

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Centering the Marginalized Voices of Black Patients with Gynecological Cancer as a First Step in Healthcare Curriculum Development

Principal Investigators:

Onyinye D. Balogun, M.D.
Assistant Professor of Radiation Oncology
Weill Cornell Medicine

Amelia Greiner Safi, PhD, MS
Associate Professor of Practice, Master of Public Health Program
Department of Public and Ecosystem Health
Cornell University

Key points:

1. What is this study about? Who is leading this study?
 - o **We are doing this study to hear stories directly from Black patients with gynecologic cancer.** Some of these stories may involve experiences of discrimination. We hope to make health care better for Black patients by listening to their stories.
 - o **Black cancer patients and caregivers, Black research experts, and other gynecological cancer patients, are researchers in this study.** Our research team includes a diverse group of doctors, researchers, patients, caregivers, and university students.
 - o We are proud partners of the community organizations SHARE Cancer Support based in NY and Gilda's Club of Metro Detroit.

2. What does the study involve?
 - o If you want to join the study, you will be asked to talk about the care you got as a cancer patient. We will talk to you and about 6 other people together. This is called a focus group. We will meet over the computer for about 90 minutes.
 - o This study will take place on Zoom and will be recorded. The recording will not be shared.

- o **You will get \$25 for taking part in the study.** Also, your story may help make cancer care better for other Black patients.
 - o You can join this study if you want to, or you can say no. If you join, you can stop at any time. You can skip any question you do not want to answer.
3. What happens next?
- o Read this consent form and ask questions to see if you want to join.

o If you join the focus group, it means you affirm that you are:

- Identify as Black
 - 18 years of age or older
 - Ability to understand and converse in English
 - Access to the internet with a computer, smart phone, or tablet with a camera to participate in a Zoom focus group
 - Have been diagnosed at any time with gynecologic cancer (ovarian/fallopian tube/primary peritoneal, uterine/endometrial, cervical, vaginal or vulvar cancer)
- o **If you join the focus group, entering Zoom means you give your consent to participate and be recorded.**

2. PURPOSE OF THE STUDY

We want to learn more about differences in healthcare caused by racism. We believe that Black patients with cancer can tell us about what they have gone through during screening, diagnosis, treatment, and survivorship. We hope that what we learn from listening to Black patients will help to teach us how to give better care. It will also help support groups like SHARE and Gilda's Club create better resources for Black patients.

3. WHO CAN PARTICIPATE?

3.1 Who can take part in this study?

Patients need to meet four (4) criteria:

1. Identify as Black.
2. Be at least 18 years old.
3. Have currently or have had any gynecologic cancer.
4. Can read and speak English

3.2 How many people are expected to take part in this study?

We will talk to a total of about 64 people. We will meet in small groups of about 8 people together. Each small group is called a focus group.

4. STUDY DETAILS

4.1 What will happen to me in this study?

- We will talk to you over the computer in small groups. We will use zoom.
- We are going to record the small groups. We will keep the recordings private and secure.
- We will write down everything that is talked about during the focus group meetings. When we write things down we will take out any information that shows who was talking.
- The recordings will be destroyed once we write everything down that is talked about during the focus group meetings.
- The written record of the focus group meeting will be kept private and secure for 7 years.

4.2 How much of my time will be needed to take part in this study?

We will take about 90 minutes of your time. If you say yes, we may contact you later on to ask more questions about your experiences as a cancer patient.

5. STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Talking about the hard times that you may have gone through while getting healthcare can bring up bad thoughts and feelings. You do not have to answer any questions you do not want to answer.

You will be sharing personal information about your care. There is always a chance that someone who is not part of the research team could find your information. The researchers have put steps in place to keep your information private and secure. You can read more about those steps in Section 8 of this consent.

5.1.1 What happens if I get hurt, become sick, or have other problems because of this research?

There are no known physical risks of participating in a Zoom call. Please tell the researchers if you have any injuries or problems related to your time on the study.

5.2 How could I benefit if I take part in this study? How could others benefit?

You may find it meaningful to have your story and voice heard by clinicians, advocates and researchers who are interested in addressing racism via changes to medical education, practice and policy in their own medical systems and throughout the US.

