COVER PAGE:

Cancer Survivorship and Caregiver Leadership Education for Clergy Wives & Widows (CSC for CWWs)

NCT: NCT04544241

Date of Document: October 24, 2021

Charles R. Drew University of Medicine and Science
Office of Research Integrity and Compliance
Institutional Review Board

DATE:	October 25, 2021
TO:	Sharon Cobb, PhD
FROM:	CDU Institutional Review Board
PROJECT TITLE:	[1530494-3] Cancer Survivorship and Caregiver Leadership Education for Clergy Wives and Widows_
SUBMISSION TYPE:	Amendment/Modification
ACTION:	APPROVED
APPROVAL DATE:	October 24, 2021
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	45CFR46.110 Category (b)(1)(ii)
FUNDING SOURCE:	NIH/NIMHD U54MD007598 Accelerating Excellence in Translational Science (AXIS) Jaydutt Vadgama, PhD
FWA NUMBER:	FWA00002736

Thank you for the Amendment/Modification submission for this project. The Charles R. Drew University of Medicine and Science (CDU) Institutional Review Board (IRB) has APPROVED your submission.

This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

The amendment approval includes the following changes:

- Program activity name changed from workshops to conferences.
- Addition of a $40 digital gift card for conference participants as financial compensation for their time and participation at the conferences and completing surveys.
- Revisions to conference participant consent form to address the name change and addition of gift card compensation.

- Added a flyer for recruitment of conference participants.
- Submitted curriculum for training clergy widows and wives.

REGULATORY DETERMINATION(S):

- Expedited Review 45CFR46.110(b)(1)(ii)

LIST OF STUDY DOCUMENTS IN THIS PACKAGE:

- Amendment/Modification - F112 - Amendment Application 10_2021.doc (UPDATED: 10/18/2021)
- Application Form - 10.17.2021.tracked copy_Appendix B - IRB Research Protocol Template CSC for CWWs.doc (UPDATED: 10/18/2021)
- Application Form - 10.17.2021.clean copy_Appendix B - IRB Research Protocol Template CSC for CWWs.doc (UPDATED: 10/18/2021)
- Application Form - clean copy - Application for Study Review CSC for CWWs_10_10_2021.doc (UPDATED: 10/10/2021)
- Application Form - tracked copy - Application for Study Review CSC for CWWs_10_10_2021.doc (UPDATED: 10/10/2021)
- Consent Form - clean_copy_consent form_conference attendees_10_19_2021.docx (UPDATED: 10/20/2021)
- Consent Form - consent form_conference attendees_10_19_2021_tracked copy.docx (UPDATED: 10/20/2021)
- Other - CWW curriculum_2021.docx (UPDATED: 10/18/2021)
- Publication Materials - Flyer_CSC.pdf (UPDATED: 10/20/2021)

If you have any questions, please contact Margie Dike at 323-357-3649 or margiedike@cdrewu.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been issued in accordance with all applicable regulations, and a copy is retained within Charles R. Drew University of Medicine and Science's records.

Responsibilities of the Principal Investigator

The Principle Investigator has the ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human participants, and adherence to any stipulations imposed by the IRB.

The Principle Investigator and the study team must follow the Charles R. Drew University of Medicine and Science policies and procedures, all applicable federal regulations, state and local laws regarding the protection of human participants in research. In addition,

1. Have qualified personnel, who have been properly trained on protecting human research participants, to conduct the project according to the protocol approved by the IRB.
2. Do not implement changes in the approved protocol, informed consent, or documents without prior approval by the IRB (except when necessary to eliminate apparent immediate hazards to the participant). Please use the appropriate amendment form for this procedure.
3. Obtain legally effective written consent from research participant or their legally authorized representative (LAR) using only the currently approved consent form, if written consent is required.
4. Report unanticipated problems involving risks to participants or others and serious or unexpected adverse events, protocol deviations or incidents, according to the IRB reporting requirements. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.
5. Ensure that adequate resources are available to protect the participants before starting the research project.
6. Arrange for a co-investigator to assume direct responsibility in your absence, if you are unavailable to direct this research personally, as when on leave or on vacation. If there is no co-investigator in the application, you must provide written notification to the IRB of the responsible party in advance.
7. Please be aware that IRB approval is not in itself an approval to start the research. Investigators must obtain other regulatory approvals, institutional clearances or external approvals, as appropriate, before starting the study.

