Title of research study: Incorporating Endoscopic Ultrasound and Elastography towards improving outcomes of Pediatric Pancreatitis Management

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.

Investigator:

David Vitale, MD

Contact Info:

Tyler Thompson:

513-517-1055

Funding: National Pancreas Foundation (NPF)

COMBINED 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 find out more about acute recurrent pancreatitis and chronic pancreatitis in children. There are few studies on childhood pancreatitis, so diagnosis and treatment are based on adult studies. This limits our understanding and treatment of these disorders in children.

Endoscopic ultrasound (EUS) is a tool used to assess and diagnose pancreatic disease. We can use ultrasound with shear wave elastography (SWE) to measure fibrosis (scarring) of the pancreas. We can use SWE on both EUS and transabdominal ultrasound (TUS) systems. Both TUS and EUS SWE have been studied for diagnosis of chronic pancreatitis in adult patients, however they have not been studied in children.

We plan to use EUS SWE and TUS SWE information in this study to help us understand pancreatitis in children. Children with pancreatitis and children without pancreatitis (controls) will be invited to participate in this study.

Study Procedures:

You will be able to ask questions to make sure that you understand what will happen during the study. If you agree to participate in this study, the following will happen:

Data: As part of the research, information will be gathered from your medical chart. This will include demographic information like your age, gender, race and ethnicity, past medical history, and family history as well as medical information related to your diagnosis.

If appropriate, findings from your clinical samples will be reviewed for the presence of fibrosis.

Endoscopic Ultrasound (EUS): EUS will be performed as part of your clinical care. During your EUS, the doctor will take additional SWE measurements for research. This will add approximately 5 minutes to the total procedure time.

Transabdominal ultrasound (TUS): We will ask you to have a TUS for research purposes. The TUS SWE will take no more than 20 minutes and may or may not occur on the same day as the EUS.

Risks to Participate:

The clinical team will review the risks associated with your clinical EUS. There is no additional risk for the research measurements during the EUS or with TUS. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

One of the risks of participating in research is the loss of confidentiality. Every effort will be made to keep your personal information confidential. Please see the section titled "How will your information be kept private" in this consent form for detailed information on how your information will be protected.

Benefits to Participate:

There are no benefits to you from your taking part in this research. However it can help other children in future by improving outcomes of pediatric pancreatitis management.

Other Options:

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

Your alternative to participating in this research study is to not participate.

Cost to Participate:

You and your insurance company will be charged for the healthcare services that you would ordinarily be responsible to pay. There are no additional costs to take part in this research study.

Payment:

If you agree to take part in this research study, we will pay you $75 for your time and effort.

You (your child) will receive payment for this study in the form of a reloadable debit card (Clincard). 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, Cincinnati Children's 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 Cincinnati Children's business office. 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	**Dr. David Vitale**	Phone: 513.803.2123
• Emergencies • General study questions	**Tyler Thompson**	Phone: 513-517-1055

Who to talk to…	You can call …	At …
• Research-related injuries • Any research concerns or complaints		
• 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.	Phone: (513) 636-8039

Change of Mind/Study Withdrawal:

You can leave the research at any time; it will not be held against you.

Privacy:

Data collected for this study will be given a unique code and stored in a secure location to which only our study team has access. No identifying information will be published.

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 IRB and other representatives of this organization.

Data collected for or generated from this study could be shared and used for future research. Data may be shared with other collaborators at Cincinnati Children's and possibly with outside collaborators, who may be at another institution or for-profit company.

All future researchers will be given the least amount of information needed to meet the goals of their research project. Researchers that use this information must agree to never try to re-identify a participant from a coded dataset. Researchers will only be allowed to use the provided information for approved research purposes. Any researchers planning to do research with information that may identify you will need to have extra review and approval by the Cincinnati Children's Institutional Review Board (IRB). An IRB is a group of scientists and non-scientists who look at research projects like these and make sure research participants' rights and welfare are protected.

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?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will need to use and share your PHI as part of this study. This PHI will come from:

- Your Cincinnati Children's 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 If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your child's other medical care be impacted?

By signing this document, you / your child agrees to participate in this research study and give permission to Cincinnati Children's to use and share you/your child's PHI for the purpose of this research study. If you refuse to sign this document, you/your child will not be able to participate in the study. However, you/your child's 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.

_____
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