Certification of Completion of the Informed Consent

IRB #

Title:

I have discussed the "Informed Consent for Participation in Research Activities" in its entirety for the above referenced research study, with the research participant listed below (or the research participant's legally authorized representative). During the review of the consent form, the possible benefits, risks and discomforts involved in his/her participation on the study, as well as potential alternatives were reviewed.

The research participant has been encouraged to ask questions, and all questions asked by the participant have been answered. The research participant affirmed that he/she has received all information that he/she desires at this time, and a copy of the signed consent form has been provided to the participant.

PRINTED NAME of Person Obtaining Informed (Consenter)	SIGNATURE	TITLE	DATE	TIME

ADULT INFORMED CONSENT

COH Protocol # 17327
TITLE: Open-Label Randomized Phase II Trial of Megestrol Acetate with or without Pterostilbene in Patients with Endometrial Cancer Scheduled for Hysterectomy
Version date: 11/09/2021

PRINCIPAL INVESTIGATOR: Thanh Dellinger, M.D.

24-HOUR TELEPHONE NUMBER: (626) 256-4673 Ext. 85200
DAY TIME TELEPHONE NUMBER FROM THE HOURS OF 8:00 AM TO 5:00 PM: (626) 218-7100

EXPERIMENTAL PARTICIPANT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study, also known as an experiment or clinical trial. As a research participant, you have the following rights:

1. To be told what the research study is trying to find out.
2. To be told what will happen to you and whether any of the procedures to be used are different from what would be used in standard practice.
3. To be told about the discomforts, side effects and risks of the things that will happen to you as part of the research study.
4. To be told if you can expect any benefit from participating in the research study.
5. To be told of the other choices you have and how they may be better or worse than being in the research study.
6. To be told what medical treatment is available if any complications arise.
7. To be allowed to ask any questions concerning the research study, both before agreeing to be in the study and during the course of the study.
8. To refuse to participate in the research study or to change your mind about participation after the study is started. To be informed that this decision will not affect your right to receive the care you would receive if you were not in the study.
9. To receive a copy of the signed and dated research study consent form.
10. To be free of pressure when considering whether you wish to agree to be in the research study.

ADULT INFORMED CONSENT

COH Protocol # 17327
TITLE: Open-Label Randomized Phase II Trial of Megestrol Acetate with or without Pterostilbene in Patients with Endometrial Cancer Scheduled for Hysterectomy

PRINCIPAL INVESTIGATOR: Thanh Dellinger, M.D.

INTRODUCTION

You are invited to take part in a clinical trial, a type of research study, because you have endometrial cancer (EC). We hope to evaluate the tolerability and effectiveness of megestrol acetate (MA) with or without pterostilbene (PTE). This research study is looking at a low-cost, low-toxicity addition or alternative treatment for EC.

This research study is sponsored by COH.

It is expected that about 36 people will take part in this research study.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and at any time in the future. Please take as much time as you need to read the consent form. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. We will give you a copy so that you can refer to it while you are involved in this research study. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

A. WHY IS THIS RESEARCH STUDY BEING DONE?

This research study is a Phase II clinical trial. Phase II clinical trials test the safety and effectiveness of an investigational (experimental) intervention to learn whether the intervention works in treating a specific disease. "Investigational" means that the intervention is being studied.

The FDA (the U.S. Food and Drug Administration) has not approved **pterostilbene** as a treatment for any disease.

The FDA (the U.S. Food and Drug Administration) has not approved **megestrol acetate** for your specific disease but it has been approved for other uses.

The names of the study interventions involved in this study are:

- Pterostilbene
- Megestrol acetate

Endometrial cancer (EC) is the fourth most common cancer among U.S. women. While early stage EC is frequently curable, recurrent and metastatic endometrial cancer, which has spread to another location, is an incurable cancer. We have tested a natural supplement called pterostilbene (PTE), which is an antioxidant derived from blueberries or grapes, in mice with endometrial cancer, and shown that it is effective in killing tumor cells and reducing the cancer burden when given in combination with megestrol acetate (MA).

We are therefore proposing a clinical trial to test MA with or without PTE in endometrial cancer patients to determine safety of PTE in these patients, and a preliminary assessment in effectiveness.

