PARENTAL PERMISSION AND CHILD ASSENT TO PARTICIPATE IN A RESEARCH STUDY AT THE CHILDREN'S MERCY HOSPITALS & CLINICS

Comparison of the use of Wireless Capsule Endoscopy with Magnetic Resonance Enterography in Children with Inflammatory Bowel Disease

WHO IS DOING THIS STUDY?

A study team led by Nadia Hijaz, MD is doing this study. Other health care professionals may help them.

We are asking your child to be a part of this research study. Please read the information below and ask questions about anything that you do not understand before you make a choice.

WHY IS THIS STUDY BEING DONE?

Inflammatory Bowel Disease (IBD) is an inflammatory (swelling or soreness) condition of the intestine (bowel). IBD can lead to abdominal pain, severe diarrhea and even malnutrition. Two forms of IBD are Crohn's Disease (CD) and Ulcerative Colitis (UC). Crohn's disease can occur anywhere in the gastrointestinal (GI) tract, from the mouth to the anus, and often spreads deep into the lining in the intestine. UC is usually only located in a part of the intestine called the colon. Indeterminate colitis is like Crohn's in some ways but sometimes is also like UC.

Endoscopy and colonoscopy are procedures performed to look inside of the body at the lining of the intestine. The human intestine is very long and these two procedures do not reach a part of the gut called the small intestine. To provide the best therapy we sometimes need to look at this part of the intestine to see if the disease is there. This can affect what treatment a doctor chooses for a patient. Looking at this part of the intestine can be done by magnetic resonance enterography (MRE) or wireless capsule endoscopy (WCE).

Wireless capsule endoscopy (WCE) is a procedure that allows the doctor to look at the small intestine by using a tiny "pill sized" video camera inside a capsule that is swallowed. As the capsule moves through the intestine the camera takes thousands of pictures that are recorded on a sensor belt that is worn by the patient.

The Wireless Capsule is an FDA approved device currently used for small bowel imaging in children and adults over the age of 2.

The purpose of this research study is to see if WCE is a more useful procedure than MRE when examining Crohn's and Indeterminate Colitis.

WHO CAN BE IN THIS STUDY?

We are asking your child to be a part of this research study because he or she has been diagnosed with Crohn's Disease or Indeterminate Colitis and is going to have an MRE procedure for standard care.

Up to 50 children and adults, ages 4 through 17 will be asked to be in this study at The Children's Mercy Hospitals & Clinics.

WHAT WILL HAPPEN TO MY CHILD IN THIS STUDY?

Being in this study involves a wireless capsule endoscopy procedure and collecting information from your child's medical record. If you agree for your child to be in this study, he/she will be in this study for up to one week after your child's regularly scheduled MRE.

If you choose for your child to participate, the study team will collect information from your child's medical record. The information collected will include the following:

- Diagnosis, medications, endoscopy/colonoscopy results, imaging test results, medical and surgical history

The day of your child's scheduled MRE:

- Your child will go to the Radiology department at the scheduled time for their MRE.
- Blood will be taken by needle stick from a vein in your child's arm. There will be one blood draw of about 2 teaspoons taken for the study. If applicable this blood will be drawn at the time of your child's IV start for the MRE. If it is not drawn at the time of your child's MRE it may be drawn at another study visit.

- After your child's MRE you and your child will be guided through the patency capsule procedures.
    - At times patients with Crohn's disease have swelling and narrowing in their bowel. Patency capsule (PC) is a small pill that is the same size as the Wireless Capsule Endoscopy (WCE) pill. It has the ability to dissolve in the body and works like a practice pill. The doctor will make sure the practice pill will pass through your child's bowel first before having your child swallow the WCE pill.
    - If you and your child are unable to complete patency capsule procedures the same day as the MRE your child will be asked to return in 1-2 days to complete these procedures. Your will also have the option of having your child swallow the patency capsule at home or with a parent/caregiver at school during the lunch period or the following morning.

