University of California
Permission to Use Personal Health Information for Research

Study Title: UCDCC#261: A Selective Frontline Cabazitaxel Therapeutic Pathway for Castration-Resistant Prostate Cancer with Integrated Biomarkers

Sponsor/Funding Agency: UC Davis Comprehensive Cancer Center/Sanofi

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information to the research team unless you give your permission. The research team includes the researchers and people hired by the University or the sponsor to do the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that the researcher, research team and research sponsor may use your health information for the research study. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing your health care provider to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records and information that can identify you. For example, Personal Health Information may include your name, address, phone number or social security number.

X Entire Medical Record
☐ Radiology Reports
☐ Pathology Reports
☐ Laboratory Reports
☐ Dental Records
☐ Operative Reports
☐ Other:

☐ Emergency Medicine Center Reports
☐ Progress Notes
☐ History & Physical Exams
☐ Discharge Summary
☐ Consultations

☐ Outpatient Clinic Records
☐ EKG
☐ Radiology images
☐ Psychological Tests
☐ Health Care Billing Statements

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

____ I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

____ I agree to the release of HIV/AIDS testing information.

____ I agree to the release of genetic testing information.

____ I agree to the release of information pertaining to mental health diagnosis or treatment as follows:

_____.

D. How will my Personal Health Information be used?

Your Personal Health Information may be released to these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC who are required by law to review the research;
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration and Department of Health and Human Services, the research sponsor or the sponsor's affiliate organization, or government agencies in other countries. These organizations and their representatives may see your Personal Health Information. They may not copy or take it from your medical records unless permitted or required by law.

Your PHI used in this study will include all information which is used to determine your eligibility and collected from the procedures and tests that are carried out as part of this study. This may include, but is not limited to, the following types of medical information:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

E. How will my Personal Health Information be used in a research report?

If you agree to be in this study, the research team may fill out a research report. (This is sometimes called "a case report".) The research report will **not** include your name, address, or telephone or social security number. The research report may include your date of birth, initials, dates you received medical care, and a tracking code. The research report will also include information the research team collects for the study.

The research team and the research sponsor may use the research report and share it with others in the following ways:

1. To perform more research;
2. Share it with researchers in the U.S. or other countries;
3. Place it into research databases;
4. Use it to improve the design of future studies;
5. Use it to publish articles or for presentations to other researchers;
6. Share it with business partners of the sponsor; or
7. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. AM I REQUIRED TO SIGN THIS DOCUMENT?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Does my permission expire?

This permission to release your Personal Health Information expires 50 years when the research ends and all required study monitoring is over. Research reports can be used forever. You have the right to see and copy any of the research data gathered about you, but not until the study is complete. If the research data contains information that may affect your health or safety during your participation, the study staff will notify you and your personal care doctor(s) of the results. If needed, the study staff will send a copy of the relevant information to your personal care doctor(s) to help them evaluate your true condition.

H. Can I cancel my permission?

You may revoke your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

I. Signature

If you agree to the use and release of your Personal Health Information, please sign below. You will be given a signed copy of this form**.**

_____
Subject's Name (print)

_____ _____
Subject's Signature Date

Note: if the subject is a minor, an individual signing with an "X", an adult incapable of giving consent, or is unable to read the authorization, fill out and attach the "special signatures" page (sections "J" and "K").

SPECIAL SIGNATURES PAGE

J. If the subject is a minor, or an individual signing with an "X", or an adult incapable of giving consent (where IRB approved), the legally authorized representative or witness signs here:

_____	_____
Legally Authorized Representative's Name or Witness to the "X" (print)	Relationship to the Subject
_____	_____
Representative or Witness Signature	Date

K. If the subject is unable to read the authorization, the translator or reader and a witness sign here:

I have accurately and completely read this Authorization to _____ (subject's name) in _____ (language), the subject's primary language.

The subject has verbally affirmed his/her Authorization to me and to the witness.