B. WHAT IS INVOLVED IN THE STUDY?

If you decide to take part, this is what will happen:

If you take part in this research study you will be given a drug diary. You will be asked to document information in the drug diary about the study drug you are being asked to take.

Before the research starts (screening):

After signing this consent form, you will be asked to undergo some screening tests or procedures to find out if you can be in the research study. Many of these tests and procedures are likely to be part of regular cancer care and may be done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may or may not have to be repeated.

- **A medical history,** which includes questions about your health, current medications, and any allergies.
- **Performance status**, which evaluates how you are able to carry on with your usual activities.
- **Blood tests** to check your blood counts and organ function (about 1-2 teaspoons of blood will be drawn from a vein in your arm)
- **Blood tests** for research purposes (about 1-2 teaspoons of blood will be drawn from a vein in your arm)

If these tests show that you are eligible to participate in the research study, you will begin the study treatment. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

Study Procedures:

If you are eligible to participate in this research study, the following test and procedures will occur. A chart summarizing the timing of these tests and procedures is also provided below. Some tests and procedures may be part of your standard of care.

This is a Phase II trial of neoadjuvant therapy (treatments that are administered before the primary cancer treatment) during the preoperative window period with MA ± PTE for endometrioid EC patients who are scheduled to undergo total hysterectomy.

- **Clinical Exams:** During this visit you will have a physical exam and you will be asked questions about your general health and specific questions about any problems that you might be having and any medications you may be taking.
- **Performance status**, which evaluates how you are able to perform your daily usual activities.
- **Blood tests**
  - Blood tests to check your blood counts and organ function (about 1-2 teaspoons of blood will be drawn from a vein in your arm)
  - Blood tests for research purposes (about 1-2 teaspoons of blood will be drawn from a vein in your arm)
- **Optional Research Tests:** At the end of this consent form, you will be asked to decide if we can keep your samples and store them for future testing.

Treatment is administered in the outpatient setting for 3 weeks. For participants receiving combination therapy, if one agent is permanently discontinued, then the participant will discontinue all trial therapies.

Day 1 is defined by the administration of MA ± PTE.

Protocol Therapy

Pterostilbene (PTE)

- When combined with MA, the morning PTE dose will be taken first on Day 1.
- Participants will be instructed to take PTE twice daily at approximately 12 hours apart with a glass of water. The capsules should not be opened, broken or chewed. The capsules should be swallowed whole.
- If a participant misses a dose and more than 4 hours have passed since the scheduled dose time, the missed dose will be skipped and will not be made up.
- If a PTE dose is vomited wait until the next scheduled dose; any vomited doses should not be made up.
- Participants will be given a drug diary to document each dose of PTE that is taken or missed.

Megestrol acetate (MA)

- When combined with PTE, the morning MA dose will be taken after PTE on Day 1.

- When taken alone (without PTE), the morning MA dose will be taken first on Day 1.
- Participants will be instructed to take MA twice daily at approximately 12 hours apart with a glass of water. The tablets should not be opened, broken or chewed. The tablets should be swallowed whole.
- If a participant misses a dose and more than 4 hours have passed since the scheduled dose time, the missed dose will be skipped and will not be made up.
- If a MA dose is vomited wait until the next scheduled dose; any vomited doses should not be made up.
- Participants will be given a drug diary to document each dose of MA that is taken or missed.

The date of scheduled surgery will define the duration of the preoperative window period and therefore, protocol therapy. Study treatment will last 3 weeks, depending on the timing of surgery. Protocol therapy will end the day before the scheduled surgery.

Follow-up

Post-surgery, participants will enter follow-up. This is comprised of standard of care clinic visits and safety follow-up at the following time points:

- 6 weeks (± 14 days)

Research Study Calendar:

		Preoperative Window Period (3 weeks)			Follow-Up Post-surgery
	Visit 1	Protocol Therapy (Pterostilbene ± Megestrol)		Surgery	6 weeks**
	Screening	Day 1	Day 2*		
Medical History	X				
Physical Exam	X	X[1]		X[2]	X
Blood Tests	X	X[1]		X[2]	X
AE assessment[3]		X		X	X
Biopsy[4]	X			X	
Receive MA		Twice Daily			
Receive PTE (If receiving combination therapy)		Twice Daily			
MA Drug Diary		X		X[5]	
PTE Drug Diary (If receiving combination therapy:)		X		X[5]	
Surgery (hysterectomy)				X	

