IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 01/10/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes-** this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study.

We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

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Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
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Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[X] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

09#9

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	3-1-17
Signature of Participant	Date
X [redacted]	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x	
Signature of person obtaining informed consent	Date
x	3/1/17

Witness if required

x	2-1-17
Signature of witness	Date
x KATHERINE KUTNEY	

UNIVERSITY HOSPITALS
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Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

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You can still participate in the study of MRI technology without participating in this study.

Financial Information

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You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
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Confidentiality

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Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

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- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

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Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
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Future Research Studies

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[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
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X [redacted]	3/7/17
Signature of Participant	Date
X [redacted]	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x	
Signature of person obtaining informed consent	Date
x [signature]	3/7/17

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
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Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
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Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes-** this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study.

We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X	
Signature of Participant	Date
X	
Printed name of minor if used to obtain assent	
x [redacted]	3/7/17
Signature of Parent/Legal Guardian	Date
x [redacted]	
Printed name of Parent/Legal Guardian	
x [redacted]	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x	3/7/17
Signature of person obtaining informed consent	Date
x	

Witness if required

x	
Signature of witness	Date
x	

IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 01/10/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
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The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

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CONSENT FOR INVESTIGATIONAL STUDIES

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Confidentiality

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UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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Termination of Participation

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Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

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• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

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Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[X] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X	[redacted] 3-8-17
Signature of Participant	Date
X	[redacted]
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x	3-8-17
Signature of person obtaining informed consent	Date
x	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes**- this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study.

We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later. 614-256-0640

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[X] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	3/15/17
Signature of Participant	Date
X	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x [signature]	3-15-17
Signature of person obtaining informed consent	Date
x	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 01/10/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

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CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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If you have **not had an Oral Glucose Tolerance Test in the last six months**

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Benefits

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Because of the nature of this research the only alternative is to not participate in this study.

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Financial Information

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You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
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Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Student/Employee Rights

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Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
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Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

Cell # 614-256-0640

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[X] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	
Signature of Participant	Date 3/15/17
X [redacted]	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x [signature]	3/15/17
Signature of person obtaining informed consent	Date
x	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes-** this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study.

We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

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Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

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We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

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Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

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• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

614-256-0640

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If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

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Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	3-22-17
Signature of Participant	Date
X [redacted]	
Printed name of minor if used to obtain assent	
x [redacted]	3.22.17
Signature of Parent/Legal Guardian	Date
x [redacted]	
Printed name of Parent/Legal Guardian	
x [redacted]	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x [redacted]	
Signature of person obtaining informed consent	Date
x	3-22-17

Witness if required

x	
Signature of witness	Date
x	

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IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 01/10/2017
IRB EXPIRATION DATE: 09/12/2017

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Benefits

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Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

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You can still participate in the study of MRI technology without participating in this study.

Financial Information

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You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
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Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

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If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X	
Signature of Participant	Date
X	
Printed name of minor if used to obtain assent	
x [redacted]	
Signature of Parent/Legal Guardian	Date
x [redacted]	3-22-17
Printed name of Parent/Legal Guardian	
x [redacted]	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x [redacted]	3.22.17
Signature of person obtaining informed consent	Date
x	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 01/10/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes**- this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study.

We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

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Principal Investigator: Katherine Kutney MD

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Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Katherine Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

614.252.0640

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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X [redacted]	
Signature of Participant	Date 04/05/2017
X [redacted]	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x K KUTNEY	
Signature of person obtaining informed consent	Date
x [signature]	4/5/17

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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CONSENT FOR INVESTIGATIONAL STUDIES

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UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

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MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

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CLEVELAND MEDICAL CENTER
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Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

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Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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You can still participate in the study of MRI technology without participating in this study.

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Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

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- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr. Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

614-256-0640

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	
Signature of Participant	Date 5/30/17
X [redacted]	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x [signature]	5-30-17
Signature of person obtaining informed consent	Date
x Katherine Kutney	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 01/10/2017
IRB EXPIRATION DATE: 09/12/2017

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UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes-** this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study.

We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

[redacted]

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr. Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

→ 614-256-0640

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[X] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

[redacted]

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	4-12-17
Signature of Participant	Date
X [redacted]	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x K Kutney	4/12/17
Signature of person obtaining informed consent	Date
x	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

12

IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 01/10/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose

You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

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Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes-** this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study.

We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

614-256-0640

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	4/12/17
Signature of Participant	Date
X [redacted]	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x	
Signature of person obtaining informed consent	Date
x	

Witness if required

x	K Kutney
Signature of witness	Date
x	4/12/17

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 01/10/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes**- this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study.

We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

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• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

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Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

614-736-0640

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X	[redacted]
Signature of Participant	Date 4-12-17
X	[redacted]
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x	K Kutney
Signature of person obtaining informed consent	Date
x	4-12-17

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

IRB NUMBER: 09-16-07
IRB APPROVAL DATE: 01/10/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
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- **No diabetes**- this is also called Normal glucose tolerance
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- **CF related diabetes**

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We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

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As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

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CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

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Principal Investigator: Katherine Kutney MD

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Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

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There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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Financial Information

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You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
Funds are given directly to the study participant regardless of age.

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Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

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Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[X] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	4-21-17
Signature of Participant	Date
X [redacted]	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x Ashlee Parsons	21 APR 2017
Signature of person obtaining informed consent	Date
x Ashlee Parsons	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 01/10/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes**- this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study.

We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

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Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

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Disclosure of your study records

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Contact information

Heather Tridat has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X	[redacted]	
Signature of Participant		Date
X	[redacted]	4-21-2017
Printed name of minor if used to obtain assent		
x		
Signature of Parent/Legal Guardian		Date
x		
Printed name of Parent/Legal Guardian		
x		
If Legal Guardian, indicate relationship to child		

Study personnel (only individuals designated on the checklist may obtain consent)

x	Heather Tribas	4/21/2017
Signature of person obtaining informed consent		Date
x	Heather Tribas	

Witness if required

x		
Signature of witness		Date
x		

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose

You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

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Based on the result of this test, patients can be separated into three groups:

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- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study.

We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

Initials

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

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Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
Funds are given directly to the study participant regardless of age.

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Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

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UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

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- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

(614) 256-0640

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X	
Signature of Participant	Date
X	
Printed name of minor if used to obtain assent	
x [redacted]	
Signature of Parent/Legal Guardian	Date 4/25/17
x [redacted]	
Printed name of Parent/Legal Guardian	
x mother	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x Katherine Kutney	4-25-17
Signature of person obtaining informed consent	Date
x	
Witness if required	

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
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Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes-** this is also called Normal glucose tolerance
- **Borderline diabetes-** this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study. People with borderline diabetes might complete the study if we do not know they have borderline diabetes until after the MRI is completed.
We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

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CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

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We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

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You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

If you do not need an Oral Glucose Tolerance Test, you will receive $30 for this research study.

If you do need an Oral Glucose Tolerance Test, you will receive $60 for the Oral Glucose Tolerance Test. If you qualify to get the MRI done or if you get the MRI done before we know the result of the Oral Glucose Tolerance Test, you will receive an additional $15. This is a total of $75 for the Oral Glucose Tolerance Test and MRI.

You will be given a parking pass.

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To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

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Principal Investigator: Katherine Kutney MD

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Contact information

Katherine Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later. 614-256-0640

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

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[✓] YES, you may contact me for future research studies
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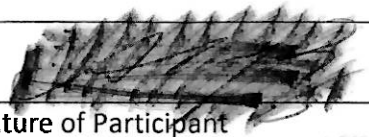
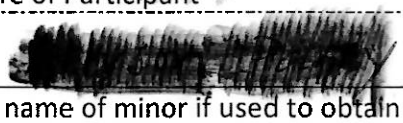
X	
Signature of Participant	Date 5/3/17
X	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x	5/3/17
Signature of person obtaining informed consent	Date
x	Katherin Kutney

Witness if required

x	
Signature of witness	Date
x	

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IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 04/21/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

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- **Borderline diabetes-** this is also called Impaired glucose tolerance or impaired fasting glucose
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Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

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MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

If you do not need an Oral Glucose Tolerance Test, you will receive $30 for this research study.

If you do need an Oral Glucose Tolerance Test, you will receive $60 for the Oral Glucose Tolerance Test. If you qualify to get the MRI done or if you get the MRI done before we know the result of the Oral Glucose Tolerance Test, you will receive an additional $15. This is a total of $75 for the Oral Glucose Tolerance Test and MRI.

