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

Version number, Date: **1.0 Dated June 16th 2022**

Part 2 of 2: STUDY SITE INFORMATION

Site Name:	University of Miami, Sylvester Comprehensive Cancer Center
Site Principal Investigator:	Abdulrahman Sinno, MD
Site Principal Investigator Contact:	(305) 2432233
Site IRB Number:	20220781
Site Study Coordinator *(if applicable)*:	Peggy Gonzalez
Site Study Coordinator Contact *(if applicable)*:	305-243-8091 786-252-9103
Contact for questions about rights as a research participant:	University of Washington Human Subjects Division (206) 543-0098

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!

Who can I call if I am injured or harmed by study activities?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (305) 243-2233 Abdulrahman Sinno, MD

An Institutional Review Board ("IRB") reviewed and allowed this research to move forward. An IRB is a group of people who consider the risks and benefits of research to determine whether the research should happen. The Human Subject Research Office (HSRO) is the team that supports the University of Miami's IRBs.

Please call the HSRO at 305-243-3195 if:

- The research team has not answered your questions, concerns, or complaints.
- 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 subject.
- You want to get information or provide input about this research.

Although risks are unlikely, if you are injured, treatment will be available in most cases. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will need to pay. Funds to compensate you for pain, expenses, lost wages and other damages caused by the injury are not available. This policy does not prevent you from trying to obtain compensation through the legal system.

Who can I call if I have questions about study activities?
You may call the SISTER central study line for information about the study, at (1-844-374-7837) or study coordinator 305-243-8091 office or 786-252-9103 cell

Payment for participation

All participants will receive a $25 electronic gift card for completing each survey, with an additional $5 bonus at the primary endpoint (6 months) if they have completed all prior surveys. Participants who complete in the optional phone interview will receive an additional $90 gift card

We may ask you for your social security number for payment purposes. We will not use it for any other purpose without your permission.

If you receive $600 or more during a calendar year from the University for taking part in this research, you may receive a 1099 for tax reporting purposes. Reimbursements for travel and other expenses are not included in this amount.

If you are, or have been, a patient at a UM/JHS facility, you will have a UM/JHS electronic medical record (EMR). We will add research data to your EMR so doctors taking care of you can use this information for your medical care. Your EMR will show that you are in a research study. We will also include a copy of this signed consent form in the EMR to show your doctors that you are in this research.

The data may describe the investigational products you received and anything else that may affect your medical care or place you at greater risk of harm. The intent is to give information to caregivers who provide your medical care while you are on this study.

UM/JHS doctors, nurses and other staff will have access to this data. These people are not part of the research team but are involved in providing your medical care, or they perform other tasks related to your medical care. Laws, such as HIPPA, will require them to keep your data confidential.

We suggest that you tell any non-UM/JHS doctors that you are in a research study and they can obtain more information if they request it.

The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

UHealth will grant direct access to your medical records to the sponsor, monitors, auditors, the IRB, and the FDA so they can conduct or oversee the research. By signing this document, you are agreeing to this access.

Federal law provides more protections for your medical records and related health information. The second part of this consent form, the University of Miami/Jackson Health Systems Research Authorization, describes these safeguards.

What other information do I need to know about joining the SISTER study from UNIVERSITY OF MIAMI?
If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____

Date Signature of participant

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Printed name of participant

ADDENDUM 1: UNIVERSITY OF MIAMI/JACKSON HEALTH SYSTEMS

RESEARCH AUTHORIZATION

What is the purpose of this part of the form?

State and federal privacy laws protect the use and disclosure of your Protected Health Information "PHI". Under these laws, your health care providers generally cannot disclose your health information for the research listed above unless you give your permission. You will use this form to give your permission. By signing this form, you authorize the University of Miami (UM), Jackson Health Systems, the Principal Investigator and his/her/their/its collaborators and staff to obtain, use and disclose your health information, as described below. We call these people and institutions "Providers" in this form.

What Protected Health Information will be used or shared?

You are authorizing the use and sharing of all of the information collected or created during this research as described in the first part of this document, including information in your medical records that is relevant to this research study. Information that may be relevant includes:

- Your past medical history,
- Medical information from your primary care physician,
- All other medical information relating to your participation in the study listed at the top of this document,
- Genetic analysis or genomic sequencing if these procedures are part of this research.

Who may receive my Protected Health Information?

The Providers may use and share your health information with:

- The Principal Investigator and his/her research staff

- Representatives of government agencies that have oversight of the study or who the law permits to access the information such as the U.S. Food and Drug Administration, the Department of Health and Human Services, and the Florida Department of Health
- Groups that collaborate and sponsor research (Cooperative Groups)
- Institutional Review Boards (groups of people who oversee research)
- Other persons who watch over the safety, effectiveness, and conduct of research
- The Sponsor of the research, its agents, monitors, and contractors
- Other participating researchers; and
- Independent data and safety monitoring boards

Authorized staff such as doctors and nurses who are taking care of your but are not involved in this research may be aware that you are participating in a research study and may have access to research information about you. If the study is related to your medical care, we may include the study-related information in your permanent hospital, clinic, or physician's office records.

Why will my Protected Health Information be used and disclosed?

- Researchers (those individuals in charge of the study) and research team members will use your information to conduct the research study described in this informed consent document and other activities related to the research, such as evaluating the safety of the study.
- The research sponsor, its authorized representatives, business partners, clinical research organizations and affiliates will use your information for the purposes described in the first part of this document and for other activities related to the research. These activities include assessing the safety or effectiveness of the drug, device or treatment that we are studying, improving designs of future studies or obtaining approval for new drugs, devices or health care products.
- The UM/JHS's clinical trial organizations will use your information to review and support clinical trials at the University.
- Other UM/JHS's offices involved in regulatory compliance, including the Institutional Review Board (IRB), Offices of General Counsel, and Compliance may use your information to ensure the study teams are performing the research correctly.

- U.S. government agencies, such as the Food and Drug Administration and the Office for Human Research Protections, government agencies from other countries, and others who must use your information to review or oversee this research and to review the data so they can decide whether to approve a new drug, device or other health care product for marketing.

What other information should I know?

1. Once the study team has disclosed your information to a third party, the federal privacy law may no longer protect the information from further disclosure.
2. You do not have to sign this Authorization, but if you do not sign it, you may not participate in the research and receive the research treatment; however, your r decision will not affect your right to other medical care.
3. You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you must write to the study doctor or to the Human Subjects Research Office at Gables One Tower, 1320 S. Dixie Highway, #650, Coral Gables, FL 33146.
4. If you revoke this Authorization, you will not be able to continue taking part in the research.
5. While the research is in progress, you cannot access and read your health information that is created or collected by the institutions and people listed above. After the research is finished, you may see your health information.
6. This Authorization does not have an expiration date. There is no set date at which your information will be destroyed or no longer used because the research will need to analyze the information for many years and it is not possible to know when they will complete the analysis.
7. A study team member will give to you a copy of this authorization after you sign it.

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Signature of participant or participant's legal representative Date

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Printed name of participant