Imaging Biomarkers of Pancreatic Function and Disease

NCT05659147

Version 1

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Title of research study: **Imaging Biomarkers of Pancreatic Function and Disease**

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

Investigator:
Andrew Trout, MD

Contact Info:
Andrew Trout, MD
(513) 803-3004

Funding:
National Institutes of Health (NIH)

Reason for the study:

The main reason for this research study is to see how magnetic resonance imaging (MRI) can measure pancreas health and function in children and to see if MRI can predict disease progression in children with pancreatitis. We are enrolling patients with and without pancreatic disease.

Procedures:

You will have a clinically-indicated endoscopy at CCHMC. Unless you are having endoscopic pancreatic function tests (ePFTs) for clinical care, you will be asked to allow the team to perform ePFTs for research purposes during your clinical endoscopy. This means you will be given secretin by an IV already placed for the clinical procedure and fluid will be collected from your intestines. This will increase your clinically indicated endoscopy by approximately 15 minutes.

In addition, two weeks after your clinical endoscopy you will be asked to attend one research or combined clinical and research visit. The research visit will be approximately 3 hours long.

The following things will happen as part of the research visit unless they are already happening as part of your clinical care:

- You will not eat or drink for 8 hours before the research visit, and you will not be able to drink for 4 hours before the research visit, or for the approximately 3 hour long 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 place an IV will be for a blood sample to be collected from you/your child, and to administer secretin for the MRI
- We will perform an MRI with secretin while we ask you do different things like hold your breath
- We will ask you/your child to collect a stool specimen

You may also be asked to attend a second research only visit where you will be asked to answer questions about your medical history and where we will perform the same MRI with secretin. For this second visit you would not be able to eat or drink for 4 hours before the research visit or for the approximately 2 hour research visit.

If you are scheduled to have ePFTs, an MRI or labs for clinical care we will collect these from your chart for use in this study.

Approximately 1 year after your research MRI we will review your chart and will call you by phone to ask you some questions. We will do this every year going forward for up to 5 years**.**

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

Risks of participating:

For the clinical endoscopy, there is a risk of aspiration. Additionally, for the research ePFT, the time for which you are asleep will be longer to do the research pancreatic function testing. This will mean approximately 15 minutes of extra anesthesia time, which is not expected to carry any more than minimal risk.

The secretin that will be used during your ePFT and your MRI(s) will be administered by the intravenous (IV) catheter. Possible discomforts when placing the IV include, pain, bruising, redness and swelling, and fainting. Some people may have an unknown allergy to secretin which could result in symptoms such as a rash and itchy skin. Staff will ask you questions and review your history closely before you are given secretin to confirm you should have it.

There are no known risks from having an MRI when participants are screened and safety procedures are followed. The MRI will use techniques that are used every day for clinical care at Cincinnati Children's and will also use new investigational techniques that are not approved by the The US Food and Drug Administration (FDA). These new techniques are limited to investigational use and will not be used for clinical practice. All MRI techniques will be performed within FDA limits of the MRI scanner. 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 up to 60 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.

There is a likely risk of minor discomfort from obtaining blood samples. Possible discomforts specifically include, pain, bruising, redness and swelling, and fainting.

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	• Minor discomfort
• Anxiety	• Loss of confidentiality

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

Benefits of participating:

We cannot promise any benefits to you or others from your taking part in this research. However, all participants will receive results related to exocrine and endocrine function of the pancreas. It is possible that these results may result in a diagnosis that could impact your clinical care.

This research has the potential to broadly benefit children with known or suspected pancreatic disease by diagnosing and monitoring pancreatic disease by using MRI.

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:

You and your insurance company will be charged for the clinically indicated endoscopy that you would ordinarily be responsible to pay. Anesthesia, including the anesthesia for the research endoscopy, will be billed to you and your insurance company. You will be billed no more than 15 minutes of additional anesthesia time.

There is no additional cost to you to participate in this study.

Payment:

If you agree to take part in this research study, you will be reimbursed for your time and effort as follows:

Procedure (as applicable)	Reimbursement
ePFT and MRI with secretin	$100
Blood sample	$20
Stool sample	$30
Additional MRI with secretin	$100

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, Cincinnati Children's 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 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 Cincinnati Children's 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.