[1]Will only be repeated if greater than 30 days from screening visit
[2]Pre-op physical exam + full labs to be performed on day of surgery
[3]Assessment of the toxicities following completion of the treatment before surgery can be done in the pre-op area before surgery
[4]Endometrial biopsy – these slides will be obtained post-informed consent prior to therapy initiation and on day of surgery. Endometrial biopsy at screening time point does not need to be performed if the block is readily available for histologic analysis from a previous endometrial biopsy within 30 days of screening.
[5]2nd drug diary review can be done within 3 days of surgery date (in person or over the phone)
*Day 2 really means day 2+ (starting day 2 and inclusive of subsequent days until surgery)
**The 6 week f/u is not an exact time point (can be +/- 2 weeks)

Planned Follow-up:

We would like to keep track of your medical condition for the rest of your life. We would like to do this by calling you on the telephone once a year to see how you are doing. Keeping in touch with you and checking your condition every year helps us look at the long-term effects of the research study.

C. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

You will be in this research study for about 2 months post-surgery.

D. WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are risks to taking part in any research study. One risk is that you may get a study drug that does not help treat your disease or that makes your condition or disease worse. Another risk is that there may be side effects.

All cancer treatments can have side effects, which can range from mild and reversible to severe, long lasting and possibly life-threatening. There is a great deal of variability among side effects of different cancer treatments and between individuals. In a research study, all of the risks or side effects may not be known before you start the study. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.**

Everyone in the research study will be watched carefully for side effects. You will be monitored during the administration of study drugs to keep track of your blood counts and organ function, particularly your kidney and liver function. If you experience side effects, they may go away after you stop taking the study drug. You will be monitored closely for any severe, life-threatening side effects listed below. Some of these side effects may be permanent. Appropriate medical care will be provided, if necessary, including additional treatment, hospitalization and/or surgery.

Possible risks and discomforts you could experience during this study include:

Risks associated with the Pterostilbene

Commonly Occurring Side Effects (10 out of 100 research participants)

- Metabolism and Nutrition
  - Increased appetite
- Musculoskeletal and Connective Tissue
  - Muscle pain

Risks associated with the Megestrol Acetate

Commonly Occurring Side Effects (seen in more than 5 out of 100 research participants)

- nausea
- diarrhea
- impotence
- rash
- flatulence
- hypertension (high blood pressure)

- thromboembolic events (blocking of a blood vessel by a blood)
    - Deep Vein Thrombosis (blood clots formed in veins often located in the legs)
    - Pulmonary Embolism (blockage of an artery in the lungs)
- asthenia (abnormal physical weakness or lack of energy)

Occasional Side Effects (seen in 1 to 3 out of 100 research participants)

Listed below by body system

- **Body as a Whole**
    - abdominal pain
    - chest pain
    - infection
    - moniliasis (yeast infection)
    - sarcoma (Cancerous (malignant) tumors of the connective tissues)
- **Cardiovascular System**
    - cardiomyopathy (acquired or hereditary disease of the heart muscle)
    - palpitation (having rapid, fluttering or pounding heart)
- **Digestive System**
    - constipation
    - dry mouth
    - hepatomegaly (enlarged liver)
    - increased salivation
    - oral moniliasis (yeast infection of the mouth and throat)
- **Hemic and Lymphatic System (spleen, bone marrow and stem cells, and the lymph nodes)**
    - leukopenia (decrease in the number of white blood cells (leukocytes) found in the blood)
- **Metabolic and Nutritional**
    - LDH increased (an enzyme required during the process of turning sugar into energy for your cell)
    - edema (swelling)
    - peripheral edema (swelling legs, feet, and ankles)
- **Nervous System**
    - paresthesia (burning or prickling sensation that is usually felt in the hands, arms, legs, or feet)
    - confusion
    - convulsion (uncontrolled shaking of the body)
    - depression
    - neuropathy (peripheral nerves become damaged or disrupted)
    - hypesthesia (diminished capacity for physical sensation, especially of the skin)
    - abnormal thinking (delusions)
- **Respiratory System**
    - dyspnea (difficult or labored breathing)

- cough
- pharyngitis (swelling in the back of the throat)

Since the effect of the study drug(s) taken with other medications may not be known, it is important that you tell the research doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take. There may also be some foods that you should avoid while on this research study and your research doctor will review this information with you.

