Consent Form
University of Oklahoma Health Sciences Center (OUHSC)
Stephenson Cancer Center

Phase IB Feasability Trial of Paclitaxel/Carboplatin + Galunisertib (a Small Molecular Inhibitor of the Kinase Domain of Type 1 TGF-β Receptor) in Patients with Newly Diagnosed, Persistent or Recurrent Carcinosarcoma of the Uterus or Ovary

Principal Investigator: Kathleen Moore, MD

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You have the choice not to participate. You may discuss your decision with your friends, family and doctors. If you have any questions, you can ask your study doctor for more information at any time.

This study is being conducted by the University of Oklahoma Stephenson Cancer Center. Lilly pharmaceutical company is providing the study medicine, galunisertib, free of charge.

Why Have I Been Asked To Participate In This Study?

You are being asked to take part in this study because you have a form of uterine or ovarian cancer that requires additional medical treatment. Medicine that targets cancer cells is referred to as "chemotherapy."

Why Is This Study Being Done?

The usual treatment for your cancer is a combination of two chemotherapy medicines, carboplatin and paclitaxel. Even with this treatment, many women with this type of cancer either do not have their cancer go away entirely or have their cancer come back. Galunisertib is a new medicine that works against a part of the tumor that is thought to play a role in allowing your cancer type to become more aggressive.

The purpose of this study is to find out if the addition of the new medicine, to the paclitaxel and carboplatin, is safe in patients with this type of cancer. We will collect information about any side effects and how you feel with the three medications. We will also look to see if the medicine is helpful in shrinking cancers, keeping them from growing or spreading, or helping patients live longer.

We are also interested in collecting a piece of your tumor tissue, either from a recent surgery or new biopsy. It will be used to help understand why this treatment might help. Some patients will have blood drawn 5 times to check the levels of the drug in your bloodstream.

What is the Status of the Drugs involved in this study?

Galiunisertib is an investigational medicine. An investigational medicine is one that has not yet been approved by the US Food and Drug Administration (FDA).

Carboplatin and paclitaxel are approved by the US Food and Drug Administration (FDA) for treatment of your cancer.

How Many People Will Take Part In The Study?

About 36 people will be in this study. All participants will be at this location.

What Is Involved In The Study?

Before you begin the study

You will need to have the following exams, tests or procedures to find out if you can be treated in the study. 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.

- Doctor's visit with examination to include a pelvic examination
- Blood work to measure blood counts, blood salt levels, and how well your liver and kidneys are working
- A pregnancy test if you are capable of becoming pregnant
- Urinalysis (examination of urine)
- CT scan or MRI of the chest, abdomen and pelvis to measure your tumor

You will need to have the following tests as part of the study. The following exams are not standard of care:

- Possible tumor tissue biopsy

During the study

If the exams, tests and procedures show that you can be treated in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

- Doctor's visit with examination to include a pelvic examination every treatment cycle (typically every 4 weeks)
- Blood tests to measure blood counts, blood salt levels, and how well your liver and kidneys are working (as often as once weekly during combination treatment then monthly during maintenance treatment)
- Urinalysis (examination of urine) done once every treatment cycle (typically every 4 weeks)
- Repeat CT scans every other cycle (typically every 8 weeks) during combination treatment then every 4 cycle during maintenance treatment.

You will have the following tests that are not part of regular cancer care and are being done only because you are in this study:

- Possible blood draws to monitor the galunisertib levels in the blood
- Possible tumor tissue biopsy after first cycle if your disease is still measurable

You will receive treatment with paclitaxel and carboplatin by vein (IV) on day 1. On days 4-17 of the cycle, you will take the study pill, twice a day by mouth. On days 17-28 of cycle, you will

not have any medicine. On day 29, if your oncologist feels you may safely continue treatment, you will begin a new 28 day cycle. After you have had 4 cycles of treatment, if you do not have any active cancer, your physician may discuss continuing treatment with the study pill, galunisertib, alone for up to 1 year.

Note: You may receive treatment with Docetaxel and carboplatin by vein (IV) on day 1 if you are allergic to paclitaxel.