_____	
Translator or Reader's Name (print)	
_____	_____
Translator or Reader's Signature	Date
_____	
Witness Name (print)	
_____	_____
Witness Signature	Date

UNIVERSITY OF CALIFORNIA, DAVIS
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: UCDCC#261: A Selective Cabazitaxel Therapeutic Pathway for Castration-Resistant Prostate Cancer with Integrated Biomarkers [Protocol version: 05/23/2018]

Principal Investigator: Christopher Evans, MD
Department: Urology/Oncology

CALIFORNIA EXPERIMENTAL BILL OF RIGHTS LANGUAGE:
What should I know about a research study?
(Experimental Subject's Bill of Rights)

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
  - Other procedures, drugs, or devices that might be helpful, and their risks and benefits compared to this study.
  - Medical treatment, if any, that is available for complications.

- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [redacted]. If you are unable to the reach the Principal Investigator of this study, Christopher Evans, M.D., please contact the clinical research coordinator (CRC) responsible for your care. The CRC's contact information will be provided to you. The CRC will assist you in contacting another investigator for this study. If For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to the medical oncologist on call. In the case of an emergency, dial 911 from any phone.

UC Davis Comprehensive Cancer Center Contact information (including the 24-hour number) is summarized below:
Christopher Evans, M.D.
24-hour phone number: [redacted] (ask for the medical oncologist on call)

This research has been reviewed and approved by an Institutional Review Board ("IRB"). Information to help you understand research is on-line at http://www.research.ucdavis.edu/policiescompliance/irb-admin/. You may talk to an IRB staff member at [redacted] for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
868922	September 10, 2018

INTRODUCTION

This is a research study. Research studies only include subjects who choose to participate. Your study doctor will explain the clinical trial to you. As a study participant you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is to make you better informed so that you may give or withhold your consent to participate in this research study. Please take your time to make your decision and discuss it with your family, friends, or with your personal physician. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you have newly confirmed metastatic castrate resistant prostate cancer or your cancer has progressed after one treatment with abiraterone or enzalutamide. We hope to learn more about your type of cancer. You must be 18 years of age or older. In order to participate in this study, it will be necessary to give your written consent.

The study drug, Cabazitaxel, is an investigational drug or experimental agent that has not yet been approved by the Food and Drug Administration (FDA) for use in this type of cancer.

WHY IS THIS STUDY BEING DONE?

The purpose of the study is to test whether men with a poor initial response to androgen depravation therapy have a better therapeutic response to cabazitaxel as compared to prior use of metastatic castrate resistant prostate cancer therapy with abiraterone or enzalutamide. Therapeutic response is defined as a PSA response rate of greater than a 50% reduction from baseline.

The goal of the study is to see if:

1) We can determine the PSA response rate from baseline.
2) We can determine the safety and effectiveness of cabazitaxel on your disease.
3) We can determine the overall response rate, progression free survival and overall survival rate.
4) We will collect serum and tumor tissues samples for molecular markers to determine the predictive benefits of cabazitaxel.

The study treatment regimen includes a 1 hour infusion of cabazitaxel by IV every three weeks, plus prednisone taken by mouth every day.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We plan to enroll up to 45 people to this study here at UC Davis Comprehensive Cancer Center.

BEFORE YOU BEGIN THE STUDY

If you choose to take part in this study and sign this informed consent form, you will complete “pre-study screening tests” to determine if you meet the study requirements. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of these tests/procedures, they may not need to be repeated. This will be up to your study doctor. Any “pre-study screening tests” that need to be repeated or have not been done recently will be done for the sole purpose of this study. The pre-study screening tests are listed below.

