

PATIENT INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

Title of Study: Building a Multidisciplinary Bridge across the Quality Chasm in Thoracic Oncology

Sponsor: Patient Centered Outcomes Research Institute (PCORI)

Investigator:
Raymond Osarogiagbon, MD
Baptist Cancer Center
80 Humphreys Center Drive, Suite 340
Memphis, TN 38120

Participating Investigators: Ken Ward, Ph.D., University of Memphis, School of Public Health

Telephone: 901-725-1785

INTRODUCTION

You are being asked to participate in a research study. Before agreeing to participate in this research study it is important that you read and understand the following explanation of the proposed procedures. This document describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative treatments/procedures that are available to you and your rights to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

Sponsor (PCORI) is paying the Site (Baptist Cancer Center), who then in turn pays PI (Raymond Osarogiagbon, MD) and other parties that provide services as part of the conduct of this study.

PURPOSE

The purpose of this research study is to test the possible benefits of receiving care from a team of doctors working together during a single appointment (multidisciplinary care) as opposed to receiving care from several different doctors at separate times (serial care). Serial care is the current standard and practice of care for lung cancer patients.

This study is being done by the Baptist Cancer Center. We expect about 1000 people will take part in this study. Your participation in this study is expected to last approximately 6 months.

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RESEARCH STUDY PARTICIPANTS

Addressograph / Patient Label

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PROCEDURES

Your participation in this study will include providing access to your medical information about all hospital and clinic visits related to your cancer diagnosis and treatment.

During this study, you will be seen by your doctor(s) one or more times to begin or continue your care for lung cancer. The doctor(s) will discuss the results of your tests with you as well as your treatment options. The doctor(s) will also recommend the best treatment option for you. During this time, if you and your doctor(s) decide that any additional procedure should be done that procedure will be scheduled for you as soon as possible. During this study, our research team will collect information about each visit, test or treatment from your medical records. This information will include the type of visit, test or treatment, its date, and results of each.

In addition, we will also follow-up with you and your home caregiver (the person on whom you rely for help with your care at home) through a series of surveys in order to receive feedback from you about your experience of care for lung cancer. Specifically, you will be asked about your satisfaction with the care you receive, your quality of life, and your emotional health. These surveys are part of the research study and are not part of the standard of care treatment you receive. This survey will be administered three times. The first time will be at the beginning of your cancer care. The second time will be about 3 months after you enter the study, and the third time will be about 6 months after you enter the study.

Your participation will continue until you tell us you no longer want us to access your information or the researchers end the study.

POSSIBLE RISKS

There are no known risks from receiving multidisciplinary or serial care. The greatest risk to you would be the accidental breach of confidentiality of your medical information. However, we have many measures in place to ensure that this does not occur. However, absolute confidentiality cannot be guaranteed.

The possible risks of completing the surveys are that you may tire from answering the questions or there may be questions that make you uncomfortable to answer or are of a sensitive nature. You are free to skip any questions you do not feel comfortable answering.

There may be risks or side effects which are unknown at this time.

ALTERNATIVE TREATMENTS & CHOICES

The alternative to joining this study would be to receive your care without being asked to answer any surveys about the care you received. You may choose not to take part in this study without

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any penalty or loss of benefits that you are otherwise entitled to. The care you receive will not change as a result of refusing to join this study. The study doctor will discuss all of your options with you.

POSSIBLE BENEFITS

There may be no benefit to you from receiving one type of care instead of another. However, this study may find that one type of care provides better results when compared to the other. This might include more direct patient involvement in decision-making, faster delivery of care, and better explanation about your cancer, any of which could improve the quality of care you receive.

COSTS

This study includes surveys that are conducted solely for the research study. The costs to administer these surveys by the study staff is paid for by the study Sponsor. You and/or your insurance company are responsible for all tests, procedures and treatments related to your care. This study does not cover any costs related to your routine care or treatment or provide any financial aid or compensation for your clinical care.

COMPENSATION FOR INJURY

In the event of physical or psychological injury from this research procedure, Baptist Memorial Hospital and Baptist Cancer Center does not have funds for patient compensation either for lost wages or for treatment. Therefore, Baptist Memorial Hospital and Baptist Cancer Center does not provide reimbursement for such injuries. Baptist Memorial Hospital and Baptist Cancer Center will provide the medical and ancillary services ordered by your physician at the established charges for those services.

If you think you have been hurt by this research, let the study investigator know right away by calling Dr. Raymond Osarogiagbon at 901-725-1785. This is a 24-hour number. After hours, you may call your doctor's office for instructions about how to contact your doctor or the doctor on-call.

You do not waive any legal rights by signing this consent form.

