., respondents will only see items for which they are eligible to respond). All survey data will be housed in a secure location.

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

We employed several methods to ensure that this primary data collection effort would not be a duplication of other current or previous projects. First, this project was reviewed and approved by CDC leadership at multiple levels: Branch (Epidemiology and Applied Research Branch), Division (Division of Cancer Prevention and Control), and Center (National Center for Chronic Disease Prevention and Health Promotion). Leadership recognized a gap in knowledge and viewed this project as a pilot model of studying barriers related to social determinants of health along a disease continuum, which could be applied to other chronic diseases (e.g., diabetes, heart disease) in the future.

During the development of the Wave 1/Wave 2 Survivor and Caregiver Survey instruments, we conducted a brief environmental scan to identify previous surveys related to economic and social barriers along the cancer care continuum. We were unable to identify any U.S. studies related to barriers along the full cancer care continuum faced by Black or African American and White survivors who had different types of cancer (i.e., breast, cervical, and colorectal). A PubMed search of barriers along the cancer care continuum revealed that only a small number of studies have explored this topic, and none of the studies used primary data collection. For example, Fan et al. (2022) published a

dissemination commentary on formal presentations and panel discussions from the 2021 National Cancer Policy Forum of the National Academies of Science, Engineering, and Medicine, which had sponsored series of webinars that addressed social determinants of health and their associations with cancer care and patient/survivor outcomes. Fan et al. (2022) concluded that housing insecurity is an important barrier related to social determinants of health that impacts care along the cancer care continuum, from screening to survivorship. Gomez et al. (2015) conducted a literature review to explore the impact of neighborhood social and built environment factors on cancer diagnosis, treatment, and survivorship (but not screening). Finally, Winkfield et al. (2021) described convening an expert roundtable to develop an actionable framework that addresses cancer disparities among medically underserved groups in the US. The framework includes strategies to address barriers along the cancer care continuum.

Previous CDC projects have used primary data collection to explore barriers related to social determinants of health for survivors of one specific type of cancer, at one point along the cancer care continuum. For example, *Patterns of initial and repeat mammography screening among African American and white women: a comparative study* (2019-2022) explored the impact of factors including social determinants of health on screening patterns of African American and White breast cancer survivors. Additionally, *Insurance Coverage, Employment Status, and Copayments/Deductibles Faced by Young Women Diagnosed with Breast Cancer* (2014-2018) investigated the financial barriers faced by young breast cancer survivors and whether these barriers varied by age at diagnosis (when compared by subgroups).

Neither the existing literature nor past studies have conducted explored barriers across the entire cancer care continuum. Furthermore, other Federal agencies are not doing this work and there is no duplication of effort in asking these research questions. The current planned study is important to address this knowledge gap. The findings from our project can be used for planning future interventions to reduce cancer disparities and other health disparities.

A.5. Impact on Small Businesses or Other Small Entities

The proposed collection does not include any small entities, only individuals who were previously diagnosed with cancer and their caregivers, as well individual staff representatives from cancer patient/survivor advocacy organizations.

A.6. Consequences of Collecting the Information Less Frequently

We have devised an efficient process to collect the required information. Individuals' diagnosis with cancer will receive a first survey on cancer screening, diagnosis, and treatment barriers. The individuals who respond to Wave 1 will receive the Wave 2 survey to explore barriers related to the survivorship period. The two rounds of data collection will provide comprehensive information on barriers across the cancer care continuum. Caregivers are only contacted once to complete the survey. Survivors and caregivers will be interviewed one time after completing their first surveys. Additionally, representatives from cancer patient/survivor and caregiver advocacy organizations will participate in focus groups one time. If the collection is conducted less frequently, we will be unable to obtain comprehensive and complete data from the perspective of both individuals diagnosed with cancer and their caregivers, as well as the organizations that support them. Our team may not be able to identify the key findings and data-driven evidence that can address barriers to care along the cancer continuum.

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

This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the FRN and Efforts to Consult Outside the Agency

Part A: Public Notice

A 60-day Federal Register Notice was published in the *Federal Register* on September 26, 2023, vol. 88 No. 185, pp. 66004 (see **Attachment 9**).

CDC did not receive public comments related to this notice.

Part B: Consultation

The following consultations were made for this data collection.

