	INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 6/6/2019)	DATE: MRN: NAME:
APPROVED **07-January-2022** **INSTITUTIONAL REVIEW BOARD**	**PROJECT TITLE:** **Prospective evaluation of quality of life and treatment-related side effects of women undergoing multimodality treatment for advanced stage endometrial carcinoma**	

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1. INTRODUCTION

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. More detailed information is provided after the box. No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document.

Key Information for You to Consider
Voluntary Consent. You are being asked to participate in a research study. Participation is voluntary. There will be no penalty or loss of benefits if you choose not to participate or discontinue participation. **Purpose**. The purpose of this research is to examine side effects, quality of life outcomes, and survival outcomes in patients who have stage III endometrial cancer receiving chemotherapy and radiation therapy (RT). **Duration**. It is expected that your participation will last 2 years. **Procedures and Activities**. You will be asked to undergo the standard of care chemotherapy and RT to treat your endometrial cancer. During this time, you will undergo regular assessment of your side effects, which will be treated as needed. Also, you will be asked to complete a questionnaire at regular intervals to assess your quality life and the severity of the treatment side effects. You will ask that you complete the questionnaire at baseline (first follow-up visit after surgery), at 3 months (this coincides with the fourth cycle of chemotherapy), at 6 months (likely first follow-up after completion of all treatment), at 12

months, and finally at 24 months. The questionnaire will be completed a total of 5 times.

Risks. Some of the foreseeable risks or discomforts of your participation are related to the chemotherapy and radiation treatments. These side effects include nausea/vomiting, diarrhea, dehydration, lowered blood counts that increase risk of infection, and nerve pain in hands/feet. More detailed information can be found in the "*What Are The Risks, Discomforts, And Inconveniences Of The Study?*" section in the Consent Form.

Benefits. Some of the benefits that may be expected include improved survival outcomes using this chemotherapy and RT treatment. You will also be followed very closely so that we can assess your side effects. In more general terms, you will help us to evaluate side effect patterns of this treatment, which will help other patients as well.

Alternatives. Participation is voluntary and the alternative remains the standard of care with combined chemotherapy and radiation.

2. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST

The Henry Ford Health System (HFHS) investigator(s) on this study are also healthcare providers. They are interested in the knowledge to be gained from this study and are interested in your well-being. Investigators may obtain salary or other financial support for conducting the research.

3. WHY IS THIS RESEARCH BEING DONE?

You have been asked to take part in a research study because you have been diagnosed with stage III endometrial cancer and will be recommended to undergo both chemotherapy and radiation treatments.

The purpose of this Phase II study is to find out what effects (good and/or bad) combined chemotherapy and RT has on you and your quality life, side effect profile, and survival outcomes.

A total of 60 people will be enrolled in this study at Henry Ford Health System (HFHS).

4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you agree to take part in this study, your participation in this study will last a total of 24 months (2 years). As part of this study, you will undergo combined chemotherapy and RT, which is the standard of care in women who have diagnosed with this disease. You will also be asked to fill-out a questionnaire at regular intervals during your treatment. We will ask you to fill-out this form at baseline, 3, 6, 12, 18 and 24 months after surgery. These forms will be filled out in an outpatient setting. The time expected to fill out each form is between 5-10 minutes. These questionnaires will be filled out at standard follow-up visits, and you will not need to make a special trip to the hospital to complete them.

During the study, you will have the following procedures:
• Experimental components: Questionnaire at baseline, 3, 6, 12, 18, and 24 months • Standard components: Combined RT and chemotherapy, treatment of side effects

For some research studies, including the one you are being asked to join, you will be given the results of certain tests that are standard of care including blood tests and follow-up scans to assess your response to therapy and any side effects you may be having.

5. WHAT ARE THE RISKS, DISCOMFORTS, OR INCONVENIENCES OF THE STUDY?

While you are in the study, you are at risk for the following side effects:

Likely
• **Fatigue, nausea/vomiting, dehydration, weight loss, diarrhea, burning with urination, low blood counts (low white blood cells, platelets, red blood cells) that may put you at risk for infection or bleeding, nerve pain in hands/feet, bone pain**

Less Likely
• **Rectal bleeding, blood in urine, vaginal dryness, pain with sexual intercourse, allergic reaction to medications**
Rare but Serious
• **Sepsis (systemic infection), small bowel obstruction, secondary malignancy (cancer caused by treatment), rupture of spleen, death**

These side effects are related to both chemotherapy and radiation treatments. Receiving both treatments together increases the risk of them happening as well as their severity.

Blood samples will be obtained from your veins. Possible side effects of obtaining blood samples are pain, bruising, bleeding, or infection at the blood draw site. Occasionally nausea, lightheadedness or fainting may occur.

