CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY:

11-GYN-098-MCC: Neoadjuvant Platinum-based Chemotherapy in Advanced Ovarian, Fallopian Tube, and Primary Peritoneal Carcinoma Trial Protocol

INVESTIGATOR INFORMATION:
Rachel W. Miller, M.D.
Division of Gynecologic Oncology
331 Whitney Hendrickson Building
Ph: 859-323-2169 (Day)
(Evenings & Weekends) 859-323-5321 ask Operator to page the Gynecologic Oncologist on call

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about chemotherapy in ovarian, fallopian tube, and primary peritoneal cancer because you have ovarian, fallopian tube, or primary peritoneal cancer. If you volunteer to take part in this study, you will be one of about 30 people to do so at the University of Kentucky.

WHO IS DOING THE STUDY?

The person in charge of this study is Rachel W. Miller, M.D., University of Kentucky, Department of Obstetrics and Gynecology, Division of Gynecologic Oncology. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

The current standard treatment for ovarian, fallopian tube, and primary peritoneal cancer is a combination of surgery for removal of the cancer, followed by chemotherapy drugs, carboplatin and paclitaxel, given every three weeks. Recently, investigators have shown that performing surgery after 3 cycles of chemotherapy (instead of prior to chemotherapy) can improve outcomes at surgery without compromising the effects of treatment. The purpose of this study is to determine the effectiveness and side effects of carboplatin and paclitaxel for 3 cycles, followed by surgery to remove as much disease as possible (called interval cytoreduction), and then additional carboplatin and paclitaxel for 3-5 cycles.

Effectiveness of treatment will be measured in terms of survival, side effects, and quality of life (wellness and physical functioning).

In addition to the treatment part of this study, the researchers plan to test samples of your blood and tumor tissue. The purpose of this research is to determine if this testing can be used in the future to determine ahead of time which patients may respond to treatment or have good prognosis.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

You should not participate in this study if you have received previous chemotherapy for any abdominal or pelvis tumor, or radiation to any part of your abdomen or pelvis, had evidence of any other cancer within the last three years other than non-melanoma skin cancer.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the Markey Cancer Center, UK Medical Center. You will need to come to the Markey Cancer Center, once every 3 weeks (3 weeks equals one cycle) for a total of six to eight cycles (about 5 months). You will have surgery approximately 3 weeks after the 3rd cycle of chemotherapy, and then resume the subsequent cycles of chemotherapy (cycles 4-6 or 8) about 2 weeks after surgery. Each of the visits for chemotherapy will take about 4-6 hours.

WHAT WILL YOU BE ASKED TO DO?

Before you begin the study

You will need to have the following exams, tests or procedures to find out if you can be in the study. Unless otherwise noted, these exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- History and physical examination which may include pelvic examination
- Blood tests to assess blood cell counts; liver and kidney function; blood mineral levels; blood clotting tests
- A blood pregnancy test if you are capable of becoming pregnant

You will undergo the following procedures that are not part of regular cancer care and are being done only because you are in this study.

- Collection of one extra vial of blood for research at the time of regularly scheduled blood draws prior to beginning study treatment.
- Filling out of an approximately 20-minute quality of life questionnaire during a regularly scheduled pre-treatment office visit.

During the study

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures before beginning treatment, and periodically during treatment and after treatment is completed. They are part of regular cancer care.

- Periodic history and physical examination which may include pelvic examination.
- Electrocardiogram (EKG) to measure your heart function before beginning treatment.
- Chest x-ray or CT scan of the chest.
- Detectable tumor will be measured periodically by physical examination, CT scan, or MRI scan.

- Periodic blood testing for CA-125 level. CA-125 is a blood test that is generally performed for patients with your type of cancer to monitor the effectiveness of treatment.
- Periodic blood tests to assess blood cell counts; liver and kidney function; blood mineral levels.

You will undergo the following procedures that are not part of regular cancer care and are being done only because you are in this study.

- Collection of two extra vials of blood for research at the time of regularly scheduled blood draws prior to the first chemotherapy cycle, prior to surgery, and one time between 24 – 72 hours after surgery
- A small part of the tumor removed during surgery will be studied in a research lab to assess the effects of chemotherapy on the tumor cells.
- Filling out of an approximately 20-minute quality of life questionnaire during four of the regularly scheduled office visits.

