Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Dr. Marta Ann Crispens **Revision Date:** July 22, 2021
Study Title: A Phase I/II Study of Olaparib with Entinostat in the Treatment of Recurrent, Platinum-Refractory or Resistant, Homologous Recombination Repair Proficient Ovarian, Primary Peritoneal and Fallopian Tube Cancers
Institution/Hospital: Vanderbilt University Medical Center **NCT03924245**

This informed consent applies to adult females in Phase I of the study.

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to take part in this Phase I past of a research study (also known as a clinical trial) because you have ovarian cancer that has come back, spread, or is not responding well after treatment with platinum based chemotherapy.

If you participate in this study, you will receive two drugs in combination; olaparib and entinostat.

A capsule of form of olaparib (tradename Lynparza™) is approved by the US Food and Drug Administration (FDA) for the treatment of women with advanced BRCA-mutated ovarian cancer. A tablet form of olaparib is being tested in this study. It is a new formulation which is more convenient for patients than the approved capsule formulation because fewer tablets of olaparib need to be taken daily than with capsules. This formulation is not approved by the FDA.

The combination of olaparib and entinostat is experimental which means it is not approved by the FDA.

The purpose of the Phase I part of this study is to determine the maximum tolerated dose (the highest dose of medicine that can be taken before the side effects are too much) of olaparib, entinostat, and/or the combination of the two drugs. If we determine the dose of the study drugs that are tolerable, we will start Phase II of the study with this dose. We will continue to study the combination of olaparib and entinostat to determine if it is safe, tolerable and effective. If you are still taking the study drugs when we start Phase II of the study, you may continue into Phase II.

This Phase I portion of the study will include about 30 women at two academic medical centers. Vanderbilt University Medical Center is the Sponsor of this study. AstraZeneca Pharmaceuticals is providing funding and the olaparib. Syndax Pharmaceuticals, Inc. is providing the entinostat.

2. What will happen and how long will you be in the study?

Screening

You will need to have exams, tests or procedures to find out if you can be in the study. This is called “screening.” These are done to make sure it is okay for you to be in the study.

These tests are sometimes part of regular medical care. They 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 is up to the study doctor.

It is possible that after the tests are reviewed, you will not be able to be in the study. There may be other reasons why you cannot be in this study. These reasons will be discussed with you by your study doctor or the study staff.

Tumor tissue collection:

- If you have tumor tissue available from a previous biopsy, we will ask your doctor to provide a sample of your tumor to help understand why different patients do or do not respond to the study treatment.

Treatment Plan

Entinostat

- You will take Entinostat once a week. Entinostat should be taken on an empty stomach at least 2 hours after a meal or 1 hour before a meal. It should be taken the same day each week.

- If a dose of entinostat is missed, you can take it any time that same day. If you do not remember until the next day or after, do not take entinostat until the next scheduled dose time the next week.

Olaparib

- After the first week, you will also start taking two doses of Olaparib at the same time each day, morning and evening, about 12 hours apart, with one glass of water and with or without food.

- If you miss a scheduled dose for any reason (e.g., forgetting to take the tablets or vomiting), you will be allowed to take the scheduled dose up to 2 hours after that scheduled dose time. If it is more than 2 hours after the scheduled dose time, you should not take the missed dose and you should take your next dose at the next scheduled time.

Entinostat and Olaparib

- If vomiting occurs shortly after either of the study drug tablets are swallowed, the dose should only be replaced if all of the intact tablets can be seen and counted.

- Entinostat and olaparib tablets should be swallowed as whole pills and not chewed, crushed, dissolved or divided.

- On the days you take olaparib and entinostat together, you will take them on an empty stomach because entinostat cannot be taken with food.

Dosing Diary - We will give you a diary to write down when you take the study drugs and if you have problems or questions about the study drugs. You will need to bring this diary with you to every clinic visit.

Restrictions while taking the study drugs

- You should not drink grapefruit juice as this can affect the way the study medication works.

- There are certain medications that you will **not** be allowed to take with the study drugs. This includes anti-cancer therapies and some vaccines. Your study doctor has a list of medications that you cannot take while you are taking your study medication so it is important to ask them before taking anything new.