After your treatments are completed:

To monitor your well-being and the status of your cancer, you will have these tests and procedures that are part of regular cancer care:

- Doctor's visit with examination which may include pelvic examination
  - every 3 months for two years
  - then every 6 months for three years
  - then every year thereafter
- Blood work if your physician feels they are necessary for monitoring
- CT scan or MRI

Study Chart

You will receive a combination of three medications every 4 weeks in this study. This 4-week period of time is called a cycle. The cycle will be repeated until either

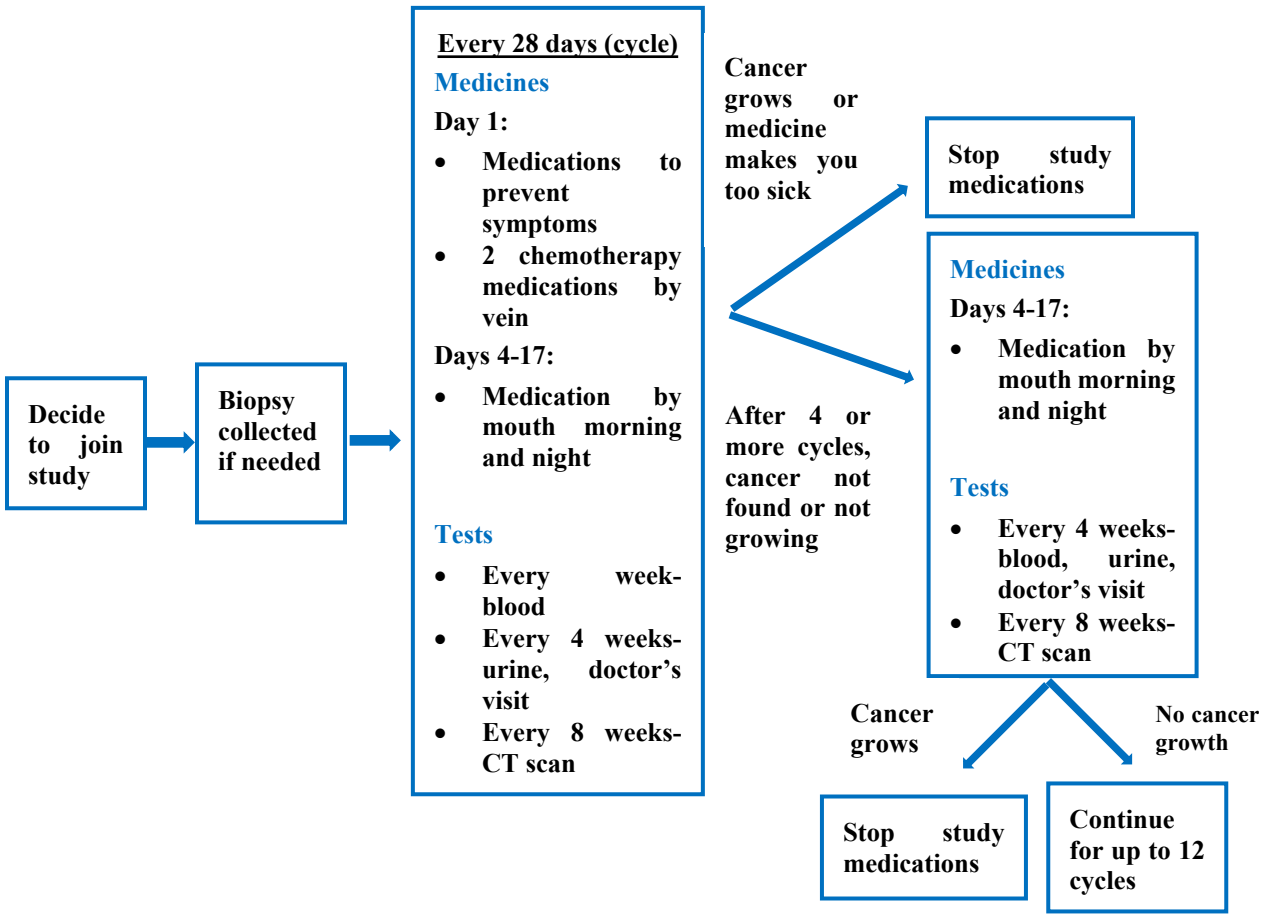
- your cancer grows or spreads
- the medications cause you too many side effects
- or your cancer has gone away on a cat scan and you have received at least 4 cycles.