Once you are enrolled in the research study, you will receive the following treatment every 21 days (a cycle) for 6-8 cycles: Paclitaxel into your vein over 3 hours, and Carboplatin into your vein over 30 minutes on Day 1. You will have interval cytoreductive surgery between cycles 3 and 4. The number of cycles will be determined by the amount of residual cancer at the time of surgery and by the response to chemotherapy.

On the day of chemotherapy you will be asked to take a steroid medication (dexamethasone) prior to the expected infusion time. This is given to prevent allergic reactions to the paclitaxel. You will also be given intravenous medication to block allergic reactions to paclitaxel, and drugs to prevent side effects including nausea and vomiting.

Your doctor may decide to give you a drug called docetaxel instead of paclitaxel if you have an allergic reaction or severe numbness in your hands and feet when you are treated with paclitaxel. The docetaxel will be given into your vein every 21 days.

In addition, you will be asked to provide blood for laboratory testing that is not part of regular cancer care and is being done only because you are in this study.

QUALITY OF LIFE

We want to know your view of how your life has been affected by cancer and your treatment. "Quality of life" looks at how you are feeling physically and emotionally during your cancer treatment. It also looks at how you are able to carry out your day-to-day activities.

This information will help doctors better understand how patients feel during treatments and what effects the medicines are having. In the future, this information may help patients and doctors as they decide which medicines to use to treat cancer.

You will be asked to complete five questionnaires: one on your first visit, one before surgery, one before the fourth cycle, one 3 weeks after finishing treatment, and one 3 months after finishing treatment. It takes about 10-20 minutes to fill out each questionnaire. You will be asked to complete the questionnaire regardless of whether you have discontinued treatment for any reason.

If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

After your treatments are completed:

To monitor your well-being and the status of your cancer, you will undergo these tests and procedures that are part of regular cancer care, every three months for two years, then every six months for three years, then yearly:

- History and physical examination which will include pelvic examination.
- Blood tests to assess blood cell counts; liver and kidney function; blood mineral levels if your physician feels they are necessary for monitoring
- Hearing test, if your physician feels it is necessary for monitoring
- CA-125 blood tests
- CT or MRI scan, if previously detectable tumor was monitored using these methods or if your physician has concern about the possibility of cancer recurrence.
- Blood clotting function tests if your physician feels it is necessary.

Study Chart

You will receive paclitaxel and carboplatin every 21 days in this study. This 21-day period of time is called a cycle. You will receive paclitaxel and carboplatin for 6-8 cycles.

Each cycle is numbered in order. The chart below shows what will happen to you during Cycle 1 and future treatment cycles as explained previously. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

Cycle 1 (All Patients)

Day	What you do
Within 28 days before starting study	• History and physical examination, which may include a pelvic exam • Electrocardiogram (EKG) to measure heart function • Audiogram (if there is a history of hearing loss) • A CT scan or MRI of abdomen and pelvis to measure tumor • Fill out quality of life questionnaire (will take approximately 20 minutes)
Within 14 days before starting treatment	• Get routine blood tests and urinalysis • Get a pregnancy test if you could possibly become pregnant. • Blood tests for research
Day 1	• Pre-chemotherapy medications by IV (into your vein) or mouth to prevent allergic reactions • Go to your doctor's office or infusion center for treatment with IV paclitaxel and carboplatin chemotherapy. You will be there for approximately 4 hours.
Day 8	• Get routine blood tests.
Day 15	• Get routine blood tests.
Between Days 18 & 21	• Physical examination • Get routine blood tests
Day 22	• Begin Cycle 2 (Day 1 of Cycle 2, see next chart)

Cycle 2

Day	What you do
Day 1	• Pre-chemotherapy medications by IV or mouth to prevent allergic reactions • Go to your doctor's office or infusion center for treatment. • Receive paclitaxel and carboplatin into your vein. You will be there for approximately 4 hours.
Day 8	• Get routine blood tests.
Day 15	• Get routine blood tests.
Between Days 18 & 21	• History and physical examination • Routine blood tests.
Day 22	• Begin next cycle (Day 1 of next Cycle)

Cycles 3 and 4 (for patients who will have interval cytoreductive surgery)