- Your child will swallow the PC. Your child will be asked to follow the schedule below:
    - Your child will be asked to return to radiology for a stomach x-ray 28-40 hours after swallowing the patency capsule. This x-ray will look at the location of the patency capsule to make sure your child's bowel is large enough for the WCE pill to pass through. If you and your child see the pill pass in your child's stool, your child will not need to return for this x-ray.
    - After your child's MRE and patency capsule the study doctor and your child's GI doctor will discuss your child's results and if your child is eligible to proceed to WCE. You still will have the choice to withdraw your child from the study at this point.

Wireless Capsule Endoscopy:

- Will take place within 5 days of the PC.
- The day before your child's visit they will need to do the following bowel cleanout/preparation:
    - Your child will drink only liquid foods starting at 12:00 pm (noon) the day before the visit.
    - Your child will drink one packet of Miralax mixed in 4-8 oz of a clear liquid starting at 1:00 pm

- Your child will repeat the Miralax dose at 2, 3 and 4 o'clock.
- Your child will not eat or drink anything by mouth after 12:00 am (midnight)
- If your child will be in school at the times of the Miralax doses the study team can discuss alternative times for your child to begin the prep.

The day of your child's Wireless Capsule Endoscopy:

- Your child will be asked about any symptoms he/she is having.
- You and your child will receive instructions what to do after the visit.
- Your child will swallow the capsule with water.
- Your child will be able to drink clear liquids 3 hours after swallowing the capsule.
- Your child will be able to resume a full diet 6 hours after swallowing the capsule.
- Your child will be fitted with a sensor belt under his/ her clothing with a recorder attached to it.
- Your child will wear a small sensor belt under his/her clothing with a recorder attached to it for the duration of the Wireless Capsule Endoscopy.
- Your child will then be able to resume his/her usual activities except for sports or physical activities.
- You and your child will return the WCE recording device to the research nurse in GI procedure room 8 - 12 hours after swallowing the capsule or when the lights turn off.
- You and your child will be asked to observe for the timing of passage of capsule in your child's stool if possible.
    - If you and your child have not seen the capsule pass in 2 weeks your child will be asked to return for a stomach x-ray to check to see if the pill is still in your child's bowel.
    - If the WCE pill is still in your child's bowel your child's regular GI doctor will be notified so they can start treatment with your child to help the WCE pill pass through his/her bowel.

The results of your child's WCE will be made available to your child's regular GI doctor and they will be able to further discuss the results of the imaging with you and your child.

WHAT ARE THE RISKS OF THE STUDY?

There are certain risks in this study.

- There is a slight risk of loss of confidentiality. Your child's confidentiality will be protected to the greatest extent possible.

- Clean out: Miralax (polyethylene glycol) is a safe medication for bowel cleans out. It is available over the counter and is a colorless, tasteless powder when it is mixed with clear liquids. It is not absorbed to blood stream. The goal of its use in this study is to cause loosen the stool which cleans out the intestine to make it easier to see the intestinal lining. Loose stool may cause stomach pain.

- Patency Capsule (PC): The capsule measures 11 × 26 mm, similar to a vitamin tablet. If there is a narrow part of bowel then it may not pass through easily. This capsule is able to breakdown in to smaller pieces in the body to help it pass through and eventually come out through a bowel movement. Stomach pain, nausea and vomiting are possible risks with this procedure. There is a very rare risk that this capsule may be come stuck in the bowel if there is a narrow space for it to pass through. There are treatments available that can be provided by your child's regular GI doctor in this case.

- Wireless Capsule Endoscopy (WCE): The capsule is measures 11 × 26 mm, similar to vitamin tablet size. If there is a very narrow part of the bowel, it is possible the WCE pill may find it by becoming stuck. To try to prevent this, patency capsule will help exclude patients who could have narrowed areas that are at risk for the capsule getting stuck. It is possible that the MRE and PC will not find narrowing in the bowel, but the WCE capsule will find this area and not be able to pass. If the capsule stays in your child's intestinal tract more than 2 weeks, your child may need medications or surgery remove the diseased portion of your child's bowl that is causing this narrow area. There is a rare risk of bleeding, perforation and mucosal injury of the bowel.

    - Avoid contact with electromagnetic fields such as MRE until you/your child knows the capsule has passed.

- This research study involves getting an x-ray of your child's abdomen (belly). This x-ray is not necessary for your child's medical care and is for research purposes only. The maximum amount of radiation your child will get is 0.2 mSv or 20 mrem. This is about the same as 24 days of natural background radiation. This means that this x-ray is minimal (very small) risk to your child.