The chart below shows what will happen to you during each cycle. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

Cycle Day	What you do
Within 7 days of treatment	• Have a doctor's visit with an exam which may include pelvic exam • Vital signs including heart rate, blood pressure and weight • Get blood and urine tests
Day 1	• Vital signs including heart rate, blood pressure and weight • Receive medicines to prevent side-effects of the chemotherapy • Receive carboplatin and paclitaxel by vein
Day 4-17	• Take study pills by mouth twice daily
Day 8, 15, 22	• Get blood work
Prior to Day 1 of Cycle 3, 5, 7, etc	• CT scan • heart ecg and Doppler (due before cycle 3 and every 6 months)

Study Plan

Another way to find understand what will happen to you during the study is to read the chart below. Start reading at the left and continue across the chart, following the lines and arrows.



How Long Will I Be In The Study?

You will be asked to take the study medicines as long as there is evidence that your tumor is not growing or spreading and you are not having any bad side effects. If there is no cancer on your scans after 4 cycles of treatment (~ 4 months), you may stop the two medicines by vein and continue with the medicine by mouth alone for one more year.

After you have finished treatment, the study doctor will follow up your survival status through phone check in every 3 month for two years from date of registration. After this, 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 you every year helps us look at the long-term effects of the study medicines.

Can I Stop Being in the Study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping, so any risks from the study treatment can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what other care and testing could be most helpful for you.

There may be situations under which you will not receive any more study treatments even though you want to.

- The doctor feels that it is safest for you.
- Your cancer or medical illnesses worsen.
- New information becomes available that suggests another treatment would be better for you
- You do not follow study requirements.
- The study is stopped by the sponsor.

What Are The Risks of The Study?

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 medications**.** In some cases, side effects can be serious because they can last a long time, may never go away, may result in hospitalization, may be life-threatening, or even cause 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 <u>Paclitaxel</u> include those which are:

<u>Likely (>10%):</u>

- 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
- 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

<u>Less likely, but potentially serious (≤10%):</u>

- 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
- Nausea and/or vomiting
- Diarrhea
- Sores in the mouth or throat (that can lead to difficulty swallowing and dehydration)

- Fatigue
- 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 irritation and swelling if the drug leaks from the vein into the surrounding skin 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
- High or low blood pressure
- Allergic reaction, which may be life-threatening with hives, wheezing and low blood pressure

Rare, but serious (< 1%):

- Liver failure
- Seizures

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

Likely (> 10%):

- 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
- Fatigue
- 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 lowering of magnesium and potassium

Less likely, but serious (≤10%):

- 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 (< 1%):

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

Risks and side effects related to Docetaxel include those which are:

Likely (> 20%):

- Swelling of the body
- Hair loss
- Change in nails
- Rash, itching
- Vomiting, diarrhea, nausea, constipation
- Sores in mouth which may cause difficulty swallowing
- Infection, especially when white blood cell count is low
- Anemia which may require blood transfusions
- Bruising, bleeding
- Tiredness
- Numbness and tingling of the arms and legs
- Fever
- Absence of menstrual period
- Swelling and redness of the arms, leg or face
- Pain
- Watering, itchy eyes

Less likely (4-20%):

- Severe skin rash with blisters and peeling which can involve inside of mouth and other parts of the body
- Belly pain
- Kidney damage which may require dialysis
- Blood clot which may cause swelling, pain, shortness of breath
- Abnormal heart rate
- Shortness of breath, wheezing
- Chest pain

Rare, but serious (≤3%):

- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Cancer of bone marrow (leukemia) caused by chemotherapy

Risks and side effects related to Galunisertib

Given that this medicine is new, not all of the potential side effects are known. The medicine has been used in other small numbers of patients with few side effects. Possible side effects that may occur given what we know about the medicine are listed below.

Possible Risks

- Blood clots in legs or lung
- Decreased ability to fight infections
- Increased size of the aorta (blood vessel) which can lead to the vessel tearing
- Low blood pressure
- High heart rate
- Heart damage causing the heart to beat less effectively
- Over reactive immune system which leads to inflammation of the lungs, bowel, joints, or other parts of the body
- Birth defects if taken during pregnancy
- Low platelet count - this may make you bruise more easily and bleed longer if injured

Additional Risks or Discomforts

Tumor Biopsy:

If you undergo a tumor biopsy, there may be side effects such as:

- Pain
- Bruising
- Bleeding
- Infection

The risks may vary depending on the location of the tumor mass being biopsied. Mild pain is related to the procedure itself, occurs in most patients, and is typically transient and well-controlled by the administration of pain medication, if necessary. The risk of infection is low. If infection does occur, antibiotics will be administered. The risk of bleeding with these biopsies is also typically low, but it is not known if treatment with Galunisertib may increase the risk of bleeding. Your study doctor can specifically discuss the risk of bleeding in your particular situation with you.

