INFORMED CONSENT

TITLE: RTOG 0214: A PHASE III COMPARISON OF PROPHYLACTIC CRANIAL IRRADIATION VERSUS OBSERVATION IN PATIENTS WITH LOCALLY ADVANCED NON-SMALL CELL LUNG CANCER

SPONSOR: National Cancer Institute

PRINCIPAL INVESTIGATOR: Ruby F Meredith, M.D., PhD

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part. Please take your time to make your decision. Discuss it with your friends and family. The National Cancer Institute (NCI) booklet, "Taking Part in Clinical Trials: What Cancer Patients Need To Know," is available from your doctor.

You are being asked to take part in this study because you have non-small cell lung cancer.

The Coordinating Group for this intergroup trial is the Radiation Therapy Oncology Group (RTOG).

WHY IS THIS STUDY BEING DONE?

In fifty percent of patients with locally advanced non-small cell lung cancer, the cancer will spread to the central nervous system at some time during the course of their disease. The usual treatment for patients who have had effective treatment for locally advanced non-small cell lung cancer is observation or monitoring of your health.

The purpose of this study is to compare the effects (good and bad) of brain irradiation with the standard treatment of observation to see if brain irradiation results in patients living longer. The study will also evaluate whether there is a lower risk of tumor in the brain with the use of radiation. In addition, the study will evaluate the effects of brain irradiation on the thinking skills and quality of life of those patients who receive it.

This research is being done because we do not know whether or not brain irradiation helps patients with non-small cell lung cancer live longer.

We also do not know if brain irradiation is safe or if it prevents growth of small tumor deposits which already may be in the brain of patients with non-small lung cancer.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY

About 1058 people will take part in this study.

UAB-IRB
Consent Form Approval 2-1-06
Expiration Date 11-02-06

Version: December 8, 2005
Amendment 4
Participant's Initials: _______
WHAT IS INVOLVED IN THE STUDY?

You will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin.

A computer will determine into which group you are placed. Neither you nor the researcher will choose what group you will be in. You will have approximately an equal chance of being placed in one of the two groups below:

Group 1

If you are randomized to this group, you will receive radiation therapy to the brain once a day, Monday through Friday, for three weeks.

Group 2

If you are randomized to this group, you will not receive radiation therapy to the brain. Your health and progress will be monitored.

If you take part in this study, you will have the following tests and procedures:

A physical exam prior to study entry, and at 3, 6, 12, 18, 24, 30, 36, and 48 months; If you are randomized to Group 1, you also will have a physical exam weekly during radiation therapy.
  - Blood tests prior to study entry
  - A bone scan, only if indicated by your blood test results
  - An MRI or CT scan of your head, with and without contrast material, prior to study entry, at 6 and 12 months after study entry, then annually
  - A CT scan of your chest, liver, and adrenal glands prior to study entry
  - For women who are able to have children, a test prior to study entry to see if you are pregnant

Written and verbal tests to evaluate your memory and thinking skills, prior to study entry and at 3, 6, 12, 18, 24, 30, 36, and 48 months. In addition, self-report questionnaires asking about you and your health prior to study entry and at 6, 12, 24, 36, and 48 months. These tests will take about 30 minutes to complete each time you take them.

HOW LONG WILL I BE IN THE STUDY?

If you are randomized to Group 1, you will receive brain irradiation for three weeks; follow-up for both Group 1 and 2 will continue for ten years after the end of treatment. Your doctor may decide to take you off this study if your doctor believes it is in your medical best interest or if your condition worsens. You may also be taken off this study if new information becomes available about how to better prevent growth of small tumor deposits already in the brain of patients with non-small lung cancer.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

Version: December 8, 2005
Amendment 4
Participant’s Initials: _______
WHAT ARE THE RISKS OF THE STUDY?

While on the study, you are at risk for these side effects. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict. Other drugs will be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the brain irradiation is stopped, but in some cases side effects can be serious or long-lasting or permanent.

Brain Irradiation
A small risk of cancer, cataracts, and other radiation effects, which may not be known at this time may develop from this therapy.

Very Likely
- Hair loss, which may be permanent
- Scalp reddening or tanning and irritation
- Dry mouth and/or change in taste
- Nausea and/or vomiting
- Headaches
- Tiredness
- Increased sleepiness (occurring 4-10 weeks after radiation therapy is complete and often lasting for several days up to a few weeks)

Less Likely, But Serious
- Drainage from the ears or plugging of the ears with decreased hearing
- Cataracts and eye damage with the possibility of blindness
- Severe local damage to normal brain tissue, which may require surgery
- Memory loss, behavioral change (This risk may be permanent because it is a potential effect associated with brain irradiation.)
- In very rare cases, growth of abnormal tissue, which may be cancerous, and/or death may result

When possible, additional medications will be offered to you, such as medications to control nausea and to minimize the side effects associated with radiation therapy.

This study may be harmful to a nursing infant or an unborn child. If you are a woman able to have children and have not been surgically sterilized (tubal ligation or hysterectomy), you should have a pregnancy test before enrolling in this study. If you are unwilling to use adequate birth control measures to prevent pregnancy, you should not participate in this study.