- Blood Draws: Risks of drawing blood from your child's arm include discomfort and/or bruising. Numbing cream may help ease the pain of needle sticks. There is a very low risk of infection, bleeding, clotting, or fainting.

If your child has any of these problems or changes in the way he or she feels, you should tell the investigator or other study personnel as soon as possible.

You and your child should contact Dr. Hijaz if your child has not passed the WCE pill in more than 2 weeks after swallowing the pill.

There may be risks we don't know about right now. We will tell you about any new information that might change your decision to keep your child in the study.

WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?

There may be direct benefit to your child from being in this study. Possible benefits may include finding the extent of your child's Crohn's disease in areas of their bowel we cannot see by x-ray or endoscopy. By being in this study, your child may help children with Crohn's in the future.

WHAT ABOUT EXTRA COSTS?

- Taking part in this study may lead to added costs to you and/or your child's health insurance company.
- There are no plans for the study to pay for these costs.
- Insurance may still be billed for routine care. Your child's research visit may be combined with a routine care visit. Although study funds may pay for certain study-related items and services, you or your child's insurance company will still be required to pay for all of your child's routine care that would have occurred if your child was not part of this research study. These charges may include your child's clinic visit(s), any continuing medical care and/or hospitalizations, all clinical and laboratory evaluations, imaging scans such as MRE or x-ray and surgeries (if needed).
- Findings of diseased intestine by the capsule imaging or the inability to pass the capsule will result in treatment that will be billed to a third party payer such as your insurance company.
- Please ask about additional costs you/your child could incur from participating in this study.

WHAT ABOUT CONFIDENTIALITY?

Your child has rights regarding the privacy and confidentiality of his or her health information. When health information includes identifiers (like names, addresses, phone numbers and social security or individual taxpayer identification (ITIN) numbers) that link it directly to an individual, it is called protected health information (PHI). Federal laws require that PHI be kept secure and private. In certain situations, federal law also requires that you approve how your child's PHI is used or disclosed. A research study is one of those situations.

By signing this permission/assent form, you are permitting the following people to have access to your child's medical record and use your child's PHI for the research purposes described in this form. You are also permitting your child's PHI to be shared with everyone listed below:

- The research team, which includes the study personnel listed on this form and other persons involved in this study at The Children's Mercy Hospitals & Clinics;
- Your child's regular GI provider at The Children's Mercy Hospitals & Clinics;
- The Institutional Review Board at The Children's Mercy Hospitals & Clinics;
- Other researchers, hospitals, and institutions that are part of this study and their Institutional Review Boards;
- A group that oversees the data (study information) and safety of this research;
- People from organizations that provide independent accreditation and oversight of hospitals and research;
- Federal agencies such as the Office for Human Research Protections and the Food and Drug Administration.

The research record is separate from your child's medical record. Information about your child that is obtained during this study will be recorded in a research record and may also be recorded in your child's medical record. The results of your child's capsule endoscopy will be recorded in their medical record. The recorded images taken during WCE and your child's name, medical record number, research account number, date of service, the WCE device ID number and date of birth will be retained indefinitely on the CMH computer that records the images. The computer is password protected. A research record will be created and kept in Gastroenterology Research Office. The research record may include documents that have your child's name, assigned study ID number, telephone number, research account number, dates of service, medical device number. All research records will be maintained in a confidential manner.

Some people or groups who get your child's identifiable health information might not have to follow the same privacy rules that we follow. We will share your child's health information only when we must, will only share the information that is needed, and will ask anyone who receives it from us to protect your child's privacy. However, once your child's information is shared outside of CMH, we cannot promise that it will remain private.

You may choose not to sign this permission/assent form and not have your child be in the study. You may cancel your permission to use and share your child's PHI at any time by contacting the study personnel listed on this form. You may also contact The Children's Mercy Hospitals & Clinics Health Information Management (HIM) in writing. If you

cancel your permission, your child may no longer participate in this study. Your child's PHI that has already been collected for the study may still be used; however, no new information will be collected except information related to adverse events or other safety issues.

