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Informed Consent for Research

Study Title: Social Interventions for Support During Treatment for Endometrial Cancer and Recurrence -- The SISTER Study

Version Number, Date: 1.41, 07/30/2021

Part 1 of 2: BROAD CONSENT

STUDY CONTACT INFORMATION	
Phone	1-844-3SISTER (1-844-374-7837)
Website	oursisterstudy.com
Email	sisterstudy@uw.edu

You are being invited to take part in a research study called SISTER. SISTER stands for Social Interventions for Support during Treatment for Endometrial cancer and Recurrence. There are two forms to look at before you decide. If you still have questions after reviewing the forms, let us know! We want you to have as much information as you need to decide about signing up. You can also listen to an audio-recorded version of this information.

KEY INFORMATION:

- Signing up is completely optional
- The SISTER study is comparing different kinds of support for Black patients during endometrial cancer treatment
- If you decide to join, you will be in the study for six months
- Being in the study means that you will be asked to complete surveys, and give us access to your medical records about your endometrial cancer diagnosis and treatment
- **Your identifying info will be kept confidential**
- There are no health risks to joining. If at any time you feel uncomfortable with answering survey questions, you can skip questions
- A benefit of joining is feeling more supported during treatment by other Black women who have been in treatment before

What are the benefits of volunteering?

You will be contributing greatly to new knowledge about how to best support Black and African American people with cancer. We expect that participants of the SISTER study will feel less lonely during their cancer treatments. It may also result in better rates of treatment completion.

Who is leading this study?

A team of majority-Black women designed SISTER study. The lead researcher, Dr. Kemi Doll, is a gynecologic oncologist at the University of Washington. Dr. Doll's research focuses on improving outcomes for Black women with endometrial cancer. Dr. Doll designed SISTER study in equal partnership with our Peer Supporters. They are a team of Black women who have gone through endometrial cancer treatment. They helped write the grant, choose the survey questions, and have equal say in making big study decisions.

How is the study set up?

SISTER is a "randomized controlled trial", or RCT. This means that if you decide to volunteer, a computer will assign you to a group. There are three groups in the study, and you will get support no matter what group you are in. We have the computer do the assignments to make sure that the groups are fair and balanced. The SISTER study will include up to 252 participants from 10 or more hospitals.

Informed Consent for Research

Study Title:

**Social Interventions for Support During Treatment for
Endometrial Cancer and Recurrence -- The SISTER Study**

Version Number, Date: 1.41, 07/30/2021

The groups in the SISTER study that the computer could put you in:

- Support materials: You will receive a mailed care package with information about cancer treatment, or,
- Group support: You will join a weekly support group led by a SISTER Peer Supporter. Each week will focus on different aspects of cancer treatment and recovery, or,
- 1-on-1 Peer support: You will connect one-on-one with a SISTER Peer Supporter. Each call will be around the time of each of your cancer treatments.

What happens after I sign up?

There are two main study activities:

1. Filling out study surveys
2. Giving us permission to collect information from your medical records. (We will only collect information that is related to the study.)
3. There are other, additional study activities too, like a phone interview or more surveys. There are more details about these on page 3.

The table below describes when we will contact you for surveys and when we will access your medical record. The surveys are the same no matter which group you are in. You will be paid for your time to complete these surveys.

	Timing of study activities			
	Today	1 month from today	3 months from today	6 months from today
Survey	X	X	X	X
SISTER study team collects data from your medical records	X		X	X

What is involved in doing the surveys?

For each survey, we will contact you to complete a survey in-person, by phone, mail, or on the internet, based on what works best for you. We will make multiple attempts to reach you, over a "window" of time (usually 2-4 weeks) for each survey.

The questionnaires may take up to 60 minutes to complete. The surveys have a lot of questions. This is because it is the best way for us to get a good idea of how your treatment is going, and your life outside of cancer treatment. This information will help us to understand more about what kinds of social support work best. All the surveys were designed in partnership with our SISTER Peer Supporter team.

The surveys ask about things like treatment side effects and financial stress. We also will ask about other sources of support during treatment. The information that you provide in the SISTER study surveys is confidential. The only reason we would intentionally share your information, is if you report any symptoms suggesting mental health crises, such as a desire to hurt yourself or others. We will also ask you about things like recalling your experiences with racial discrimination and feelings of loneliness.

Informed Consent for Research

Study Title:

**Social Interventions for Support During Treatment for
Endometrial Cancer and Recurrence -- The SISTER Study**

Version Number, Date: 1.41, 07/30/2021

What does it mean for me to give you access to my medical records?

During the study, we will collect and save information from your medical records. We can do this remotely, from our central study office, but not without your signed permission.

Right after you join the study, we will collect things like age, type of insurance, and your treatment plan. At other time points, we will collect information on your medical history, lab results, and how many treatments you finish. We will also look for data about any hospital stays that you may have, related to your endometrial cancer. Like the surveys, we collect this information to better understand what types of social support work best for each person. The data that we collect will not change your treatment in any way.

If you go to another hospital or clinic for cancer care during the study, we will ask you to give permission for us to access those health records as well. This is so that we can have as complete a picture of possible as your treatment and health. We will have access to your health records for up to 12 months to ensure we have complete treatment information for you.

What else will I be asked to do?