Day	What you do
Day 1	• Pre-chemotherapy medications by IV or mouth to prevent allergic reactions • Go to your doctor's office or infusion center for treatment. • Receive paclitaxel and carboplatin into your vein. You will be there for approximately 4 hours. • Examination of incision (cycle 4)
Day 8	• Get routine blood tests.
Day 15	• Get routine blood tests.
Between Days 15 & 21	• CT or MRI scan (Cycle 3 and Cycle 6) • Fill out quality of life questionnaire (Cycle 3) (this will take approximately 20 minutes) • Have interval cytoreductive surgery (cycle 3) • Research blood samples before cytoreduction surgery and within 24 to 72 hours after surgery
Between Days 18 & 21	• History and physical examination • Routine blood tests.
Day 22	• Begin next cycle (Day 1 of next Cycle)

Cycles 5 through 6-8

Day	What you do
Day 1	• Pre-chemotherapy medications by IV or mouth to prevent allergic reactions • Go to your doctor's office or infusion center for treatment. • Receive paclitaxel and carboplatin into your vein. You will be there for approximately 2 hours.
Day 8	• Get routine blood tests.
Day 15	• Get routine blood tests.
Between Days 15 & 21	• CT or MRI scan (Cycle 3 and Cycle 6)

Between Days 18 & 21	• History and physical examination • Routine blood tests.

After Treatment

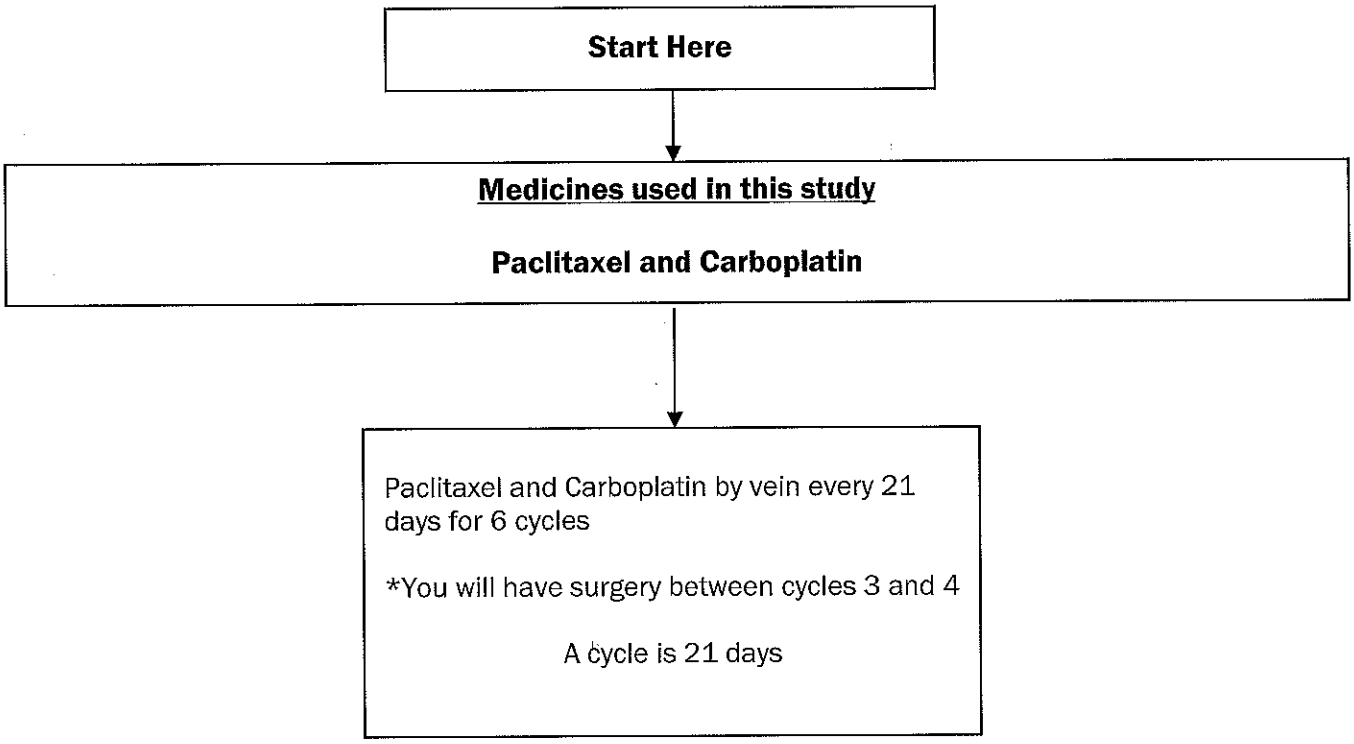
3 weeks after completions of chemotherapy	• Fill out quality of life questionnaire (will take approximately 20 minutes)
3 months after completions of chemotherapy	• Fill out quality of life questionnaire (will take approximately 20 minutes)

