

University of North Carolina at Chapel Hill
Consent for Biological Specimens – Stool/Vaginal

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?

Research 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 study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the 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 study in order to receive health care.

Details about this 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 study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this specimen repository or "biobank?"

Research with blood, tissue or body fluids (specimens) can help researchers understand how the human body works. Research can also answer other questions by using specimens. Researchers may develop new tests to find diseases, or new ways to treat diseases. In the future, research may help to develop new products, such as drugs. Specimens are commonly used for genetic research. Sometimes researchers collect and store many specimens together and use them for different kinds of research, or share them with other scientists; this is called a specimen repository or "biobank."

The purpose of this particular repository or biobank is to make specimens and medical records data available for researchers to study the genetic material in both your stool and vaginal microbiome. Analyzing the genetic material from these samples, they will look at certain changes in the genes (genetic material) to see if these changes are related to your cancer or its treatment (as recorded in your medical records).

How will the specimens be collected?

You will be asked to complete 2 self-collection kits to provide the necessary specimens. One self-collection kit will collect stool to provide a gut microbiome sample. The second self-collection kit will collect a vaginal swab to provide a vaginal microbiome sample. These kits will be mailed to you and contain 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 visit.

What will happen to the specimens?

Any specimens we collect will be stored indefinitely in a University of North Carolina at Chapel Hill (UNC-CH) or UNC-CH-affiliated storage facility. For future research, researchers from universities, hospitals, and other health organizations conducting research using specimens may contact the UNC-CH for their studies. The UNC Institutional Review Board (IRB) and study researchers will review the way these studies will be done and decide if any of the UNC-CH samples may be used.

What are the possible benefits to you?

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 with the use of your specimens?

This research poses minimal risk. For all participants, there is a risk of breach of confidentiality. Every precaution will be taken to secure your personal information. All information is stored under conditions designed to protect the privacy of study participants. There is a possibility that coded information about you may be inadvertently released to members of the public, insurers, employers, and law enforcement agencies. When data are stored electronically, there is also a risk of breach of computer security. If future research on your specimens involves genetic studies, there is also a potential risk for breach of privacy for some of your relatives and other members of your ethnic group, since they share some of your genetic makeup. Every precaution will be taken to keep all information from your medical records and specimen analysis confidential and used only for the purposes of this study.

Will there be any cost to you for storage of the specimens?

There will be no cost to you for the storage and use of the specimens for research purposes.

Will you receive anything for the use of your specimens?

Your participation in this sub-study is completely voluntary. You will receive \$50 for completing the 2 microbiome self-collection kits. You will also receive \$40 as a “thank you” for completing the home visit survey with the nurse interviewer. Payment will be mailed to you within 3 to 4 weeks of the home visit/receipt of completed materials.

With your permission, study staff may follow up with you if the microbiome sample(s) fail to produce enough material to request another self-collection sample. This is not a requirement. You can choose not to participate in providing additional microbiome samples and it will not affect your participation in the study.

Who owns the specimens?

Any stool and/or vaginal specimens obtained for this purpose become the exclusive property of the University of North Carolina at Chapel Hill (UNC-CH). This organization may retain, preserve or dispose of these specimens and may use these specimens for research that may result in commercial applications. There are no plans to compensate you for any future commercial use of these specimens.

How will information about you be protected?

All information that you provide, including information from medical records 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, finalized survey data, and the laboratory results. Every effort will be taken to protect the identity of the participants in the study. No individuals will be identified in any report or publication of this 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.

Will my genetic information be shared?

Your stool and vaginal samples contain genes that are made of DNA unique to you. To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this sub-study, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by this institution, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.” A researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with information from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small but may grow in the future as technology advances. Researchers will always have a duty to protect your privacy and to keep your information confidential.

Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Will researchers seek approval from you to do future studies involving the specimens?

By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants. We may use de-identified data and/or specimens from this study in future research without additional consent. However, in some cases, the IRB may require that you be re-contacted and asked for your consent to use your specimens in a specific research study. You have the right, at that future time, not to participate in any research study for which your consent is sought. Refusal to participate will not affect your medical care or result in loss of benefits to which you are entitled.

Will you receive results from research involving your specimens?

Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about general research results. The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.

Can you withdraw the specimens from the research repository?

You can change your mind at any time. If you decide that you no longer wish for the specimens to be stored, you should contact the researchers on the front page of this form. It is best to make your request in writing.

Any analysis in progress at the time of your request or already performed prior to your request being received by the researcher will continue to be used as part of the research study. Once the researchers have been notified, your remaining specimens would be destroyed. If you do not make such a request, the specimens may be stored forever. The researchers may choose to destroy the specimens at any time.

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 research?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research subject?

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 you may contact, anonymously if you wish, the Institutional Review Board at (919) 966-3113 or by e-mail to IRB_subjects@unc.edu.

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Principal Investigator: Andrew Olshan, PhD

Participant's Agreement:

I have read the information contained in this consent, and I may contact the study personnel listed on this consent if I have any questions or concerns.

Please indicate your wishes below:

1. Consent to Obtain Stool Microbiome Sample – Choose one:

I voluntarily **agree** to allow this study to request a stool microbiome sample from me.

OR

I **refuse** to allow this study to obtain a stool microbiome sample from me.

2. Consent for Future Use of Stool Microbiome Samples – Choose one:

Yes, I voluntarily **agree** that my stool microbiome samples **may** be used in the future for research. I agree to my specimen(s) being stored without any identifying information.

OR

No, my stool microbiome samples **may not** be used in the future. They must be destroyed when the current study is complete.

Signature of Study Participant

Date

Print Name of Study Participant

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Principal Investigator: Andrew Olshan, PhD

Participant's Agreement:

I have read the information contained in this consent, and I may contact the study personnel listed on this consent if I have any questions or concerns.

Please indicate your wishes below:

1. Consent to Obtain Vaginal Microbiome Sample – Choose one:

I voluntarily **agree** to allow this study to request a vaginal microbiome sample from me.

OR

I **refuse** to allow this study to obtain a vaginal microbiome sample from me.

2. Consent for Future Use of Vaginal Microbiome Samples – Choose one:

Yes, I voluntarily **agree** that my vaginal microbiome samples **may** be used in the future for research. I agree to my specimen(s) being stored without any identifying information.

OR

No, my vaginal microbiome samples **may not** be used in the future. They must be destroyed when the current study is complete.

Signature of Study Participant

Date

Print Name of Study Participant