CONSENT FOR CANCER RESEARCH

Project Title: (CASE 7314) Feasibility and Clinical Application of Magnetic Resonance Fingerprinting

Principal Investigator: Deborah Rukin Gold, MD

Cancer research studies are coordinated by physicians and scientists from Cleveland Clinic, University Hospitals and Case Western Reserve University (CWRU) through the NIH National Cancer Institute (NCI) designated Case Comprehensive Cancer Center (Case CCC). The goal of this collaboration is to enhance cancer treatment and research in Northeast Ohio. This study is being offered at University Hospitals (UH)

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child; "we" means the doctors and other staff.

INTRODUCTION

We are asking you to participate in a research study. The purpose of this document is to summarize your discussion with the research team and provide you with written information to help you decide whether you want to participate in research. Your decision is completely voluntary.

Your treating doctor may also be an investigator on this research study. If so, your doctor will have an interest in both your welfare and in the research study. You are not required to take part in this research study offered by your doctor. You may ask for a second opinion from another doctor who is not linked to this study. If you choose not to be in this study, the quality of your regular medical care will not be affected.

Please ask any questions you may have about the study or this consent form before signing it. Please take your time to make your decision. You will be given a copy of this form to keep.

WHY ARE YOU BEING ASKED TO TAKE PART IN THIS STUDY?

You are being asked to participate in a research study of magnetic resonance fingerprinting (MRF) because your doctor has requested a MRI of your brain. MRF is a new MRI method that may be faster and better than traditional MRI. This study will examine the usefulness of MRF in people with brain tumors.

This Consent Form describes the study and your role in it as a participant. Your study doctor or study staff member will answer any questions you have about this study or this consent form. You are to read this form carefully and ask any questions you have regarding the information it contains.

Please Note: This Consent Form may contain words that you do not understand. Please ask your study doctor or a study staff member to explain words that you do not clearly understand. You may discuss the study with family, friends or anyone you choose before making a decision

CONSENT FOR CANCER RESEARCH

Project Title: (CASE 7314) Feasibility and Clinical Application of Magnetic Resonance Fingerprinting

Principal Investigator: Deborah Rukin Gold, MD

---

to participate. This form is only one part of the informed consent process. The study doctor or study staff will explain this form and the study to you in detail. Do not sign this form unless the study doctor or study staff has answered your questions and you decide that you want to participate.

WHY IS THIS STUDY BEING DONE?

The goal of this study is to determine whether MRF is practical and whether it offers more information about brain tumors. MRF is a type of fast MRI that may give more information about brain and tumor tissues than traditional MRI. MRF may help tell tumor from normal tissue or show where tumor is hidden among normal tissue. It may also tell when treatments are working in the tumor. In this study, we are asking people with and without brain tumors to have MRF performed during their traditional MRI. In people with brain tumors, we will also look at characteristics of your tumor.

The information collected from this study will be very valuable if MRF can reduce the time that people spend in the MR scanner. It may also be useful in giving doctors more information about children's brain tumors or about your brain.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 80 patients (ages 0-34) with and without brain tumors will participate in this study at UH.

WHAT WILL HAPPEN ON THIS STUDY?

After signing this Consent Form, you will be enrolled in the study. If you consent to the study, the following will happen.

We will review your medical records and any past MRIs to determine if you meet the requirements for the study. During this review we will document your age, gender, and whether you have neurofibromatosis type 1. If you have an optic pathway glioma, we will also document your most recent eye doctor exam.

During your next brain MRI, MRF will be performed. This test will be the same as your regular MRI, except for the computer software used to control the scanner and process the data, and the antenna placed inside the MRI machine and next to your body to receive radio waves. MRF will take about 15 additional minutes and does not use radiation.

If you have regular MRI scans, MRF will be repeated during these scans over the next year. If you have a tumor that will be removed with surgery, MRF will be repeated after your surgery is

complete. If your tumor comes back, MRF will be performed at that time, as well. Tumor pathology and type of therapy will also be recorded.

All information will be kept confidential. The principal investigator, study doctors and authorized study personnel will be the only people who will be able to access this information. Your participation in this study will not impact your typical care.

HOW LONG IS THE STUDY?

If you have a tumor, we will collect information about you and your tumor for the next 5 years. All other participants will have MRF added to their regular scans over the next year. You may decide to take yourself off the study at any time by talking with your doctor or the principal investigator. Your doctor may decide to take you off this study if he/she believes that it is in your best interest or if your care is transferred from your hospital to another hospital.

WHAT SIDE EFFECTS OR DISCOMFORT CAN I EXPECT FROM BEING IN THE STUDY?

Some patients complain of claustrophobia or the sensation of being enclosed in a small space when inside the large tube of the MRI machine. MRF may increase the time spent in this tube by about 15 minutes. If you are uncomfortable during the scan, we can stop the scan. If you are sedated (given medicine to make you calm or sleepy) during your scan, taking MRF scans may involve about 15 more minutes under sedation. In addition, there is always a risk of losing confidentiality but we will work our hardest to keep your information safe in a secured, password-protected database accessible only to the principal investigator and study coordinator.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

We hope that your MRF scans will help your doctors interpret your regular MRI better. Your participation in this study may provide more accurate MRI images of your illness than a standard MRI study, and may help your doctors identify abnormal tissue. Your regular MRI scan will be reviewed by a radiologist, and MRF scans will be available to your radiologist. Your participation in this study may help us determine whether MRF is practical in children and whether MRF can help us learn more about children's brain tumors.