On Study Follow-up Weekly – You will return to the clinic once a week for examinations and testing.

On Study Follow-up Every 8 weeks - You will have **CT or MRI scan** of your chest, abdomen, and pelvis and any other area of your body where your doctor thinks your cancer may have spread. These scans are part of your routine cancer care. We will collect the results of these scans.

How long you will be in the Study

You will keep taking the study drugs until one of the following happens:

- Scans show that your cancer has advanced (progressed) or if you were to develop a leukemia
- You get bad side effects from the study drugs that you cannot tolerate
- You decide to stop taking the study drugs but continue in the study. We will continue to follow you according to the follow-up schedule.
- You wish to stop the study and withdraw participation.
- The study stops

Because these things could happen at any time, we cannot say for sure how long you will be in this study.

Follow-up after End of Treatment – If you stop taking the study drug, you will come back for a follow-up visit about 30 days after your last dose of the study drug. We will continue to follow collect information about how you are doing every 12 weeks after your last study follow-up visit. We may look at your medical records or call you or your doctors.

Study Procedures - The following describes each of the study procedures in more detail

- **Demographics**: Recording of information, including your age, sex, and race/ethnicity
- **Medical history & Medications:** You will be asked about your health and any illnesses, surgeries, and treatments you may have or had in the past. You will be asked about medicines you are taking (including over-the-counter medicines, vitamins, and herbal treatments).
- **Physical examination & performance status:** We will do a complete physical examination and measure your ability to do your daily activities.
- **Vital signs:** We will measure your height (only at screening), weight, temperature, blood pressure, and heart rate.
- **Electrocardiogram (ECG):** This will record the electrical activity of your heart.
- **Pregnancy Test:** If you are able to have children (pre-menopausal), you will have blood or urine tests to be sure you aren't pregnant.

- **Blood tests:**
  - **Blood tests to check your health (about 4 teaspoons):** A small amount of your blood will be drawn from a vein for lab tests. These blood tests include chemistry tests, blood counts, blood clotting, lipid tests, and Cancer Antigen-125 (a marker for certain kinds of cancer).
  - **Blood test for pregnancy:** If a urine pregnancy test result cannot be confirmed as negative, a blood pregnancy test will be performed (Only for women able to have children).
  - **Blood tests for immune and tumor cells (about 4 teaspoons):** This blood will allow us see if there are any changes that happen in these cells in your blood after you have taken the study drugs.
- **Urine for a urinalysis**
- **CT or MRI scan** (Computed Tomography or Magnetic Resonance Imaging) of your chest, abdomen, and pelvis and any other area of your body where your doctor thinks your cancer may have spread.
  - During screening, we will review the results of this scan that is part of your routine cancer care but if you have not had a scan within 28 days of starting the study treatment, the scan will need to be repeated and will be done just for this study.
  - As part of your routine care, these scans will be repeated every 8 weeks and we will receive the results.
- **Side-effects:** You will be asked about any side-effects you may be having.
- **Optional Tumor Biopsies** within 7 days prior to starting cycle #3 and one at the end of treatment. We will ask you if you are willing to allow these optional biopsies. As these are optional procedures, we will describe this in an optional consent that will allow you to decide if you are willing to participate in this optional part of the study.

Study Calendar: The following table shows the timing of study procedures

A cycle of treatment lasts 28 days (approximately 4 weeks).

	Screening	7 days before Day 1 of the First Cycle	Day 1 of Each Cycle	Days 8, 15, & 22 of Each Cycle	Twice Daily Starting Day 1 of the first cycle	Within 7 Days Prior to cycle #3	Every 8 Weeks	End of Treatment
Olaparib					X			
Entinostat		X (First Dose)	X	X				
Tumor Tissue Sample for testing	X							
Demographics	X							
Medical History & Medications	X	X	X	X				X
Physical Exam & Vitals	X	X	X	X				X
Performance Status	X	X	X					X
Blood Clotting Tests	X	X						
Complete Blood Count	X	X	X	X				X
Chemistry Blood Tests	X	X	X	X				X
Blood Lipid Tests	X	X	X					
Urinalysis	X	X	X					
Ca-125 Blood Test		X	X					X
Side Effects Assessment	X	X	X	X				X
CT/MRI Scan Tumor Assessment	X						X	
Pregnancy Testing	X	X	X					
ECG	X		X	X				X
Optional Tumor Biopsy						X		X
Blood tests Immune & Tumor Cells			X			X		X

If you move into Phase II of the study, you will no longer continue to have urinalysis testing and will not have a physical exam, medical history and medications assessment, blood tests, ECGs, and side effect assessments on days 8, 15, 22 of each cycle. These assessments will only be done on Day 1 of each cycle and at the end of treatment.

