COVER PAGE: Informed Consent

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

NCT: NCT04544241

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Charles R. Drew University of Medicine and Science
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
Version #2, Date: 8/31/2020

Title of the Study: **Cancer Survivorship and Caregiver Leadership Education for Clergy Wives & Widows (CSC for CWWs)—Clergy Wives & Widows**
Principal Investigator: Sharon Cobb, PhD, RN
Telephone Number: 323-568-3329

Key Information about this Research Study

You are being invited to take part in a research study about the development of a cancer survivorship and caregiver leadership educational course for clergy wives and widows.

Why is this research study being done?

The purpose of this research study is to create and evaluate a cancer survivorship and caregiver leadership educational course for clergy wives and widows.

What will I be asked to do and how long will I be in the study?

You are being asked to participate in an online training program for clergy wives and widows that focuses on various areas of the cancer survivorship experience, including the delivery of cultural competency and care and providing hope and comfort. This course was specially designed with input from underrepresented minority cancer survivors and caregivers, with a focus on various need assessments and oncology navigational training.

You will meet monthly in a structured setting and participate in cancer and/or caregiver related online community seminars on Zoom. In addition, the program will culminate with four workshops you will develop and present in an online community event. Following, you will be invited to participate in a focus group to describe your experience in this program.

What are some reasons why I might want to take part in this study?

There are various reasons why you may want to take part in this study: 1) able to gain knowledge on cancer survivorship and caregiving, 2) effectively understand how oncology navigation plays a role in cancer diagnosis, treatment, and management, especially for underrepresented minorities, and 3) clergy members can benefit by applying cancer-related knowledge with their church congregation.

What are some reasons why I might <u>not</u> want to take part in this study?

There are various reasons why you may not want to take part in this study: 1) unable to participate due to other commitments, 2) unable to provide time to participate in the study, and 3) not interested in partaking in a cancer-related study.

Do I have to take part in the study?

Taking part in research study is voluntary. You do not have to take part and you can stop at any time.

What if I have questions or concerns?

Please contact Dr. Sharon Cobb, PhD, RN, PHN from the School of Nursing at Charles R. Drew University of Medicine and Science and Mrs. Kathye Jenkins, MPH, from the Cynthia Perry Ray Foundation. Additional contact information can be found on the last page of this informed consent.

Additional Information about this Research Study

The researchers will tell you about this study. It is your decision to take part or not take part in the research. Before you decide to volunteer for this study, you should

1. ask questions you do not understand;
2. learn as much as you can about the study; and
3. talk it over with your family, friends, and doctor.

WHY AM I BEING ASKED TO TAKE PART IN THE STUDY?

To be eligible for this study, you 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 a computer laptop or desktop with internet, tablet with internet, or phone with internet. You are being asked to take part in this research study because you are eligible for this study based on the criteria above.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

At total of 50 clergy wives and widows, will take part in this research study.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about one year. There will be at least 6 months of trainings that you will need to attend.

WHAT WILL HAPPEN IF I TAKE PART IN THE RESEARCH STUDY?

During the study

- You are being asked to participate in an online year-long training program for clergy wives and widows that focuses on various areas of the cancer survivorship experience, including the delivery of cultural competency and care and providing hope and comfort. This course was specially designed with input from underrepresented minority cancer survivors and caregivers, with a focus on various need assessments and oncology navigational training.
- Initially, you will be able to answer a few questions on the *SurveyMonkey* site that will determine if you are eligible for this study. If you are eligible, you can decide to proceed to the next section of the SurveyMonkey site in which you can read this consent form and electronically sign the consent. After you submit the consent form on the *SurveyMonkey site,* you will receive a signed digital copy of the consent form via email.
- You will meet monthly in a structured setting and participate in cancer and/or caregiver related online community seminars on a digital teleconferencing platform, Zoom. In addition, the program will culminate with four workshops you will develop and present in an online community event. Following, you will be invited to participate in a focus group to describe your experience in this program.
- You will complete the CSC for CWWs program and also complete pre- and post-questionnaires that will assess your self-efficacy and knowledge of both cancer survivorship and cancer caregiving. To receive full credit for completion of the CSC for CWWs training program, you must assist in the organization and presentation on cancer and/or caregiver related topic at one of four faith-based/community workshops. You will also be invited to participate in a post-intervention focus group to describe your experience in the program. Our research team will send dates and times and you will select which times are preferable for you. Once we receive responses for preferable dates and times, we will select a specific date and time and notify you via email/phone. We plan to have focus group session on a digital teleconferencing platform (*Zoom),* which is likely to be preferable for you since you can participate from anywhere. The focus group session is expected to last one hour.
- After the completion the CSC for CWWs program, an online conference in which you will present your workshop presentations to the university audience and community members. You will provide written consent to participate in the CSC for CWWs program and for collection of data. You will complete a demographic questionnaire and a self-efficacy and knowledge survey prior and after completion of the CSC for CWWs program.
- After fulfilling all requirements of the CSC for CWWs program, you will be compensated with a $200 digital gift card and certificate for your time and participation in the CSC for CWWs program. You will also receive a $50 digital gift card if you participate in the post-intervention focus group. Scheduling of the sessions will be accordance with the preference of your time.

WHAT RISKS OR DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?

There are no observable or substantial risks to you. There are also no invasive tests or physical risks that will occur with this study. Although we do not perceive any major problems, you may experience mild emotional distress at hearing the suffering of cancer patients. If so, we will provide emotional support and if necessary, referral to your personal provider for more in-depth follow-up. In addition, you may report time management issues with having to manage additional time for this study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There are multiple potential benefits that may result of this study. For clergy wives and widows, the knowledge you will gain is cancer diagnosis and treatment, cultural perceptions and care of care of cancer and caregiving, knowledge and attitudes of cancer and caregiving, and consideration of age on the health of URM cancer survivors and caregivers.

ARE THERE ANY BENEFITS TO OTHERS?

Information collected in this study has the potential to be used to create a leadership education training program targeting clergy members, including wives and widows that will be designed to meet the needs of cancer survivorship, including underrepresented minority cancer survivors and caregivers

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

You may choose not to take part in this study.

WILL I BE PAID?

You will be given a $200 digital gift card for your participation in this study. If you participate in the post-intervention focus group, you will be compensated with a $50 digital gift card.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There are no financial costs associated with this study for you. Neither you nor your insurance company will be billed for you taking part in this research.

HOW WILL MY PRIVATE INFORMATION BE KEPT CONFIDENTIAL?

The researchers will do their best to keep your personal information confidential. However, researchers cannot promise total privacy. The research team will be contacting you via email as well as emailing you a copy of your signed consent form. This may include sensitive information (i.e. your name) and identification that you 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.

You will be given a study specific identification number and a pseudonym that starts with one letter after your original first name. No real names will be used. All references to your real name during sessions views will be redacted for confidentiality. The only people who will have access to the data will be the members of the research team. PI Dr Cobb, Co-Investigator, Mrs. Jenkins, and Research Assistants - Ms. Phoenix Williamson. Your health care provider will not know that you are part of the research study. All study materials including recordings and documents will be locked in a encrypted laptop, encrypted cloud drive files, or a cabinet of the office of the PI (Dr. Sharon Cobb) on the CDU campus. All study data will be shredded and destroyed after the study is completed. Data will be kept for seven years before destruction if no longer being used for publications or presentations

Photographs, Videos, Audio-tape Recording

Please note that you may be photographed and/or video-taped if you attend the culmination workshop/conference. These pictures and or video may be used on publications and presentation and may be used on CDU and/or other collaborating community or research website.