Table 1. External Consultations

Name	Title	Affiliation	Phone	Email	Role
OUTSIDE CONSULTANTS					
Sahar Zangeneh, PhD, MA, MS	Principal Investigator	RTI	(919) 541-6000	szangeneh@rti.org	Oversee all instrument development, data collection, analyses, and dissemination activities.
Nikie Sarris Esquivel, PMH	Analyst	RTI	(919) 541-1248	nsarris@rti.org	Lead overall survey content development. Lead IRB and OMB application development.
Timothy Flanigan, MA	Programmer	RTI	(919) 485-7743	tsf@rti.org	Lead online survey programming and cognitive testing of the online instrument. Oversee paper instrument development.
Juliet Sheridan, MPH	Analyst	RTI	(919) 485-7625	jsheridan@rti.org	Lead development of Wave 2 Survey, support development of Wave 1 and Caregiver Surveys. Support translation of surveys and communication materials into Spanish.
Madeleine Jones, BS	Project Manager and Analyst	RTI	(608) 417-9156	madeleinejones@rti.org	Lead project management activities. Lead the development of communication materials.
Amarilys Bernacet, MPH	Analyst	RTI	(919) 316-3760	abernacet@rti.org	Lead Spanish translation of instruments and communication materials.
Carson Hurt, BA	Programmer	RTI	(919) 541-5927	churt@rti.org	Test online survey. Lead development of paper instruments.
Sujha Subramanian, PhD, MA	President and Chief Scientist	Implenomics	(302) 222-5034	sujha.subramanian@implenomics.com	Provides scientific guidance for developing survey instruments, data analysis and dissemination of findings.
Nathan Heffernan, BA	Analyst	Implenomics	(281) 615-4554	nathan.heffernan@implenomics.com	Supports project management activities. Leads outreach to partner advocacy organizations.
Sonja Hoover, MPP	Senior Analyst	Implenomics	(978) 335-7731	sonja.hoover@implenomics.com	Provide support for qualitative data collection and analyses

Table 2. Consultations within CDC

Name	Title	Affiliation	Phone	Email	Role
Florence Tangka, PhD, MS	Health Economist	Division of Cancer Prevention and Control's Epidemiology and Applied Research Branch	(770) 488-1183	fbt9@cdc.gov	Provides oversight, offers input for survey development & guides prioritization of findings for publication
Jane Henley, MSPH	Epidemiologist	Division of Cancer Prevention and Control's Cancer Surveillance Branch	(770) 488-4157	skh3@cdc.gov	Provides oversight, offers input for survey development & guides prioritization of findings for publication
Susan Sabatino, MD, MPH	Medical Officer	Division of Cancer Prevention and Control's Epidemiology and Applied Research Branch	(770) 488-8372	bzo8@cdc.gov	Provides oversight, offers input for survey development & guides prioritization of findings for publication
Cheryll Thomas, MSPH	Epidemiologist	Division of Cancer Prevention and Control's Office of the Director	(770) 488-3254	Zzg3@cdc.gov	Provides oversight, offers input for survey development & guides prioritization of findings for publication

A.9. Explanation of Any Payment or Gift to Respondents

Survey participants (to Wave 1 Survivor Survey, Wave 2 Survivor Survey, and Caregiver Survey) will each receive an incentive of $40 for each completed survey. Incentives have shown to increase the response rate. We want to maximize response to the survey to ensure adequate sample size among demographic groups (e.g., rural, race and ethnicity, cancer type) in order to have enough power to assess potential variation across groups that experience cancer disparities. This incentive is consistent with federal guidelines.

Participants diagnosed with cancer and their caregivers who will be interviewed, and representatives from cancer patient/survivor advocacy groups who will participate in focus groups, will be asked to volunteer their time to participate and will not receive monetary incentives. Participants will likely be motivated to participate knowing that their insights are contributing to improving access to care along the cancer continuum.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondent

The National Center for Chronic Disease Prevention and Health Promotion's Information Security Officer has reviewed the submission and has determined that the Privacy Act does not apply.

Individuals who complete the Wave 1, Wave 2 or Caregiver Survey will be asked for contact information (i.e., name and email address; name and mailing address) in order to process their incentive. Individuals who complete the Wave 1 or Caregiver Survey will be asked to provide contact information (i.e., email address and/or phone number) if they would like to volunteer for a one-hour interview. This contact information will not be linked to data in our analysis; data will be deidentified for analysis. The contractor and subcontractor will use the contact information for the sole purposes of processing incentives and communicating with individuals about scheduling a follow-up interview. The consent form for the Wave 1 Survey is located in **Attachment 2e** (English) and **Attachment 2f** (Spanish). The consent form for the Wave 2 Survey is located in **Attachment 3e** (English) and **Attachment 3f** (Spanish). The consent form for the Caregiver Survey is located in **Attachment 4e** (English) and **Attachment 4f** (Spanish).

Individuals who participate in interviews and focus groups will not be asked to provide additional contact information as part of the data collection, as there are no incentives for participating. The consent form for the survivor interviews is located in **Attachment 5b**. The consent form for the

caregiver interviews is located in **Attachment 6b**. The consent form for the focus groups with representatives from cancer patient/survivor advocacy groups is located in **Attachment 7b**.