Reproductive Risks: You must not be and should not become pregnant nor breast-feed an infant while on this study. Taking the study medicine while you are pregnant or breastfeeding may involve risks to an unborn baby, including birth defects which are currently unforeseeable. **It is important you understand that if you could become pregnant, you must use birth control consistently while on this study and for one month after stopping the medicines.** In order to reduce your risk of pregnancy, you or your partner should use one or more of the acceptable methods of birth control listed below, always while you are in this study.

Acceptable methods of birth control include:

- An approved birth control pill
- Intra-uterine device (IUD)
- Hormone implants
- Depo-Provera
- Diaphragm with spermicidal gel or condoms
- Birth control patch
- Birth control ring
- Tubal ligation, hysterectomy or vasectomy
- Abstinence

If you are already using a method of birth control, check with the study doctor to make sure it is safe for this study. Certain drugs may interact with some methods of birth control and reduce how well they work. You should inform the study doctor of all medicines (prescription and over-the-counter) that you are currently taking or begin taking during the study.

If you become pregnant or suspect that you are pregnant during this study, immediately tell one of the study staff. If you become pregnant or suspect that you are pregnant while on this study, tell the study doctor immediately; the study doctor will perform a pregnancy test. The study drug may be stopped until the result of the pregnancy test is known. If you are pregnant, you may be asked to permanently stop the study. The study doctor will assist you in getting obstetrical care at your cost. Payment for all aspects of obstetrical, child, or related care will be your responsibility.

Are There Benefits to Taking Part in The Study?

Taking part in this study may or may not make your health better. While doctors hope the addition of the study medicine to chemotherapy will improve the benefits of treatment, there is no proof of this yet. Information from this study will help doctors learn more about adding the study medicine to chemotherapy as a treatment for this type of cancer. This information could help future cancer patients.

What Other Options Are There?

Your other choices may include:

- Getting treatment for your cancer without being in a study which may include chemotherapy, radiation, or a combination of chemotherapy and radiation
- Taking part in another study
- Getting no anti-cancer medicine and instead taking only medicines to control the symptoms of your cancer (palliative care).
- Getting no care at this time

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

What About Confidentiality?

Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee

absolute confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate form for use or sharing of your protected health information.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the US Food & Drug Administration, and other regulatory agencies, Lilly Oncology. The OUHSC Human Research Participant Program office, the Institutional Review Board, and the OUHSC Office of Compliance may also inspect and/or cop your research records for these purposes. .

Under NCI policy, 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.

When the research results are published or discussed in conferences, no information will be included that reveals your identity. In a few rare situations, federal or state law requires disclosure of personal information.

What Are the Costs?

You and/or your health plan/ insurance company will need to pay for some of the costs of treating your cancer in this study, including the cost of managing the side effects of therapy. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. You will be responsible for paying any deductibles, co-insurance, and co-payments as required under the terms of your insurance plan(s). Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

Paclitaxel and carboplatin are both FDA-approved, commercially available drugs. You or your insurance company will be responsible for the costs of your chemotherapy.

Galunisertib is an investigational drug and will be provided free of charge by Lilly Oncology. The heart tests which are specifically needed to check for side effects of this medicine will be covered under the study.

You will not be paid for taking part in this study. The institution receives payment that covers some, but not all, of the costs of the 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.

What if I am Injured or Become Ill While Participating in this Study?

In the case of injury or illness resulting from this study, emergency medical treatment is available. No funds have been set aside by The University of Oklahoma Health Sciences Center or OU Medical Center to compensate you in the event of injury.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

What Are My Rights As a Participant?

Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time. However, at certain times during the treatment, it may be harmful for you to withdraw, so please be sure to discuss leaving the study with the principal investigator or your regular doctor. You may stop being in the study at any time without penalty or loss of benefits, to which you are otherwise entitled.

We will provide you with any important new findings developed during the course of the research that may affect your health, welfare or willingness to continue being in this study.

You have the right to access the medical information that has been collected about you as a part of this research study. However, you may not have access to this medical information until the entire research study has completely finished and you consent to this temporary restriction.

Where Can I Get More Information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. If you want more information about this study, ask your study doctor.

