Determination of Normal Liver Stiffness by MR Elastography in Children

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CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER
PERMISSION FOR PARTICIPATION IN RESEARCH

STUDY TITLE: Determination of Normal Liver Stiffness by MR Elastography in Children.

STUDY NUMBER: 2017-1599

INVESTIGATOR INFORMATION: Andrew Trout, MD (513-803-3004)

ABOUT THIS CONSENT FORM

Parents/Guardians: You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. The word "you" or "I" in this form refers to your child/teen. If your child is older than 10 years of age, they will also sign this form indicating their assent to participate.

INTRODUCTION:

You are being asked to participate in a research study. Your participation will assist study staff in comparing imaging techniques using magnetic resonance (MR or MRI) to measure liver stiffness. Liver stiffness is one way to measure the health of the liver. MR imaging uses the magnetic field to takes pictures of organs and structures inside of the body. No guarantee or assurance can be made as to the results of the study. Participation is completely voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw from the study at any time without penalty.

WHY ARE WE DOING THIS RESEARCH?

The purpose of this study is to determine normal liver stiffness values using MRI. The MRI sequences being investigated are all FDA approved sequences.

WHO IS IN CHARGE OF THE RESEARCH?

Dr. Andrew Trout is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that oversees this study. The Society for Pediatric Radiology Research and Education Foundation is funding this study.

WHO SHOULD NOT BE IN THIS STUDY

You cannot be in this study if:

1. You are younger than 7 years old
2. You are older than 17 years old
3. You have documented history of liver disease
4. You have had anything to eat or drink in the past 4 hours
5. You are pregnant
6. You are unable to lie still for 30 minutes
7. You are unable to hold your breath for about 15-20 seconds
8. You have any implanted metal that prevents you from having an MRI

WHAT WILL HAPPEN IN THE STUDY?

If you participate in this study you will come to CCHMC for one research visit that is about 2 hours long.

You will not be able to eat or drink for four hours before the visit.

At the start of the study visit, you will be weighed and measured. We will then perform MRI images of the liver on a research MRI scanner in the Imaging Research Center (IRC) at CCHMC. This scanner is the same scanner as two clinical scanners that are used every day at CCHMC. We will use the MRI images in order to determine values of normal liver stiffness. Total imaging time for this study will be about 30 minutes. Before undergoing analysis, the images will have your identifiable information, such as name and date of birth, removed. The images will then be sent to an industry partner for analysis, and will be retained in de-identified form for potential future study.

After the MRI scan, we will then perform a blood draw. We will draw approximately 3 teaspoons of blood. We will use the

blood sample to confirm that you have no liver health issues. This blood draw will be performed in the Schubert Research Center by a nurse. We will also review your medical chart for information related to liver health.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?
Being in this study may not help you right now. When we finish the study, we hope that we will know more about using MRI methods for seeing and measuring liver stiffness. This may help patients in the future.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?
There are no known risks from having an MRI or from use of the imaging sequences being investigated. However, some people are claustrophobic and may become anxious, fearful, or nervous in the MR scanner. Should you become uncomfortable at any time the scan will be stopped immediately. Additionally, pregnant people should not participate in this study.

A board-certified radiologist will review your MRI exam. Any unexpected finding requiring further medical evaluation will be shared with you and/or your physician. Your research MRI exam will be identified by a number assigned to you as a part of the research study and will not become a part of your permanent medical record.

The blood draw may be associated with temporary mild discomfort and the potential for mild bruising or fainting. There may be unknown or unforeseen risks associated with study participation. If any such risks are identified, you will be informed of those risks.

WHAT OTHER CHOICES ARE THERE?
Instead of being in this study, you can choose not to be in it.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?
Making sure that information about you remains private is important to us. To protect your privacy in this research study, data that we collect will be stored in locked rooms and password protected files. As soon as we have finished collecting data on all the patients, we will separate identifying information about you from the data we are collecting. Only the primary investigator and select study personnel will have access to information that might be used to identify you.

WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?
The study doctor will tell you if they find out about new information from this or other studies that may affect your health, safety or willingness to stay in this study.

WILL IT COST YOU ANYTHING EXTRA TO BE IN THE RESEARCH STUDY?
You or your insurance company will not be charged for the research MRI or for the research blood draw.

WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?
You will be reimbursed for your time and effort while you are in this research study. You will be paid $50.00 as reimbursement for your time and effort.

You will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you a handout that will explain how to use the card. Because you are being paid for your participation, CCHMC is required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay you. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your Social Security number. This form will be given to the CCHMC business office. It will not be kept as part of your study chart. If you move, you will need to complete another W-9 with an updated address.

WHAT HAPPENS IF YOU ARE INJURED FROM BEING IN THIS STUDY?
If you believe that you have been injured as a result of this research you should contact Dr. Andrew Trout, (513) 803-3004, as soon as possible to discuss your concerns.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?
For questions, concerns, or complaints about this research study you can contact Dr. Andrew Trout, (513) 803-3004. If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional

Review Board at 513-636-8039.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH:

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

CCHMC will need to use and share your PHI as part of this study. This PHI will come from:

- Research records
- Your medical record

The types of information that will be used and shared from these records include:

- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- Laboratory and biopsy results

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to you as part of this study
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that PHI is not misused?

People that receive PHI as part of the research are generally limited in how they can use PHI. In addition, most people who receive PHI are also required by federal privacy laws to protect PHI. However, some people that may receive PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your other medical care be impacted?

By signing this document you are agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES: I have read the information given above. The investigator or his/her designee have personally discussed with me the research study and have answered my questions. I am aware that, like in any research, the investigators cannot always predict what may happen or possibly go wrong. I have been given sufficient time to consider if I should participate in this study. I hereby give my permission to take part in this study as a research study participant. I will receive a copy of this signed form for my records.

_____ _____
Signature of Participant Indicating Assent Date

_____
Participant Name Printed

_____ _____
Signature of Parent or Legally Authorized Representative* Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of individual obtaining permission Date