The researchers will try to minimize these risks with regular follow-up and close physician supervision. In addition to addressing side effects as needed, patients will be administered growth factor injections on a weekly basis during chemotherapy and RT treatments in order to minimize the risk of developing low blood counts. Growth factor administration is a routine part of care in patients undergoing this treatment. Additionally, many side effects can be managed with medications for symptomatic relief (e.g. loperamide for diarrhea, phenazopyridine for burning with urination).

There may be additional risks or discomforts that are not known at this time. Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. If you are currently in another study, took part in one recently, or if you consider another study in the future, please inform the research staff right away.

Additional risks include a potential breach of confidentiality of your personal information. The measures taken to protect your personal information and any possible disclosure are described in the section below titled "*How will my personal information be protected*?"

6. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

You may not directly benefit from this research and we hope that others are helped in the future by what is learned.

7. WHAT OTHER OPTIONS ARE THERE AND WHAT ARE MY ALTERNATIVES?

Participation is voluntary. You do not have to participate in this study.

Your other choices may include:

- Receiving the standard of care therapy which is combined chemotherapy and radiation, which may include different types of chemotherapy treatments combined with radiation
- Receiving no treatment at all

Talk to your doctor and family about your choices before you decide if you will take part in this study.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

Research records will not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. Your research information will not be made a part of your regular medical record. If the researcher orders any tests, the order and results may become part of your regular medical record. All electronic files containing identifiable information will be password protected on a secure Henry Ford network drive and only the members of the research staff will have access to the passwords. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. The researchers will maintain any data described in this paragraph in accordance with the security provisions of this paragraph until destroyed by the researchers.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without your additional informed consent.

You should also know that the HFHS Institutional Review Board (IRB) and IRB Administration Office may inspect study records as part of its auditing program, but these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

9. WHAT IF I GET SICK OR I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study.

By signing this consent form, you do not give up any of your legal rights in the event of an injury.

10. WHO DO I CONTACT WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Dr. Elshaikh, or his staff member has explained this research study and has offered to answer any questions. If you have any additional questions about the study procedures, or to report an injury you may contact Dr. Elshaikh by phone at (313) 916-1021 or by email at melshai1@hfhs.org. Medical treatment is available to you in case of an injury.

If you would like to discuss your rights as a research participant, discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research, you may contact the Henry Ford Health System IRB Administration Office by phone at (313) 874-4464 or by email at research_admin@hfhs.org. The IRB is a group of people who review the research to protect your rights.

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

11. DO I HAVE TO PARTICIPATE IN THIS STUDY?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. Inform the research staff/study doctor if you are thinking about stopping or decide to stop. There are no penalties or loss of benefits to which you are otherwise entitled if you decide that you do not want to participate.

If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study. You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

You do not have to answer any question that you do not want to answer.

12. WHO ELSE CAN STOP MY PARTICIPATION?

The PI, sponsor, or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons. Reasons that we may end your participation include poor tolerance to therapy including low blood counts leading to infection or intolerable side effects.

13. WILL IT COST ANYTHING TO PARTICIPATE?

There will be no charge to you for your participation in this study.

14. WILL I BE PAID TO PARTICIPATE?

There is no compensation available to you for your participation in this study.

DOCUMENTATION OF CONSENT

By signing this form, I agree that I have read and understand this form and that I agree to participate in the research project described above. I have been given enough time and opportunity to ask about the details of the research study and to decide whether or not to participate. Its general purposes, the particulars of my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time without giving any reason without my medical care or legal rights being affected. My signature also indicates that I have received a copy of this consent form.

The researchers in this study might want to ask you to participate in additional studies. In some cases, you might be a good candidate for a particular study because of your health history or genetic information.

I am willing to be contacted for future research studies. Please initial below.

_____ I agree

_____ I refuse

I understand that the investigator may use publicly available databases to determine whether I am living, for purposes related to my participation in this study only. Please initial below.

_____ I agree

_____ I refuse

_____ _____ _____

Signature of Subject Date Time

_____

Printed Name of Subject

_____ _____ _____

Witness to Signature Date Time

_____ _____ _____

Signature of Person Obtaining Consent Date Time

_____

Printed Name of Person Obtaining Consent

I am unable to read but this consent document has been read and explained to me by _____ (name of reader). I volunteer to participate in this research.

_____ _____ _____

Signature of Subject/Representative Date Time

_____

Printed Name of Subject/Representative (and Relationship if Someone other than the Subject)

_____	_____	_____
Witness to Signature	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

_____

Print Name of Person Obtaining Consent