Risks Associated with Blood Draw

Risks of blood draws include mild pain or discomfort, bruising and swelling around the puncture site, dizziness or fainting, or infection (rare).

Cancer research often includes biopsies, scans, x-rays that are also provided as routine care. The following describes the side effects of procedures done only for the purposes of research.

Incidental Findings:

It is possible the research procedures could find a medical problem unrelated to the purpose of this study that you did not know about before. If during the research procedures we learn information that may be important for you to know about, such as the possibility of a previously unknown medical condition, we will tell you. You may authorize the release and communication of the findings to your personal doctor. These findings may require additional testing or treatment. You will be responsible for the cost of any additional tests or related treatment.

Reproductive Risks:

You must not use hormonal birth control while on this study. Acceptable forms of birth control during this study are:

- Abstinence,
- Surgical sterilization (tubal ligation or hysterectomy for women, or vasectomy for men),
- Double-barrier methods (i.e. condoms, diaphragm, cervical cap, or sponge used with spermicidal gel or foam),
- Intrauterine device (IUD) (i.e. Copper), but not progestin IUDs (e.g. Mirena)

Other Risks:

Because of side effects or the time required for tests and clinic visits while you are on this research study, you may be unable to keep up with your normal daily activities.

Risks associated with Breach of Confidentiality*:*

There is a small risk that people who are not connected with this study will learn your identity or your personal information.

Risks associated with Highly Sensitive Information:

You are providing highly sensitive, personal information in this study. If people not connected with the study learn this information, you could have problems getting a new job, keeping your current job, and finding housing, or getting insurance (health, disability, or life insurance). In highly unlikely situations, you could be charged with a crime.

E. WILL YOU RECEIVE NEW INFORMATION ABOUT THIS STUDY?

During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

F. HOW WILL YOUR INFORMATION BE KEPT CONFIDENTIAL?

Any information learned from this study in which you might be identified will be confidential and disclosed only with your permission. Every effort will be made to keep any information collected about you confidential. However, it is impossible to guarantee that information about you will not be mistakenly released. If, despite our best efforts, identifying information about you is released, it could negatively impact you or your family members. This risk is small.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor COH and any drug company (Elysium Health) supporting the study
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- Regulatory agencies such as the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and the National Cancer Institute (NCI) in the U.S., and similar ones if other countries are involved in the study as required by law.

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

G. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS RESEARCH STUDY?

There is no guarantee that you will receive any benefits from this study. The possible benefit of the study drug in the treatment of endometrial cancer is not known. If you decide to participate in this study, your health will be monitored very closely. By being in this study, you will give doctors more information about how well the study drug works. It may help doctors understand your condition better and may help future patients with this medical condition.

H. WHAT OTHER OPTIONS ARE THERE?

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

- You may choose to have the usual approach for your cancer,

- You may choose to take part in a different study, if one is available, or
- You may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

I. ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

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

Possible Commercial Products

We may use your samples and information to develop a new product or medical test to be sold. The sponsor and hospital may benefit if this happens. Donors of blood, tissue and other biological materials do not retain any property rights to the materials. Therefore, you would not share in any money or other benefits that any entity might receive for these inventions or discoveries.

J. WHAT ARE THE COSTS?

Taking part in this research study might lead to added costs to you or your insurance company. Pterostilbene will be provided to you at no cost while you take part in the study. It is possible that the Pterostilbene may not continue to be supplied while you are on the study. If this occurs, the research doctor will talk to you about your options.

The commercially available drug(s), Megestrol Acetate will be provided free of charge.

Most of the tests, procedures, and/or drugs provided to you as part of this study are routinely used to treat your illness. You would receive these tests, procedures, and/or drugs even if you were not participating in this study. You or your health plan/insurance company will need to pay for this routine care. You will also be responsible for any co-payments or deductibles required by your health plan/insurance company. Some health plans/insurance companies will not pay the costs associated with these tests, procedures, and/or drugs because you are in a research study. If your health plan/insurance company will not pay these costs, you will have additional expenses from being in this study, such as the costs associated with treating side effects.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services is:

- City of Hope Financial Support Services: 626-256-HOPE (4673), extension: 80258.