Additional Study Information:

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

If you 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	Andrew Trout, MD	Phone: (513) 803-3004
• Your 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

Detailed Procedures:

The following procedures will be completed when you arrive for each research visit. Anything being already completed for clinical care will not be repeated for this study:

	Duration	**Who**
Clinical endoscopy and ePFT visit		
Nothing to eat for 8 hours and nothing to drink for 4 hours	N/A	
Enrollment screening (chart review)	N/A	Research Coordinator/Study team
Written Informed Consent obtained	20 minutes	Research Coordinator/Study team
IV placement for endoscopy (used for ePFT)	N/A	Clinical endoscopy team
ePFT	15 minutes	Clinical endoscopy team
MRI visit		
Nothing to eat or drink for 8 hours, and nothing to drink for 4 hours, prior to the MRI visit	N/A	
Pregnancy screening (if applicable)	10 minutes	Research Coordinator/Study team
Questionnaire completed	20 minutes	
Height and weight obtained	5 minutes	Research Coordinator/Study team
IV placed (for labs and genetic analysis)	15 minutes	Nurse
Blood draw (for labs and genetic analysis, if applicable)	5 minutes	Nurse

MRI safety screening	5 minutes	MRI technologist
MRI performed	60 minutes	MRI technologist
Secretin administration	5 minutes (during MRI)	Nurse
IV removal	5 minutes	Nurse
MRI visit #2 (if applicable)		
Nothing to eat or drink for 4 hours prior to the MRI visit	N/A	
Questionnaire completed	20 minutes	
Height and weight obtained	5 minutes	Research Coordinator/Study team
IV placed (for secretin administration)	15 minutes	Nurse
MRI safety screening	5 minutes	MRI technologist
MRI performed	60 minutes	MRI technologist
Secretin administration	5 minutes (during MRI)	Nurse
IV removal	5 minutes	Nurse
Annual follow up		
Chart review	N/A	Research Coordinator/Study team
Phone Questionnaire completed	15 minutes	

ePFT Details

Endoscopic pancreatic function tests are routinely done for clinical care. To do this test, secretin will be given through an IV that you will already have for your clinical endoscopy. This will happen while you are still under anesthesia or asleep. Over the next 15 minutes fluid will be collected from your small intestine. This fluid will be sent for analysis to measure the function of your pancreas.

Pregnancy Screening

Prior to the research MRI, you may be verbally screened for potential pregnancy. If you indicate that you could be pregnant, you will be asked to complete a urine pregnancy screening. If the test is positive, the information will be given to you and your parents if you are a minor, 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(s), 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 technologists may ask you to hold your breath for up to 15 seconds while they are taking pictures. Pictures are seen on a monitor and sent to the study doctor for review. The research MRI exam will last no longer than 60 minutes. During the MRI, you will be given secretin to measure fluid made by the pancreas. If you are having an MRI for clinical care, we will do less than 20 minutes of additional MRI imaging for this study.

Survey Details

During the MRI visit(s) you will complete a survey on paper about your personal history. These will help our research team answer questions about pancreatic disease.

During follow-up you will complete a survey over the phone every year for up to 5 years about your personal history. This will help our research team answer questions about the progression of pancreatic disease.

Blood Draw Details

You will have a maximum of 10 ml of blood taken. This is about 1 tablespoon. The blood will be taken from your arm. The blood you provide is for research and not for a medical diagnosis or treatment. Any extra blood, including genetic material, not used for this study will be saved for future analysis.

Stool Sample Details

You will collect a sample of your stool. The study team will give you a kit to do this collection. You can do the collection at home and bring or mail it to the hospital, or you can do the collection at the hospital. Any stool not used for this study will be saved for future analysis.

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:

ePFT

Adding the research ePFT on to your clinical endoscopy exam means you will be under anesthesia for an extra 15 minutes. This is only a minimal risk to you because the greatest risk is the start and end of anesthesia. There is a risk of aspiration during endoscopy which will continue while you are having your research ePFTs.

Secretin

Some people may have an unknown allergy to secretin which could result in symptoms such as a rash and itchy skin. Staff will ask you questions and review your history closely before you are given secretin to confirm you should have it.

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.

Blood Draw and IV placement

The risks of inserting an IV and taking blood include pain, a bruise at the point where the needle is inserted, redness and swelling of the vein and infection, and a risk of fainting.

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 FDA, Cincinnati Children's Hospital Medical Center (CCHMC), the IRB and other representatives of this organization.

Samples and/or data collected for or generated from this study could be shared and used for future research. Samples and/or 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.

If information that could identify you is removed from your information or samples collected during this research, that information or those samples could be stored and used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The sponsor, monitors, auditors, the IRB, the FDA 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 researchers 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.

If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

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 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 never expire.

Will your other medical care be impacted?

By signing this document, you agree to participate in this research study and give permission to Cincinnati Children'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 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.

Study Involvement: In regards to my research study participation, I **AGREE** the following procedures:

- ☐ Initials: _____ I agree to the collection of ePFTs for research
- ☐ Initials: _____ I agree to an MRI with secretin for research
- ☐ Initials: _____ I agree to the collection of a stool sample for research
- ☐ Initials: _____ I agree to the collection of a blood sample for research
- ☐ Initials: _____ I agree to genetic analysis of my blood for research
- ☐ Initials: _____ I agree to a second MRI with secretin for research
- ☐ Initials: _____ I agree to be contacted by the pancreas research team regarding pancreas research follow up

_____
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