After Completion of Treatment (ALL REGIMENS)

Timing	What you do
Every 3 months, 8 times, then every 6 months, 6 times, then every year	• History and physical examination • Assessment of side effects • CA-125 blood test • CT or MRI scan
If physician feels there is a possibility of cancer re-growth	• CT or MRI scan

Study Plan

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



You will be asked to take paclitaxel and carboplatin for approximately five to seven months. After you are finished with your study treatment, the study doctor will ask you to visit the office for follow-up exams every three months for the first two years and then every six months for the next three years after completion of your treatment. At the end of this five-year period we would like to keep track of your medical condition for the rest of your life by calling you once a year to see how you are doing. Keeping in touch with you and checking on your condition every year helps us look at the long-term effects of the study.

If you experience a severe allergic reaction to IV paclitaxel that cannot be overcome with standard anti-allergy medications, or numbness or tingling in your hands or feet which would cause discontinuation of paclitaxel, then the drug docetaxel (Taxotere) will be substituted for paclitaxel. Docetaxel has been found to be as effective in patients with ovarian and primary peritoneal cancer as paclitaxel. Docetaxel is from the same chemical family as paclitaxel and generally has the same type of side effects as paclitaxel with some important differences. When compared to paclitaxel, docetaxel has been found to cause less tingling and numbness in the hands and feet but has been found to cause lower white blood cell counts and higher risk of infection and a chance of severe fluid retention (see below). It has also been found that some patients who experience allergic reactions to paclitaxel do not demonstrate allergic reactions to docetaxel.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen.

Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the paclitaxel and carboplatin. In some cases, side effects can be serious because they can be long lasting, may never go away, may result in hospitalization, or may be life-threatening. There is also a risk of death.

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

Risks and side effects related to **Paclitaxel (Taxol)** include those which are:

Likely:

- Low white blood cell counts - this may make you more open to infection
- Low platelet count - this may make you bruise more easily and bleed longer if injured
- Low red blood cell count which may cause tiredness, shortness of breath or fatigue
- Mild to severe allergic reaction which may be life-threatening with hives, wheezing (difficulty breathing) and change in blood pressure (low or high)
- Numbness and pain of the hands and feet that sometimes worsens with additional treatment and may not disappear after the drug is stopped. This may lead to difficulty walking, buttoning clothes, etc. (may be serious)
- Hair loss
- Muscle weakness and muscle loss
- Muscle and joint aches
- Nausea and/or vomiting
- Diarrhea
- Sores in the mouth or throat (that can lead to difficulty swallowing and dehydration)

Less likely:

- Low blood pressure
- Irregular heartbeats
- Fever
- Fatigue, weakness
- Swelling, accumulation of fluid
- Elevation in liver function blood tests
- Confusion; mood changes
- Skin tissue irritation, swelling or discoloration around the injection site
- Skin tissue damage if some of the drug leaks from the vein while it is being given
- Changes in taste
- Rash

Rare but serious:

- Elevation of serum creatinine in kidneys (may be reversible or can lead to kidney damage)
- Inflammation of the colon, pancreas or lungs (may be serious)
- Liver failure
- Seizures
- A slowing of the heart rate (a slow pulse is not harmful; however, if you should develop any other irregularities in heart rate during treatment, an EKG and other tests may be required.)
- Heart attack
- Blood clots
- Blockage in the intestines

- Opening in the bowel wall

Risks and side effects related to **Docetaxel (Taxotere)** include those which are:

Likely:

- Low white blood cell counts - this may make you more open to infection
- Low platelet count - this may make you bruise more easily and bleed longer if injured
- Low red blood cell count which may cause tiredness, shortness of breath or fatigue
- Mild to severe allergic reaction which may be life-threatening with hives, wheezing and low blood pressure
- Numbness and pain of the hands and feet that sometimes worsens with additional treatment and may not disappear after the drug is stopped. This may lead to difficulty walking, buttoning clothes, etc.
- Hair loss
- Muscle weakness and muscle loss; muscle and joint aches
- Shortness of breath
- Skin irritation (including hives and itching if allergic reactions)
- Low or high blood pressure
- Nausea and/or vomiting
- Diarrhea
- Mouth and throat sores
- Fatigue
- Excessive tearing of the eyes
- Chills; fever
- Fluid retention, in the form of weight gain, poorly tolerated swelling of the legs, arms, tissues beneath the skin, sometimes fluid collections in the chest causing shortness of breath and strain on the heart, and sometimes fluid collections in the abdomen (ascites) which can cause abdominal discomfort, distention and indigestion.
- Nail changes (e.g. discoloration, fungal infection, bleeding under the nail, etc.)

Less likely, but serious:

- A slowing of the heart rate (a slow pulse is not harmful; however if you should develop any other irregularities in heart rate during treatment, an EKG and other tests may be required.)
- Irregular heartbeats
- Heart attack
- Sores in the mouth or throat (that can lead to difficulty swallowing and dehydration)
- Lightheadedness
- Headaches
- Kidney damage
- An increase in triglycerides (a blood lipid) levels which could increase risk of hardening of the arteries
- Liver damage
- Confusion; mood changes
- Skin tissue damage if some of the drug leaks from the vein while it is being given
- Changes in taste
- Irritation and swelling of the skin in an area previously treated with radiation therapy
- Rash
- Inflammation of the colon, pancreas or lungs
- Blurred vision or other changes in eyesight such as sensation of flashing lights or spots
- Infection and/or bleeding complications as a result of decreased blood counts

Rare, but serious:

- Liver failure
- Swelling of the Brain
- Seizures
- Severe allergic reaction resulting in development of a rash, difficulty breathing , and low blood pressure
- Acute leukemia

Risks and side effects related to **Carboplatin** include those which are:

Likely:

- Low white blood cell counts - this may make you more open to infection
- Low platelet count - this may make you bruise more easily and bleed longer if injured
- Low red blood cell count which may cause tiredness, shortness of breath or fatigue
- Tiredness
- Loss of appetite and weight loss
- Diarrhea, constipation, nausea and vomiting, and abdominal pain
- Complete hair loss
- Skin rash
- Changes in taste
- Changes in electrolytes in the blood such as magnesium and potassium

Less likely, but serious:

- Numbness or tingling in fingers or toes
- Ringing in the ears and hearing loss
- Allergic reactions
- Chills and fever with aches and pains
- Decrease in kidney or liver function
- Sores in mouth and throat (that can lead to difficulty swallowing and dehydration)
- Altered vision

Rare, but serious:

- Seizures
- Secondary cancers such as acute leukemia
- Kidney failure requiring dialysis
- Deafness
- Death

Dexamethasone may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- upset stomach
- stomach irritation
- vomiting
- headache
- dizziness
- insomnia
- restlessness
- depression
- anxiety
- acne

- increased hair growth
- easy bruising
- irregular or absent menstrual periods

If you experience any of the following symptoms, call your doctor immediately:

- skin rash
- swollen face, lower legs, or ankles
- vision problems
- cold or infection that lasts a long time
- muscle weakness
- black or tarry stool

Reproductive risks:
You should not become pregnant while on this study because the drug(s) in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. **It is important you understand that if you could become pregnant, you need to use birth control while on this study.** Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. If you are capable of becoming pregnant, a pregnancy test will be required before starting the study. You should notify your health care team immediately if you think you have become pregnant while participating in this study.

For more information about risks and side effects, ask your study doctor.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. Your willingness to take part, however, may, in the future, help doctors better understand and/or treat others who have your condition.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of medical care you receive.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, there are other choices such as getting treatment or care for your cancer without being in a study. The standard treatment for ovarian, fallopian tube, and primary peritoneal cancer is surgery for removal of the cancer followed by chemotherapy drugs, carboplatin and paclitaxel. Your other choices are getting no treatment and getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems, and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

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

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment you receive during this study that you would normally receive for your condition. These are costs that are considered medically reasonable and necessary and will be part of the care you receive if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare or Medicaid for the medical procedures done strictly for research. Some health plans will not pay the cost of managing the side effects of therapy for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Medicare or Medicaid may pay medically necessary costs. If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid at 1-800-635-2570. A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be substantial.

