Study Title

MR Fingerprinting: A Novel Sequence Applied To Neuroimaging

Informed Consent Form

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: December 8, 2020
IRB Study # 18-2071
Title of Study: MR fingerprinting: A novel sequence applied to neuroimaging
Principal Investigator: Yueh Lee, MD, PhD
Principal Investigator Department: Radiology
Principal Investigator Phone number: 919-843-4395
Principal Investigator Email Address: yueh_lee@med.unc.edu
Co-Investigators: Yong Chen

Study Contact Telephone Number: Markeela Lipscomb (984) 974-8157; Desma Jones (919) 843-9463; Terry Hartman (919) 966-4997; Shanah Kirk (919) 966-6957

Study Contact Email: markeela_lipscomb@med.unc.edu; desma_jones@med.unc.edu; terry_hartman@med.unc.edu; shanah_kirk@med.unc.edu

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What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to study the use of a new MRI imaging sequence at UNC. A new sequence that has not yet been approved by the FDA will be added to the MRI of the brain you will receive for standard of care.

You are being asked to be in the study because you are scheduled to have a neurological MRI at UNC.

Are there any reasons you should not be in this study?
You should not be in this study if you have any reason that you cannot have an MRI.

How many people will take part in this study?
There will be approximately 100 people in this research study.

How long will your part in this study last?
Your participation will be limited to 1 additional sequence during your MRI. This sequence will last less than 15 minutes.

What will happen if you take part in the study?
If you agree to participate, you will receive 1 additional research sequence during your clinical MRI scan.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. There is no direct benefit from being in this research study. Since the additional sequence has not yet been reviewed by the FDA, you will not be notified of any additional information identified in your research portion of the scan.

What are the possible risks or discomforts involved from being in this study?
There may be uncommon or previously unknown risks. You should report any problems to the researcher. Risk is limited to a minimal risk of a breach of confidentiality. To minimize this risk, we will not identify you by name. Your research scan will be coded with a unique research ID and individuals outside of the research team will not be able to link these images back to you.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such

reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will receive a 2-hour parking pass for taking part in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study. The additional sequence will not be charged to you. However, you and/or your insurance company will be billed for your standard MRI in the same manner that you usually are.

Who is sponsoring this study?
This research is supported by UNC Chapel Hill (the sponsor). In addition, Dr. Yong Chen, a co-investigator on this study, is an inventor of a new technology, a new MRI technique being studied in this trial. Siemens USA could possibly sell this technology in the future. If this technology or approach is successful at some point in the future, Dr. Chen may receive financial benefits.

If you would like more information, please ask the researchers listed in the first page of this form.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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Principal Investigator: Yueh Lee, MD, PhD

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Signature of Research Participant	Date
Printed Name of Research Participant	
Signature of Research Team Member Obtaining Consent	Date
Printed Name of Research Team Member Obtaining Consent	