If you do not cancel your permission, your child's PHI may continue to be recorded until the entire study is finished. This may take years. Any study information recorded in your child's medical record will be kept forever. Unless stated elsewhere in this form, you may not have access to your child's research record or research test results.

Results of this study may be made public. If made public, your child will not be identified in any publications or presentations.

In addition to the use of data described above, a description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?

Instead of being in this study, you may choose for your child not to participate.

WHAT ARE MY CHILD'S RIGHTS AS A STUDY PARTICIPANT?

Being in a research study is voluntary. Your child does not have to be in this study to receive medical care. If you choose not to have your child participate, there will be no penalty or loss of benefits to which your child is otherwise entitled.

You may withdraw your child from the study at any time without penalty or loss of benefits to which your child is otherwise entitled. We will inform you of any new information that develops during this study. This information may affect your decision to keep your child in the study. If you choose to withdraw your child from the study or if you are asked by your child's personal doctor to withdraw your child from the study, you must tell the research doctor as soon as possible.

If you withdraw your child from the study early for any reason, the information that already has been collected will be kept in the research study and included in the data analysis. No further information will be collected for the study.

Dr. Hijaz, the Institutional Review Board or the FDA may stop the study at any time. The investigator(s) or your child's doctor may remove your child from the study at any time without your permission.

If you withdraw your child or your child is removed from the study for any reason, the study doctor may ask you if they may continue to follow your child for monitoring. This visit could include any of the assessments/tests mentioned earlier and any other procedures that the study doctor feels are necessary for your child's safety.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Dr. Hijaz is in charge of this research study. You may call Dr. Hijaz at 417-347-3100 with questions at any time during the study. You may also call Allison Gordy, the study coordinator, at 816-302-3079 with any questions you may have.

You should call Dr. Hijaz if you believe that your child has suffered injury of any kind or is sicker as a result of being in this research study.

You may also call the Children's Mercy Hospitals & Clinics Pediatric Institutional Review Board (IRB) at (816) 701-4358 with questions or complaints about this study. The IRB is a committee of physicians, statisticians, researchers, community advocates, and others that ensures that a research study is ethical and that the rights of study participants are protected.

SPONSOR AND INSTITUTIONAL RESPONSIBILITIES

In the case of illness or injury resulting from this study, treatment is available at The Children's Mercy Hospitals & Clinics, but will be provided at the usual charge. Payment for this treatment will be your responsibility. The hospital may not bill insurance or other third party payers for this care. The Children's Mercy Hospitals & Clinics does not have funds set aside to pay research participants if the research results in injury. By signing this form, you, or your child, are not giving up any legal rights to seek compensation for injury.

PERMISSION OF PARENT OR LEGALLY AUTHORIZED REPRESENTATIVE

The purposes, procedures, and risks of this research study have been explained to me. I have had a chance to read this form and ask questions about the study. Any questions I had have been answered to my satisfaction. I give permission for _____ to participate in this research study. A copy of this signed form will be given to me.

_____ _____ _____
Signature of Parent/Legally Authorized Representative Date and Time Relationship to Participant

ASSENT OF MINOR

I have been told that if I am in this study I will swallow a practice pill and a camera pill, I may have blood drawn one time and I will have 1 or 2 x-rays. I have been told that I don't have to be in this study. I may quit the study at any time, and no one will be mad at me. I have had a chance to discuss the study and ask questions. My questions have been answered. I agree to be in the study and do what I am asked to do as long as I continue in the study.

_____ _____ _____
Signature of Minor Date Time

STUDY PERSONNEL
I have explained the purposes, procedures, and risks involved in this study in detail to:

_____
Print name(s) of Parents/ Legally Authorized Representative, and

_____, who in my opinion ___ IS / ___ IS NOT capable of assenting to participate in this study.
Print child's name. If child IS NOT capable of assenting, please state reason why:

__ Age of child:_____ (insert age)

__ Limitation in understanding based on child's condition

__ Other, please explain_____

_____ _____ _____
Signature of Person Obtaining Permission/Assent Date Time

Print Name of Person Obtaining Permission/Assent _____

WITNESS

I have witnessed the permission/assent process and signature(s) for this research study:

_____ _____ _____
Signature of Witness Date Time

Print Name of Witness_____