Charles R. Drew University of Medicine and Science
Office of Research Integrity and Compliance
Institutional Review Board

IRB Research Protocol

Version # 3; Date: 10-10-2021

Date: 10-10-2021	Federal Funding:	☐ No ☒ Yes
IRBNet#: 1515756-3	FDA-regulated Study:	☒ No ☐ Yes If yes, use the NIH protocol template.
☒ New Project ☐ Amendment ☐ Other:		
☒ Faculty ☐ Student ☐ Resident ☐ Staff ☐ Other:		

Title of the Research Protocol

Cancer Survivorship and Caregiver Leadership Education for Clergy Wives & Widows (CSC for CWWs)

I. Project Information

1. Principal Investigator: Sharon Cobb, PhD, RN

2. Faculty Sponsor(s)/Co-Investigators: Kathye Jenkins, MPH

II. Research Question

1. Hypothesis: State hypothesis if applicable.

2. Background or Introduction: State the background of the study, including a critical evaluation of existing knowledge and the information gaps that this research proposes to fill. Describe previous work that provides a basis for the proposed research and that supports the expectations of obtaining useful information without undue risk to human participants. Please include relevant citations.

The National Cancer Institute report that African Americans (AAs) have higher death rates when compared to Whites for many types of cancers, such as prostate cancer and breast cancer[4]. The target geographical area of this proposed study is designated as Service Planning Area 6 (SPA 6) in Los Angeles County, including cities of Watts, Compton, and areas of South Los Angeles. The SPA 6 area is primarily populated by underrepresented minority groups, with 27% identifying as AA[5]. The death rate per 100,000 individuals in SPA 6 for lung, breast, cervical,

and colorectal cancer is 30.7, 22.8, 5.8, 16.0, respectively.[5] Culturally and spiritual sensitive interventions for cancer survivorship and caregiving among AAs are significant to promoting and improving quality of life. Racial/ethnic disparities in cancer survivorship continue to persist, which can be attributed to factors such as lack of medical insurance, barriers of detection and screening, more advanced stage of cancer and comorbidities at diagnosis among minorities, and unequal access to cancer treatment[6].

In the African American church, clergy wives and widows (CWWs) are faith-based stakeholders that can facilitate educational sessions for African Americans on cancer survivorship and caregiving [7]. Faith leaders are commonly utilized to lead interventions and work with research partners to improve the health of populations. However, wives and widows of faith leaders commonly perform many roles in faith-based institutions, such as the leader of the women's ministry group. Even though their role may not be very visible compared to their spouses, they hold a dynamic role in the African American church. Many CWWs perform activities and foster mentorship with congregation members using spirituality as the centrality of their relationships and communication with others, especially congregation members. Spirituality is uniquely different from religious development as the focus is more on personal relationship between a higher divine being and the individual and expressing positive attitudes and behaviors with others[8]. This group of spiritual women are influential in increasing social support and disseminating health information are identifying critical needs. Fear of being diagnosed with cancer and cancer fatalism is more prevalent among minority groups as compared to Whites[9], which may decrease with the therapeutic group of CWWs. Minority populations also have fewer discussions of health promotion and behaviors with their healthcare providers[10], which may be assisted with the prompting and education with CWWs. Additionally, CWWs can be beneficial in improving cancer outcomes among their faith-based institution and improving cancer screening rates. Even though they are understudied, CWWs may be aware of current cancer survivorship and caregiving burdens among their faith-based congregation and attempted to provide a degree of patient navigation and advocacy. More importantly, these CWWs may understand the complexity of the cancer survivor and/or caregivers, and other related factors, such as culture and spirituality to improve quality of cancer care and the cancer survivor and caregiver outcomes in the symbiotic relationship. Throughout this program, CWWs will gain support from their cohort of peers and facilitators.