Data will be encrypted and stored by the contractor in a secure database. Technical controls are in place to manage user identity, identity proofing, authentication, and authorization. Records will be retained, stored, and disposed of in accordance with CDC's Records Control Schedule for Scientific and Research Project Records (N1-442-09-01). PII will be removed before records are archived. The approach to make any survey data publicly available will be developed in concordance with CDC and cancer registry data sharing policy.

The subcontractor will only have access to contact details (i.e., name, address, phone number and email) necessary to send invitations to request participation in the survivor and caregiver interviews. We will be requesting participants to self-identify in the survey if they are willing to participate in the interviews. Interview responses will contain no identifiers and will only be linked to the patient contact details via the study ID. All information will be stored in a secure electronic folder that will be password protected and only accessible to authorized study team members.

CDC will retain de-identified data records according to the Federal Records Retention Schedule for Scientific and Research Project records. The information collection contractor and subcontractor will transmit records to CDC before the funding award terminates.

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

The contractor's IRB determined that this study constitutes research with human subjects; the contractor's IRB reviewed the proposed study and approved the proposed data collection, analysis and dissemination activities on March 19, 2024 (**Attachment 10**). The surveys and interviews will include topics that may be of a sensitive nature to participants including their co-morbidities, experience encountering discrimination from a health care professional, and various social determinants of health (e.g., employment status, insurance status, housing, primary mode of transportation). In addition to written consent forms, which will be provided to all survey participants in the mailing with their introductory survey invitation, the launch page of each web survey and the first page of each paper instruments will summarize the consent form and reiterate that participation is voluntary. Similarly, all interview and focus group participants will receive a consent form prior to the date of their interview/focus group and will be verbally reminded prior to the start of each interview/focus group about the key components of consent (e.g., purpose of the study, that their participation is voluntary).

All reminder/follow-up communications for each group of potential participants will include elements of consent as well.

A.12. Estimates of Annualized Burden Hours and Costs

The Wave 1 Survivor Survey and Wave 2 Survivor Survey are each designed to be no longer than 20 minutes to complete. These surveys will be available online and on paper. We will invite 12,000 cancer survivors to participate in the Wave 1 Survivor Survey; all respondents to the Wave 1 Survivor Survey will be invited to participate in the Wave 2 Survivor Survey. Based on past studies, we anticipate that the Wave 1 Survivor Survey will be completed by up to 3,000 respondents and a subset of these respondents (n=1,200) will complete the Wave 2 Survivor Survey. Each respondent who completes the Wave 1 Survivor Survey will be asked to provide the contact information for one of their caregivers to complete the Caregiver Survey. The Caregiver Survey is designed to take no more than 15 minutes to complete. This survey will be available online and on paper. If all 12,000 cancer survivors completed the Wave 1 Survivor Survey and provided contact information for one caregiver, 12,000 caregivers could be invited to participate in the Caregiver Survey; however, we estimate that 900 caregivers will complete the Caregiver Survey. The survivor interviews will take up to 1 hour per interview to complete. We will interview 20 survivors. The caregiver interviews will take up to 1 hour per interview to complete. We will interview 20 caregivers. We will hold focus groups with staff from patient/survivor advocacy organizations which will each take up to 1 hour. There will be 2 focus groups, with 8 respondents in each group.

Responses to all data collection instruments will be completely voluntary. For all data collection, the total estimated burden response is **1,681 hours**, as shown in **Table A12A.**

The total cost to respondents is **$32,798.02**, as summarized below in ***Table A12-B***.

The average hourly wage of an individual previously diagnosed with cancer and a caregiver ($19.46/hr) was calculated taking the median annual income per person in the US ($40,480) and dividing by the average number of hours worked by someone in the US per year (2,080 hours, which is the equivalent of 40 hours per week times 52 weeks). We captured these metrics from the Federal Reserve Bank of St. Louis, with additional information from the U.S. Bureau of the Census census(U.S. Bureau of the Census, 2023).

We capture the average hourly wage of representatives from cancer patient/survivor nonprofit advocacy organizations using the labor category for “community and social service specialists, all

other" from the Bureau of Labor Statistics (Bureau of Labor Statistics, 2022, May) (May 2022 National Occupational Employment and Wage Estimates (bls.gov)).