GENERAL INFORMATION ABOUT THE COLLECTION AND USE OF SPECIMENS FOR RESEARCH

You are being asked to allow samples from your tumor and blood to be submitted and used in 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, 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, 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 University uses procedures designed to protect your privacy and confidentiality. The chance that information from your health records would 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 personal information. In addition, your specimens will never be labeled with your name or other type of personal identifier. Your specimens will be labeled with a unique series of letters and numbers in order to keep track of the specimens. Research investigators receive specimens labeled only with these codes.

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

If you agree now that your tumor specimen and/or blood specimens can be submitted and used for this research study and/or future research, you can change your mind at any time. At that time, 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.

SPECIFIC INFORMATION FOR THIS RESEARCH STUDY

Requirements

We would like to have your permission to have some of your tumor, if available, from a recent surgery. If you have not recently had surgery or your tissue sample is not enough, we are requesting you undergo a biopsy to obtain a small piece of your tumor. If you still have measurable disease after first cycle, you will undergo a second biopsy. The reason for this is to study your tumor and the effect of this treatment on it.

We are also asking some participants to provide two teaspoons of blood at 6 time points to better understand how long the study medicine stays in your body when taken with this chemotherapy. These include

- 3 times on day 4 of cycle 1 (first day of the medication by mouth)
- Once on day 8 of cycle 1
- Once on day 15 of cycle 1

Agreement for additional procedures and release of tumor samples

When you agree to participate in this study, the study team will determine if the additional blood work or biopsy is needed.

1. **Do you give permission for your blood to be collected for these additional studies?**
   Yes **No** _____**Initials of Patient**

2. **Do you agree to allow your tumor that was already collected to be used for this study?**
   Yes **No** _____**Initials of Patient**

3. Do you agree to have a tumor biopsy completed prior to starting treatment on this study?

Yes No N/A _____Initials of Patient

SPECIFIC INFORMATION FOR FUTURE RESEARCH

The last section of the consent will ask you to decide whether your tumor samples, 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 we 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. Reports of this research done in your specimens will not be given to you or your doctor, and will not be put in your health record.

Risks of genetic testing:

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you or your family against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Also, GINA does not prohibit discrimination of individuals with a genetic disorder that has been diagnosed. However, in order to do everything possible to keep this from happening, the results of this test will NOT be given to anyone outside the study staff. This means that it will not be made available to you, your family members, your private physician, your employer, your insurance company or any other party as allowed by law.

The choice to let us use 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, circle "Yes" or "No". **No matter what you decide to do, it will not affect your care.** If you have any questions, please talk to your doctor, nurse or other type of healthcare provider.

1. **Do you give permission for your specimens to be used in future research to learn about, prevent, or treat cancer?**
   Yes **No** _____**Initial**

2. **Do you give permission for your specimens 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)?**
   Yes **No** _____**Initial**

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?**
   Yes **No** _____**Initial**

4. **Do you give permission for your specimens to be used for future research to study changes in genetic material?**
   Yes **No** _____**Initial**

5. **Do you give permission for someone from the cancer center such as your doctor or nurse to contact you in the future to ask you to take part in more research?**
   Yes **No** _____**Initial**

Whom Do I Call If I have Questions or Problems?

If you have questions, concerns, or complaints about the study or have a research-related injury, contact study doctor Kathleen Moore, M.D. at (405) 271-8707 (anytime).

If you cannot reach Dr. Moore or wish to speak to someone other than the study doctor, contact the OUHSC Director, Office of Human Research Participant Protection at 405-271-2045.

For questions about your rights as a research participant, contact the OUHSC Director, Office of Human Research Participant Protection at 405-271-2045.

Signature:

By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

Signature of Research Participant	Printed Name of Research Participant	Date
Signature of Person Obtaining Informed Consent	Printed Name of Person Obtaining Informed Consent	Date

AUTHORIZATION TO USE or SHARE HEALTH INFORMATION[1] THAT IDENTIFIES YOU FOR RESEARCH THAT ALSO INCLUDES A RESEARCH REPOSITORY

An Informed Consent Document for Research Participation may also be required.
A different form must be used for research involving psychotherapy notes.

Title of Research Project: Phase IB Feasability Trial of Paclitaxel/Carboplatin + Galunisertib (a Small Molecular Inhibitor of the Kinase Domain of Type 1 TGF-β Receptor) in Patients with Newly Diagnosed, Persistent or Recurrent Carcinosarcoma of the Uterus or Ovary

Leader of Research Team: Kathleen Moore, MD

Address: 800 NE 10th Street, Oklahoma City, OK 73104

Phone Number: 405 271-8707

Purpose of Repository: To determine if Galunisertib in combination with Carboplatin and Paclitaxel is helpful in treating carcinosarcoma of the uterus or ovary. Your samples may also be used in future research to help patients with this type of cancer.

