ACOSOG
American College Of Surgeons Oncology Group
Surgeons, Science, and Collaborations in Action

ACOSOG Z4099/RTOG 1021: AMENDMENT 2 PATIENT BROCHURE

TO: Z4099 Investigators and Staff

FROM: Susan Budinger
Protocol Editor

DATE: August 15, 2012

RE: Z4099 **Amendment 2** Patient Information Brochure

Attached for your use is the patient information brochure for ACOSOG Z4099**, "**A Randomized Phase III Study of Sublobar Resection (+/- Brachytherapy) versus Stereotactic Body Radiation Therapy in High Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC)."

The brochure is intended as a patient information tool to increase awareness of the trial. It provides an introduction to the study in layman's terms and encourages patients to consult their physician for more information.

The brochure has been approved by the Central IRB. **If your site does not use the CIRB, then the brochure must be reviewed and approved by your local IRB before distribution to potential participants.**

Please feel free to contact me at (919) 668-9390 or susan.budinger@duke.edu with any questions.

If you have an early-stage lung tumor, you may be able to participate in a new clinical study of surgery and radiation therapy.

Z4099: A Randomized Phase III Study of Sublobar Resection (+/- Brachytherapy) versus Stereotactic Body Radiation Therapy in High Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC)

WHAT IS A CLINICAL STUDY?

Clinical studies (or "trials") are a type of research involving patient volunteers. They are designed to find better ways to treat disease.

WHAT TYPE OF STUDY IS THIS?

This study is a clinical trial for patients whose lung tumor may be removable with surgery, but who are considered "high-risk" for surgery. This study is looking at radiation therapy as an alternative to surgery.

WHO CAN PARTICIPATE IN THIS STUDY?

You can participate in this study if:

- You have a lung tumor suspicious for early-stage lung cancer
- You have no evidence of cancer spread to other organs
- You are considered by your doctor to be "high risk" for surgery due to other health issues

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to compare **sublobar resection** (removal of a small portion of a lung) with or without brachytherapy (radioactive seeds placed in the body, which are used if that is standard-of-care at the hospital where you will be treated) to **stereotactic body radiation therapy (SBRT)**, which is radiation given by a specialized x-ray machine that targets your lung cancer. The study will compare the effects these treatments have on you and your lung cancer to find out if SBRT is as effective as sublobar resection. This study is being done because SBRT may have fewer side effects than sublobar resection, but we do not know if SBRT is as effective at preventing your cancer from returning or at prolonging your life. SBRT is the current standard treatment for patients who are not candidates for surgery.

WHO IS CONDUCTING THIS STUDY?

This research study is being conducted by the American College of Surgeons Oncology Group (ACOSOG). ACOSOG is a research group funded by the National Cancer Institute.

WHAT IS INVOLVED IN THE STUDY?

If you decide to participate in this study, you will read and sign a consent form that explains the study in more detail. If you meet all of the

study requirements, you will then be randomly assigned (similar to a coin flip) to undergo treatment with sublobar resection or SBRT.

WHAT ARE THE COSTS OF THE STUDY?

There are no extra costs for this study. You or your insurance company will be responsible for the costs of the tests and treatment required for this study, but these tests would be done even if you were not part of this study.

WHAT WILL I HAVE TO DO DURING THE STUDY?

If you choose to join this study, you will have tests done before surgery or SBRT. The tests include:

- Health history and physical exam
- Laboratory studies and blood tests
- CT and PET scans
- Lung function test
- Possible biopsy of your tumor and any enlarged lymph nodes. Your study doctor will decide if a biopsy is needed.

You also will complete some questionnaires about your health and your quality of life. These are being done as part of the study at no cost to you.

You will have surgery or SBRT at the hospital. After treatment, you will be asked to visit your doctor every few months for tests. Your health will be monitored for a total of 5 years. You will receive further therapy according to your doctor's advice.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

Information from this study will help doctors learn more about SBRT as a treatment for lung cancer. This information could help future cancer patients in choosing the method by which their lung cancer will be treated.

ARE THERE POSSIBLE SIDE EFFECTS?

You may experience side effects while in this study. Your doctor or nurse will explain them to you.

AM I REQUIRED TO BE IN THIS STUDY?

No. Taking part in this study is voluntary. You are free to choose to join, not to join, or to leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

HOW DO I PARTICIPATE?

If you are interested in this study, please speak to your doctor and the members of your health care team to discuss the possible benefits and risks of participating. We encourage you to discuss this brochure and this study with your physician, family and friends.

WHERE CAN I GET MORE INFORMATION?

You may call the NCI's Cancer Information Service at 1–800–4–CANCER (1–800–422-6237) or TTY: 1–800–332–8615 or visit the NCI Website at http://www.cancer.gov or visit the ACOSOG website at http://www.acosog.org.