University of North Carolina at Chapel Hill
Consent to Participate in a Research Study – Home Visit Sub-Study
Adult Participants

Consent Form Version Date: May 5, 2022
IRB Study # 19-1928
Title of Study: Carolina Endometrial Cancer Study (CECS): A Population Cohort to Investigate Endometrial Cancer Epidemiology, Biology, and Outcomes – Home Visit Sub-Study

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Funding Source and/or Sponsor: University of North Carolina at Chapel Hill Lineberger Comprehensive Cancer Center

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Concise Summary (Sub-Study)

The purpose of this home visit sub-study is to enable preliminary studies of the post-treatment microbiome in relation to sexual and bowel function, and the potential to evaluate longitudinal changes in adults with endometrial cancer. Initial enrollment goals are for 50 adults already participating in the Carolina Endometrial Cancer Study and living within approximately 100 miles of Chapel Hill, NC.

Participants will be asked to allow a nurse-interviewer to visit their home for one hour to obtain standardized body and blood pressure measurements, record medication use information, obtain signed consents, and gather completed microbiome samples and questionnaires that are mailed to participants for self-collection prior to the visit. The duration of this sub-study is limited to the completion of the nurse-interviewer visit and/or gathering of materials consented by the participant to obtain.

The greatest risks of this sub-study include the possibility of psychosocial discomfort or stress during completion of the home visit and the potential for breach of confidentiality.

If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research sub-studies?

You are being asked to take part in a research sub-study. To join the sub-study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the sub-study, for any reason, without penalty.

Research sub-studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research sub-study. There also may be risks to being in research sub-studies.

Deciding not to be in the sub-study or leaving the sub-study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research sub-study in order to receive health care.

Details about this sub-study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research sub-study.

What is the purpose of this sub-study?

You are being asked to be in the sub-study because you are participating in the Carolina Endometrial Cancer Study (CECS) and live within approximately 100 miles of Chapel Hill, NC. The purpose of the sub-study is to obtain standardized body and blood pressure measurements, record medication use information, and gather microbiome samples and questionnaires from a sub-set of participants in the CECS. We want to learn more about the post-treatment effects on the lower extremities and microbiome in relation to sexual and bowel function, and potentially evaluate longitudinal changes.

Are there any reasons you should not be in this sub-study?

You should not be in this sub-study if you don't believe you have been diagnosed with endometrial cancer.

How many people will take part in this sub-study?

Approximately 50 adults participating in the Carolina Endometrial Cancer Study, living within approximately 100 miles of Chapel Hill, NC will participate in this sub-study.

How long will your part in this sub-study last?

Taking part in this sub-study does not involve any kind of treatment. An appointment will be made for a trained nurse-interviewer to visit your home, obtain standardized body and blood pressure measurements, record medication use information, sign consents, and gather microbiome samples and questionnaires that are mailed to you for self-collection prior to the visit. It will take about 1 hour to do all of these things. The duration of this sub-study is limited to the completion of the nurse-interviewer visit and/or gathering of materials you've consented for us to obtain.

What will happen if you take part in the sub-study?

If you decide to take part in this sub-study, we would ask you to do the following things:

Schedule a Home Visit: Study staff will discuss the sub-study with you, confirm eligibility, and schedule a time for the nurse-interviewer to visit with you.

Short Questionnaires/Worksheets: Shortly before the home visit, we would like to send you some materials in the mail. This would include questionnaires related to sexual, bowel, and bladder function, and instructions for measuring leg circumference with a fabric measuring tape and washable skin marker. We would like to see if participants in the study, who live farther away, can take these measurements without a nurse present. It is requested that you complete the questionnaires and measurements before the home visit so that the nurse-interviewer can collect them.

Do you consent to participate in short questionnaire/worksheet materials for this sub-study?

☐ **Yes**, I agree to participate in the short questionnaires/worksheets.

☐ **No**, I refuse to participate in the short questionnaires/worksheets.

Microbiome samples: Once eligibility and your interest in participating in the sub-study are confirmed, we would like to mail you a biological specimens consent form, 2 microbiome self-collection kits, and a specimen collection worksheet for the collection of stool and vaginal microbiome samples. Each kit contains detailed instructions and all necessary components for collecting high quality samples in the privacy of your home. It is requested that you complete the collection of microbiome samples before the nurse-interviewer visit so they can take the samples with them when they complete their time with you.