COMPENSATION FOR PARTICIPATION

You will receive a \$10.00 Kroger gift card for the time you spend completing the surveys. This gift card will be given to you upon completion of the final survey

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CONFIDENTIALITY (HIPAA)

If you choose to join this study, you are agreeing to allow specific study staff, employed by the Baptist Memorial Health Care Corporation and the Baptist Cancer Center, to have access to your personal health records and to receive information from your doctor and/or the hospitals and clinics where you have received health care. These records include your medical history, the results of physical exams, lab tests, x-ray exams and other tests or treatments. Basic information, such as your date of birth, age, sex, race, and zip code where you live, will be collected and is considered protected health information (PHI). Under federal privacy regulations, you have the right to determine who has access to your PHI. PHI collected for this study is kept private and your identity will be protected to the full extent of the law.

The Institutional Review Board (IRB) at Baptist Memorial Hospital may review your PHI as part of its responsibility to protect the rights and welfare of research subjects. The IRB is a group of people whose job is to protect patients' rights and safety through regular review of a hospital's research methods and results. Your PHI will be used only for the research purposes described in this form. Your PHI will be used only until the study is completed. If information from this study is published or presented at scientific meetings, no identifying personal information will be used.

You may cancel the approval for PHI access in writing at any time by contacting Dr. Osarogiagbon, or any of his identified study staff. If you cancel approval, continued use of your PHI is permitted if it was obtained before the cancellation and its use is necessary to complete the research. However, PHI collected after your cancellation will not be used in this study. If you refuse to provide approval, you will not be able to participate in the research study. If you cancel approval, then you will be withdrawn from the study. Finally, federal regulations allow you to obtain access to your PHI collected or used in this study. However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. When the study is completed, your right of access to this information will be reinstated.

Groups that may look at and/or copy records for research, quality assurance and data analysis include:

- Baptist Memorial Hospital
- Baptist Memorial Hospital Institutional Review Board
- Baptist Cancer Center

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- The National Institutes of Health (NIH), the Patient Centered Outcomes Research Institute (PCORI) and other local, state, and/or federal government agencies, like the Food & Drug Administration (FDA), involved in keeping research safe for people

Steps used to keep your data private are:

- Labeling your data with a unique identification (ID) number instead of your name. This ID number does not contain any identifying information about you.
- Limiting who sees your data.
- Keeping your data in locked files.
- Shredding all papers when they are no longer needed.
- Using special, password-protected computer systems and documents.

A copy of this signed consent form is required to be present on your medical chart throughout your hospitalization at any Baptist Memorial Hospital research location and will be put in your medical record and be made a permanent part of your index medical record. Subsequent hospitalizations can refer to the index medical record for the informed consent.

CONTACT FOR QUESTIONS

If you have any questions, concerns or complaints, you should contact Dr. Raymond Osarogiagbon at 901-725-1785. This is a 24-hour number.

If you would like to speak to a person who is not affiliated with this research study to discuss problems, concerns or questions, or to obtain information or offer input please call Rev. Anthony Burdick, Director of Pastoral Care, Baptist Memorial Health Care Corporation at 901-226-5025.

VOLUNTARY PARTICIPATION

Participation in this study is voluntary. You may refuse to participate or remove yourself from this study at any time. If you choose to remove yourself from the study after the study starts, please notify Dr. Osarogiagbon, or any of his identified study staff, and ask them to remove you from the study. Your decision not to take part in this study will not affect your current or future medical care from your doctor(s) in any way nor will it affect any benefits to which you may be entitled.

Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

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A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

STUDY WITHDRAWAL

If you choose to withdraw you should talk to your doctor about the potential risks and discuss the best way to withdraw from the study. Once you withdraw you will not be able to continue in the study. No new data related to you will be added to the database once you withdraw, but all data collected prior to withdrawal may still be used as part of the study.

If you wish to withdraw from the study, contact Dr. Raymond Osarogiagbon at 901-725-1785.

Your doctor(s) may remove you from this study at any time for the following reasons:

- You are unable to complete study requirements or have not followed study instructions.
- Your study doctor feels it is in your best interest.
- The sponsor has stopped the study.
- Administrative reasons that require your withdrawal.
- Or for any other reason.

NEW FINDINGS

Any new findings that may impact your decision to continue participation will be provided to you in a timely manner. You may be asked to sign a new consent form if this occurs.

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CONSENT TO PARTICIPATE

The research study, procedures, risks and benefits have been explained to me. I have read and understand all of the above, have been given the opportunity to ask questions and all my questions have been answered to my satisfaction. I voluntarily agree to participate in this research study. I will be given a copy of this signed and dated consent form for my own records. I do not give up any of my legal rights by signing this consent form.

Name of Adult Participant (printed)

Signature of Adult Participant

Date/Time

Or

Legally Authorized Representative (printed)

Signature of the Legally Authorized Representative

Date/Time

Relationship to Patient

Name of Person Obtaining Consent (printed)

Signature of Person Obtaining Consent

Date/Time

*If authorization is to be obtained from a legally authorized representative (e.g., parent(s), legal guardian or conservator) a description of his/her authority to act for the participant is also required.

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