Table A12A. 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 Hours
Wave 1 Survivor Survey Respondents	W1 Survey Instrument	3,000	1	20/60	1,000
Wave 2 Survivor Survey Respondents	W2 Survey Instrument	1,200	1	20/60	400
Survivor Interviewees	Survivor Interview Guide	20	1	1	20
Caregiver Survey Respondents	Caregiver Survey Instrument	900	1	15/60	225
Caregiver Interviewees	Caregiver Interview Guide	20	1	1	20
Patient/Survivor Advocacy Group – Focus Group Participants	Advocacy Representatives Focus Group Guide	16	1	1	16
Total					**1,681**

Table A12-B: Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Annual Burden Hours	Average Hourly Wage Rate	Total Respondent Labor Cost
Individuals previously diagnosed with cancer	W1 Survey Instrument	1,000	$19.46*	$19,460.00
Individuals previously diagnosed with cancer	W2 Survey Instrument	400	$19.46*	$7,784.00
Individuals previously diagnosed with cancer	Survivor Interview Guide	20	$19.46*	$389.20
Caregivers	Caregiver Survey Instrument	225	$19.46*	$4,378.50
Caregivers	Caregiver Interview Guide	20	$19.46*	$389.20
Representatives from cancer patient/survivor advocacy organizations	Advocacy Representatives Focus Group Guide	16	$24.82**	$397.12
Total				**$32,798.02**

*U.S. Bureau of the Census. (2023), Real median personal income in the United States [MEPAINUSA672N]. Retrieved from FRED, Federal Reserve Bank of St. Louis tabwebsite: https://fred.stlouisfed.org/series/MEPAINUSA672N

** U.S. Bureau of Labor Statistics. (2022), May 2022 National Occupational Employment and Wage Estimates, United States. Retrieved from Occupational Employment and Wage Statistics website: May 2022 National Occupational Employment and Wage Estimates (bls.gov)

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

There are no other costs. The survey collection tool requires no special hardware or software and is free to all individuals. Paper surveys will be mailed with prepaid business reply envelopes. The Zoom software for interviews and focus groups is free to all individuals, and participants may choose to join via phone only if they do not have internet access.

A.14. Annualized Cost to the Federal Government

Costs to the federal government include the costs of CDC personnel associated with the project and the cost of a contractor for information collection and management. The total annualized cost to the government is $696,473. Annual costs include personnel costs of federal employees involved in oversight and analysis. The annual staff cost is estimated at $49,072 (0.15 GS-14 Health Economist FTE [$25,181], two .05 GS-14 Health Scientists FTE [$8,394 each], and .05 GS-13 Health Scientist FTE [$7,103]). The average annual cost for the contractor (for the development of data collection instruments, data collection, data analysis, interpretation of findings, reporting, and dissemination) is $647,401 per year for a three-year total of $1,942,203. The breakdown of how that estimate was reached is also presented below (See ***Table A14-A***).

Table A14.-A. Estimated Annualized Federal Government Cost Distribution

Job Title	Annualized Cost
CDC Personnel Cost	$49,072
GS-14/10 health economist at 15% FTE, $25,181	
GS-14/10 Medical Officer at 5% FTE, $8,394	
GS-14/10 Epidemiologist at 5% FTE, $8,394	
GS-13/10 health scientist at 5% FTE, $7,103	
Contractor Cost	$647,401
Total	$696,473

A.15. Explanation for Program Changes or Adjustments

This is a new request for approval.

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

We will link each individual with cancer's survey data to their cancer registry data, creating a linked analytical data file (which will be deidentified for subsequent analysis). All quantitative (survey)

data from survivors and caregivers will be analyzed using statistical analysis software (e.g., SAS, R). We will conduct descriptive analysis and use regression analysis to assess associations between individual- and community-level barriers to care and cancer-related outcomes across the cancer care continuum.

For qualitative data analysis, we will use an inductive–deductive approach. Interview and focus group data will be coded in qualitative analysis software or Excel. We will conduct a thematic analysis to identify common themes from focus group and interview participants.

In collaboration with CDC, the contractor and subcontractor will disseminate the results of the study to colleagues in federal agencies, cancer patient/survivor advocacy organizations, public health researchers, and the general public. We anticipate findings will be shared in a final report and at least three publications of manuscripts in peer-reviewed journals (See ***Table A16***).

Table A.16. Estimated Time Schedule for Project Activities

Activity	Timeline
Receive approval from California, North Carolina, and Texas state IRBs	1-2 months after OMB approval
Identify sampling frame (i.e., collaborate with cancer registries to obtain sample information)	3-5 months after OMB approval
Administer Wave 1 Survivor Survey (mail recruitment letters w/ enclosed consent forms)	3-7 months after OMB approval
Administer Caregiver Survey	9-13 months after OMB approval
Conduct Survivor and Caregiver Interviews	8-14 months after OMB approval
Administer Wave 2 Survivor Survey	15-17 months after OMB approval
Conduct focus groups with representatives from cancer patient/survivor advocacy organizations	18-19 months after OMB approval
Complete quantitative data cleaning and analysis for all 3 surveys (on a rolling basis)	6-17 months after OMB approval
Complete qualitative data cleaning and analysis for all interviews and focus groups	8-19 months after OMB approval
Complete final report	23 months after OMB approval
Publication(s)	Within 24 months after OMB approval

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

The display of the OMB expiration date is appropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

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