You may benefit from being validated by other focus group members and through empathetic responses.

You may feel pride in trying to improve experiences and outcomes for other Black gynecologic cancer patients in the future.

Other Black patients in the future may benefit if their healthcare providers are more attuned to ways their actions and views related to race negatively impact patient experience and outcomes and have the skills to prevent such injustices.

These stories can give clear examples of the challenges that need to be addressed and can inform what kind of intervention is needed to address the impact of racism in gynecologic cancer care. We hope these future interventions will benefit healthcare providers as they will be more competent in their profession in addition to benefiting patients by having more culturally competent, less biased care.

5.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn about any new information that may change your mind about taking part in this study.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You can leave the study at any time. If you decide to leave the study before it is finished, please tell anyone on Section 9 “Contact Information.” You do not have to tell the researchers why you are leaving the study. If you do choose to tell the researchers, your reasons may be kept as part of the information collected.

The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in research, it will not be possible to remove your information.

7. COMPENSATION

7.1 Will I be paid or given anything for taking part in this study?

Yes. You will get a \$25 online gift card for taking part in the study.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

The focus group recordings will be kept on an encrypted server with a password; transcripts will also be on an encrypted server with a password.

8.2 Who will have access to my research records?

Only researchers will have access to the recordings and transcripts. Your personal information will not be shared. Your name will not be part of any transcripts.

The Institutional Review Board (IRB) may ask for general information to make sure that the study is done in a safe and proper way.

8.3 What will happen to the information collected in this study?

This study involves video recordings (which includes audio). These recordings will only be used to generate transcripts. After a transcript is created, the video recordings will be destroyed and the transcripts will be kept securely with the PIs for 3 years after the study is closed.

No video will be shared outside the study team. Some on our study team have found that there is more trust among participants when they are all on video.

We will also write down key points during the focus group. When we write things down we will take out any identifying information.

8.4 Will other study participants share my information?

The researchers will take every precaution to maintain confidentiality of the data. Because focus groups involve other participants and we ask them to keep all information confidential, we cannot promise they will do so.

The researchers would like to remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others. You may use your real name or not when participating.

8.5 Will my information be used for future research or shared with others?

We may use or share findings from this study for future research studies. If we share data with other researchers, it will not contain your name or other information that can directly identify you.

9. WHO CAN I CONTACT?

You can call or email the researcher below if you want to:

- Find out more information about this study
- Leave this study before it is finished
- Share a concern about this study

Principal Investigator: Onyinye D. Balogun, M.D.

Email: onb9003@med.cornell.edu

Phone: 718-780-3677

Principal Investigator: Amelia Greiner Safi, PhD

Email: alg52@cornell.edu

Phone: 607-255-7498

You should call your regular doctor if you have any questions about your cancer, or any illness, injury, or other problem.

If you have any questions or concerns about your rights as a research subject, you may contact the Cornell Institutional Review Board (IRB) at 607-255-5138, or you may access their website at <http://www.irb.cornell.edu>. You may also report your concerns or complaints anonymously through Ethicspoint (www.hotline.cornell.edu) or by calling toll free at 1-866-293-3077. Ethicspoint is an independent organization that serves as a liaison between the University and the person bringing the complaint so that anonymity can be ensured.

10. AFFIRMATION OF IDENTITY AND CONSENT

- **By deciding to join the focus group, it means you**
 - consent to participate in the study and
 - agree to be recorded.
- **You will have the chance to ask questions during a phone call or email before the study to decide if you want to join or not.**
- **Joining the study means you affirm that you:**
 - are at least 18 years old
 - identify as Black
 - have or have had gynecologic cancer
 - can speak English

11. PARTICIPATION IN FUTURE RESEARCH

Researchers may wish to keep your contact information to invite you to be in future studies. The study topics may be the same as this study, or they may be different.

During the question-and-answer phone call, if you choose to have one, you may let the researcher know if you would like to be contacted for future research or not.

You may also call or email the study leads (see page 5) to let them know you are interested.