You will not be paid for taking part in this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep private all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Electronic data will be password protected to protect your confidentiality. You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else.

The University of Kentucky procedures include removing your name and other identifying information from data collected during the study, in order to protect your privacy. Your registration information including your name, medical record number and social security number are electronic records that are password protected by the database. All other records are de-identified by research staff at the University of Kentucky before being shared with others. However, we cannot guarantee total confidentiality. Your records may be accessed by the University of Kentucky for research, quality assurance, and data analysis purposes.

In addition, your records may be reviewed by the Food and Drug Administration (FDA); or for research or regulatory purposes.

Data from this study may be provided to another researcher at some future time for use in an approved research project. If this occurs, the researcher must agree to keep individual patient information confidential.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to withdraw you from the study if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the researchers decide to stop the study early for a variety of scientific reasons.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Rachel Miller, M.D. immediately at 859-323-2169 (8am-4:30pm). *After hours* call UK Healthcare General Information at 859-323-5000 or the UK Healthcare Paging Operator at 859-323-5321 and ask for your doctor. Dr. Miller will determine what type of treatment, if any, that is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

The medical costs related to your care and treatment because of research related harm will be your responsibility. Your insurer may agree to pay those costs (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances). Medicare or Medicaid may pay medically necessary costs (if you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare 1-800-633-4227) or Medicaid 1-800-635-2570). A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs). The amount of this co-payment/deductible may be substantial.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the principal investigator, Rachel Miller, M.D. at 859-323-2169. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WHAT ELSE DO YOU NEED TO KNOW?

The sample(s) (blood and tumor tissue) that you are giving might be used in studies that lead to new products for research, diagnosis or treatment. These products might have some commercial value. There are no plans to provide financial compensation to you should this occur.

This study is being carried out under the sponsorship of the Markey Cancer Center.

GENERAL INFORMATION ABOUT THE COLLECTION AND USE OF SPECIMENS FOR RESEARCH

You are being asked to allow some of your blood and tumor tissue to be submitted and used for research. Such bodily materials are referred to as specimens and are very important in helping doctors and scientists learn more about caring for and treating people with cancer and other diseases. The use of specimens in scientific research can also help doctors and scientists understand why some people develop cancer and others don't, and why some people have cancers that respond or don't respond well to current therapies, and why some people have or don't have side effects to cancer therapies, for example.

The research that may be done with your specimens is not designed specifically to help you, but it may help others with cancer or other diseases in the future. Reports about research done with your specimens will not be given to you or your doctor, or be put in your health record. The research will not have an effect on your care.

When research is performed on specimens connected with clinical information about the person including the person's disease and how the person responds to treatment, for example, doctors and scientists can specifically study how to prevent, detect, treat and cure cancer and other diseases, or how to predict response to therapy, toxicities, recurrence and overall survival.

The investigators of this study utilize procedures and policies to protect your privacy and confidentiality. The chance that information from your health records will be incorrectly released is very small, but you should be aware of this risk. To protect your privacy and confidentiality, the research investigators that study your specimens will never be given your name, address, phone number, Social Security number or any other type of personal identifier. In addition, your specimens will never be labeled with your name or other type of personal identifier. Your specimen will be labeled with a unique series of letters and numbers.

Your specimens will be used for research purposes and will not be sold. However, the research done with your clinical specimens may help to develop new products and therapies in the future, or may be used to establish a cell line or test that could be patented and licensed. In any event, there are no plans to provide you with any direct financial compensation.

A new federal law called Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans and employers of 15 or more person to discriminate against you based on your genetic information. Health Insurance companies and group health plans may not request your genetic information that we get from this research. This means they must not use your genetic information when making decisions regarding insurability. Be aware this new law does not protect you against genetic discrimination by companies that sell life, disability and/or long-term care insurance.