The proposed project is ***significant*** for the training of CWWs as leaders of cancer and caregiver related issues among African American populations in their faith-based institutions. A community-based partnership consisting of CWWs will provide a structured learning program to enhance their knowledge of cancer survivorship and caregiving and their issues, with special consideration of culture and spirituality [11]. The long term outcome for this program is to contribute to the reduction of system-level and provider barriers by enabling CWWs as community navigators for cancer care and caregiving management[12].

Preliminary Studies

Our research team has been working with both minority cancer survivors and caregivers. The core investigator (Dr. Cobb) is currently conducting a pre-post intervention study on providing leadership education to nursing students in the areas of cancer survivorship and caregiving and assessing their need for essential services and education and providing support and resources. In addition, another recent study focused on the need of an oncology patient navigation training course for all healthcare-focused students that would involve aspects of management and care. Focus group findings revealed that specialized training and education for health care focused students on cancer survivorship and caregiving would equip them with skills and knowledge to

not only understand their experience but aid in improving health care outcomes as future healthcare providers.

3. Objective(s): The objective of this study is to

The *long-term goal* of this proposed study is to develop a leadership training program for CWWs with emphasis on cancer survivorship and caregiving. The *objective of this pilot project* is to develop and test the CSC for CWWs, with specific emphasis of cultural and spiritual considerations of African American cancer survivors and caregivers.

4. Purpose of the study: What are the specific scientific aims of this study?

We will test the feasibility of the proposed program implementation by pursuing the following specific aims:

1) To increase cancer survivorship and caregiving leadership education and activities for AA CWWs by creating an educational partnership program aimed towards mentorship
2) Develop skills and knowledge to perform an in-depth culturally sensitive need assessment and intervention map tailored for aging African American cancer survivors and caregivers, and
3) Enhance awareness of cancer-related health issues and its relationship to key determinants among aging cancer survivors and caregivers

III. Research Design and Methodology

5. Study Design: What type of study is this? (*e.g*. Retrospective, prospective, longitudinal) Describe the research procedures that will be followed. Please indicate those that are experimental and those that may be considered to be standard treatment. Describe all activities involving human participants (what types of participants will the study involve? –be specific: gender, race, age…) and explain the frequency and duration of each activity. Specify recruitment techniques. What variables will be taken into consideration? And include an exact number of participants (*e.g*. 100 instead of 100-135).

   This is a prospective study. The project has 4 phases.
   Phase I will consist of focus groups of both URM cancer survivors and caregivers (*Aim 1*).
   Phase II analyzes the focus group sessions to develop a need assessment for URM cancer survivors and caregivers and the content and organizational structure for the CSC for CWWs training education program for clergy wives and widows (*Aim 2).*
   Phase III implements the year-long CSC for CWWs training program for clergy wives and widows at CDU that focuses on various areas of the cancer survivorship experience, including the delivery of cultural competency and care and providing hope and comfort (*Aim 3)*.
   Phase IV focuses on the evaluation of performance data, strategies, and discussion of barriers and successes.

   Focus Groups: We will have 20 participants (cancer survivors and caregivers).
   CSC for CWWs: We will 50 clergy wives and widows
   Conference Participants: We will have at least 40 participants

For Administration of the Consent Process: The PI, Co-I, and the research assistants would be able to invite potential participants and describe the program to them via telephone,

teleconferencing meeting, or email. The PIs will review study protocol with participants and obtain signed informed consent from each participant before they could participate in the study. Participants will complete the eligibility screening questionnaire on SurveyMonkey. If they are deemed eligible, they can decide to proceed to the next section of the SurveyMonkey site in which they can read the consent form and electronically sign the consent. After they submit the consent form on the *SurveyMonkey site,* they will receive a signed copy of the consent form and a blank copy of the consent form via email from the research team.

All research personnel will have completed the CITI training requirements for investigators involved in social/behavioral research with human subjects and the Health Information and Privacy Security (HIPS) training and have been trained in the research area to administer the consent process.

