Subject's Name: _____ MCC# 15042
Subject's Medical Record #: _____ IRB#: 106178d

Informed Consent to Participate in Research and Authorization to Collect, Use and Share Your Health Information
University of South Florida/H. Lee Moffitt Cancer Center & Research Institute, Inc.
Information to Consider Before Taking Part in This Research Study

Doctors and researchers at H. Lee Moffitt Cancer Center & Research Institute study diseases and other health problems people may have. Our goal is to try to find better ways to help treat these health problems. To do this, we need the help of people who are willing to take part in a research study.

We are asking you to take part in a research study that is called:

"A Pilot Prospective Trial of Genomic Directed Salvage Chemotherapy with Either Liposomal Doxorubicin or Topotecan in Recurrent or Persistent Ovarian Cancer Within 12 Months of Platinum-Based Chemotherapy"

The person who is in charge of this research study is Dr. Robert Wenham. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge. The person explaining the research to you may be someone other than the Principal Investigator.

Other research personnel who you may be involved with include: Dr. Johnathan Lancaster, Dr. Sachin Apte, and Sierra Theodore, RN.

The research will be done at H. Lee Moffitt Cancer Center & Research Institute and Duke Medical Center.

This research is being paid for by the Department of Defense (DOD). The National Functional Genomics Center will pay for the molecular aspects of this study. Clinical components of the study reflect the current standard of care and will be funded using usual clinical funding mechanisms.

Should you take part in this study?

This form tells you about this research study. After reading through this form and having the research explained to you by someone conducting this research, you can decide if you want to take part in it.

Before you decide:

- Read this form and make sure you know what the study is about.
- Talk about this study with the study doctor or the person explaining the study. You can have someone with you when you talk about the research study.

IRB Approval
FWA 00001669
IRB Number: 106178
From 10/30/07
Thru 10/7/08

This form explains:

- Why this study is being done.
- What will happen during this study and what you will need to do.
- Whether there is any chance you might experience potential benefits from being in this study.
- The risks of having problems because you are in this study.
- How the information collected about you during this study will be used and with whom it may be shared.

You can ask questions:

- You may have questions this form does not answer. If you do have questions, feel free to ask the study doctor or the person explaining the study, as you go along.
- You don't have to guess at things you don't understand. Ask the people doing the study to explain things in a way you can understand.

After you read this form, you can:

- Take your time to think about the information that has been provided to you.
- Have a friend or family member go over the form with you.
- Talk it over with your regular doctor.

It's up to you. If you choose to be in the study, then you should sign the form. If you **do not** want to take part in this study, you should **not** sign the form.

Why is this research being done?

- This pilot study will help us determine the success of using microarray technology to make genomic predictions for individual women about which of two therapies, liposomal doxorubicin or topotecan, will be more effective in treating recurrent ovarian cancer. We believe that this study may lead to a means by which microarray technology can predict the most effective treatment decision, based on the genetic characteristics of her tumor tissue, for a woman with recurrent ovarian cancer.
- Another purpose of this study is to determine the treatment response rate and to evaluate the accuracy of the genomic predictions.

Why are you being asked to take part?

We are asking you to take part in this research study because you have ovarian cancer that has recurred or persisted within 12 months of cisplatin or carboplatin.

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How long will you be asked to stay in the study?

You will be asked to spend about 12 weeks participating in this study. You may participate much longer in the study if your cancer is stable or decreasing in size. A participant must receive at least two cycles of chemotherapy to determine response.

How often will you need to come for research study visits?

A research study visit is one you have with the study doctor or research personnel. This visit is much like the visits you make with your regular doctor. You will need to come for **about 5-6** study visits, or more if your cancer is stable or decreasing and you choose to participate longer.

At each visit, you will be assessed by a doctor and/or research nurse. You will also have blood work and IV chemotherapy. The chemotherapy intervals are explained in a subsequent section of this document. Every 8 weeks you will have a radiologic evaluation of your tumor.

How many other people will take part?

About 30 women will take part in this study at H. Lee Moffitt Cancer Center.