Study Samples
Your samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, and/or others. If this happens, there are no plans to provide money to you.

Pregnancy
The study drugs may harm an unborn child. If you are female, you must not be pregnant or be breast-feeding, and you must not become pregnant during the study. Tell your study doctor immediately if you become pregnant while taking study drugs or within 6 months after your last dose of any study drug, or if you are planning a pregnancy, or if you are breast-feeding.

Female patients of child-bearing potential. If you are not completely abstaining from sex with a male partner, you and your male partner must always use two highly effective forms of birth control to ensure you do not become pregnant. This should be started from the signing of this informed consent form and continue while taking the study drug, and for 6 months after the last dose of study drug. You should talk to your study doctor or nurse about acceptable methods of birth control.

Acceptable birth control methods:

- Your sexual partner has had a vasectomy and uses a male condom.
- You have had your tubes tied and your partner uses a male condom with spermicide
- IUD that contains copper and your partner uses a male condom with spermicide
- Etonogestrel implants (such as Implanon, Nexplanon) and your partner uses a male condom with spermicide
- Normal and low dose combined oral birth control pills and your partner uses a male condom with spermicide.
- Norelgestromin/ethinyl estradiol birth control patch and your partner uses a male condom with spermicide
- Etonogestrel/ethinyl estradiol vaginal ring and your partner uses a male condom with spermicide

3. Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact

this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if you take part in this study:

There may be side effects if you take part in this study. Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- It is possible that the drugs used in this study may interact when given in combination to cause side effects that are more severe than if the drugs were given separately. The side effects of giving olaparib in combination with entinostat is not known. Recovery from side effects may take longer than that observed when the medications are given on their own. You will be closely monitored for any side effects.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study staff if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects that researchers know about. You may experience none, some or all of those listed below.

There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Remember, as part of screening and treatment, we will ask you about any current medications you are taking. It is particularly important to always inform the study team if any of your medications change to ensure that there are no interactions with the study drugs, including supplements and over the counter medications.

What side effects could olaparib cause?

Tell your doctor right away if you notice any of the following side effects – you may need urgent treatment:

Common ≥ 10%	• Nausea (feeling sick) • Vomiting (being sick) • Tiredness/weakness • Dyspepsia (indigestion/heartburn) • Loss of appetite • Headache • Dysgeusia (change in taste of foods) • Dizziness • Cough • Dyspnea (shortness of breath) • Anemia (decrease in the number of red blood cells which can be associated with symptoms of shortness of breath, fatigue, pale skin or fast heart beat) • Lymphopenia (decrease in the number of white blood cells that support the immune system which can be associated with increased risk of infection) • Increase in blood creatinine (test showing how your kidneys are working) • Diarrhea. Your doctor may prescribe a medicine to treat this. If it gets severe, tell your doctor straight away. • Leukopenia & Neutropenia (decrease in the number of total white blood cells and certain white blood cells that protect from infection, which can be associated with symptoms of fever) • Thrombocytopenia (decrease in platelets in blood which can be associated with symptoms of bruising or bleeding for longer if injured) • Stomatitis (sore mouth) • Upper abdominal pain (pain in the stomach area under the ribs) • Rash

Uncommon ≤ 10%	• Mean cell volume elevation (an increase in size of red blood cells) • Myelodysplastic syndrome/Acute Myeloid Leukemia (see below) • Dermatitis (itchy rash on swollen, reddened skin) • Angioedema (rapid swelling of the skin and lips that can lead to breathing difficulties and may require emergency treatment) • Hypersensitivity (i.e. allergic reactions)

Rare ≤ 1%	• Erythema nodosum (tender bumps under the skin)

Other potential risks
Other side effects have been seen in previous studies, but it is not yet known if these were related to olaparib, or if they were unrelated events possibly due to the patient's cancer or other cause. Assessing the full range of side effects of olaparib is an important part of this study.