6. Inclusion criteria: Who will be included?

Focus Group*:* For the focus group sessions, participants will consist of cancer survivors and caregivers. To be eligible for the focus group, the participant must: 1) be either a cancer survivor or cancer caregiver, 2) identify as an underrepresented minority (African American/ Black, Asian/Pacific Islander, Hispanic/Latino, or American Indian/Alaskan Native), 3) have access to the internet on a computer desktop, laptop, tablet, or cell phone, and 4) at least 45 years or older.
CSC for CWWs program: To be eligible for CSC for CWWs program, the participant must: 1) be either a clergy wife or widow, 2) identify as African American/Black, 3) live within the boundaries of Los Angeles County, 4) speak and/or read English, and 5) have access to the internet on a computer desktop, laptop, tablet, or cell phone..
Conference Participants: For the workshops led by CWWs, participants will consist of community residing individuals. To be eligible for the conferences, the participant must: 1) speak and/or read English, 2) at least 18 years of age or older, and 3) have access to the internet on a computer desktop, laptop, tablet, or cell phone.

7. Exclusion criteria: Who will be excluded?

Participants who do not identify as a clergy wife or widow and African American/Black will be excluded from the CSC for CWWs study. Individuals who are not cancer-survivors or caregivers and younger than 45 years old will be excluded from the initial focus group. Those who are under the age of 18 will be excluded from the CSC for CWWs intervention program and workshops. All participants who are unable to *have access to the internet on a computer desktop, laptop, tablet, or cell phone will be excluded.*

8. Procedures: What cases will be identified and by what means? (*i.e*. reviewing hospital database systems, focus groups, etc). How long would the study take if retrospective or prospective? How the study will be conducted after approval is obtained from the IRB.

Focus Group*:* For the focus group sessions, qualified participants who are cancer survivors and caregivers. Using a purposive sampling approach, all researcher team members will utilize their contacts to recruit participants for all aspects of the study, through email invitations to participate. We will distribute flyers and emails throughout the CDU physical and digital environment, local community organizations, and senior centers. The research staff will follow-up with interested individuals by telephone to schedule them for the focus group with a given

date and time. The participants will provide written consent at the time of the focus group. We are targeting to recruit and retain 10 cancer survivors and 10 cancer caregivers.

CSC for CWWs program: We will distribute flyers and emails throughout the CDU physical and digital environment, in addition to the Cynthia Perry Ray Foundation. The research staff will also conduct brief presentations at various meetings for the Cynthia Perry Ray Foundation about the study and provide a contact number and email for interested participants. We will obtain consent prior to the start of the CSC for CWWs program. We are targeting to recruit and retain 50 participants.

Conferences Led by CWWs: Flyers and emails will also be distributed throughout the CDU physical and digital environment, *Cynthia Perry Ray Foundation*, and local faith-based organizations and churches. We are hoping to recruit 40 attendees as participants. The flyers and emails will have information on when the conferences will be held.

Study Procedures

Phase I: After recruitment of cancer survivors and caregivers, we will plan the dates and times of the two focus group sessions with scheduling preferences of the participants. The goal is to have all focus group sessions held on a digital platform (*Zoom*), which will be password protected. Each focus group session is expected to last one hour. Prior to focus group session, we will obtain written consent and participants will complete a demographic questionnaire on Survey Monkey. The focus group sessions will inquire about cancer and caregiving related knowledge, resources and perceived support issues among cancer survivors and caregivers. Each participant will be compensated with a $50 digital gift card for their time and participation.

Phase II: To meet Aim 1 of creating an educational program aimed towards mentorships, the PIs will analyze the data from the focus group and create the focused curriculum and content area for the CSC for CWWs program (Month 4). The investigators will convene weekly (via in-person or online) to discuss themes and codes of the focus group sessions to inform the CSC for CWWs program development, including embedding culture and community considerations for each topic area and content outlines. The American Society of Clinical Oncology have developed a Core Curriculum for Cancer Survivorship Education (ASCO), with consideration of survivorship care recommendations from the Institute of Medicine[17]. The ASCO was cultivated by utilizing best practices and evidence-based recommendations for oncology care and management. Informed by the ASCO template, we will create the CSC for CWWs program topic curriculum. Each bi-monthly session of the CSC for CWWs program is expected to last two hours and will be delivered in a lecture format over the 6-month program. In addition, the themes and codes of the focus group sessions will assist the investigators in the creation of a specialized survivorship and caregiving care plan that involves cultural and spiritual considerations.