If you are a man able to father children, the treatment you receive may risk harm to an unborn child unless you use a form of birth control approved by your doctor. If you are unwilling to use adequate birth control measures to prevent pregnancy, you should not participate in this study.
Whether you are a man or a woman, you are asked to practice an effective method of birth control method, which includes oral or implanted contraceptives, IUD, condoms (male, female) diaphragm with spermicide, cervical cap, abstinence, or a sterile sexual partner during treatment. Ask about counseling and more information about preventing pregnancy. You cannot participate on this study if you are pregnant or a nursing mother.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. Brain irradiation may prevent growth of small tumor deposits already in the brain, but this is not certain or guaranteed.

We hope the information learned from this study will benefit other patients with non-small cell lung cancer in the future.

WHAT OTHER OPTIONS ARE THERE?

You may choose to not participate in this study. Other treatments that could be considered for your condition may include the following: (1) radiation therapy outside this study or (2) monitoring of your health and progress outside of this study. Standard of care for your disease does not include prophylactic irradiation and patients in a non-investigational setting would be observed. Your doctor can tell you more about your condition and the possible benefits of the available treatments. Please talk to your regular doctor about these and other options.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Records of your progress while on the study will be kept in a confidential form at this institution and in a computer file at the headquarters of the Radiation Therapy Oncology Group (RTOG). Your personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Food and Drug Administration (FDA), the National Cancer Institute (NCI) or its authorized representatives, the UAB Institutional Review Board and other groups or organizations that have a role in this study.

Information relating to this study, including your name, medical record number, date of birth and social security number may be shared with the billing office of UAB and UAB Health System-affiliated entities so that claims may be appropriately submitted to either the study sponsor or your insurance company for clinical services and procedures provided to you during the course of this study.

If you receive services in University Hospital as part of this trial, this informed consent document will be placed in and made part of your permanent medical record at this facility.
WHAT ARE THE COSTS?

The cost of your standard medical care will be billed to you and/or your insurance company in the usual manner.

WILL I RECEIVE PAYMENT FOR RESEARCH RELATED INJURIES?

UAB, RTOG, and the NCI has made no provisions for monetary compensation in the event of injury resulting from the research, and in the event of such injury, treatment is provided, but is not free of charge.

You or your insurance company will be charged for continuing medical care and/or hospitalization. Medicare should be considered a health insurance provider.

WILL I RECEIVE PAYMENT FOR PARTICIPATING IN THIS STUDY?

You will receive no payment for taking part in this study.

MAY I WITHDRAW FROM THE STUDY?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

WILL I BE TOLD ABOUT NEW FINDINGS?

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher Dr. Ruby F Meredith, Principal Investigator. She may be reached at (205) 934-4763 or in the event of an after-hours emergency, call (205) 934-3411 and ask for the hematology/oncology fellow on call.

For questions about your rights as a research participant, contact the UAB Institutional Review Board Director, Sheila Moore. Ms Moore can be reached at (205) 934-3789 or 1-800-822-8816, press the option for an operator/attendant and ask for extension 4-3789 between the hours of 8:00 a.m. and 5:00 p.m. CT, Monday through Friday.
It may be necessary to contact you at a future date regarding new information about the treatment you have received. For this reason, we ask that you notify the institution where you received treatment on this study of any changes in address.

You also may call the Project Office of the NCI Central Institutional Review Board (CIRB) at 888-549-0715 (from the continental U.S. only) or 800-937-8281, ext. 4445 (from sites outside the continental U.S.).

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.

Visit the NCI’s Web sites for comprehensive clinical trials information at http://cancertrials.ncl.nih.gov or for accurate cancer information including PDQ (Physician Data Query) visit http://cancer.gov.

Cancer Fax: Includes NCI information about cancer treatment, screening, prevention, and supportive care. To obtain a contents list, dial 301-402-5874 or 800-624-2511 from a fax machine handset and follow the recorded instructions.

WHAT ABOUT MY LEGAL RIGHTS?

You will not be waiving any of your legal rights by signing this consent form.
SIGNATURES

You are deciding whether or not to take part in this study. If you sign, it means that you have decided to volunteer to take part in this study and that you have read, or had read to you, all the information on this form. You will be given a signed copy of this form.

Participant Signature (or legal Representative)   Date

________________________________________  ________________________
Investigator (or person obtaining consent)       Date

________________________________________  ________________________
Witness                                       Date

Version: December 8, 2005
Amendment 4
University of Alabama at Birmingham
Authorization for Use/Disclosure of Health Information for Research

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant name: ___________________________  IRB Protocol Number: F030225001
Research Protocol: RTOG 0214-A Phase III Comparison  Principal Investigator: Ruby F. Meredith, MD, PhD
Of Prophylactic Cranial Irradiation Versus Observation  Sponsor: National Cancer Institute
In Patients With Locally Advanced Non-Small Cell Lung Cancer

What health information do the researchers want to use? All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, The Children’s Hospital of Alabama, Callahan Eye Foundation Hospital and the Jefferson County Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: ___________________________  Date: __________________

or participants’ legally authorized representative: ___________________________  Date: __________________

Printed Name of participant’s representative: ___________________________

Relationship to the participant: ___________________________

Version: December 8, 2005
Amendment 4