Please check one of the boxes below and initial:

☐ _____ I agree to be [videotaped, photographed, audio-taped].
Initials

☐ _____ I do not want to be [videotaped, photographed, audio-taped].
Initials

CAN I STOP BEING IN THE STUDY?

Your participation in this research is VOLUNTARY. If you choose not to take part in the research study, that will not affect your relationship with CDU, or your right to health care or other services to which you are otherwise entitled. If you decide to take part in the study, you are free to withdraw your consent and stop at any time without affecting your relationship with CDU.

If you are a CDU student, you may choose not to take part or drop out of the study at any time. This will not affect your grades or class standing at CDU. You will not be offered or receive any special consideration if you take part in this research.

If you are a CDU employee, your participation in this research is in no way part of your university duties, and your refusal to take part will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment. You will not be offered or received any special consideration if you take part in research.

CAN THE RESEARCHERS REMOVE ME FROM THE STUDY?

The researcher may remove you from taking part in this research for several reasons. If you do not meet the inclusion criteria or if you become sick during the research, you may have to drop out, even if you would like to continue. The PIs will make the decision and let you know. The decision may be made to protect your health and safety, or because it is part of the research plan that people who develop certain conditions, missed scheduled visits, or did not follow instructions may not continue to take part in the study.

NEW FINDINGS

During the study, you will be told of any important new findings (either good or bad) that might cause you to change your mind about staying in the study. If new information is given to you, your consent to continue participating in this study will be re-obtained.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the researchers listed below. If you have any questions about the research, please feel free to contact [identify all personnel involved in the research as listed in the protocol under the following subheadings: Sharon Cobb, PhD, RN -Principal Investigator (323-568-3329), Kathye Jenkins, MPH - Co-Investigator, and Phenix Williamson - Research Staff.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

You may withdraw your consent at any time and end your participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research participant, please contact,

Charles R. Drew University of Medicine and Science
Institutional Review Board/Office of Research Integrity and Compliance
1731 East 120th Street, Los Angeles, CA 90059
Telephone: 323-563-5902
FAX: 323-563-4826
e-mail: irb@cdrewu.edu

SIGNATURE OF RESEARCH PARTICIPANT OR LEGALLY AUTHORIZED REPRESENTATIVE

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I am not giving up any of my legal rights by signing this consent form. I have received a copy of this consent form, which will show all signatures and dates. In addition, a copy of the Participant's Bill of Rights will be given to me, if applicable.

BY SIGNING THIS FORM, I AGREE TO TAKE PART IN THE RESEARCH DESCRIBED IN THIS CONSENT FORM.

_____
Name of Participant

_____
Name of Legally Authorized Representative (if applicable)

_____ _____
Signature of Participant or Legally Authorized Representative Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the participant or his/her legally authorized representative and answered all of his/her questions to the best of my knowledge.

_____ _____
Name of Individual Obtaining Consent Role in the Study (e.g. PI, coordinator)

_____ _____
Signature of Individual Obtaining Consent Date (must be the same date as participant)

SIGNATURE OF WITNESS (IF REQUIRED BY THE IRB)

My signature as witness certifies that the participant or his/her legally authorized representative signed this consent form in my presence as his/her voluntary act and deed.

_____
Name of Witness

_____ _____
Signature of Witness Date (must be the same date as participant)

Important Contact Numbers for the Research Study

Questions about the Research Study

Principal Investigator: Dr. Sharon Cobb
Charles Drew University of Medicine and Science
1731 East 120th Street
Los Angeles, CA 90059
Phone #: 323-568-3329

Co-Investigator: Kathye Jenkins
Cynthia Perry Ray Foundation
Tel 310-567-4231

Questions about Possible Research-related Injury

Principal Investigator: Dr. Sharon Cobb

Co- Investigator: Kathye Jenkins

After Hours Contact: 323-568-3317

Emergency: Call 911

Questions about Your Rights as a Research Participant

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E-mail: irb@cdrewu.edu