## You are being asked to take part in a research study.

## Before you agree to take part, someone will explain to you:

1. That the study involves research
2. The purposes of the research
3. How long you will be in the research
4. What will happen to you
5. What is experimental
6. Risks or discomforts to you
7. Benefits to you or others
8. Other choices you might have
9. Who will see your information
10. You volunteer to be in a research study
11. Whether or not you take part is up to you
12. You can choose not to take part in the research study
13. You can agree to take part now and later change your mind
14. Whatever you decide it will not be held against you
15. If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the research team at (916) \_\_\_\_ - \_\_\_\_\_\_
16. 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.
17. 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 a IRB staff member at (916) 703-9151, IRBAdmin@ucdmc.ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 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

## When applicable, someone will explain to you:

1. Whether you will get treated or paid if injury occurs
2. The possibility of unknown risks
3. When you may be taken off the research without your agreement
4. Added costs from taking part
5. What will happen if you stop taking part
6. Steps to safely stop taking part
7. When new information will be told to you
8. The number of people expected to take part in the research
9. That the Food and Drug Administration may inspect the records
10. What happens to collected data if you stop taking part
11. An explanation of [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)

## What are my rights as a research subject?

As a research subject, you have the following rights:

* Be told of the nature and purpose of the research study.
* Be told of the procedures to be followed, and any drug or device to be used.
* Be told any common or important discomforts and risks.
* Be told of any benefits you might expect.
* Be told of other procedures, drugs or devices that might be better, and their risks and benefits.
* Be told what medical treatment, if any, is available for complications.
* Be given a chance to ask questions about the research study.
* Be told you can stop taking part in the research study at any time without affecting how you are treated.
* Be given a copy of the signed and dated written consent form.
* Be given enough time to decide whether to take part without force, fraud, deceit, duress, coercion, or undue influence.

**Signature Block for Capable Adult**

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| Your signature documents your agreement to take part in this research. |
|  |  |  |
| Signature of subject |  | Date |
|  |  |
| Printed name of subject |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |
| Printed name of person obtaining consent |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |