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

Version number, Date: **1.2, 05/06/2021**

Part 2 of 2: STUDY SITE INFORMATION

Site Name:	MedStar Washington Hospital Center
Site Principal Investigator:	[Charlotte Gamble, MD
Site Principal Investigator Contact:	202-877-8839, 202-877-6751 (24-hour number)
Site Study Coordinator *(if applicable)*:	Shelley Collins
Site Study Coordinator Contact *(if applicable)*:	202-877-6241
Contact for questions about rights as a research participant:	202-877-8839, 202-877-6751 (24-hour number)

This is part 2 of the SISTER study consent form. It includes information that is specific to the site where you are getting your cancer care. We will review both forms with you, before you sign up for the study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you allow to receive your medical record will also get this information.

Similar to part 1 that you just reviewed, part 2 answers common questions about the SISTER study. If you still have questions about the study after reviewing, let us know!

Policy/Procedures or Research Related Injuries

The Policy and Procedure for the Sponsor 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.

The Policy and Procedure for Georgetown University Medical Center and MedStar Health Research Institute are as follows:
We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive necessary medical care. The costs of this care will be charged to you or your third party payor (e.g., your health insurer) in the usual manner and consistent with applicable laws. No funds have been set aside by Georgetown University, Georgetown University Hospital, MedStar Health Research Institute, or their affiliates, to repay you or compensate you for a study related injury or illness.

Who can I call if I have questions about study activities?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Charlotte Gamble, MD 202-877-8839, 202-877-6751 (24-hour number)

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (301) 560-2912 or MHRI-ORIHelpDesk@medstar.net if:

Your questions, concerns, or complaints are not being answered by the research team.
You cannot reach the research team.
You want to talk to someone besides the research team.
You have questions about your rights as a research participant.
You want to get information or provide input about this research.

HIPAA Authorization

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.

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information including the health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. The health information we may collect from you and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well as diaries and questionnaires

- Records about study medication or drugs

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Georgetown University, MedStar Health, etc., and its clinical partners (or affiliates): the Georgetown University Office for Research Integrity; The MedStar Office for Research Integrity, the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law, Georgetown University policy, or MedStar Health policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the MedStar Health workforce, who may need to see your information, such as administrative staff members from the MedStar Health Research Institute-Georgetown University Institutional Review Board (IRB) Office and it's agents, and members of the Institutional Review Board.
- Laboratories and other individuals and organizations that may need to see your health information in connection with this study.
- Other Georgetown University and MedStar Health research centers, and Georgetown University contractors and MedStar Health contractors who are also working on the study.
- Study monitors and auditors who make sure that the study is being done properly,
- SISTER who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Your consent will not expire unless you revoke it.

After the expiration date, Georgetown University and MedStar Health may not gather new information about you or use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Georgetown University and MedStar Health obtain permission to do so from you.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Charlotte Gamble, MD
Institution: Washington Cancer Institute at MedStar Washington Hospital Center
Department: Gynecologic Oncology
Address: 110 Irving St., NW, Washington, DC 20010

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study if you do not allow this. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	IRB Approval Date