Pre-study Screening Tests:

- Complete medical history including history of prior diagnosis and treatment
- You will be asked about medications that you are currently taking, including over-the-counter medications, herbal remedies, vitamins, and supplements.
- Physical examination, which includes measuring your temperature, blood pressure, height, weight, heart rate, breathing rate, and health status
- Evaluation of how well you are performing your day-to-day activities
- Archival Tumor tissue collection (looking at previously collected samples of your tumor)
- EKG (test that checks for problems with the electrical activity of your heart)

- Computed tomography (CT) scan of chest/abdomen/pelvis or MRI
- Bone Scan
- Blood tests for routine laboratory tests (approximately 2 teaspoons / 10 mL)
- Blood tests for blood chemistries (approximately 2 teaspoons/ 10 mL)
- Blood test to check for PSA and serum testosterone (approximately 2 teaspoons/ 10 mL)
- Urine test

Description of Tests/Procedures:

- **Blood drawing (venipuncture):** Day one of each cycle a blood sample will be drawn by inserting a needle into a vein in your arm. Each sample will be approximately 5 teaspoons. The total amount of blood to be drawn will depend on how long you are in the study.

- **CT scan:** You will have a computed tomography (CT) [/computerized axial tomography (CAT)] scan of your abdomen/chest/pelvis, done every 12 weeks, in order to check the progression of your disease. A CT scan uses special x-ray equipment to make detailed pictures of body tissues and organs. You will need to lie still on a table with your torso inside a large doughnut-shaped machine. The table will move and the machine will make clicking and whirring noises as the pictures are taken. Each CT scan will take about 15 minutes to a half hour.
  or
- **MRI:** [Once every two weeks,] you will have a Magnetic Resonance Imaging (MRI) exam. For the MRI exam, you will lie down on a narrow bed, which will then be placed in a tunnel that is 6 feet long by 22 inches wide and open at each end. You will need to lie there quietly for about one hour, during which time there will be a loud banging noise. You may feel warm during this procedure.

- **Bone Scan:** A bone scan involves injecting a very small amount of radioactive material (radiotracer) into a vein. The substance travels through your blood to the bones and organs. As it wears off, it gives off a little bit of radiation. This radiation is detected by a camera that slowly scans your body. The camera takes pictures of how much radiotracer collects in the bones.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you decide to participate in this study, you will be asked to do the following:
Based upon the results of the study tests and procedures, if you qualify to participate in the study, you will be scheduled for your first study visit and you will be assigned to receive cabazitaxel by IV every 3 weeks plus prednisone given orally twice daily for 6 cycles or until disease progression, unacceptable toxicity or discontinuation. One cycle of study treatment lasts 3 weeks, or 21 days. Your doctor will see you at the beginning of each cycle, starting with Cycle 1.

Your study doctor will monitor you closely for any potential side effects from the study treatment. If side effects occur, your study doctor may lower the dose of study drug, stop treatment temporarily, or discontinue it permanently. If you agree to take part in this study, you agree to return to your study doctor for scheduled appointments.

You will continue the cabazitaxel plus prednisone study treatment as long as you tolerate the drug and your prostate cancer does not spread to other parts of the body or you discontinue.

The following procedures are part of regular care and may be done even if you do not join the study:

- Physical exam and vital signs
- Routine blood tests (blood counts)
- Blood chemistry tests
- PSA's after treatment
- Bone Scans during long term follow up
- CT scans and/or MRI

The following procedures are NOT PART OF REGULAR CARE AND WILL ONLY BE DONE IF YOU JOIN THE STUDY:

- Blood sample for research purposes
- Archival Tumor Tissue collection
- Screening Physical exam and vital signs
- Screening routine blood tests (blood counts)
- Screening blood chemistry tests
- Blood test for GGT (liver enzyme test)
- Screening CT scan and/or MRI
- Bone Scans
- Screening PSA's
- Screening urine tests
- EKGs
- Serum Testosterone

Another way to find out what will happen to me during the study is to read the chart/table below.

