The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: **Counseling Intervention during Radiation Therapy for Women with Gynecologic Cancer**

Principal Investigator: **Allison Quick, MD**

Sponsor: **The Ohio State University**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

The study team to determine the feasibility and efficacy of a sexual health counseling intervention before or at any point during radiation therapy and after radiation therapy for patients with gynecologic cancer. If you are interested in the study, you will undergo two sessions of counseling with a licensed sexual health therapist via video or in-person visit. You will be asked to complete questionnaires related to general and sexual health and participate in the study for approximately one year after completing radiation therapy.

1. Why is this study being done?

You are being asked to take part in this study because you have diagnosed with gynecologic cancer (endometrial, cervical, vaginal or vulvar cancer) and are going to be treated with radiation therapy as part of your treatment. Women that received radiation treatment for gynecologic cancer can develop problems with multiple side effects including but not limited to painful intercourse, vaginal dryness, vaginal changes, anxiety and depression, that can affect quality of life (QOL).

The purpose of this study is to determine the feasibility of a sexual health counseling intervention before or at any point during radiation therapy and after radiation therapy and evaluate the efficacy of counseling intervention.

Your doctor will explain to you separately from this study the details of the radiation treatment as the radiation therapy you receive will not be part of this research study. Participating in this study does not mean you will have a specific radiation treatment. Your radiation doctor will make a type of radiation based on your individual case.

2. How many people will take part in this study?

Approximately 30 people will take part in this study at The Ohio State University

3. What will happen if I take part in this study?

Prior to taking part in this study, you will be asked to review and sign this consent form.

Screening/Registration
After signing this consent form, you will:

- Give a medical history and undergo physical examination
- Assess how you are feeling
- Undergo a gynecologic exam (vaginal exam) which is optional if not clinically needed
- Take the EORTC QLQ-C30 and EORTC QLQ-CX24, questionnaires that are designed to measure health-related quality of life
- Take the FSDS, a questionnaire that is designed to measure sexually related health status
- Take the SSES-F, a questionnaire that is designed to measure confidence for sexual activities
- Take the ISEL that is designed to document social support information
- Counseling from a licensed sexual health therapist via video telemedicine visit or in-person visit at the outpatient care center in Upper Arlington which can done before or at any point during radiation therapy

At the last day of Radiation Therapy

- Assess how you are feeling and if you have had any adverse effects from radiation treatment
- Take the EORTC QLQ-CX24, a questionnaire that is designed to measure health-related quality of life
- Take the FSDS, a questionnaire that is designed to measure sexually related health status
- Take the SSES-F, a questionnaire that is designed to measure confidence for sexual activities

After Radiation Therapy

Once your radiation therapy is complete, you will be asked to return for several follow-up visits. These visits will be approximately 1 month, 6 months, and 12 months after completing your radiation therapy to complete the following items:

- Physical examination
- Assess how you are feeling and if you have had any adverse effects from radiation treatment
- Undergo a vaginal exam if clinically needed
- Take the EORTC QLQ-C30, a questionnaire that is designed to measure health-related quality of life (only 1 month and 12 months)
- Take the EORTC QLQ-CX24, a questionnaire that is designed to measure health-related quality of life
- Take the FSDS, a questionnaire that is designed to measure sexually related health status
- Take the SSES-F, a questionnaire that is designed to measure confidence for sexual activities
- Counseling from a licensed sexual health therapist via video telemedicine visit or in-person visit at the outpatient care center in Upper Arlington (one session sometime between 1 - 3 months)
- Take the patient evaluation survey, a questionnaire that is designed to measure your satisfaction for the counseling intervention (only 6 and 12 months)

4. How long will I be in the study?

You will be in this study for approximately one year.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

You may have side effects while on the study. Side effects related to the standard radiation treatment are not related to the study.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risk of Breach of Confidentiality:

As part of this study you are at risk for a breach in confidentiality of your protected health information (PHI). We will protect your PHI by storing your data in a secure database and coding your PHI however you are still at risk for a breach in confidentiality.

We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.

Your data will be protected with a code to reduce the risk that other people can view the responses.

Discomfort during Questionnaires and Counseling:

You will be asked to answer questions about your personal health (including sexual activities and your feeling), your ability to perform daily living activities, and social support information during questionnaires and sexual counseling. It is possible that answering these questions and/or discussing your personal health information may make you feel uncomfortable. You will be given as much time is needed to complete these questionnaires. You may choose to skip questions if you are uncomfortable answering.

7. What benefits can I expect from being in the study?

There may or may not be any benefit to you from participating in this study. It is hoped that this study will provide information about sexual health and counseling before/after radiation therapy for women with gynecologic cancer that will affect the treatment of future patients.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. You will still receive your standard of care radiation therapy.

9. What are the costs of taking part in this study?

You and/or your insurance company will not be charged for the following:

- Counseling from a licensed sexual health therapist prior to or at any point during radiation treatment and one session at 1 - 3 months post radiation treatment
- Completion of questionnaires including EORTC QLQ-C30, QLQ-CX24, FSDS, SSES-F, and SSQ6

Most of the care you will receive during this study is considered routine for your disease. This includes your radiation therapy, doctor's visits, and vaginal exams, and medical care or follow-up for any conditions unrelated to this study. These routine services will be billed to you/your insurance in the usual manner. The deductible, copayments, and coinsurance required by your plan will apply to these routine services.

Most private and government health plans cover routine medical costs when you are participating in an approved clinical trial. The routine costs of your care will be billed to you and/or your insurance. You will be responsible for any deductibles, coinsurance or co-payments required by your health plan. Some plans limit the amount they will pay. We recommend that you ask your insurance carrier about any limitations or restrictions that may be specific to your plan.

If you are a Medicare Advantage Plan participant (HMO or PPO), original Medicare is billed first for routine, study-related services while you participate in an approved trial. Your Advantage Plan is billed second for their share of your costs. You may or may not have additional out of pocket costs after Medicare or your Advantage Plan pays. Additional information can be obtained from your Advantage Plan and online at:

https://www.medicare.gov/Pubs/pdf/02226-Medicare-and-Clinical-Research-Studies.pdf

Notice for Managed Care (Medicare Advantage Plan) Beneficiaries
Certain services that are required for your care as a participant in a clinical trial can be billed to, and paid by, your medical insurance. These services are referred to as "covered" clinical trial services. However, if you have a Medicare Advantage Plan as part of your medical insurance, this insurance cannot be billed for covered clinical trial services. Instead, traditional Medicare will be billed, and will pay for those services. This has an impact to you. When traditional Medicare pays for such services, you will be responsible for paying the coinsurance amounts applicable to these services, in addition to any other deductibles or co-insurance you may have on your other health coverage. Please speak with a financial counselor to understand what the specific financial impact will be for you associated with participating in this clinical trial.

10. Will I be paid for taking part in this study?

You will not receive any payment for participating in this study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;

- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Treatment for your cancer diagnosis
- Information gathered for this research about:
  - Physical exams
  - Questionnaires
  - Sexual counseling
  - The diagnosis and treatment of a mental health condition

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;

IV. Your information may be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Allison Quick, MD** at **614-293-8415** or by mail at**:**

460 W. 10th Ave.
2nd Floor
Columbus, OH 43210

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the **HIPAA Privacy Officer in the College of Medicine** at **614-292-2856** or by mail at:

HIPAA Privacy officer
Suite E2140
600 Ackerman Rd.
Columbus, OH 43202

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at **1-800-678-6251**.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Allison Quick, MD** at **614-293-8415** or by mail at**:**

460 W. 10th Ave.
2nd Floor
Columbus, OH 43210

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time