Pneumonitis (lung inflammation) has been reported in a small number of patients treated with olaparib in previous studies, and some reports have been fatal. It is not known if olaparib caused the pneumonitis in these patients as they had other possible causes such as lung cancer and/or metastases in the lungs, pre-existing lung disease, were smokers, or had been treated previously with chemotherapy or radiotherapy.

If you experience any new or worsening symptoms of shortness of breath, cough and fever, you should contact your Study Doctor as soon as you can.

Myelodysplastic syndrome and acute myeloid leukemia: These side effects have been reported in a small number of patients treated with olaparib in previous studies and the majority of cases have been fatal. It is not known if olaparib caused myelodysplastic syndrome and/or acute myeloid leukaemia in these patients as they had other possible causes, in particular they had received extensive previous chemotherapy. Your Study Doctor will monitor your blood cell levels during the study and may decide you need to have further tests, which may include a bone marrow sample or a blood sample.

- Myelodysplastic syndrome is a pre-cancerous condition where the bone marrow isn't as good at producing blood cells as it was before (red blood cells and/or white blood cells and/or platelets). This condition has the potential to transform into acute myeloid leukemia
- Acute myeloid leukemia is a cancer of the bone marrow where many abnormal and immature white blood cells (blast cells) are made while normal functioning blood cells are not made.

Driving and using machines - Olaparib may affect your ability to drive or use machines. If you feel dizzy, weak, or tired while taking your study treatment, take special care when driving or using tools or machines.

What side effects could entinostat cause?

The following side effects are based on information from previous studies with entinostat and occurred in patients with cancer receiving entinostat only. The side effects of Entinostat in combination with other anti-cancer drugs was similar to when entinostat was given alone. These events may or may not be related to entinostat.

Very Common ≥ 20%	• Fatigue (tiredness) • Nausea (feeling sick) • Constipation • Swelling in the legs, feet and/or ankles • Weight loss • Rash • Cough • Shortness of breath or difficulty breathing • Decreased number of platelets in the blood that may cause you to bruise easily and for your blood to clot slowly after bleeding • Decrease in the number of blood cells that carry oxygen which may cause you to feel tired or short of breath • Decreased level of potassium in the blood which may cause you to feel tired, weak or have constipation or muscle cramps. • Vomiting • Decreased number of a type of white blood cell called neutrophils in the blood which may increase your risk of infection • Diarrhea • Decreased number of a type of white blood cell called leukocytes in the blood • Feeling not hungry (decreased appetite) • Decreased level of phosphate in the blood which may cause muscle weakness or confusion • Low level of salt in blood that may cause you to feel tired, confused, or have headache, muscle cramps or upset stomach • Decreased level of a form of protein called albumin in the blood • Headache

Common ≥ 10% to 20%	• Increased level of glucose in the blood • Decreased level of calcium in the blood which may cause you to feel tired or have muscle weakness or muscle cramps. • Increase in the level of alkaline phosphatase in your blood • Decreased number of lymphocytes in the blood which may cause enlarged lymph nodes, cold like symptoms, painful joints or rash. • Pain in your abdomen • Fever • Muscle pain • Salty, metallic taste sensation • Indigestion • Dehydration

Serious Side Effects ≥ 5%	• Fatigue (tiredness) • Shortness of breath or difficulty breathing • Feeling not hungry (decreased appetite) • Decreased number of a type of white blood cell called neutrophils in the blood which may increase your risk of infection • Dehydration • Decrease in the number of blood cells that carry oxygen which may cause you to feel tired or short of breath • Fever • Nausea • Pain in your abdomen • Diarrhea • Infection • Decreased number of platelets in the blood that may cause you to bruise easily and for your blood to clot slowly after bleeding

Blood Draw
Risks of having blood drawn are soreness and/or a black and blue mark at the site from where the blood is drawn. Sometimes, people feel uncomfortable at the time of the blood draw. Occasionally people feel lightheaded or faint. There is also a small risk of infection whenever blood is drawn.