Phone interview:

We may ask if you would like to do a phone interview about your experiences with endometrial cancer. The interview will take about 60 minutes and we will pay you for your time. The interview will ask about how you made treatment decisions, and your general thoughts and reflections. These details will help the study team learn what types of social support work best for different people. It's important to get detailed stories that we cannot get from survey questions or your medical records. This interview will be either audio or video-based and will be recorded. The interviews will take place sometime between now and 6 months from now, when you complete your time in the study.

If you would like to be considered for the optional interview, please check the box below:

☐ I would like to be contacted about the optional open-ended phone interview. I am willing to share about my experiences with endometrial cancer. I understand not all participants will be interviewed.

Additional surveys and future studies:

Your SISTER study enrollment is complete after six months. However, if the study team decides to add more surveys, we will want to contact you. We may also want to contact you about volunteering for other studies.

If you would like to be considered for more surveys and future studies, please check the box below:

☐ It is okay for the study team to contact me about completing additional surveys, or to learn about future studies. I understand that I may not be eligible for future studies. I understand that the study team may decide to not conduct more surveys. I understand that I will be provided with more details if I decide to do future surveys or studies.

Informed Consent for Research

Study Title:

**Social Interventions for Support During Treatment for
Endometrial Cancer and Recurrence -- The SISTER Study**

Version Number, Date: 1.41, 07/30/2021

How much are the payments for participating? Does it cost anything to sign up?

- Joining the study is free, you will receive up to \$105 for completing all study surveys
- Today's survey payment: \$25
- One-month and three-month survey payments: \$25 each
- Six-month survey: \$25, with a \$5 bonus if you have done all the other surveys
- If you complete the phone interview, you will get \$90
- Payments will be mailed or sent to you electronically from the University of Washington

Outside of the study, you are responsible for the cost of your clinical care. All medications, laboratory fees, physician hospital costs will be charged to you in the same way as if you were not a part of this study, like through your insurance.

What are the risks of signing up?

SISTER is a study that provides social support and does not provide medical treatment. You may have some discomfort answering survey questions. We also ask questions related to your physical, emotional, and financial health, as well as any experiences with discrimination. Some of the questions are sensitive. You can skip any question for any reason. You can take a break at any time or stop answering the questions.

The SISTER study team takes privacy very seriously and makes every effort to protect your information. Even with all protections in place, there is a possibility that there could be a loss of confidentiality. In the unlikely event that this does happen, we will tell you. Finally, this study may pose risks that we do not currently know about.

Do I have any alternatives to signing up?

You do not have to be in this research study. You may choose not to be in this study without changing your healthcare, services, or other rights. We will not share your decision about signing up with your doctor. You can stop being in this study at any time. If we learn something new about the risks or benefits of this study, we will tell you.

What will happen if I decide to stop being in this study?

If you want to withdraw from the study, please notify the SISTER study team, via phone or email. The study contact information is at the beginning of this form. The team will ask you why you would like to stop being in the study, and we will document it in your study record. If you withdraw from the study surveys, we will not ask you to complete any other surveys. Any data you provided before you withdraw from the study may be kept and used. Deciding to not be part of the study will not change your regular medical care in any way.

Where can I find more information about the study?

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

How is the study funded?

The study is paid for by the Patient-Centered Outcomes Research Institute (PCORI).

How does the SISTER study team protect my information?

Informed Consent for Research

Study Title:

**Social Interventions for Support During Treatment for
Endometrial Cancer and Recurrence -- The SISTER Study**

Version Number, Date: 1.41, 07/30/2021

We will assign a unique study code to your study information. We keep your personal information in a secure location. After the end of the relevant required record retention periods, we will destroy any link between the study information and your identity.

All participant data collected on paper will be stored in locked cabinets located in the site research offices. All data collected online will be stored on a secure website called REDCap (Research Electronic Data Capture). REDCap is a program that was originally designed to keep research data safe. Data stored on REDCap is only accessible to SISTER study team members. We follow all rules and guidance under the Health Insurance Portability and Accountability Act (HIPAA).

Sometimes, studies like SISTER are reviewed by government or University officials to make sure they are being done safely, accurately, and legally. If a review of this study takes place, your study information or research records may be examined. The reviewers will protect your privacy. Your study information or research record will not be used to put you at legal risk of harm.

How will my privacy be protected in future studies?

The SISTER Study team may partner with other researchers to answer new questions about endometrial cancer and treatment. These partnerships require approval from the SISTER Advocate Advisory Board (AAB). The AAB is made up of Black survivors of endometrial cancer and caregivers. Researchers must follow the SISTER Study principles of community engagement. If new partnerships are approved, information about you may be made available to others to use for new research projects. To protect your privacy, we will not release your name or any identifying information. Other information about you will be shared without getting additional permission from you. It is also possible that in the future we may want to use or share information that has identifier removed but might be able to identify you. If we do, a review board will decide whether we need to get additional permission from you. Other study teams will not ever have direct access to your medical record. These studies may help us, or other researchers learn more about how to provide better care to Black women during endometrial cancer treatment.

How will I learn about the study results?

The results of this study will be published in medical journals. In addition, we will share results directly with patients, caregivers, national advocacy organizations via presentations and events. Study results will never contain any identifying information about individual study participants.

End of part 1; please review part 2.