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:
www.cancer.gov or 1-800-4-CANCER (1-800-422-6237)

K. WHAT HAPPENS IF YOU GET INJURED AS A RESULT OF THIS STUDY?

If you think you have been hurt by taking part in this study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form. City of Hope will offer you the care needed to treat injuries directly resulting from taking part in this research. This care will be billed to you or your insurance company. You will be responsible for deductible and co-payments, or any costs not paid by your insurer. There are no plans to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

L. WHAT ARE YOUR RIGHTS IF YOU TAKE PART IN THIS STUDY AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this research study is voluntary. You are free to withdraw your consent for participation in this study without any loss of benefits, penalty, or interference with any future treatment at City of Hope.

You can decide to stop at any time and you may still be treated at your hospital or clinic. Tell your study doctor if you are thinking about stopping or decide to stop. You should talk to the doctor about leaving the study before you decide so that he/she can find out if you are having any side effects from study treatment. Another reason to tell your doctor that you are thinking about stopping is so that he/she can talk to you about any other treatments that could be helpful to you.

If you decide to stop being in this study, you will still be asked to come back to the hospital or clinic for the end of treatment tests described above. You may also be asked to take part in the follow-up phone calls and/or visits. This information is important to make sure that there are no lasting side effects from the study treatment and to see if your cancer got better, stayed the same, or got worse after treatment.

M. CAN YOU BE REMOVED FROM THE STUDY?

You may be removed from this study without your consent for any of the following reasons: you do not follow the study doctor's instructions, at the discretion of the study doctor or the sponsor, your disease gets worse, or the sponsor closes the study. If this happens, the study doctor will discuss other options with you.

N. WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

The principal investigator, Dr. Thanh Dellinger or a colleague, Dr. _____, responsible for your care or treatment, has offered to and has answered any and all questions regarding your participation in this research study. If you have any further questions or in the event of a research related injury, you can contact Dr. Thanh Dellinger at (626) 256-HOPE (4673) ext. 67100 or Dr. _____ at (626) 256-HOPE (4673) ext. _____.

This study has been reviewed and approved by the Institutional Review Board (IRB). If you have any questions regarding your rights as a research participant, you may contact a representative of that Board, from the Office of Human Research Subjects Protection, at (626) 256-HOPE (4673) ext. 62700.

O. ADDITIONAL STUDIES SECTION:

This section is about optional studies you can choose to take part in. You will make your selection at the end of this section. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say "no" to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

At the end of the document, circle your choice of "yes" or "no" for each of the following studies.

Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part, an optional baseline biopsy will be collected. The researchers ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking".

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) A sample of tissue will be collected from the optional extra biopsy.
2) Your sample, and possibly specimens left over from diagnostic and clinical tests and some related health information may be stored in the Biorepository (Biobank), along with samples and information from other people who take part. The samples will be kept until they are used up. Information from your medical record will be updated from time to time.
3) Qualified researchers can submit a request to use the materials stored in the Biorepository (Biobank). An ethics committee review will be done to ensure that the request is necessary

and proper. Researchers will not be given your name or any other information that could directly identify you.

4) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
5) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

1) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
2) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
3) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your sample(s) is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biorepository (Biobank) and staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom City of Hope sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part.

Your samples may be helpful to research whether you do or do not have cancer. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Some of this research may result in new inventions or discoveries that may be of potential commercial value and may be patented and licensed for the development of new products. Donors of blood, tissue and other biological materials do not retain any property rights to the materials. Therefore, you would not share in any money or other benefits that any entity might receive for these inventions or discoveries. Your decision not to allow storage or future use of your tissue or specimens will not affect your ability to participate in this study.

WHAT IF I CHANGE MY MIND?