Do you consent to participate in the microbiome self-collection samples for this sub-study?

☐ **Yes**, I agree to participate in the microbiome sample collection.

☐ **No**, I refuse to participate in the microbiome sample collection.

Nurse-Interviewer Home Visit: Once scheduled, a nurse-interviewer would visit you at home or other convenient location to collect any completed materials sent prior the visit. They would review and answer any questions you have about the consent forms. Once consent is received, they would take several standardized body and blood pressure measurements, record information about medication use, and ask a few questions related to the collection of the microbiome samples.

Do you consent to a home visit interview?

☐ **Yes**, I agree to participate in the home visit interview.

☐ **No**, I refuse to participate in the home visit interview.

Do you consent for body measurements to include all or some of the following: blood pressure, height, weight, waist, hip, and leg measurements?

☐ **Yes**, I agree to participate in body measurements.

☐ **No**, I refuse to participate in body measurements.

What are the possible benefits from being in this sub-study?

Research is designed to benefit society by gaining new knowledge. This new information may help people in the future. There is little chance you will benefit personally from being in this research study other than knowing you have contributed to knowledge that may help people in the future.

What are the possible risks or discomforts involved from being in this sub-study?

This research poses minimal risk. The sample collection kits are designed to minimize any physical discomfort. Participating in the home visit could cause some emotional distress. You may refuse to answer any question or refuse any measurement. There is the potential loss of privacy due to the personal nature of some of the questions asked in the interview. Every precaution will be taken to keep all medical records and test results confidential and used only for the purposes of this study. Information that could be used to identify you will be kept separate from all research information. The link between your identifying and research information will be kept secure at the University of North Carolina.

Everyone working on this study has signed a statement promising to keep all information you provide confidential. Despite all precautions mentioned here and in the *How will information about you be protected?* section below, there remains the risk of a breach of confidentiality.

What if we learn about new findings or information during the sub-study?

You will be given any new information gained during the course of the sub-study that might affect your willingness to continue your participation.

How will information about you be protected?

All information that you provide, including information from questionnaires and laboratory results from testing of your samples, will be kept strictly confidential. No one, other than certified study staff, will have access to your records. Your name and other identifying information will be stored separately from the stool and vaginal samples, the interview information and the laboratory results. Every effort will be taken to protect the identity of the participants in the sub-study. No individuals will be identified in any report or publication of this sub-study or its results. Your data will be stored and may be shared with other researchers in the future who have approvals to receive the data for research purposes. Before any data is shared, all identifying information, including your name, will be removed.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.
The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What if you want to stop before your part in the sub-study is complete?
You can withdraw from this sub-study at any time, without penalty. The investigators also have the right to stop your participation at any time. This might happen if the investigators determine you are ineligible or the entire sub-study has been stopped.

If you withdraw or are withdrawn from this sub-study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?
Your participation in this sub-study is completely voluntary. You will receive $40 as a "thank you" for completing the home visit questionnaire with the nurse interviewer. You will also receive up to $50 for completion of the 2 microbiome self-collection kits ($25 per completed kit). Payment will be mailed to you within 3 to 4 weeks of the home visit/receipt of completed materials.

Will it cost you anything to be in this sub-study?
It will not cost you anything to be in this sub-study.

Who is sponsoring this sub-study?
This research is funded by the University of North Carolina at Chapel Hill Lineberger Comprehensive Cancer Center.

What if you have questions about this sub-study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the sub-study, including payments, complaints, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at (919) 966-3113 or by email to IRB_subjects@unc.edu.

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Participant's Agreement

I have read the information provided. I have asked all the questions I have at this time. I voluntarily **agree** to participate in this home visit sub-study.

_____ _____
Signature of Study Participant **Date**

_____
Print Name of Study Participant

For Personal Representative of the Study Participant (if applicable)

Print Name of Personal Representative: _____

Please explain your authority to act on behalf of this Study Participant:

_____

I am giving this permission by signing this Consent to Participate in a Research Study on behalf of the Study Participant.

_____ _____
Signature of Personal Representative Date