Title of research study: *Helmsley 3.0: Abbreviated MRE*

Investigator:
<<Insert Site PI>>

Contact Info:
<<Insert Contact Details/Phone>>

Funding:
The Leona M. and Harry B. Helmsley Charitable Trust

Key Information:

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

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. If you sign this form, you will receive a signed copy for your records.

Parental Permission/Assent: 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 form, we mean you or your child; "we" means the study doctor and other staff.

Reason for the study:

The main reason for this research study is to compare a shortened, research MRI of the bowel, or MR enterography (MRE) with the clinical MREs that we perform on patients here at <***insert facility name***>. In addition, by using a survey to be completed by your child and/or you, we will compare patient experiences and preferences between the research MRE and the clinical MRE performed. We will also ask some questions to see how much MRE image detail you are willing to "trade-off" for an improved MRE experience. If you are the parent of a child 10-17 years of age, we will ask you and your child to complete a survey and "trade-off" questions" to understand how your child's experience may differ from how you view your child's experience.

Procedures:

You will be asked to come to <***insert facility name***>for a research MRE visit. This research visit is expected to last approximately 2 hours. The research visit must be scheduled within 10 days of your clinical MRE. The MRE exam will take up to 30 minutes and will be similar to other MRE scans we do routinely at <***insert facility name***>, but

you will not need an IV, injections, or to drink Breeza. Once the research MRE and the clinical MRE have been performed, your child and/or you will be asked to complete the follow up survey. Your involvement in the study will end once the research and standard, clinical MREs, along with the follow up survey are completed.

Study Procedures

- You will not be able to eat or drink for 4 hours before the research visit
- You will answer questions about your medical history
- You may complete a pregnancy screening, if applicable
- We will measure your height and weight
- We will ask you to drink water. The amount of water you will drink will be based on your weight.
- Your child and/or you will ask you to answer a survey at the completion of the clinical and research MREs.

More detailed information about the study procedures can be found under ***"(Detailed Procedures)"***

Risks to Participate:

There are no known risks from having an MRI when participants are screened and safety procedures are followed. The research MRE will use techniques that are used every day for clinical care at ***<insert facility name>.*** Staff will review your history closely before you have an MRI exam to confirm you are eligible for this study.

Some people are claustrophobic and may become anxious, fearful, or nervous during the MRI. Should you become uncomfortable at any time the MRI will be stopped immediately.

It is possible that you may feel some slight discomfort from lying down for approximately 15 minutes at a time during the MRI. Should you become uncomfortable and repositioning does not make you feel better, the MRI will be stopped immediately.

It is possible that when completing the questionnaires about your history you may become upset when answering some of the questions. We have social workers available to talk to you, if needed. You do not have to answer any questions that you don't want to answer.

One risk of participation is loss of confidentiality. Every effort will be made to keep your personal information confidential. There may be other risks that we do not know about yet. If we become aware of any risks during the course of this study, you will be notified.

COMMON	
• Claustrophobia • Anxiety	• Minor discomfort • Loss of Confidentiality

More detailed information about the risks of this study can be found under ***"(Detailed Risks)"***

Benefits to Participate:

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits participants could benefit from our abbreviated research MRE in the future. The abbreviated MRE could be better tolerated, allow more frequent imaging, have shorter examination times, and have lower healthcare costs.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive.

Cost to Participate:

The research MRE will be performed at no cost to you. You and your insurance company will be billed for the cost of the clinically ordered MRE that you would ordinarily be responsible for.

Payment:

If you agree to take part in this research study, we will pay you $100 for your time and effort.

You will receive $80 for completing the MRI, and $20 for completing the survey.

You (your child) will be reimbursed for your time, effort and travel (if applicable) while you are in this research study. You (your child) will receive payment for this study in the form <***insert site specific method of reimbursement***>. We will give you (your child) a handout that will explain how to use the card. Because you (your child) are being paid for your participation, <***insert facility name***>. is required by the Internal Revenue Service (IRS) to collect and use your (your child's) social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your child's Social Security number. This form will be given to the <***insert facility name***>. It will not be kept as part of your child's study chart. If you move, you will need to complete another W-9 with an updated address.

