CLINICAL PROVIDER 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 a patient 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.

RESEARCH STUDY PARTICIPANTS

Addressograph / Patient Label

A copy of the signed consent form is required to be present on the research participant's (patient's) medical record throughout their hospitalization/treatment at any Baptist Memorial Health Care location and be made a permanent part of the patient's index medical record. Subsequent hospitalizations can refer to the index medical record for the informed consent form.

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PROCEDURES

Your participation in this study will include providing feedback about your experience as a clinical provider for a patient with lung cancer. Specifically, you will be asked to complete a survey that measures your satisfaction with the multidisciplinary thoracic oncology program. These surveys are part of the research study and are not part of the standard of care treatment you would provide patients in your care. If you only refer patients into the multidisciplinary thoracic oncology program, this survey will be administered 3 times, in 6 month intervals, beginning after at least five of your patients have been evaluated or treated in the multidisciplinary thoracic oncology program. If you provide clinical care to patients in the multidisciplinary care environment, surveys will be administered 3 months, 6 months and 12 months after you begin active involvement in the multidisciplinary clinic.

Your participation will continue until you tell us you no longer want to take these surveys or the researchers end the study.

POSSIBLE RISKS

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. The greatest risk to you would be the accidental breach of confidentiality of your survey responses. We do have many measures in place to ensure that this does not occur. However, absolute confidentiality cannot be guaranteed.

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

ALTERNATIVE TREATMENTS AND CHOICES

The alternative to joining this study would be for the patients whom you refer for cancer care, or treat in the multidisciplinary clinic, to receive their care without you being asked to answer any surveys. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. The care your patients 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 completing these surveys. However, this study may find that one type of care provides better results when compared to the other. This might include more direct clinical provider involvement in decision-making, faster delivery of care, and stage-appropriate diagnosis and treatment, any of which could improve the quality of care your patients receive.

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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. There may be some tests, procedures and treatments which the Principal Investigator considers routine care for the patient's disease (meaning the patient would receive this care whether or not they are in the research study) and these tests, procedures and/or treatments are billable to the patient and their insurance company. This study does not cover any costs related to routine care or treatment or provide any financial aid.

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 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 expected medical and ancillary services 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 no financial compensation for participating in this study.

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 survey responses, as well as your relationship to the patient, your medical specialty and certain basic demographic information. This basic information, such as your name, gender, and age 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

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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
- 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 will be kept on file with the study research records at the Baptist Cancer Center.

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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 involvement with the Baptist Multidisciplinary Thoracic Oncology Program, either your ability to refer patients into the program or to participate in the clinical care of patients within the program.

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

A description of this clinical trial will be available on http:www.ClinicalTrials.gov, as required by U.S. 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.

You may be removed from this study at any time for the following reasons:

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

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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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