Will your regular medical treatment change if you take part in this study?

The kind of treatment you now get from your Moffitt doctor will change because you take part in this study. By taking part in this study you will receive either Liposomal doxorubicin or Topotecan. The decision about which drug you receive will be made following a genomic analysis of your own biopsied tissue. The genomic analysis will be used to try to predict which of these drugs is likely to be more appropriate for you.

You can talk to your regular doctor <u>and</u> your study doctor about the medicines or treatments you will be given.

If you have an emergency, you can get emergency care. If possible, let the emergency care doctor or nurse know that you are participating in a research study. Also, let the study doctor know that you have had to seek emergency care as soon as possible.

What other choices do you have if you decide not to take part in this study?

If you decide you do not want to take part in this study that is okay. If you decide not to participate in this research, there are other choices such as;

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment

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Talk to your doctor about your choices before you decide if you will take part in this study. If you choose not to participate you can continue to see your regular doctor for management of your condition or disease.

How do you get started?

If you decide to take part in this study, you begin by signing this form, which is your consent to take part in the research. This form is also your agreement to allow us to use your personal health information as needed in the research study. Until you have agreed to take part in the study and have signed this form, no research actions or measures will take place.

If you decide to take part in the study, we will do some screening tests to see if you are able to be in the study.

- You will be asked questions about your medical history and health and undergo a complete physical exam
- Tumor biopsy, which will be needed for the genomic analysis
- A complete blood count and chemistry test (about 1 tablespoon of blood will be taken)
- A CT scan and/or MRI so that we can assess your tumor
- Performance status tests (will determine your ability to perform everyday functions).
- A pregnancy test will be done if you are able to become pregnant
- An EKG and possibly a MUGA scan, depending on which treatment drug is selected for you

Upon analysis of results, you and the research study team will decide whether or not you should be in the study.

What will happen during this study?

After the initial visit and fulfillment of the tests that are required to determine eligibility, if you are eligible you must provide signed informed consent. Using tissue from a CT guided core biopsy, microarray analysis will be performed to help predict which of the two drugs appears to be better suited to individual genomic factors. The results will result in being assigned to treatment with either liposomal doxorubicin or topotecan.

If you receive liposomal doxorubicin, IV chemotherapeutic treatment will occur 3 times, 28 days apart, weeks 1, 5, and 9. At each of these visits you will be evaluated and have blood work to check your liver tests and electrolytes. Every 8 weeks you will have a radiologic evaluation of your tumor.

If you receive topotecan, IV chemotherapeutic treatment will occur 4 times, 21 days apart, weeks 1, 4, 7, and 10. At each of these visits you will be evaluated and have blood work to check levels of liver tests and electrolytes. Every 8 weeks you will have a radiologic evaluation of your tumor.

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During this study, here is what you will need to do:

You will need to comply with the required examination and treatment dates, which will be communicated in advance.

What if the research study or consent form changes?

If the study plan or the consent form for this research study changes while you are taking part in the research study, you may be asked to sign a new consent form with those changes so that you can stay in the study. We will contact you if that happens.

You will be told of any new information that may affect your willingness to take part in this research study.

Will you be paid for taking part in this study?

We will not pay you for the time you volunteer while being in this study.

What will it cost you to take part in this study?

The sponsor of this research will pay the costs of the microarray analyses.

You or your insurance company, Medicare or Medicaid, will be expected to pay the costs for the drugs that are provided during this study because you would receive these as part of your regular medical care. These are costs that are considered medically reasonable and necessary and would be part of the care you would receive if you did not take part in this study. However, you may want to check with your insurer to see if they will cover these costs.

What are the potential benefits if you take part in this study?

We do not know if you will get any health benefits by taking part in this study. We do not know if the experimental procedure will help your disease. We are doing this study to develop a reliable method for selecting the treatment to which a woman is most likely to respond, based on pre-treatment genomic microarray analyses of her own tumor tissue. We do not know if the micorarray analysis will accurately predict a chemotherapy to which you will respond. This research study should help us learn more about whether this procedure will improve treatment decisions in the future.

