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:	University of Chicago
Site Principal Investigator:	Nita Lee, MD
Site Principal Investigator Contact:	University of Chicago 5841 S Maryland Ave, MC 2050 Chicago, IL 60637 (773) 702-6722
Site Study Coordinator *(if applicable)*:	Cheska Zoleta
Site Study Coordinator Contact *(if applicable)*:	(773) 702-7064
Contact for questions about rights as a research participant:	University of Washington Human Subjects Division (206) 543-0098 University of Chicago BSD IRB (773) 702-6505

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 a research related injury, you should immediately contact the Department of Obstetrics & Gynecology, Section of Gynecologic Oncology at (773) 702-6123. This line is answered 24 hours a day/7 days a week.

Who can I call if I have questions about study activities?
The person in charge of the study is Dr. Nita Lee of the University of Chicago. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, their contact information is: (773) 702-6722.

Authorization to Use/Disclose Protected Health Information
Taking part in this study is voluntary. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

You may choose not to participate at any time during the study. You will not lose any services, benefits or rights you would normally have if you choose to leave the study. The University of

Chicago/University of Chicago Medical Center will not condition (withhold or refuse) treating you on whether you sign this Authorization or revoke your authorization at a later time. If you do not sign this form, you will not receive the research-related intervention(s).

During this study, Dr. Lee and her research team will collect protected health information (PHI) about you for the purposes of this research. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. Some of this information will come from your medical record. This will include your name, contact information (address, telephone/fax numbers, and/or email), medical record number, insurance information, demographic information (gender, birth date, race/ethnicity), dates (of consent, study interventions), and the dates and results of any tests to check your health or disease status. We will use these identifiers to schedule visits, check on your health status, and for long term follow up.

As part of the study, Dr. Lee and her research team will report the results of your study-related procedures and tests explained above to the sponsor University of Washington and/or its representatives (including Seattle Cancer Care Alliance, Fred Hutchinson Cancer Research Center, laboratories, independent auditors and monitors) and collaborators. These include your name and contact information (phone and/or email address), assigned study number, demographic information (gender, birth date, race/ethnicity), dates (of consent, study interventions), and the dates and results of any tests to check your health or disease status. This information is being sent to assure the quality of how the study is run, and to allow for the following activities: gathering and analyzing study data, confirming study results, publishing study results, and for research directly related endometrial cancer.

The study sponsor or their representatives, including monitoring agencies, may also review the entirety of your medical record (for example, in the event of an audit). If the medical record is accessed, it is possible that all of the PHI used on this study would be viewed, including your name.

Your PHI may be shared with governmental agencies, including the National Institutes of Health (NIH) and the National Cancer Institute, for federally mandated reporting purposes.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Office of Human Research Protections (OHRP). Representatives of the University of Chicago, including the Institutional Review Board (a committee that oversees the research) and the Office of Clinical Research may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

Once information is shared outside the University of Chicago, please note that your identifiable health information may be shared with someone else. The same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your medical record. Dr. Lee is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least six years.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Lee in writing at the address on the first page. Dr. Lee and the study sponsor may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. Your authorization to use and disclose your health information does not have an expiration date.

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

_____

Printed name of participant

PERSON OBTAINING CONSENT

I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

_____ _____

Date Signature of person obtaining consent

_____

Printed name of person obtaining consent