Phase III: Starting in Month 5, the PI and Co-I will begin to recruit CWWs. To meet Aim 2, CWWs will complete the CSC for CWWs program during Months 9-15 and also complete pre- and post- questionnaires (*Cancer Survivorship and Survivorship Self-Efficacy Surveys)* that assess their self-efficacy of both cancer survivorship and cancer caregiving. Each meeting session with CWWs will be monthly and lasts for 2-3 hours during the ten-month duration. During each meeting session, experienced community and academic leaders will present their expertise with relationship to cancer survivorship and caregiving. To receive credit for completion of the CSC for CWWs training program, each participant must provide written consent to participate in the CSC for CWWs program and for collection of data. They will complete a demographic questionnaire and a self-efficacy survey prior and after completion of

the CSC for CWWs program. To meet Aim 3, CWWs will be placed in groups of 10 to collectively create and present four online conferences focused on cancer survivorship and/or caregiving for community faith-based institutions and parishioners as a culminating activity.

The four planned conferences will be tailored around African American survivors and caregivers and will focus on: 1) caregiving for cancer survivors, 2) cancer social support needs and mental wellness, 3) cancer stigma and cancer survivorship care toolkit development, and 4) Cancer awareness, risk factors, and screening. The purpose of the conferences is to provide further information on cancer survivorship and caregiving to the community. Attendees will be asked following the conferences to participate in the post-conference survey. Attendees will provide informed consent and complete survey questions following the online conference through SurveyMonkey. They will receive a $40 gift card for their completion of the survey.

After the completion of the conferences, we will plan and host a CDU online conference (Month 15) in which the participants will present their experience and conferences presentations to the university audience and community members. After fulfilling all requirements of the program, they will be compensated with $200 digital gift card and certificate for their time and participation. Scheduling of the CSC for CWWs monthly sessions will be accordance with the preference of the program participants. In addition, a focus group will be scheduled in Month 15 for the CWWs participants to discuss program outcomes and share experiences of community-led conferences, in addition to perspectives of future directions for community-led research in cancer survivorship and caregiving. CWWs can receive a $50 digital gift card for participation in this focus group.

Phase IV: The investigators will then convene throughout months 15-16 to evaluate performance data, review strategies, discuss barriers and success, and update materials and resources for future CSCLENS program cycles.

IV. Risk/Benefit Assessment

9. Benefits to participants: What is the risk benefit ratio of this research, compared with available alternatives? Describe the potential benefits the participants may receive as a result of their participation in the research**.** *The potential benefits of the research must justify the risks to human participants. The risk benefit ratio of the research must be at least as favorable for the participants as that presented by standard treatments for their condition. When comparing the risk/benefit ratio of research with that of available alternatives, the alternative of doing nothing should be included in the analysis.*

The benefit of this program to the participants is that they will gain knowledge of cancer survivorship and caregiving program.

10. Benefits to society: What benefits to society and the community may be expected?

This study will help the society by providing training to clergy wives and widows as community leaders who are well prepared to manage the complexity faced by cancer survivors and caregivers. These individuals will support the acquisition of knowledge to care for cancer survivors and their caregivers.

11. Risk to participants: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures participants may encounter in the study. State the potential risks – physical, psychological, social, legal or other – connected with the proposed procedures and assess their likelihood and seriousness. And state the breach of confidentiality, distress due to questioning, *etc*.

There is no obvious risk for the participant. However, some participants may experience sadness over the pain experienced by cancer patients that they come in contact with. If that happens, the research team, which has an experienced mental health nurse will provide initial screening and counseling. We will also refer the participant to consult with his/her physician for more in-depth care as necessary.

The research team will be contacting participants via email as well as emailing them a copy of their signed consent form. This may include sensitive information (i.e. name) and identification that they are participating in a study about cancer. We will do our best to ensure that this information is confidential, and data is secured, but there is always risk for data security.

12. Confidentiality:

    a. How will the data be collected and recorded? How will the data be coded to protect personal privacy?

All focus group interviews will be audio-recorded. All interviews will be transcribed verbatim and coded from data codebook developed from the data through an iterative process with all the PIs.