What are the risks if you take part in this study?

The treatment might not help.

Right now we do not know for sure if it will help. If it does not help, your condition/disease may get worse.

There may be side effects.

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You may have problems related to the treatment drugs that are used in this study. These problems are called side effects. Some side effects are just a bother. Others could harm you. There may be some side effects that we don't know about yet.

Here are the known side effects that could happen with these drugs:

A. Topotecan (Hycamtin® NSC #609699) *could cause the following adverse effects:*

Hematologic

- Lowering of blood counts
  1. Decrease in red cells, or anemia, which can make you feel fatigued and tired
  2. Decrease in platelets which may increase the risk of bleeding
  3. Decrease in white blood cells which may increase the risk for infection

Gastrointestinal

- nausea and vomiting
- diarrhea
- constipation
- abdominal pain
- mouth ulcers
- loss of appetite

Dermatology/Skin

- rash
- hair loss
- skin rash
- itching
- allergic reaction

Constitutional

- fatigue
- fever

Pain

- bone or muscle pain
- headache

Pulmonary/Respiratory

- breathlessness
- cough

Neurologic

- tingling in the fingers or toes

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Hepatic
- elevated liver function enzymes.

B. Liposomal Doxorubicin DOXIL® (NSC #712227) could cause the following adverse effects:

Dermatologic
- mouth ulcers,
- redness, or pain, in the palms or soles
- rash or redness of the skin at sites of previous radiation treatments
- hair loss

Hematologic
- Lowering of blood counts
  1. Decrease in red cells, or anemia, which can make you feel fatigued and tired
  2. Decrease in platelets which may increase the risk of bleeding
  3. Decrease in white blood cells which may increase the risk for infection

Hypersensitivity
- serious, potentially life threatening allergic reaction
- reaction to an introduction of a substance into the body, usually into the blood

Gastrointestinal
- abdominal pain
- nausea,
- vomiting.

Cardiotoxicity
Cardiotoxicity is a condition when there is damage to the heart muscle. As a result of cardiotoxicity, your heart may not be able to pump blood through out your body as well. This may be due to chemotherapy drugs, or other medications you may be taking to control your disease. Cardiotoxicity, if severe, may lead to cardiomyopathy (that lead to damaged heart muscle). Injury to heart muscle may cause a disturbance in the heart's pumping action, and subsequent heart failure) Cardiotoxicity is rare with DOXIL compared to doxorubicin with a reported incidence of 0-9%.

C. Risk of CT Scan
When the contrast medium (x-ray dye) is injected during the CT scan, you may experience nausea, flushing, warmth, and a salty taste. You might be allergic to the contrast medium. You should tell the doctor and the radiologist if you are allergic to iodine. You must not move during the test, but relax and breathe normally. You might

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be uncomfortable while you are in the tunnel-shaped machine. Some people have felt claustrophobic (fear of confined spaces) during this test. You will be exposed to radiation during this test. Radiation dose from CT scan is about the same as the average person received from background radiation from everyday life in 3 years.

D. Risks of the MRI

This MRI machine uses a strong magnet and radio waves to make images of the body interior. The scanning procedure is very much like an x-ray CT scan. You will be asked to lie on a long narrow couch for a certain amount of time while the machine gathers data.

During this time you will not be exposed to x-rays, but rather a magnetic field and radio waves. You will not feel either. You will, however, hear repetitive tapping noises that arise from the radio antenna around your body. We will provide earplugs or ear phones that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" (a "closed-in" feeling).

There are no known significant risks with this procedure at this time because the radio waves and magnetic fields, at the strengths used, are thought to be without harm. The exception is if you have a cardiac pacemaker, or a certain type of metallic clip in your body (i.e., an aneurysm clip in your brain).

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you can discontinue the exam at anytime.
The magnetism and radio waves do not cause harmful effects at the levels used in the MRI machine. However, because the MR scanner uses a very strong magnet that will attract metal, all metallic objects must be removed from your person before you approach the scanner. In addition, watches and credit cards should also be removed as these could be damaged.

