University of North Carolina at Chapel Hill
Consent to Participate in a Research 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

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Concise Summary

The purpose of this research study is to learn more about the diagnosis, treatment, and survivorship experiences of adults with endometrial cancer. Initial enrollment goals are for 1,800 adults living in North Carolina at the time of their recent first diagnosis of endometrial cancer.

Participants will be asked to complete a baseline survey detailing a number of topics, including family history of cancer, sociodemographic factors, menstrual and pregnancy history, medical history, and certain aspects of daily life. In addition, consent to obtain medical records, a sample of stored tissue from diagnosis/treatment/recurrence of endometrial cancer, and a saliva self-collection kit will be pursued. This project will provide important data for integrating tumor biology, access to care, and other factors to identify contributors, and potential areas for intervention to address endometrial cancer disparities. Study staff plan to pursue annual follow-ups with participants, requesting updates to treatment status and quality of life measures for approximately 5 years.

The greatest risks of this study include the possibility of psychosocial discomfort or stress during completion of study surveys 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 studies?

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

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 study?

You are being asked to be in the study because you have been diagnosed with endometrial cancer. The purpose of the study is to understand how the characteristics of endometrial cancer patients and their tumor influence prognosis, treatment, and outcome. We want to learn more about survivorship after endometrial cancer and why some people have different outcomes and experiences.

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

You should not be in this study if you do not believe you have been diagnosed with endometrial cancer.

How many people will take part in this study?

Approximately 1,800 adults living in any county of North Carolina at the time of their diagnosis of endometrial cancer will take part in this study.

How long will your part in this study last?

Taking part in this study does not involve any kind of treatment. A trained interviewer will be contacting you within the next few weeks to ask for your participation and to complete a baseline survey that should take about 45 minutes of your time. You may also complete the survey by mail or online. After the phone call, we will send you consent forms requesting permission to obtain copies of medical records having to do with your diagnosis and treatment of endometrial cancer as well as a saliva self-collection kit. We will also ask for permission to obtain stored tissue from your diagnosis/treatment/recurrence of endometrial cancer kept at your local hospital, lab or doctor's office. It will take about 1 to 1 ½ hours to do all of these things.

The study researchers will follow up with you every year or so by telephone or mail to collect information about treatment status and quality of life measures, for approximately 5 years. If additional medical records or biological samples are needed, we may ask you to sign additional consents at that time. These follow-up contacts will take about 45 minutes to 1 hour to complete.

What will happen if you take part in the study?

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

Baseline Survey: A trained interviewer will call to discuss the study with you, confirm eligibility, and request that you complete a 45-minute survey at a time that is convenient for you. You may also complete the survey by mail or online. The survey contains questions about a number of topics, including family history of cancer, sociodemographic factors, menstrual and pregnancy history, medical history, and certain aspects of daily life. Completion of the survey is very important and highly recommended, but not required to participate in the study. You may choose not to answer any question for any reason. You will also be asked to share about your diagnosis and any treatment of endometrial cancer that you have had or may be planning to have.

Read and Sign Consent forms: After the initial call, we will mail you a consent form packet for your signature, along with a postage pre-paid envelope for you to mail them back to us. The consent packet will include medical record and HIPAA authorizations for the collection of medical records related to the diagnosis/treatment of endometrial cancer, a biological specimens consent for the collection of saliva and stored tissue from your diagnosis/treatment/recurrence of endometrial cancer, and consent to use your social security number for research purposes.

The packet will describe in detail what each consent form will be used for and why we need it. You do not have to sign and return all the consent forms, but we cannot include all your data in our analyses unless you return the signed consents.

Saliva sample: If you sign and return a biological specimens consent for saliva samples, we will also mail you a saliva self-collection kit with instructions, a prepaid label, and return packaging. Genetic material called DNA that is obtained will be used to search for genes that may cause or increase the risk of endometrial cancer, especially those genes that run in families. The results of these studies will not be put in your health records. Providing a saliva sample is very important and highly recommended, but not required to participate in the study.

Future use of samples: You will be asked to give permission for storage of your saliva and tissue from diagnosis/treatment/recurrence of endometrial cancer for future medical research. Only samples that were already collected but not used during the current research study will be stored. If you do not consent to future use of your specimens, they will be destroyed when the current study is completed.

Follow-up/Future Contact: Researchers in this study would like to contact you in the future. We may wish to clarify answers you gave during an interview. We would also like to follow up with you every year or so to see how you are doing and to collect information about treatment status and quality of life measures, for approximately 5 years. If further treatment has occurred or you've had a recurrence or second primary, we may ask you to sign additional medical record, HIPAA, and/or biological specimens consent(s). These follow-up contacts will take about 45 minutes to 1 hour to complete. This is not a requirement. You can choose not to participate in a follow-up call or provide additional medical records release and it will not affect your participation in the study.

Do you consent to future contact?

☐ **Yes**, you **may** contact me in the future.

☐ **No**, I do **not** want to be contacted in the future.

In the event we are unable to reach you for future contact at the phone number, address, or email on file, we may attempt to find updated contact information for you by reaching out to other contacts you have identified, contacting health care providers we have on file for you, or trying to find updated contact information that is available publicly on the internet, such as Yahoo or Google.

We will always maintain your privacy and confidentiality during any contact update attempts. We will say only that we are trying to reach you about a UNC health study. We will ask to speak with you directly. If you are no longer affiliated with that number, we will request your updated contact information. We will never identify the Carolina Endometrial Cancer Study by name or indicate that you are enrolled in the study. We will never mail any study materials to an address other than the one you, your other contacts, your physician, or the post office provides to us.

Do you consent for study staff to request your updated contact information from the following in the event we are unable to reach you?

Other Contacts you provide to us?	☐ Yes	☐ No
Health Care Providers you identify?	☐ Yes	☐ No
Your place of work?	☐ Yes	☐ No

Study staff may want to message you by text or e-mail, however you may say no to receiving these messages and still participate in this study. If you say yes, messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this consent. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

Do you consent for study staff to send un-encrypted messages by text or email?

☐ **Yes**, I consent to study staff utilizing the following cell phone(s)/email(s) for un-encrypted messages:

_____

_____

☐ **No**, I do **not** consent to receive unprotected communication from the study staff.

What are the possible benefits from being in this 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 study?

This research poses minimal risk. The interview contains questions about some sensitive topics, and you may feel emotional distress when you are asked to answer these questions. You may refuse to answer any question. 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 (including results from genetic tests) 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 study?
If there are any significant findings or changes to the study that might affect your willingness to continue your participation, you will be notified.

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 saliva and tissue 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.

What if you want to stop before your part in the study is complete?
You can withdraw from this 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 study has been stopped.

If you withdraw or are withdrawn from this 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 study is completely voluntary. You will receive $40 as a thank you for completing the baseline survey, $15 for returning the signed medical record and HIPAA consents, $15 for returning the signed biological specimens consent, and $40 for returning a completed saliva self-collection kit. Payment(s) will be mailed to you within 3 to 4 weeks of receipt of these items.
If a follow-up contact includes the completion of a survey, you will receive $40 and if we need to obtain additional medical records or tumor tissue, you will receive an additional $15 for returning newly signed medical record and HIPAA consent forms and $15 for returning newly signed biological specimens consent.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

Who is sponsoring this 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 study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the 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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Principal Investigators: Andrew Olshan, PhD and Hazel Nichols, PhD

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 research 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