Additional Study Information:
The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**<<Insert Name>>**	<<Insert Phone>>
• Your child's rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	CCHMC IRB Phone: (513) 636-8039

Detailed Procedures:

Visit 1	***What:***	***Duration:***	***Who:***
Step 1	Enrollment screening	5 min	Research Coordinator
Step 2	Written informed consent obtained	10 min	Research Coordinator
Step 3	Drink water 45 min before MRI	45 min	Research Coordinator
Step 4	Height and weight measured	5 min	Research Coordinator
Step 5	Urine pregnancy screening (if applicable)	5 min	Research Coordinator
Step 6	MRI safety screening	5 min	MRI Technologist
Step 7	MRI performed	15 min	MRI Technologist

Step 8	Fill out MRE survey (Participant and parent of participants ages 10-17 will be asked to complete an MRE preference survey.)	10 min	Research Coordinator

Pregnancy Screening

You may be asked to complete a urine pregnancy screening. If the test is positive, the information will be given to you and the parents of minors, and you will no longer be eligible to participate in the study. Pregnant women should not participate in the study.

MRI Safety Screening

Before the MRI exam, the MRI technologists will confirm that you can have an MRI exam by asking you questions.

MRI Details

An MRI is a big machine that takes pictures of your body. You will lie flat on a table inside the MRI machine. While you are in the MRI machine you may hear knocks and hammering noises. You will be given hearing protection. You will be able to talk to the MRI technologists during the MRI exam.

The research MRI exams that are being performed in this study are similar to other MRI scans we do routinely at <***insert facility name***>. The MRI exam will last approximately 15 minutes. You will be required to lie still.

Survey Details

Once the research MRE and the clinical MRE are performed, you will complete a survey about your MRI experience on paper or using a tablet/ipad supplied by study personnel. These questions will help our research team know how well you liked or disliked the research MRE compared to the clinical MRE. There will also be questions to help us understand how much MRE image detail you are willing to trade for a better MRE experience. If you are the parent of a child 10-17 years of age participating in this study, you and your child will be asked to complete the surveys. The answers to your survey will be compared to those of the survey your child completes to help us understand any

differences in the how you see your child's experience with MREs compared to how your child views his/her experiences.

Change of Mind/Study Withdrawal:

You can leave the research at any time; it will not be held against you. The person in charge of the research study or the sponsor can remove you from the research study without your approval.

If you stop being in the research, data already collected may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

Detailed Risks:

MRI

There are no known risks from having an MRI when participants are screened for metal and MRI safety procedures are followed. Staff will review your history closely before you have an MRI exam to confirm you are eligible for this study.

Some people are claustrophobic and may become anxious, fearful, or nervous in the MRI scanner. Should you become uncomfortable at any time the scan will be stopped immediately.

Surveys

You may feel uncomfortable thinking about your medical history. You may skip questions that make you uncomfortable. There is also a risk of breach of confidentiality, but steps have been taken to avoid such a breach. If you do not wish to answer a question, you may skip it and go to the next or stop.

Loss of Confidentiality

One risk of participation is loss of confidentiality. Every effort will be made to keep your personal information confidential.

There may be other risks that we do not know about yet. If we become aware of any risks during the course of this study, you will be notified.

Privacy

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include: The US Food and Drug Administration (FDA), CCHMC, the IRB and other representatives of CCHMC.

Data collected for or generated from this study could be shared and used for future research. Data may be shared with other collaborators at ***<insert facility name>***. and possibly with outside collaborators, who may be at another institution or for-profit company.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this study will be available on http://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.

Return of Results:

Most tests done on samples or images obtained in research studies are only for research and have no clear meaning for healthcare. If the research with your information or samples gives results that do have meaning for your health, the doctor will contact you and ask you if you would like to know what they have found. You can say No to hearing about the results at that time if you desire.

Authorization for Use/ Disclosure of Health Information for Research

<<Site may insert their HIPAA language here or use the HIPAA provided below>>

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?

<<Site Name>> will need to use and share your PHI as part of this study. This PHI will come from:

- Your <<Site Name>> medical records
- Your research records

The types of information that will be used and shared from these records include Laboratory test results, diagnosis, and medications

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

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

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your 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?

Your permission will expire at the end of the study.

Will your other medical care be impacted?

By signing this document, you agree to participate in this research study and give permission to <<Site Name>>s 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

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you/your child should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

For parents of pediatric participants (10-17 years of age):

Initials: _____ I agree to complete a survey designed to understand how I saw my child's MRE experiences compared to how my child saw their MRE experiences.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent or Assent Date

_____ _____
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 Consent Date