E. Risks associated with standard of care and alternative treatment:

As with any medication or chemotherapy treatment, there may be risks, known or unknown. The most common temporary side effects for ***some*** chemotherapy drugs may include nausea and vomiting, loss of appetite, hair loss, mouth sores, higher risk of infection (due to decreased white blood cells), bruising or bleeding, fatigue, and changes in your menstrual cycle if you are a woman, (e.g., irregular periods to symptoms of menopause [end of menstruation]).

There is always a chance that any medical treatment may cause some discomfort or harm and the drugs/procedures in this study are no different. We will do everything possible to keep you from being harmed. There may be other risks or side effects that occur that we don't know about at this time. It is important for you to tell us when you experience such a side effect.

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These side effects may be serious, may require medical care, and may cause permanent or lasting problems. If you have any of these problems, call your study doctor immediately at 813-745-7205.

A more complete listing of side effects for other therapies may be available for you to review if you wish. Please talk with your study doctor about the risks of both this experimental therapy and any alternative methods of treatment that are available.

Is there any risk to your unborn children if you take part in this study?

If you are pregnant, you may not participate in this study, since the effects of the drugs used in this study on the unborn baby are unknown. If you are an adult of child bearing potential, you will be asked to practice an appropriate form of birth control during this study.

If you are a female of childbearing potential, you will be given a pregnancy test prior to being enrolled in the study. If the pregnancy test is positive, you will be excluded from participating. The test will be done at no cost to you. Nursing (breastfeeding) mothers will not be included in this study, since there is no knowledge whether the drugs in this study will be passed on to the baby in mother's milk. If you wish to continue nursing, your study doctor will recommend another non-investigational treatment.

Examples of acceptable birth control methods for women to use while on this study include:

- Oral (birth control pills)
- Birth control patch
- Implanted (injectable contraceptive hormones or mechanical products such as intrauterine device)
- Barrier methods (diaphragm, condoms, spermicidal)
- Tubal ligation

Tell one of the study doctors right away if:

- You are pregnant.
- You get pregnant.
- You are breastfeeding.

If you take part in this study, it could be that:

- *Your unborn children may have problems now or in the future.*
- Your breastfeeding baby may have problems.

What if you get sick or hurt while you are in the study?

If you need emergency care:

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- **Go to your nearest hospital or emergency room right away. Call 911 for help.** It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.
- Call the study doctors as soon as you can. They will need to know that you are hurt or ill. Call Dr. Robert Wenham, 813-745-7205.

If you do NOT need emergency care:

- Go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

H. Lee Moffitt Cancer Center & Research Institute and University of South Florida Injury Statement

If you believe you have been injured as a result of research study procedures performed at the Moffitt Cancer Center, please contact the Risk Manager at (813) 745-4219 and the USF Self Insurance Program (SIP) at (813) 974-8008 and ask them to look into what happened.

If you are harmed because you take part in the study:

- The Moffitt Cancer Center, University of South Florida ("USF"), and Dr. Robert Wenham have made no provision for monetary compensation in the event of physical illness or injury resulting from this research study.
- In the event of such injury, medical treatment may be available to you. In some cases, costs for medical treatment not covered by your insurance company or any other person, may be repaid by the sponsor for any illness or injury that is directly related to the study. The sponsor will not pay for any injuries or medical conditions that are not directly related to the study. If your insurance and the sponsor do not pay, you may be responsible for payment.
- In no event is payment for lost wages, disability, or discomfort available.
- Florida law limits the liability of USF and the Moffitt Cancer Center. Read Florida Statute 768.28 to find out the limits of USF's and the Moffitt Cancer Center's potential liability. You can get a copy of the law by calling the Moffitt Cancer Center Research Compliance Office at (813) 745-1869.

You do not give up any of your legal rights when you sign this form.