Radiation Risks
This research study may involve exposure to radiation from one CT scan of your chest, abdomen and pelvis if we have to repeat a CT scan at screening. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you may receive by participating in this study is equal to your body receiving 39 months (3.3 years) of radiation from your natural surroundings or about 20% of the amount allowed in a year for people who are exposed to radiation as part of their work.

Loss of confidentiality
One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job. The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans
- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law also will not help you get other types of insurance (such as: life, disability or long-term care).

Despite the GINA protections and the best efforts of the research team, there may still be a risk if information about you were to become known to people outside of this study.

To minimize this risk, we will remove your name and any other information that could directly identify you from your materials. We will replace this information with codes. We will keep a master list that links those codes to your materials. Only certain project staff can access this master list. We will keep the samples in locked freezers in locked buildings. We will keep health information and research data on secure computers. These computers have many levels of protection.

Your name and other information that could directly identify you (such as address or social security number) will not be placed into any database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your information confidential.

5. Risks that are not known:

Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

This study may help doctors better understand ovarian cancer, treatment for your condition, or help us know who is more likely to benefit or have side effects from the study drugs. This information may help people with ovarian cancer or other health problems in the future.

We do not yet know if the study drugs are effective so this study may or may not help you.

8. Other treatments you could get if you decide not to be in this study:

If you decide not to take part in this study, you have other choices. For example:

- Getting treatment or care for your condition without being in a study.
- Taking part in another study.
- Getting no treatment.
- 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, but instead tries to improve how you feel and 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.

9. Payments for your time spent taking part in this study or expenses:

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

10. Reasons why the study doctor may take you out of this study:

- The results of tests show that you are not right for this study or for the study drug.
- You do not follow study instructions for treatment or follow-up visits.
- You get new health problems during the study that might not work well with continuing to participate.
- You get pregnant or decide that you want to become pregnant.
- The study doctor thinks it is best for you to stop.

11. What will happen if you decide to stop being in this study?

Your participation in the study is voluntary. You may choose to stop taking part in the study at any time. We will ask you why you want to stop but you do not have to tell us the reason. If you decide to stop being part of the study, you should tell your study doctor. Your decision will not affect your medical care in any way.

If you decide to leave the study, you and the study doctor will discuss the best way to do this. We will ask you to return any leftover study drug.

If you withdraw consent to continue participation on the study, we will ask you if we can still use all of the data and samples collected before you left the study.

12. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact **Dr. Marta Ann Crispens at 615-322-8072.** If you cannot reach the research staff, please ask to page the study doctor at (615) 322-5000.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Clinical Trials Registry.

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

14. Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your information and samples will be given a unique code instead of your name to help protect your identity. Dr. Crispens, her staff at Vanderbilt and other authorized people will be the only people who know your personal information. Results of this study may be presented in meetings or in publications. Your identity will not be released in those presentations. Your study records will be secured in the clinical trials office. Your research data will be kept for an unknown period of time. Your blood and tissue samples

will be kept in locked storage and may be used or stored indefinitely from the end of the study. Any samples that are not needed will be destroyed.

Your specimens will be assigned a code number and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in a locked file cabinet, encrypted data file, or password protected database and only the investigator and authorized study staff will have access to the file.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Crispens and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

15. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked blood and other tissue samples and related records, medical histories, physical examinations, laboratory tests, CT/MRI scans, ECG results, and any other data created or collected during the study, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, the Food and Drug Administration, National Institutes of Health, National Cancer Institute, representatives of AstraZeneca and Syndax Pharmaceuticals, Scientific Review Committees, Medicare and Insurance companies for billing purposes, etc. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Crispens in writing and let her know that you withdraw your consent. Her mailing address is 1161 21st Ave. S. Nashville, TN 37232. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

Principal Investigator: Dr. Marta Ann Crispens **Revision Date:** July 22, 2021
Study Title: A Phase I/II Study of Olaparib with Entinostat in the Treatment of Recurrent, Platinum-Refractory or Resistant, Homologous Recombination Repair Proficient Ovarian, Primary Peritoneal and Fallopian Tube Cancers
Institution/Hospital: Vanderbilt University Medical Center

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title