Study Calendar of Events

Evaluation	**Pre-Treatment**	**Pre-Treatment**	**Day 1 of each Cycle[8]**	**End of Cycle 2, 4, then every 12 weeks**	**End of Treatment[10]**	**Safety Visit** (28 days after taken off protocol treatment)	**Follow Up** (Every 3 months from time of Off Treatment)[12]
Window	-28 to -1 day	-14 to -1 day	± 3 days	± 4 days	± 4 days	± 4 days	± 7 days
Medical History	X						
Physical Exam including: height, weight, performance status, clinical tumor measurements (if applicable)		X	X			X	X
Vital signs		X	X			X	X
Blood Draw: Hematology: CBC, differential		X	X			X	
Blood Draw: Biochemistry: creatinine (serum), sodium, potassium, total bilirubin, alkaline phosphatase, AST, ALT, LDH, GGT, albumin		X	X			X	
Blood Draw: Testosterone (total)	X			X	X		
Blood Draw: PSA		X	X		X		
Urine test		X					
ECG		X			X		
Chest/abdomen/pelvis CT scan (MRI if appropriate)	X			X	X		X

Evaluation	Pre-Treatment	Pre-Treatment	Day 1 of each Cycle[8]	End of Cycle 2, 4, then every 12 weeks	End of Treatment[10]	Safety Visit (28 days after taken off protocol treatment)	Follow Up (Every 3 months from time of Off Treatment)[12]
Window	-28 to -1 day	-14 to -1 day	± 3 days	± 4 days	± 4 days	± 4 days	± 7 days
Whole body Bone scan	X			X	X		X
Correlative Blood Samples: Plasma, Serum, Whole Blood		X		X	X		
Archival Tumor Tissue		X					
Oral corticosteroids prior to cabazitaxel infusion			X				
Cabazitaxel infusion			X				
Prednisone			→				
Adverse events and Concomitant Medications	X		Continuously				

Study location: UC Davis is currently coordinating the enrollment of patients for this study at the sites listed below. We anticipate that your treatment will be administered (given) at the site of your enrollment.

UC Davis Medical Center
2315 Stockton Blvd.
Sacramento, CA 95817

UC Davis Comprehensive Cancer Center
4501 X Street
Sacramento, CA 95817

HOW LONG WILL I BE IN THE STUDY?

You will be asked to participate for as long as your cancer is not growing and you are not having any unmanageable side effects. After you are finished taking Cabazitaxel, your doctor will ask you to visit the office for follow-up exams for at least once. After that, we will continue to collect follow-up information about your cancer and any further treatment you receive for the rest of your life or a maximum of 2 years.

CAN I STOP BEING IN THE STUDY?

Yes. You can decide to stop the study at any time and it will not be held against you. Tell your study doctor if you are thinking about stopping or decide to stop. Your doctor will tell you how to stop safely. It is important to tell the study doctor if you are thinking about stopping so any risks from the treatment can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

Your study doctor may stop you from taking part in this study at any time if he or she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

There may be other reasons to stop your participation in this study that are not known at this time. If you stop participating in the study, or the study ends, you will stop receiving the study drug(s) and may be asked to come back for final tests and procedures. If you choose to stop taking the study drug before the study ends, you should discuss the following options with the study doctor:

- Continue to visit the study doctor for study related procedures or tests.

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CAN I STOP BEING IN THE STUDY? (Continued)

- Stop study related visits but allow the study doctor or his/her study staff to obtain information about your health by reviewing your medical records, by contacting you, a family member or a legal representative, or through other means as allowed by local law
- You can completely leave the study and have no more contact with the study doctor and his/her study staff for study related procedures or questions as of the date of your request.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

Risks associated with Cabazitaxel:

The most common side effects (experienced in more than 1 in 10 patients) include:

- Decrease in the number of red blood cells (anemia, 97.3%)
- Decrease in the number of white blood cells (95.7%), which are important in fighting infection
- Decrease in the number of platelets (47.4%) (risk of bleeding)
- Loss of appetite (anorexia, 15.9%)
- Alteration in sense of taste (11.1%)
- Shortness of breath (11.9%)
- Cough (10.8%)
- Stomach upset, including nausea (34.2%), vomiting (22.6%) and diarrhea (46.6%)
- Constipation (20.5%)
- Abdominal pain (11.6%)
- Short-term hair loss (10.0%) - in most cases normal hair growth should return
- Back pain (16.2%)
- Joint pain (10.5%)
- Blood in the urine (16.7%)
- Fatigue (36.7%)
- Weakness (20.5%)
- Fever (12.1%)

Common side effects (experienced in less than 1 in 10 patients but more than 1 in 100 patients) include:

- Urinary tract infection (7.3%)
- Lack of white blood cells associated with fever (7.5%)
- Dehydration (4.9%)
- Weakness of the arms and legs (8.1%)
- Feeling of numbness, tingling, burning, or decreased sensations in hands and feet (5.4%)
- Dizziness (8.1%)
- Headache (7.3%)
- Decrease in blood pressure (5.4%)
- Uncomfortable feeling in the stomach or belching after eating (6.7%)
- Stomach pain (5.4%)
- Cardiac rhythm alterations (4.6%) – cardiac failure (including fatal), ventricular fibrillation (including fatal), mainly bradycardia (abnormally slow heart rate) and tachycardia (abnormally fast heart rate)
- Hemorrhoids (4.3%)
- Gastroesophageal reflux disease (heartburn) (3.2%)
- Muscle pain (7.3%)
- Pain when passing urine (6.7%)
- Kidney disease (6.2%)
- Sores in the mouth (2.4%)
- Hypersensitivity to the study drug (1.3%)

Gastrointestinal hemorrhage (bleeding) and perforation (a small hole or holes), ileus (painful obstruction of the intestine), and enterocolitis (inflammation of the small intestine and colon) leading to death have also been reported. Risk may be

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?
Risks associated with Cabazitaxel: (Continued)

increased with neutropenia (decrease of white blood cells), age, steroid use, use of nonsteroidal anti-inflammatory drugs along with the study drug, anti-platelet therapy, or anti-coagulants, and patients with prior history of pelvic radiotherapy, intestinal adhesions, ulceration, and gastrointestinal bleeding.

Pregnancy and Contraception:
You and your partners of childbearing potential should use reliable contraception throughout treatment and are recommended to continue this for up to 6 months after the last dose of cabazitaxel.

During this study, your doctor will keep you informed of any new findings regarding the safety of Cabazitaxel.

RISKS ASSOCIATED WITH PREDNISONE/PREDNISOLONE:
The side effects of prednisone occur more frequently with higher doses and more prolonged treatment.

Common:

- Problems with vision
- Fluid retention
- Rapid weight gain
- Feeling short of breath
- Severe depression
- Mood changes
- Seizure (convulsions)
- Bloody or tarry stools
- Coughing up blood
- Low potassium, which can cause the following symptoms:
    - Confusion
    - Uneven heart rate
    - Extreme thirst
    - Increased urination
    - Leg discomfort
    - Muscle weakness or limp feeling
- Low calcium level, which can cause the following symptoms:
    - Decreased appetite
    - Nausea
    - Vomiting
    - Abdominal pain
    - Muscle weakness
    - Muscle twitching
    - Muscle cramps or spasms [including spasm of the airway]
    - Fractures
    - Numbness and tingling in the hands, feet and around the mouth
    - Fatigue
    - Anxiety
    - Increased heart rate, and if serious, can lead to heart failure
    - Seizures, confusion, and coma
- High blood pressure
- Acne
- Dry skin
- Thinning skin, bruising, or discoloration
- Slow wound healing
- Increased growth of facial hair
- Increased sweating
- Headache
- Dizziness

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WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

RISKS ASSOCIATED WITH PREDNISONE/PREDNISOLONE:

The side effects of prednisone occur more frequently with higher doses and more prolonged treatment.

