

## Informed Consent for Research

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:	Weill Cornell Medical College/New York-
	Presbyterian Brooklyn Methodist Hospital
Site Principal Investigator:	Dr. Eloise Chapman- Davis
Site Principal Investigator Contact:	212-746-3307
Site Study Coordinator:	Nadine Nicholson
Site Study Coordinator Contact:	212-746-2071
Contact for questions about rights as a	University of Washington Human Subjects
research participant:	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!

This study will be done at several sites including Weill Cornell Medical College (WCMC) and New York-Presbyterian Brooklyn Methodist Hospital (NYP-BMH). Study team members conducting research procedures at these sites have a joint WCM/NYP-BMH institutional affiliation.

## Who can I call if I have questions about the study or if I am harmed by study activities?

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Eloise Chapman- Davis at 212-747-3307 or the department of Gynecological Oncology. Be sure to inform the physician of your participation in this study.

If you have questions about your rights as a research participant, you can contact the University of Washington IRB at 206-543-0098 or hsdinfo@uw.edu or you can contact the WCMC IRB Office. For the WCMC IRB you can direct your questions to:

Institutional Review Board at: (646) 962-8200 1300 York Avenue **Box 89** 

Page 1 of 4

Weill Cornell Medicine

Sponsor: Patient-Centered Outcomes Research Institute, Amend 1.2, 5/06/2021

Consent Template Version August 2018

1

IRB: 21-08023872-01

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New York, New York 10065

# **Compensation for Research-Related Injury**

# The Policy and Procedure for Weill Cornell Medicine are as follows:

We are obligated to inform you about Weill Cornell Medicine's policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from Weill Cornell Medicine. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

# What other information do I need to know about joining the SISTER study from Weill Cornell Medicine?

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with Weill Cornell Medicine, NYP-BMH, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

### **Authorization to Use/Disclose Protected Health Information**

<u>Purposes for Using or Sharing Protected Health Information</u>: If you decide to join this study, Weill Cornell Medicine/NYP-BMH researchers need your permission to use your protected health information. If you give permission, Weill Cornell Medicine/NYP-BMH researchers may use your information or share (disclose) information about you for their research that is considered to be protected health information.

Voluntary Choice: The choice to give Weill Cornell Medicine/NYP-BMH researcher's permission to use or share your protected health information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for Weill Cornell Medicine/NYP-BMH researchers to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from Weill Cornell Medicine/NYP-BMH.

<u>Protected Health Information To Be Used or Shared:</u> Government rules require that researchers get your permission (authorization) to use or share your protected health information.

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Your medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your medical records.

Other Use and Sharing of Protected Health Information: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the study sponsor, the WCMC Institutional Review Board, inspectors who check the research, government agencies and research study staff. The researchers could also share your protected health information with Weill Cornell Medicine, New York Presbyterian Brooklyn Methodist Hospital (BMH), The Office of Human Research Protection (OHRP), Department of Health and Human Services, National Institutes of Health, The Food and Drug Administration (FDA) and/or their representatives. The University of Washington and/or their representative will have access to your files.

The information that may be shared with the sponsor and/or government agencies could include your medical record and your research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

#### **Future Research**

You may agree to allow your data, and/or sample(s) (tissue, blood, urine, etc.) to be used for future research within Weill Cornell Medicine/NYP-BMH or at outside institutions and private companies. If information goes to an outside entity, then Weill Cornell Medicine/NYP-BMH cannot ensure the privacy rule is followed.

# **CANCELING AUTHORIZATION**

**Canceling Permission:** If you give the Weill Cornell Medicine/NYP-BMH researchers permission to use or share your protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by writing to:

Privacy Office 1300 York Avenue, Box 303 New York, NY 10065

Email: privacy@med.cornell.edu

If you have questions about this and would like to discuss, call (646) 962-6930.

Page 3 of 4

Weill Cornell Medicine Sponsor: Patient-Centered Outcomes Research Institute, Amend 1.2, 5/06/2021 Consent Template Version August 2018



Informed Consent for Research

4

IRB: 21-08023872-01

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<u>End of Permission:</u> Unless you cancel it, permission for Weill Cornell Medicine/NYP-BMH researchers to use or share your protected health information for their research will never end.

#### **ACCESS TO RESEARCH RECORDS**

During the course of this study, **you will have access** to see or copy your protected health information as described in this authorization form in accordance with Weill Cornell Medicine policies. During your participation in this study, you will have access to your research record and any study information that is part of that record.

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	
	Printed name of participant	