If you agree to allow your specimens to be used for future research, you can change your mind later. If you change your mind, please ask for the "Withdrawal of Informed Consent to Continue in Participation in Research Activities" for **IRB# 17327: Open-Label Randomized Phase II Trial of Megestrol Acetate with or without Pterostilbene in Patients with Endometrial Cancer Scheduled for Hysterectomy**." Please sign the section of this this withdrawal form named "Biological Specimen Withdrawal of Consent" and send it to the principal investigator of this study at City of Hope. Once City of Hope processes your signed withdrawal of informed consent, your specimens will not be used in any new research. At that time, any of your existing specimens will be destroyed.

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor, Dr. Thanh Dellinger, at (626) 256-HOPE (4673) ext. 67100.

Please circle your answer to show whether or not you would like to take part in each option

Samples for Future Research Studies:

My samples and related information may be kept in a Biorepository (Biobank) for use in future health research.

YES NO

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

P. SIGNATURE SECTION

SIGNATURE FOR CONSENT: By signing this consent form, you are making a decision to participate in this research study. Your signature on this informed consent form indicates that you:

1. Have read and understood the information in this form.
2. Have had the information in this form explained to you.
3. Have had a chance to ask questions and these questions were answered to your satisfaction.
4. Have been informed that you will receive a copy of this signed consent form, which includes the "Experimental Subject's Bill of Rights."

I hereby agree to be a research participant in this research study:

_____ _____ _____

Research Participant's Signature Date Time

(For paper consent only, date and time must be in research participant's handwriting)

_____

Print Research Participant's Name

INDIVIDUAL OBTAINING CONSENT SIGNATURE

_____ _____ _____

Signature of Individual Obtaining Consent Date Time

_____

Print Name of Individual Obtaining Consent

FOR USE WITH IRB APPROVED TRANSLATED SHORT/LONG CONSENT FORMS FOR NON ENGLISH SPEAKING PARTICIPANTS ONLY

NOTE: To determine who should sign below, review the guidance document, *Consenting Non English Speaking Research Participants (Pediatric or Adult) – Who Signs What?*

Interpreter: By signing here, I attest that I have acted as interpreter and facilitated this consent process.

_____ _____ _____

Interpreter's Signature Date Time

_____

Print Interpreter's Name

FOR USE WHEN A WITNESS IS REQUIRED:

Witness: By signing here, I attest that I witnessed the consent process and that the entire consent form was discussed.

_____ _____ _____

Witness' Signature Date Time

_____

Print Witness' Name

IRB# 17327: Open-Label Randomized Phase II Trial of Megestrol Acetate with or without Pterostilbene in Patients with Endometrial Cancer Scheduled for Hysterectomy

AUTHORIZATION TO USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI) FOR PURPOSES OF THIS STUDY:

I. **Purpose of this Authorization**: The information about your health is something that is protected by law and cannot, except for certain purposes, be disclosed (shared) without your permission. As part of this research, you are agreeing to allow City of Hope to use and share with others your protected health information ("PHI"), as needed for the research. If you agree to participate in the study named above (called the "Study"), you must sign this authorization in addition to the *Study Consent Form*.

II. **The Information About You that is Covered By this Authorization**: PHI refers to information that we maintain about you that identifies you and includes the information contained in your medical record. Your medical record consists of information related to your health and the treatment we provide to you, such as your medical history, the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures. If you sign this authorization, you are allowing City of Hope and the individuals indicated below to use and share any PHI we maintain about you that is required for your participation in the Study.

Certain information about you that is highly confidential is needed for the Study. If you sign this form, you are allowing City of Hope and the individuals indicated below to use and disclose the following highly confidential PHI about you: information about HIV/AIDS testing or treatment (including the fact that an HIV test was ordered, performed or reported, regardless of whether the results of such tests were positive or negative).

III. **Purposes for Uses and Sharing of your PHI; Who Will Use, Share and Receive your PHI**: Your PHI will be used and shared with others for the purpose of doing this research as described in the *Study Consent Form*. Your PHI will also be used to keep the research sponsor informed about this Study, for reporting to those individuals and authorities responsible for overseeing our research activities to

make sure that the activities are properly conducted, and to report to regulatory agencies as required by the Study.

The people authorized to use and share your PHI for purposes of the Study include the Principal Investigator and the research staff supporting the Study; your City of Hope physicians and the health care team; and the Health Information Management Services Department (i.e., Medical Records Department). This also includes any agents or contractors used by these individuals or groups for purposes of conducting or managing this Study. At the City of Hope, the Institutional Review Board ("IRB"), and other City of Hope research regulatory committees will have access to your PHI as necessary to monitor research.