Common: (Continued)

- Nausea
- Heartburn
- Stomach pain and bloating
- Fatigue
- Weak muscles
- Numbness or tingling in the face, arms, legs, feet, or hands
- Changes in shape or location of body fat (such as arms, legs, face, neck, breasts, waist)
- Bulging eyes/puffing of face (moon face)
- Alteration in glucose tolerance (abnormal blood sugar)

Other side effects include:

- Difficulty sleeping or nervousness
- Weakening of the bones
- Stomach ulcer disease
- Appetite changes
- Allergic reactions that may be life-threatening

General Risks:
Blood draw Risks: Routine laboratory tests and the research blood draws may result in bruising, infection and minor pain or discomfort comparable to a needle prick.

Bone Scan risks: A bone scan test poses no greater risk than do conventional x-ray procedures. The tracers used in a bone scan produce very little radiation exposure. You might find the injection and the need to lie still during the scanning procedure mildly uncomfortable. The risk of an allergic reaction to the tracers is extremely rare.

Central venous access device risks:
These include risks associated with the surgical placement of the catheter such as pain, bleeding, or rarely, collapse of the lung. In addition, the maintenance of this catheter over the course of a study could expose you to risks such as infection or local blood clotting, possibly requiring the use of antibiotics or anticoagulants.

CT scan risks: CT scans involve the risks of radiation. In addition, if contrast material (iodine dye) is used, there is a slight risk of developing an allergic reaction, from mild (itching, rash) to severe (difficulty breathing, shock, or rarely, death). Having a CT scan may mean some added discomfort. In particular, you may be bothered by feelings of claustrophobia when placed inside the CT scanner, or by lying in one position for a long time.

EKG (ECG) risks: Since EKG is done without entering the body and does not use dyes or x-rays, there is no pain or risk associated with having an EKG.

IV Inserted in the Vein risks: Inserting a needle into a vein to inject medication may cause inflammation, pain, bruising, bleeding, or infection.

MRI risks: Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during the examination. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. The risks to a fetus from MRI are unknown; pregnant women cannot participate in this study.

Radiological risks: This study involves a radiation exposure from CT and bone scans that is higher than most other diagnostic tests using ionizing radiation. The exposure to radiation from this procedure might result in a slight increase in

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

General Risks: (Continued)

cancer risk in normal healthy individuals. However, since you already have cancer, a risk estimate cannot be accurately determined.

Unknown Risks:
The experimental treatments may have side effects that no one knows about yet. The researchers will tell you of new information that might make you change your mind about participating in the study.

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

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may not benefit from taking part in this research. The information we get from this study may help us to learn more about this study treatment, and this may help future cancer patients.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Your alternative is not to take part in this study. If you choose not to take part in this study, your future care will not be affected. Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Participating in a different study, if available
- 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 directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

We will do our best to make sure that your personal information will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

If information from the study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include:

- The investigators involved in the conduct of this study and their designees
- The sponsor of this study UC Davis Comprehensive Cancer Center
- The National Cancer Institute (NCI)/CTEP
- The Food and Drug Administration (FDA)
- The UC Davis Institutional Review Board (IRB)
- The manufacturer of Cabazitaxel (Sanofi-Genzyme)

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 study results. You can search this Web site at any time.

If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record. If that happens, your research records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/compliance/pdf/notice.pdf) and in an attached document.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the person in charge of this research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by the University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may call the IRB Administration at (916) 703-9151 or email at IRBAdmin@ucdmc.ucdavis.edu.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

The company Sanofi-Genzyme will provide Cabazitaxel free of charge for this study.

There will be no charge to you or your insurance company for processing the research blood draws or research studies on your blood tests. They will be paid for by the study. However, if the specimens are obtained during a standard diagnostic procedure, that procedure will be charged to you or your insurance company in the usual way.