WHAT OTHER OPTIONS ARE THERE?

You have the option to not participate in this study. There will be no difference in your care if you choose not to participate.

CONSENT FOR CANCER RESEARCH

Project Title: (CASE 7314) Feasibility and Clinical Application of Magnetic Resonance Fingerprinting

Principal Investigator: Deborah Rukin Gold, MD

WHAT ABOUT PRIVACY?

All results relating to the study will be kept secure in a password-protected database at Rainbow Babies and Children's Hospital/Cleveland Medical Center. Access to this information is strictly limited to the Principal Investigator, study doctors and authorized study personnel. You will be assigned a study number to keep your identity confidential. Absolute confidentiality cannot be guaranteed. If the study results are published in medical or scientific journals, you will not be identified. Data from this study will also be sent to an outside institution for review.

WHAT ARE THE COSTS?

There will be no cost for this study. While you are in the study, you will receive routine care as determined by your doctor. You or your insurance provider will be responsible for the payment of procedures or drugs that are considered standard of care. This includes eye doctor visits, MRIs, blood draws, hospital care, medications and all other medical care that would normally be part of your care. MRF will be paid for by the study.

You will not receive any payment for participating in this study.

RESEARCH RELATED INJURY

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research-related injury. To help avoid injury, it is very important to follow all study directions.

Further information about research-related injuries is available by contacting the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979.

HIPAA AUTHORIZATION SECTION

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you volunteer to participate in this research, your protected health information (PHI) that identifies you will be used or disclosed to Deborah Rukin Gold, MD, and the research study staff at University Hospitals for the purposes of this research and to Case Western Reserve University for administration.

CONSENT FOR CANCER RESEARCH

Project Title: (CASE 7314) Feasibility and Clinical Application of Magnetic Resonance Fingerprinting

Principal Investigator: Deborah Rukin Gold, MD

The PHI that we may use or disclose (release) for this research may include your name, address, phone number, date of birth, Social Security number, information from your medical record, lab tests, or certain information relating to your health or condition..

Some of the tests and procedures done solely for this research study may also be placed in your medical record so other doctors know you are in this study. Upon completion of the study, you may have access to the research information that is contained in your medical record.

In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the University Hospitals Institutional Review board and the Case Comprehensive Cancer Center Protocol Review and Monitoring Committee. Your PHI may also be used by and/or disclosed (released) to:

- Other Institutional Review Boards or Data Safety and Monitoring Boards;
- The Food and Drug Administration;
- The Department of Health and Human Services;
- Your insurance company;
- The National Committee for Quality Assurance; and
- University Hospitals Cleveland Medical Center

Once your personal health information is released it may be re-disclosed and no longer protected by privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to:

Deborah Rukin Gold, MD
University Hospitals Cleveland Medical Center
11100 Euclid Avenue
Cleveland OH 44106

Your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of this research. Also, information already disclosed outside University Hospitals cannot be retrieved. This will not affect your rights to treatment or benefits outside the research study.

University Hospitals will not use your information collected in this study for another research purpose without your written permission; unless the University Hospitals Institutional Review

CONSENT FOR CANCER RESEARCH

Project Title: (CASE 7314) Feasibility and Clinical Application of Magnetic Resonance Fingerprinting

Principal Investigator: Deborah Rukin Gold, MD

Board assures your privacy and confidentiality is protected. The IRB is a committee whose job it is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are authorizing such access to your research and medical record information. If you choose not to sign this consent form, you will not be able to participate in this research study. This Authorization does not have an expiration date.

SUMMARY OF YOUR RIGHTS AS A PARTICIPANT IN A RESEARCH STUDY

Your participation in this research study is voluntary. Choosing not to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed.

In the event new significant information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating.

CONTACT INFORMATION

If you have any questions, you can call the Principal Investigator and/or research staff at (216) 844-3345.

Emergency or after-hours contact information

If you need to contact study staff outside normal business hours, you may call 216-844-3691 and you will be transferred to the answering service, which can put you in contact with Dr. Rukin Gold or the oncologist (cancer doctor) on call.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about: concerns regarding the study, research participant's rights; research-related injury; or other human subjects issues, you may contact the Institutional Review Board (IRB) at (216) 844-1529 or the University Hospitals Cleveland Medical Center's Research Subjects Rights Phone line at 216-983-4979.

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free

CONSENT FOR CANCER RESEARCH

Project Title: (CASE 7314) Feasibility and Clinical Application of Magnetic Resonance Fingerprinting

Principal Investigator: Deborah Rukin Gold, MD

Decisi on about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

_____ _____
Printed Name of Participant Date

_____
Child's Signature if this form is used to obtain assent
(for minors ages ≥14 years of age)

_____ _____
Printed Name of Parent or Legal Guardian Date

_____ _____ _____
Signature of Parent or Legal Guardian Relationship to Child Date

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Witness Date Printed Name of Witness

I have discussed the information contained in this document with the participant/participant's parent/legal guardian and it is my opinion that the participant/participant's parent/legal guardian understands the risks, benefits, alternatives and procedures involved with this research study.

(Witness signature is only required if patient, if providing assent, or parent/guardian who is providing consent is illiterate)