Official Title: DEFINING PERSONAL AND COMMUNAL ASPECTS OF SOCIAL *DETERMINANTS OF HEALTH IN GLIOBLASTOMA POPULATION* WFBCCC 03119
Social Determinants of Health in Glioblastoma Population
NCT# 03900689
IRB-Approved Date: *12/09*/2022

Department/Section of *Department of Neurology and Internal Medicine, Section on Hematology and Oncology*

DEFINING PERSONAL AND COMMUNAL ASPECTS OF SOCIAL DETERMINANTS OF HEALTH IN GLIOBLASTOMA POPULATION

Informed Consent Form to Participate in Research
Roy Strowd, MD Principal Investigator

SUMMARY

You are invited to participate in a research study. This study is for patients who have a primary brain tumor. The purpose of this research is to understand how the conditions in which brain tumor patients are born, grow, live, work, and age affect their response to treatment. These factors are called social determinants of health. You are invited to be in this study because you have a brain tumor and are able to describe how these social factors influence your health.

Participation in this study will involve two parts. In Part 1, you will be asked to complete a one-time survey. This can be done at the time you are in clinic or taken home. The survey should take about 30 minutes to complete. A family member can help you complete the survey. After completing the survey, you will be given the choice to participate in the second part of the study. Part 2 of this study is a focus group or individual interview. A focus group is where about 6-8 brain tumor patients gather in a room and talk with a member of our study team about these social factors that influence their health. The focus group will last about 60 minutes. The focus group will be scheduled at a separate visit. If you are unable to join the focus group, we may ask to interview you in person or over the telephone.

All research studies involve some risks. The risks involved in this study are minimal and are not expected to be more than in daily life. You may be asked to provide information that you consider confidential or private. If there is a question that makes you feel uncomfortable or that you do not want to answer, you may choose not to answer that question. There is not a possibility that you will benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Roy Strowd, MD (Principal Investigator). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted]

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INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have a brain tumor. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to describe how the conditions in which brain tumor patients are born, grow, live, work, and age affect their response to treatment. These factors are called social determinants of health and include things like where you live and work, your prior education and training, access to health insurance, and other factors. The goal of this study is to describe how these social factors influence your health.

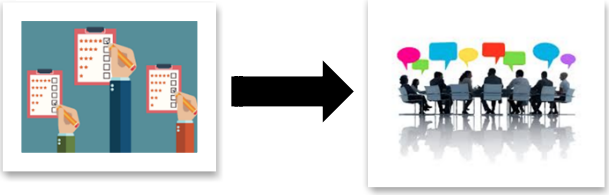
HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to 100 people will take part in Part 1 of the study, and approximately 32 people will participate in Part 2 of the study.

WHAT IS INVOLVED IN THE STUDY?

Part 1 (Visit 1)
Survey

Part 2 (Visit 2)
Focus Group



Part 1: At your first study visit, you will answer a series of survey questions. This will take about 30 minutes. You will be asked questions about the neighborhood where you live, your education level, activities that you take part in, your access to transportation and food, how your health is managed, and where you find social or spiritual support. You will also be asked about your stress levels, how you communicate with your doctor, information about your family or caretaker, and any other medical conditions that may affect you. General information (such as your age, ethnicity, and address) and your medical history will be recorded as well. In addition, we will use your name and address to obtain several scores that provide information about your health risk such as access to food, transportation, health literacy, home stability and financial stability.

Part 2: If you agree to be contacted about the second part of the study, you may be contacted in the future and can decide at that time to participate or not. If you say that you would like to participate now you may still change your mind later. In the second portion of the study you will be asked to participate in a focus group. A focus group is when a group of about 6-8 brain tumor patients sit in a room and answer questions as a group. Your family member or caretaker may come with you to the focus group. If you are invited to participate and cannot come to the focus group, we may see if you would be able to complete an interview in person or on the telephone.

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During the focus group or interview, you may be audiotaped. This is being done so that we can come back and listen to the answers to questions or concerns expressed during the focus group. The audiotape will be transcribed. Any information that could identify you will be removed so that you cannot be identified. You may request for the recording be stopped at any time during the focus group. You will not be able to inspect, review, or approve the audiotapes.

How Long Will I Be in the Study?

You will be in the study for up to 2 visits. The first visit will involve completing a survey. The second visit will occur later and involve a focus group.

You can stop participating at any time. If you agree to participate in Part 2, you may change your mind and decide not to participate later. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. Taking part in this research study may involve providing information that you consider confidential or private. If there is a question that makes you feel uncomfortable or that you would not like to answer, you may choose not to answer any question. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict.

Are There Benefits to Taking Part in the Study?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

What Are the Costs?

There are no costs for participating in this study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

Will Your Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

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WILL YOU BE PAID FOR PARTICIPATING?

All participants of part 1 and two will be given a parking voucher for study related visits. If you participate in the focus group, you will receive a $50 gift card. This will be provided at the completion of the focus group.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Comprehensive Cancer Center of Wake Forest Baptist Medical Center. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: income, education level, insurance status, occupation, social and community resources, caregiver relationship, stress levels, doctor/patient communication and other conditions or diseases you may have.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.
Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

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If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Roy Strowd that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Roy Strowd, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because you failed to follow instructions or because the entire study has been stopped.

Identifiers might be removed from your identifiable private information or identifiable biospecimens and after such removal, your information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study

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investigator, Roy Strowd, MD [redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted]

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in part 1 of this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

SIGNATURES

I agree to take part in part 2 of this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

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