

## **CONSENT FORM AND INFORMATION ABOUT**

### **Name of Study**

To be conducted at:                      **Name (Note: List all sites where the study will be conducted.)**  
**Complete address**

Principal Investigator:                      **Name**  
**Address**  
**Phone Number**

Sub-Investigators                              **Name**

### **INTRODUCTION**

It is important that you read and understand these general principles that apply to all who take part in this experimental research study: (a) Taking part in this study is entirely voluntary; (b) you may not benefit directly as a result of taking part in this study, but knowledge gained may be of benefit to others; (c) you are free to withdraw from the study at any time without affecting ongoing future care; (d) leaving the study will not cause loss of any benefits to which you are otherwise entitled.

Before you volunteer to take part in this research, the study will be explained to you and you will be given a chance to ask questions. You should discuss anything that you do not understand with the person explaining it to you before you agree to volunteer. Once all of your questions have been answered, and if you decide to participate or not to participate, you may sign the appropriate line on this consent form.

#### **I. Purpose**

The purpose of this study is to...

#### **II. Study Procedures**

If you agree to participate in this study, the following will occur as a result of your participation:

List how long the study will last or how many subjects will be enrolled in the study and how long the subject will be involved in the study.

#### **III. Risks/Side Effects/Discomforts**

The possible side effects from...

*(If applicable)* There is the possibility of side effects occurring which have not been seen previously.

**IV. Benefits and Alternative Treatments**

**A. Benefits** (Include the benefits of participating in the study.)

**B. Alternatives** (Write in other ways or options to treat the condition.)

**V. Withdrawal/Voluntary Participation**

In the opinion of your physician, if you are not benefiting from participation in this study he/she may withdraw you from the study.

Participation in this study is strictly voluntary and you have the right to refuse to participate in this research study or withdraw at any time without fear of prejudice to additional medical care.

**VI. Costs, Research Injury, Financial Implications/Any Compensation**

In the event of physical injury directly resulting from your participation in this study, you will receive medical treatment and/or hospitalization reasonably necessary to address the injury at no cost to you, so long as you follow the reasonable instructions of the study physician, and the study staff.

Expenses incurred in providing you with medical treatment and/or hospitalization required to address an injury that is determined NOT to have directly resulted from your participation in the study will be billed to you or your insurance. No funds have been set aside to provide you with financial compensation for lost wages, disability, or discomfort due to this type of injury, illness or adverse event. By signing this consent form you will not be waiving any of the legal rights which you otherwise would have as a subject in a research study.

(List specifically what tests, drugs etc. are covered by the sponsor and if any costs related to the research are to be paid by the subject.)

(If applicable, statement re: if patient is being compensated to participate.)

**VII. Confidentiality**

Any information that is obtained in connection with this study will remain confidential and will be disclosed only to other physicians and researchers within (study sponsor name), the St. Luke's / MSTI / Magic Valley IRB, (If applicable: National Cancer Institute or )the Food and Drug Administration and Office for Human Research Protections to evaluate the results of this study. Copies or portions of your medical records may need to be released to these agencies, but will be kept confidential within the extent of the law.

**VIII. Acknowledgment**

The doctors involved in my care have answered my questions about my treatment, and they have advised me they are available to answer any future questions I may have about this study and my treatment. I understand I will be informed of any new findings that develop during the course of this research study that may relate to my willingness to continue to participate in this study. In case of a research related injury or problem, or a question regarding this study, I may reach the Principal Investigator, Dr.