Conflict of Interest Statement

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The existence of the Investigator and Institutional Significant Financial Interests will be disclosed to the patients in the informed consent form using language similar to the following (with approval by the USF IRB):

> "The Moffitt Cancer Center and the collaborating institution have pending patent applications (which may become issued patents) related to one or more parts of this study. These patent applications relate to Dr. Lancaster's research. This means that it is possible that the results of this study could lead to personal profit for the Moffitt Cancer Center, the collaborating institution, and/or Dr. Lancaster. This project has been carefully reviewed to help assure that Dr. Lancaster's professional judgment will not be compromised. Dr. Lancaster will comply with all Cancer Center policies, and the study will be monitored to ensure your safety."

The use and disclosure of your personal health information

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment, we must obtain your written authorization before we use or disclose your information for this study. This form provides that authorization and helps you understand how your information will be used or disclosed.

Research at the Moffitt Cancer Center is undertaken jointly with the University of South Florida or other persons or entities under an organized health care arrangement. By signing this form you are permitting the Moffitt Cancer Center to use personal health information collected about you for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

Who will disclose, receive, and/or use your information?

Federal law says we must keep your study records private. We will keep the records of this study private by keeping them in a locked area of the H. Lee Moffitt Cancer Center & Research Institute. The following people and/or organization(s) will be allowed to disclose, use, and receive your information for the research purposes set forth in this form, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including the Moffitt Cancer Center, and each site's study team, research staff and medical staff;
- Every member of the Moffitt Cancer Center workforce who provides services in connection with this study;

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- Any laboratories and other individuals and organizations that use your health information in connection with this study;
- Any sponsor of the study, including the following sponsors: Duke Medical University Hospital
- Any federal, state or local governmental agency that regulates the study (such as the FDA and Florida Department of Health);
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study;
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center;

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study doctor and your questions will be answered. The Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. The sponsor of this study or others listed above may further disclose your information. If disclosed, the information may no longer be covered by federal privacy regulations.

What information will be used or disclosed?

By signing below, you authorize the use and disclosure of your entire study record and any medical or other records held by the Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information, except for information that you expressly exclude below. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you during the informed consent and research authorization process and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

❑ Exclude the information expressly listed below (if blank, then no information excluded):

_____

_____

_____

By signing this form, you authorize the use and/or disclosure of your protected health information described above. Your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable), and to run the business operations of the Moffitt Cancer Center. Your

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authorization to use your health information will never expire unless and until you expressly revoke it in writing.

What happens if you decide not to take part in this study?

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study to please the study doctor or the research staff.

If you decide not to take part:

- You will not be in trouble or lose any rights you normally have.
- You will still have the same health care benefits.
- You can still get your regular treatments from your regular doctor.

What if you join the study and decide you want to stop later on?

You can decide after signing this informed consent document that you no longer want to take part in this study. If you decide you want to stop taking part in the study, tell the study staff as soon as you can.

- We will tell you how to stop safely. We will tell you if there are any dangers if you stop suddenly.
- If you decide to stop, you can continue getting care from your regular doctor.

Are there reasons we might take you out of the study later on?

Even if you want to stay in the study, there may be reasons we will need to take you out of it. You may be taken out of this study if:

- We find out it is not safe for you to stay in the study. For example, your health may worsen or we may find that **liposomal doxorubicin or topotecan** might harm you.
- You are not taking your medicine properly or coming for your study visits as scheduled.
- Progression of disease
- Patient non-compliance: defined as any deviation from the protocol without prior agreement of the principal investigator
- Investigator non-compliance: defined as any significant medical or non-medical deviation from the protocol without agreement of the Principal Investigator
- Patient's request to withdraw from the study or refusal of further therapy
- Unacceptable toxicity. A patient may be removed from the study for any complication of treatment that the investigator feels is life threatening.
- If patient does not meet eligibility criteria

You can get the answers to your questions, concerns, or complaints.

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If you have any questions, concerns or complaints about this study, call Dr. Robert Wenham at 813-745-7205.

If you have questions about your rights, general questions, complaints, or issues as a person taking part in this study, call the Division of Research Integrity and Compliance of the University of South Florida at (813) 974-9343.

If you have questions about your rights as a research patient at The Moffitt Cancer Center, call *the Division of Research Compliance in the Corporate Compliance Department at The Moffitt* Cancer Center at (813) 632-1869.

Where can I get more information?

You may call the National Cancer Institute's (NCI) Information Service at: 1-800-4-CANCER (1-800-422-6237) or TTY 1-800-332-8615.

Visit the NCI's Websites at:

- CancerTrials: comprehensive clinical trial information at: http://cancertrials.nci.nih.gov
- CancerNet: accurate cancer information including PDQ at: http://cancernet.nci.nih.gov

Statement of Participation in Research (and Authorization for the Collection, Use, and Disclosure of Health Information)

It is up to you to decide whether you want to take part in this study. If you want to take part, please read the statements below and sign the form if the statements are true. A representative of the Moffitt Cancer Center must answer your questions completely before providing this form to you. You or your personal representative should read this form and understand it before signing below.

I freely give my consent to take part in this study (and authorize that my health information as agreed above, be collected/disclosed in this study). I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

_____ _____

Signature of Person Taking Part in Study **Date**

_____

Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent / Research Authorization

I have carefully explained to the person taking part in the study what he or she can expect.

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I hereby certify that when this person signs this form, to the best of my knowledge, he or she understands:

- What the study is about.
- What procedures/interventions/investigational drugs or devices will be used.
- What the potential benefits might be.
- What the known risks might be.
- How the information collected about the person will be used.

I also certify that he or she does not have any problems that could make it hard to understand what it means to take part in this research. This person speaks the language that was used to explain this research.

This person reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her.

This person does not have a medical/psychological problem that would compromise comprehension and therefore makes it hard to understand what is being explained and can, therefore, give informed consent.

This person is not taking drugs that may cloud their judgment or make it hard to understand what is being explained and can, therefore, give informed consent.

_____ _____

Signature of Person Obtaining Informed Consent / Research Authorization **Date**

_____

Printed Name of Person Obtaining Informed Consent / Research Authorization

Statement of investigator

I certify that I have taken part in the consent process prior to the patient's signature and discussed in detail the study's: aims, methods, anticipated benefits, potential hazards or discomforts, and treatment alternatives. I have answered any and all questions the patient and/or family have asked.

I certify that I am signing this form within seven days of the patient's signature and prior to randomization and/or treatment. I certify that I am signing this form after the patient's signature has been obtained.

_____ _____

Signature of Study Doctor **Date**

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_____
Printed Name of Study Doctor

The subject or his or her personal representative must be provided with a copy of this form after it has been signed.

Addendum to the Consent

Consent to take and store additional tissue samples.

We are asking you to allow us to take and store additional samples of your residual tissue or ascites (excess fluid in the space between the tissues lining the abdomen and abdominal organs)[the peritoneal cavity] for use in the future. These samples may be used for a variety of purposes but those purposes will be related to the ovarian cancer which you currently have.

This means we will take some of your tissue by core biopsy. Should tumor be hard to find to biopsy, ascites may be collected and the fluid processed immediately.

Any residual tissue or ascites will be stored in the laboratory and under the oversight of Dr. Johnathan Lancaster at H. Lee Moffitt Cancer Center and Research Institute. Dr. Lancaster will oversee the storage of that tissue, which, if subsequently used, would only be used for IRB-approved studies.

When you sign this below, you are agreeing to let us store and use your tissue for future research studies related to ovarian cancer.

We may use these samples to help us:

- Learn more about your disease.
- Learn how **liposomal doxorubicin and topotecan** work.
- Find new ways to help people with your ovarian cancer feel better.
- Someday learn how to cure your ovarian disease.

You can decide if you want us to store and use your samples in the future.

You do not have to agree to this in order to take part in the study that has been previously explained to you.

_____ I give my consent to provide tissue or fluid for that purpose.

_____ I do not give my consent to provide tissue or fluid.

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Subject's Name: _____ MCC# 15042
Subject's Medical Record #: _____ IRB#: 106178d

_____ _____
Signature of Person Taking Part in Study Date

_____ _____
Printed Name of Person Taking Part in Study

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