If you decide to participate in this research project, which may also include a Research Repository, University of Oklahoma Health Sciences Center (OUHSC) researchers may use, keep, or share information about you that identifies you (protected health information) for their research. Protected health information will be called PHI in this document.

What is a Research Repository? A Research Repository (data bank) is a collection of information from the health and medical records of many individuals and can sometimes include identifiable tissue specimens. The Repository (data bank) shares the information with researchers who study medical conditions and diseases.

The Repository (data bank) includes codes that identify each person whose information is collected. However, the Repository does not share information with researchers unless the researchers promise to keep the information confidential.

PHI To Be Used or Shared. Government rules require that the researchers get your permission (authorization) to use or share your PHI. If you give permission, the researchers could use or share with the people identified in this authorization, any PHI related to this research from your medical records and from any test results. This includes: personal information that you provide including

[1] **Protected Health Information includes all identifiable information relating to any aspect of an individual's health whether past, present or future, created or maintained by a Covered Entity.**

your age, gender, etc., the results of procedures and tests, information about your response to treatments, and other medical information relating to your participation in the study. Information used or shared will also be or might be personal information such as your name, address, telephone number, date of birth, race, government-issued identification number, medical records, and charts relating to any tests or procedures outlined in the informed consent form.

Purposes for Using or Sharing PHI. If you give permission, the researchers will use your PHI to: conduct the research and procedures described in the Informed Consent Form and as otherwise permitted by the Informed Consent Form.

Other Use and Sharing of PHI. If you give permission, the researchers could also use your PHI to develop new procedures or commercial products. They could share your PHI with the research sponsor, the OUHSC Institutional Review Board, inspectors who check the research, and government agencies like the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS). The researchers may also share your PHI with: Lilly Oncology.

Confidentiality. Although the researchers will report their findings in scientific journals or meetings, they will not identify you in their reports. The Repository and the researchers will try to keep your information confidential, but confidentiality cannot be guaranteed. The law does not require everyone who might see your information covered by this document to keep it confidential, so it might be released to others and federal law may no longer protect it.

YOU UNDERSTAND THAT YOUR PROTECTED HEALTH INFORMATION MAY INCLUDE INFORMATION REGARDING A COMMUNICABLE OR NONCOMMUNICABLE DISEASE.

Voluntary Choice. The choice to give OUHSC researchers and the Repository permission to keep or share your PHI for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for the Repository to use or share your private health information if you want to participate in the Research Repository.

Refusing to give permission will not affect your ability to get usual treatment or health care unrelated to this study from OUHSC.

Canceling Permission. If you give the Repository or OUHSC researchers permission to use or share your PHI, you have a right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the Repository or researchers have already used or shared or to information necessary to maintain the reliability or integrity of the research.

End of Permission. Unless you cancel it, permission for OUHSC researchers and the Repository to use or share your PHI for their research will never end.

Contacting OUHSC. You may find out if your PHI has been shared, get a copy of your PHI, or cancel your permission at any time by writing to:

Privacy Official or Privacy Board

University of Oklahoma Health Sciences Center
PO Box 26901, Oklahoma City, OK 73190

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PO Box 26901, Oklahoma City, OK 73190

If you have questions call: (405) 271-2511 or (405) 271-2045.

Access to Information. You have the right to review your medical records. However, your right to review your medical records in your research records is suspended until after the study is complete. You agree to this temporary restriction.

Giving Permission. By signing this form, you give OUHSC and the Research Team Leader of the study listed at the top of this form, which may also include a Repository, permission to keep your PHI and share it with researchers to use in their research.

Patient/Participant Name (Print): _____

_____ _____
Signature of Patient-Participant Date
or Parent if participant is a minor

Or

_____ _____
Signature of Legal Representative** Date

**If signed by a Legal Representative of the Patient-Participant, provide a description of the relationship to the Patient-Participant and the Authority to Act as Legal Representative:

_____
OUHSC may ask you to produce evidence of your relationship.

A signed copy of this form must be given to the Patient-Participant or the Legal Representative at the time this signed form is provided to the researcher or his representative.