If you agree now that your tissue and blood specimens can be submitted and used for this research study and/or for future research, your specimens will be used for research purposes only until they are used up or if you change your mind. If you change your mind, please contact the staff at your treating institution, typically your doctor or nurse, and tell them that you have changed your mind about allowing your specimens to be used for research. If necessary, the study investigators will destroy (incinerate) all of your specimens to make sure that they will no longer be used for research.

SPECIFIC INFORMATION FOR THIS RESEARCH STUDY

You are being asked to allow some of your blood and tumor tissue to be collected and used in research. Samples of blood and tumor tissue will only be collected from patients who give permission to allow their specimens to be used for this research study.

Requirements

We are asking permission from you to draw some of your blood during this study. Two teaspoons of your blood will be collected prior to the first cycle of chemotherapy treatment, before surgery, and one time within 24-72 hours after surgery.

What Will Happen To Your Tumor Tissue and Blood Specimens If You Agree?

If you give permission for your blood and tissue specimens to be used for this research study, your health care team will send your specimens to a laboratory at the University of Kentucky where they will be tested for certain inflammatory markers in your blood.

After the laboratory testing is finished, the results will be analyzed at the University of Kentucky. The results from the laboratory testing will be studied to determine if any of the laboratory testing

may be used to identify which patients in the future might be more or less likely to respond to the study drug, have side effects or have a good prognosis. These results will be used for research purposes only, and published after completion of this research study. Reports of this research done on your specimens will not be given to you or your doctor, or be put in your health record.

MAKING YOUR CHOICES FOR THIS RESEARCH STUDY

Please read each sentence below and think about your choice. After reading each sentence, initial "Yes" or "No". **No matter what you decide to do, it will not affect your care. You will still be allowed to participate in this research study even if you don't want your specimens to be submitted and used for this research study.** If you have any questions, please talk to your doctor, nurse or other type of healthcare provider.

1. **Do you give permission for some of your blood to be collected and used for this research study?**

   (Initial one)

   _____**Yes** _____**No**

2. **Do you give permission for a small part of the resected tumor to be collected and used for this research study?**

   (Initial one)

   _____**Yes** _____**No**

SPECIFIC INFORMATION FOR FUTURE RESEARCH

The next section of the consent will ask you to decide whether your specimens, if still available after completion of this research study, can be used for future cancer research or for research for health problems other than cancer. We will also ask your permission to use the clinical information that the investigators will collect about you as part of your participation in this research study to be utilized for future research that will use your specimens. Next, we will ask for permission to contact you in the future to participate in more research.

If you agree to allow your specimens to be used for future research, there is a chance that your specimens may be used to study changes in genetic material that are passed on in families or that are not passed on in families but are either natural changes or influenced by environment and lifestyle. These tests can focus on a section of genetic material (DNA), genetic material packaged into chromosomes or examine all of the genetic material called the whole genome. The results can then be studied to identify changes in genetic material that influence the development of diseases including cancer or the effectiveness of specific treatments.

The choice to let us collect your specimens for future research is up to you. No matter what you decide to do, it will not affect your care. You can still participate in this study if you do not allow your specimens to be used for future research.

MAKING YOUR CHOICES ABOUT FUTURE RESEARCH

Please read each sentence below and think about your choice. After reading each sentence, initial "Yes" or "No". Please talk to your doctor, nurse or other type of healthcare provider.

1. **Do you give permission for your specimens, if still available after this research study is completed, to be used in future research to learn about, prevent, or treat cancer? (Initial one)**

   _____Yes _____No

2. **Do you give permission for your specimens, if still available after this research study is completed, to be used in future research to learn about, prevent or treat health problems other than cancer (for example: diabetes, Alzheimer's disease, or heart disease)? (Initial one)**

   _____Yes _____No

3. **Do you give permission for the clinical information collected as part of your participation in this study to be used for future research that uses your specimens? (Initial one)**

   _____Yes _____No

4. **Do you give permission for your specimens, if still available after this research study is completed, to be used for future research to study changes in genetic material? (Initial one)**

   _____Yes _____No

5. **Do you give permission for someone from your institution such as your doctor or nurse to contact you in the future to ask you to take part in more research? (Initial one)**

   _____Yes _____No

_____ _____

Signature of person agreeing to take part in the study Date

_____

Printed name of person agreeing to take part in the study

_____ _____

Name of [authorized] person obtaining informed consent Date

_____

Signature of Investigator