Data Collection

Focus Groups: An experienced facilitator will conduct three focus group sessions with URM cancer survivors, caregivers and clergy wives and widows. We will use a semi-structured interview guide to assess: 1) their biopsychosocial and spiritual health needs, 2) perceived barriers for optimal quality of life and health, and 3) their ability to obtain external support and resources, 4) perceived challenges in their care based on their age and minority status, and 5) Experiences and impact of participation in the study. The interview guide is provided. The focus group interviews will be audio recorded.

Focus Group Demographic Questionnaire: This will include mostly demographic questions which center on the age, gender, education, race/ethnicity, and family income of the participant. The participant must also identify if they are a cancer survivor or cancer caregiver or both. If a cancer survivor, the participant will be asked about the cancer diagnosis and staging, length of disease, time since remission or last treatment, comorbidities and chronic health conditions, and types of cancer treatment received (chemotherapy, radiation, surgery, other (specify). If a caregiver, they will provide length of caregiving and caregiver training, involvement in nursing or medical care of CR, performance of nursing/medical care activities relationship to care recipient, diagnosis of care recipient, health status and chronic conditions hours spent with care recipient each day.

CSC for CWWs Demographic Questionnaire: Demographic information about each CSCLENS program participant will be collected prior to the CSC for CWWs program. Data will include the participant's age, gender, race/ethnicity, enrolled nursing program, years of experience in healthcare industry, and cancer survivor and/or caregiver status.

Cancer Survivorship and Cancer Caregiving Self-Efficacy Survey: Each CSC for CWWs program participant will complete the Cancer Survivorship Self-efficacy and Cancer Caregiving Self-Efficacy survey prior to the beginning of the CSC for CWWs program (T0) and at the completion of the CSC for CWWs program (T1). The instrument is a brief, Likert scale with values ranging from 0-4 for each of the nine questions related to cancer survivors and caregivers' health needs, psychosocial support, and nursing care plan education, with a total score of 36 (*Appendix B & C*). Final scores will be computed for each participant by the sum of correct answers.

Nursing Cancer Survivorship Care Knowledge Survey: This survey, adapted from Lester, Wessels, & Jung (2012) focuses on knowledge about cancer survivorship concepts, cancer treatment and side effects, survivorship issues, and comfort care[40]. All CSC for CWWs participants will complete the survey prior to the beginning of the CSC for CWWs program (T0) and at the completion of the CSC for CWWs program (T1). This measure is a Likert scale with values ranging from 0-4 for each of the 35 questions (*Appendix D)*

CWW-Led Conference Surveys:
: We will utilize the following surveys:
Caregiver Self-Assessment Questionnaire, which is a 18-item questionnaire to investigate the impact of caregiving and related stress.[31] This questionnaire will be directed toward all current and former caregivers.

-Depression, Anxiety, and Stress (DASS-21)[28,] which is a validated combination of three self-report scales designed to measure the emotional states of depression, anxiety and stress.

-Cancer Stigma Scale (CASS) which assesses six subdomains (Severity, Personal Responsibility, Awkwardness, Avoidance, Policy Opposition, and Financial Discrimination)[29,30.] This 25-item questionnaire has Likert-style responses ranging from Definitely Not to Agree Strongly to Not Sure (1-7).

- awareness, risk factors and screening which was adapted from the 2017 Cancer Awareness Measurement, UK (CAM) survey 24-27. This 27-item questionnaire will assess these outcomes of this survey, which mainly consist of Likert style and categorical questions.

Timetable

Phase I (5 months)	**Timing**
Submit initial IRB application	Month 1
Finalize data collection forms and survey instruments; obtain final IRB approval	Month 2
Recruit Cancer Survivors and caregivers	Month 3
Conduct two focus group sessions with Cancer Survivors and caregivers	Month 3-4
Phase II (2 months)	
Analyze and process focus group data and create a needs assessment plan	Month 4
Develop the curriculum and education plan and material for the CSC for CWWs program	Month 4
Phase III (12 months)	
Recruit clergy wives and widows (CWWs) for the CSC for CWWs program	Month 5
Conduct the CSC for CWWs educational program	Month 5-11
Plan and present 5 community workshops led by CWWs at faith-based institutions	Month 11-15

Organize and present CDU on-campus conference with CSC for CWWs participants' presentations	Month 15
Phase IV (5 months)	
Analyze and process outcome evaluation data of the CSC for CWWs program cycles	Months 15-16
Study Closure; initiate journal articles and R01 grant application for multi-institutional study	Month 16

b. How will the data be stored during the study?