Prednisone is commercially available and will be billed to you and/or your insurance company.

You or your health plan will be billed for the costs of routine medical care you receive during the study. These costs may include operating room fees, pharmacy charges, treatments, hospitalization, scans, etc. You will be expected to pay for the usual deductibles and co-payments, and for any routine care that is not covered. Only the costs of research or experimental procedures will be paid by the study.

Whenever possible, pre-authorization will be obtained. If the costs are not covered, these costs will be discussed prior to proceeding with the study.

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

WILL I BE COMPENSATED FOR BEING IN THIS STUDY?

You will not be compensated for your participation in this study.

Samples taken during this study may be used for research and development purposes not related to your treatment or condition. You will not have any property rights or ownership interest in products or data which may be derived from your samples.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or willingness to continue in the study.

DOES THE RESEARCHER HAVE A FINANCIAL INTEREST IN THIS RESEARCH STUDY?

Christopher Evans, M.D. from UC Davis is conducting the study. Sanofi-Genzyme, a for-profit drug company, is funding this study. Sanofi-Genzyme is giving money to UC Davis so that the study doctor can conduct the study. In addition, Dr. Evans has a financial interest with Sanofi-Genzyme. Dr. Evans has received payment from Sanofi-Genzyme as income in the amount of $10,001-$100,000. If you have any questions about this information, please feel free to contact your study coordinator or discuss it with Dr. Evans.

WILL SPECIMENS (tissue, blood, urine or other body materials) TAKEN FROM ME BE USED FOR FUTURE RESEARCH PURPOSES?

You have had a biopsy (or surgery) to see if you have cancer. Your doctor removed some body tissue to do some tests. The results of these tests were given to you by your doctor and are being used to plan your care.
We would like to keep some of the tissue, blood that is left for future research purposes. Your specimen(s) will only be used for research purposes. If you agree, these specimen(s) will be kept and used to learn more about your disease as well as other diseases.

The research that may be done with your specimen(s) will not benefit you directly nor have an effect on your care. It might help people who have your disease and other diseases in the future. Any reports about the research, done with your specimen(s), will not be shared with you or your doctor and the reports will not be put in your health record.

Your name, address, phone number and any other identifying information will be taken off anything associated with your specimen before it is given to the researcher. This would make it very difficult for any research results to be linked to you or your family. To help protect your privacy, people outside the research process will not have access to results about any one person.

The benefits of research using specimens include learning more about what causes diseases, how to prevent them, how to treat them, and how to cure them. There are very few risks to you. The greatest risk is the release of information from your health records which may be necessary for us to obtain along with your specimens. We will protect your records so that your name, address, and phone number will be kept private.
Please read each question below and think about your choice. After reading each question, initial next to "YES" or "NO". If you have any questions, please discuss this with the researcher.

1. My tissue may be kept for use in future research: YES_____ NO_____

2. Someone may contact me in the future to ask me to use my specimens in future research: YES_____ NO_____

For further information on the use of specimens for future research purposes and your rights as a research participant, please visit: http://research.ucdavis.edu/IRBAdmin/Participants.

WHERE CAN I GET MORE INFORMATION?

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

1-800-4-CANCER (1-800-422-6237)

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

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

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
868922	September 10, 2018

VOLUNTARY CONSENT:

My signature below will indicate that I have decided to participate in this study as a research subject. I have read and understand the information above. I understand that I will be given a signed and dated copy of this consent form and the Bill of Rights.

Signature of Subject	Printed Name of Subject	Date
Signature of Person Obtaining Consent	Printed Name of Person Obtaining Consent	Date

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SIGN BELOW ONLY IF A WITNESS WILL OBSERVE THE CONSENT PROCESS (for use with IRB "Short Form")

Signature of Witness to Consent Process	Printed Name of Witness	Date

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
868922	September 10, 2018
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