ATTACHMENT 7:

SCOTT AND WHITE* CONSENT FORM

Note: Scott and White requested special consent forms. This attachment includes those specially modified forms.

Scott and White Consent Form

CONSENT FORM and
AUTHORIZATION FOR USE AND DISCLOSURE
OF HEALTH INFORMATION for Research Purposes

Exploratory Research with People Living with Lung Cancer

SCOTT & WHITE CLINIC
SCOTT AND WHITE MEMORIAL HOSPITAL AND
SCOTT, SHERWOOD AND BRINDLEY FOUNDATION
TEMPLE, TEXAS 76508

You are being offered an opportunity to participate in a research study that is supported by the Centers for Disease Control and Prevention—CDC (*Sponsor).* The purpose of this research study is to learn more about the experience and needs of people living with lung cancer. The study Sponsor provides funding to Scott & White to cover some or all of the costs of conducting this research.

Before you agree to volunteer to take part in this research study, it is very important that you understand the purpose of the study, the nature of the tests and procedures you will be asked to undergo, and how health information about you may be used or given to others during the study and after the study is finished.

Purpose and Background

Individuals affected by lung cancer face many, if not all, of the challenges facing individuals diagnosed with other cancers. However, less is understood about the needs of individuals living with lung cancer. Thus, more research is needed to better address the challenges of living with lung cancer.

In understanding the needs of people living with lung cancer, it is important also to consider the role that an individual's smoking status plays in influencing individual experiences with diagnosis, treatment, and survivorship-related services.

The purpose of this research study is to investigate the preceding issues among three different groups of lung cancer survivors, *smokers*, *former smokers*, and those who *never smoked*. In particular, we will address issues of diagnosis, experience with stigma and discrimination, and the provision of counseling and support as they relate to each of these groups with the goal of potentially developing a system for providing information and services that will benefit individuals with lung cancer.

RTI International is a nonprofit research organization contracted by CDC (*Sponsor*) to perform this research study. RTI will be conducting 27 telephone interviews with people living with lung cancer. Information collected from these interviews will be used to guide or direct future research and educational efforts.

A total of approximately 27 subjects at two institutions will take part in this study. Approximately 9 subjects from this institution are expected to participate.

Procedures

As someone identified as living with lung cancer, we would like to refer you as a potential subject in this research study for a telephone interview (described above). If you are interested in participating in this research study, we will share your contact information with a representative of RTI. They can talk to you further about participation and will then perform the actual interview. By signing this consent form, you agree to be contacted by RTI and you are only saying you would like additional information. If you choose to participate in the research study, RTI will ask you to provide a separate consent agreement with them. At any point, you may refuse to participate further.

Each interview will last about an hour. It can be completed in one or two sessions, if needed. Your choice to participate in this research study is completely voluntary.
As part of the actual interview, an RTI staff member (a psychologist trained in addressing grief and depressive issues among cancer survivors who is experienced in conducting interviews with patients on sensitive health topics) will talk to you about your experiences and any challenges you have faced in living with lung cancer.

- You may choose not to answer any questions in the interview.
- You can stop the discussion at any time during the interview.
- Your choice to take part in the interview will not affect the health care you receive here at Scott & White.

Length of Study and Number of Visits

This research study consists of only the telephone interview described above.

Exclusions

You should not participate in this study if any of the following apply to you:

- If you are not able to complete an interview in English.
- If you cannot complete an hour interview in one to two sessions.
- If you are already participating in a cancer-related research study.

Discomfort and Risks

There will be no physical risks to you for participating. It is possible that some of the topics discussed during the actual interview could make you uneasy.

Reproductive Risks

There are no reproductive risks involved with participation in this research study.

Benefits

There is no direct benefit to you for being part of this research study at this time; however, there could be benefits to you and other individuals with lung cancer at some point in the future.

Alternative Therapies

You have the alternative of not participating in this study.

Cost and Compensation
Seventy-five dollars will be provided to you by CDC (*Sponsor*) to cover any costs for participating in the interview.

Compensation for Medical Treatments for Research-Related Adverse Events
In the event of injury or illness resulting from this research procedure, medical care will be available to you. There are no plans for financial compensation or free medical treatment to be offered by Scott & White Clinic or Scott and White Memorial Hospital, and Scott, Sherwood and Brindley Foundation.

New Findings

Any new findings developed during the course of your participation in the study, which may be related to your willingness to participate, will be provided to you.