All study materials including recordings and electronic documents will be kept on a encrypted laptop or encrypted cloud drive files that can only be accessed by the research team. Paper documents will locked in a cabinet in the PI- Dr. Cobb's locked office on the CDU campus.

c. Who will have access to the data and the data codes? If data with participant identifiers will be released, specify the person(s) and agencies to whom this information will be released?

The only people who will have access to the data and data codes will be the members of the research team… PI Dr. Cobb, Co-Investigator Mrs. Jenkins and Research Assistant Ms. Phoenix Williamson.

d. What will happen to the data when the study is completed? How long would the data exist before destroying it?

All study data will be shredded and destroyed after the study is completed. Data will be kept for seven years before destruction.

V. Data Analysis

13. Analysis: Please delineate the data analysis plans for this study. Include planned statistical analyses and explanation of determination sample size. What statistical test will be used?

Qualitative data obtained from the audio recordings of focus group will be transcribed verbatim. To facilitate data analysis, the data will be entered into the qualitative data software, NVivo or Atlas.ti. Data coding will begin with the reading of the transcripts by the PIs to identify the preliminary codes. Data analysis will continue with a three-level coding process: 1) open coding to identify patterns in the transcripts, 2) focused coding to explore clustered concepts, and 3) identification of major themes. A coding manual will be created in an iterative process and independently coded by all three PIs to establish inter-rater reliability. All transcripts will initially be coded by the PI and Co-I. The themes that are developed will be used to inform the CSC for CWWs curriculum and content outline and care plan assessment.

For all quantitative data analyses, sample demographic characteristics for the CSC for CWWs program and workshops will be calculated. Descriptive statistics (e.g., frequencies, central tendencies, and variabilities) will be completed for the all surveys and summarized using means, medians and other quantiles, standard deviations, interquartile range, minimum and maximum, as well as graphically (e.g., boxplots). Data will be examined for outliers and tested

for normality, linearity, and homoscedasticity. Bivariate and multivariate analysis for CSC for CWWs will be completed for trends by age and gender.

VI. Limitations of the Study

14. Indicate any limitations of your project.

Our team recognizes that there are multiple topics and contextual factors that we can cover in the CSC for CWWs program. Yet, due to the limit of covering certain topics in the program structure, possible areas for content may be not be covered. The qualitative component of our study (*Phase I*) will assist us in our CSC for CWWs program planning by addressing the critical need areas for filling out the gaps in the CSC for CWWs program development. In addition, we know there may be technical issues, which is why we will ensure participants have Zoom installed on their laptop or have the capability to join by phone.

VII. Budget

15. Write the amount needed and the use. Write none, if no money is needed.

$70,000 for 2 years

Dr. Sharon Cobb - Salary Support (4% Effort)	$10,007
Kathye Jenkins – Co- Investigator/ Consultant Costs	$7,000
Community Partner/Health Educator--	$3,000
Project Coordinator-- (4% Effort)	$11,120
Research Expense -- Stipend for CSC Cancer Survivors and Caregivers for Pre-Intervention Focus groups@ $50 each for 20 participants	$1000
Research Expenses: Gift card for CWWs Clergy Wives & Widows @ $200 each for 50 people	$10,000
Participant Incentive/Compensation for Post-Intervention Focus Groups @ $50 for 50 people	$2500
CDU On-Campus Conference	$3930
Travel Expenses - Cancer Related Conference for Research Team	$6,000
Transcription Services	$2,000
Meetings and Culmination Workshops	$5400
Gift Cards for Conference Attendees ($40 gift for 40 people for attending conference and completing survey)	$1600
Research Supplies (including office expenses)	$6,443
MAXIMUM DIRECT COSTS/YEAR	$70,000

VIII. References

16. Author, Title, Journal, Date, Volume, Page Numbers