You are also allowing your PHI to be shared with the Office for Human Research Protections ("OHRP") and with any person or agency as required by law. In addition, certain other regulatory agencies, including the Food and Drug Administration ("FDA") and the National Cancer Institute ("NCI") will have access to your PHI.

Use and disclosure of your PHI may also continue for as long as the sponsor needs to maintain the PHI for purposes of obtaining approval of the Pterostilbene, Megestrol Acetate from the FDA or for other FDA reporting.

This study also involves tissue banking (storing your specimens such as blood or tumor tissue). The tissue banked as part of this study will be kept at City of Hope. The banked tissue will be stored indefinitely.

This authorization will allow us to use and share your PHI for the Study. No other additional uses and disclosures other than for the purposes of the Study is included in this authorization. City of Hope's Notice of Privacy Practices will continue to protect your non-Study information. If necessary, another separate permission will be obtained from you for any non-Study uses or sharing of your PHI.

IV. **<u>Expiration of this Authorization</u>**: This authorization to use and share your PHI will expire twenty-five (25) years from the date that you sign this authorization.

V. **Further Sharing of Your PHI**: Your privacy is important and this is the reason for having rules which control who can use or see your PHI. City of Hope maintains control over your PHI at present, but once we share this information with a third party (for example, an individual or agency outside of the City of Hope), then it is no longer possible to maintain the same level of protection. The persons outside our control may not be governed by federal or state privacy laws and it is possible that they could share your PHI with others for whom you have not given permission.

The information from this Study may be published in scientific journals or presented at scientific meetings but your identity will be kept confidential.

VI. **Your Rights Under this Authorization**: You may cancel this permission to use and share your PHI at any time by contacting City of Hope's Privacy Officer at (626) 256-HOPE (4673) ext. 64025. You should ask for the form, *Revocation (Cancellation) of Authorization for Use of Protected Health Information for Research*. Fill this form out and return it as the form instructs. Your cancellation begins when the Health Information Management Department of City of Hope receives this form. If you cancel this authorization to use and share your PHI, you will no longer be able to participate in the Study. This is because the research under this Study cannot be conducted without your PHI.

Once you cancel your permission to use and share your PHI, the researchers and others involved in conducting the Study will no longer be able to use or share your PHI for this research. PHI already used and shared up to this point as part of this Study will continue to be used for purposes of this research. This means that any uses of your PHI and any PHI shared about you by City of Hope prior to receiving your cancellation (revocation) form cannot be taken back. While no further PHI about you will be shared for the Study, your PHI already shared will continue to be used in the overall Study.

VII. **<u>Signing this Authorization is Your Choice</u>:** Your ability to obtain care at the City of Hope will not be affected by your decision to sign this authorization form. You will be able to continue to receive health care at City of Hope if you choose not to sign this authorization form or if you sign this form and later cancel your permission to use and share your PHI.

If you agree to the use and sharing of your PHI, please sign below. You will be given a copy of this authorization form.

_____ _____ _____

Research Participant's Signature Date Time

(date and time must be in research participant's handwriting)

_____

Print Research Participant's Name

INDIVIDUAL OBTAINING CONSENT SIGNATURE

_____ _____ _____

Signature of Individual Obtaining Consent Date Time

_____

Print Name of Individual Obtaining Consent

FOR USE WITH IRB APPROVED TRANSLATED SHORT/LONG CONSENT FORMS FOR NON ENGLISH SPEAKING PARTICIPANTS ONLY

NOTE: To determine who should sign below, review the guidance document, *Consenting Non English Speaking Research Participants (Pediatric or Adult) – Who Signs What?*

Interpreter: By signing here, I attest that I have acted as interpreter and facilitated this consent process.

_____ _____ _____

Interpreter's Signature Date Time

_____

Print Interpreter's Name

FOR USE WHEN A WITNESS IS REQUIRED:

Witness: By signing here, I attest that I witnessed the consent process and that the entire consent form was discussed.

_____ _____ _____

Witness' Signature Date Time

_____

Print Witness' Name