Termination of Subject Participation
Your participation may be terminated at any time at your request. Your participation may also be terminated by the study doctor and/or the Sponsor without your consent.

Confidentiality

Study records that identify you will be maintained in a confidential manner. The health information that may be used and/or disclosed to conduct the study includes medical records and information created or collected during the study.

Health information that identifies you will be used for medical, statistical, and regulatory purposes related to this research. By agreeing to participate in this research, you are giving authorization for the research team to use and report the results of treatments, tests and examinations conducted for the purposes of this research, and matters related to study oversight and data analysis to

- the Scott & White Institutional Review Board (IRB—a group of people who strive to protect the rights of subjects);
- the Scott & White Research Compliance Office or Privacy Office;
- Scott & White employees involved in this study;
- local, state, and federal agencies (such as the Office for Human Research Protections and the U.S. Food and Drug Administration) when required by law;
- the Sponsor of the study and its representatives—The Centers for Disease Control and Prevention; and
- other non-Scott & White collaborators who are participating in this study—RTI International.

Once health information about you has been disclosed to a sponsor or anyone outside of this study, the information may no longer be protected by the federal privacy regulation.

By signing this consent form, the research team at Scott & White will release your name, address, telephone number, health plan/insurance provider information, and year of birth to RTI

International. You will not be identified by name, picture, or any other personally identifying manner if information from this study is presented publicly or published in a medical journal.

During the course of the telephone interview, you will be verbally consented by RTI and asked for permission to record the interview. Other study staff may listen to the interview so they can take notes. A staff member from CDC (*Sponsor*) may listen as well. We would also tape record the interview. The tapes help us get everything you have to say. Only study staff will be able to listen to the tapes. The tapes will be destroyed when the study is completed.

The project will not use your name on any written reports. Everything we learn will be kept private by project staff. The reports will put together what we learn from everyone in this study and will not use names.

Right to Withdraw Consent and Authorization

Participation in this study is voluntary. You may withdraw from participation and/or revoke your authorization for the use of private information at any time during the study. Your decision to withdraw and/or revoke your authorization will not result in any penalty or loss of benefits to which you are entitled. Your decision will not affect the medical care you receive at Scott & White.

You have a right to revoke your authorization. A request to revoke an authorization must be submitted in writing to Dr. Carl Boethel, 2401 South 31st Street, Temple, TX, 76508. Revoking your authorization only affects uses and sharing of information collected after your written request has been received. Information collected prior to revoking the authorization may continue to be used and disclosed for research integrity and reporting purposes only. Data that have already been sent to the Sponsor or their representatives cannot be withdrawn. If you revoke your consent or authorization, you will be removed from the study.

Right to Access

You have a right to access your private health information, including health information that is collected for the research. However, to protect the integrity of the study, your right to access your research records may be suspended during the conduct of the study. After the study is completed (meaning the end of the whole study, not just your own participation), you will be given access to these records upon your request.

This authorization does not have an expiration date.

Whom to Contact for Questions or Emergencies

If you have additional questions during the course of this study about your rights as a research subject, you may address them to the IRB Office at (254) 724-4072. If you have any questions about the research or in the case of injury or illness resulting from the research, please contact Dr. Carl Boethel at (254) 724-8193.

If you have not already received a copy of the Notice of Privacy Practices, you may request one. If you have any questions or concerns about your privacy rights, you should contact the Scott & White Privacy Office at (254) 724-7600.

Participation

Participation in this study is voluntary and refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign the authorization, you will not be allowed to participate in the research study.

Statement of Consent and Authorization

The research study has been explained to me and I have had an opportunity to read this consent form/authorization and have all of my questions answered. I have been informed that I may leave the study at any time without affecting my medical care and the Sponsor or my doctor may withdraw me from the study without my consent. I freely agree to take part in this research and authorize the research team to create, obtain, use, or disclose personally identifiable information in connection with this study. A signed copy of this consent form/authorization will be given to me.

_____	_____	_____
Printed Name of Subject	**Signature**	**Date**

Statement of Person Obtaining Consent

I have carefully explained to the subject the nature of the study. I hereby certify that to the best of my knowledge the subject signing this consent form/authorization understands clearly the nature, demands, risks and benefits involved in participating in this study. A medical problem or language or educational barrier has not prevented a clear understanding of the subject's involvement in this study.

_____	_____	_____
Printed Name of Person	**Signature**	**Date**