You will be given a parking pass.

Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the

following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate

against you based on your genetic information. This law generally will protect you in the following ways:

• Health insurance companies and group health plans may not request your genetic information that we get from this research

• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

(614) 256-0690

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[X] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	5/9/17
Signature of Participant	Date
X [redacted]	
Printed name of minor if used to obtain assent	
x [redacted]	
Signature of Parent/Legal Guardian	Date 5-9-17
x [redacted]	
Printed name of Parent/Legal Guardian	
x [redacted]	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x [redacted]	5-9-17
Signature of person obtaining informed consent	Date
x [redacted]	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 04/21/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes-** this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study. People with borderline diabetes might complete the study if we do not know they have borderline diabetes until after the MRI is completed.
We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

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CLEVELAND MEDICAL CENTER
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Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

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Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

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There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

If you do not need an Oral Glucose Tolerance Test, you will receive $30 for this research study.

If you do need an Oral Glucose Tolerance Test, you will receive $60 for the Oral Glucose Tolerance Test. If you qualify to get the MRI done or if you get the MRI done before we know the result of the Oral Glucose Tolerance Test, you will receive an additional $15. This is a total of $75 for the Oral Glucose Tolerance Test and MRI.

You will be given a parking pass.

Funds are given directly to the study participant regardless of age.

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CLEVELAND MEDICAL CENTER
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following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

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All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

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If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

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[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	5-10-17
Signature of Participant	Date
X [redacted]	5-10-17
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x	
Signature of person obtaining informed consent	Date
x	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

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You are being asked to participate in this study because you have cystic fibrosis.

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If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

If you do not need an Oral Glucose Tolerance Test, you will receive $30 for this research study.

If you do need an Oral Glucose Tolerance Test, you will receive $60 for the Oral Glucose Tolerance Test. If you qualify to get the MRI done or if you get the MRI done before we know the result of the Oral Glucose Tolerance Test, you will receive an additional $15. This is a total of $75 for the Oral Glucose Tolerance Test and MRI.

You will be given a parking pass.

Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the

following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate

against you based on your genetic information. This law generally will protect you in the following ways:

• Health insurance companies and group health plans may not request your genetic information that we get from this research

• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign

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Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

(614-256-0640

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
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Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	6-14-17
Signature of participant	Date
X [redacted]	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x [redacted]	6-14-17
Signature of person obtaining informed consent	Date
x [redacted]	

Witness if required

x	
Signature of witness	Date
x	

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Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 04/21/2017
IRB EXPIRATION DATE: 09/12/2017

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Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes**- this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study. People with borderline diabetes might complete the study if we do not know they have borderline diabetes until after the MRI is completed.
We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

[redacted]

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Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

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Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

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There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

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You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

If you do not need an Oral Glucose Tolerance Test, you will receive $30 for this research study.

If you do need an Oral Glucose Tolerance Test, you will receive $60 for the Oral Glucose Tolerance Test. If you qualify to get the MRI done or if you get the MRI done before we know the result of the Oral Glucose Tolerance Test, you will receive an additional $15. This is a total of $75 for the Oral Glucose Tolerance Test and MRI.

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Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

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Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the

following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

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• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

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Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign

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Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later. 614-256-0640

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[X] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

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Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X	[redacted]	6/20/17
	Signature of Participant	Date
X	[redacted]	
	Printed name of minor if used to obtain assent	
x		
	Signature of Parent/Legal Guardian	Date
x		
	Printed name of Parent/Legal Guardian	
x		
	If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x	KA	6/24/17
	Signature of person obtaining informed consent	Date
x	Katherine Kutney	

Witness if required

x		
	Signature of witness	Date
x		

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IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 04/21/2017
IRB EXPIRATION DATE: 09/12/2017

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Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

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Introduction/Purpose

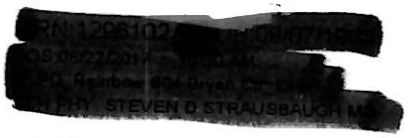
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes**- this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study. People with borderline diabetes might complete the study if we do not know they have borderline diabetes until after the MRI is completed.
We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.



UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

6 mos

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

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Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

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There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

If you do not need an Oral Glucose Tolerance Test, you will receive $30 for this research study.

If you do need an Oral Glucose Tolerance Test, you will receive $60 for the Oral Glucose Tolerance Test. If you qualify to get the MRI done or if you get the MRI done before we know the result of the Oral Glucose Tolerance Test, you will receive an additional $15. This is a total of $75 for the Oral Glucose Tolerance Test and MRI.

You will be given a parking pass.

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If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

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CLEVELAND MEDICAL CENTER
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Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the

following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate

against you based on your genetic information. This law generally will protect you in the following ways:

• Health insurance companies and group health plans may not request your genetic information that we get from this research

• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

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Principal Investigator: Katherine Kutney MD

regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later. 614-256-0640

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

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Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	
Signature of Participant	Date 6/22/17
X [redacted]	
Printed name of minor if used to obtain assent	
X	
Signature of Parent/Legal Guardian	Date
X	
Printed name of Parent/Legal Guardian	
X	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

X Katherine Kutney	6/22/17
Signature of person obtaining informed consent	Date
X	

Witness if required

X	
Signature of witness	Date
X	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

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IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 04/21/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
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Financial Information

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If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	
Signature of Participant	Date 6/28/17
X [redacted]	
Printed name of minor if used to obtain assent	
x [redacted]	6-28-17
Signature of Parent/Legal Guardian	Date
x [redacted]	
Printed name of Parent/Legal Guardian	
x [redacted]	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x [redacted]	6-28-17
Signature of person obtaining informed consent	Date
x Katherine Kutney	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 07/13/2017
IRB EXPIRATION DATE: 07/12/2018

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

15H227

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes**- this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study. People with borderline diabetes might complete the study if we do not know they have borderline diabetes until after the MRI is completed.
We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

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CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

UNIVERSITY HOSPITALS
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Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

If you do not need an Oral Glucose Tolerance Test, you will receive $30 for this research study.

If you do need an Oral Glucose Tolerance Test, you will receive $60 for the Oral Glucose Tolerance Test. If you qualify to get the MRI done or if you get the MRI done before we know the result of the Oral Glucose Tolerance Test, you will receive an additional $15. This is a total of $75 for the Oral Glucose Tolerance Test and MRI.

You will be given a parking pass.

Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
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Principal Investigator: Katherine Kutney MD

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Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the

following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate

against you based on your genetic information. This law generally will protect you in the following ways:

• Health insurance companies and group health plans may not request your genetic information that we get from this research

• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

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[X] YES, you may contact me for future research studies
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cell # (614) 256-0640

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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X	[redacted]	10/27/17
	Signature of Participant	Date
X	[redacted]	
	Printed name of minor if used to obtain assent	
x		
	Signature of Parent/Legal Guardian	Date
x		
	Printed name of Parent/Legal Guardian	
x		
	If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x	Katherine Kutney	10/27/17
	Signature of person obtaining informed consent	Date
x		

Witness if required

x		
	Signature of witness	Date
x		

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

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CONSENT FOR INVESTIGATIONAL STUDIES

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Study Procedures

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Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

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Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

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There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

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You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

If you do not need an Oral Glucose Tolerance Test, you will receive $30 for this research study.

If you do need an Oral Glucose Tolerance Test, you will receive $60 for the Oral Glucose Tolerance Test. If you qualify to get the MRI done or if you get the MRI done before we know the result of the Oral Glucose Tolerance Test, you will receive an additional $15. This is a total of $75 for the Oral Glucose Tolerance Test and MRI.

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Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

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• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr. Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later. 614-256-0640

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	01/03/17
Signature of Participant	Date
X [redacted]	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x [redacted]	7/3/17
Signature of person obtaining informed consent	Date
x Katherine Kutney	

Witness if required

x	
Signature of witness	Date
x	

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CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 04/21/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
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Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes-** this is also called Normal glucose tolerance
- **Borderline diabetes-** this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study. People with borderline diabetes might complete the study if we do not know they have borderline diabetes until after the MRI is completed.
We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

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Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

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Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

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There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

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You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

If you do not need an Oral Glucose Tolerance Test, you will receive $30 for this research study.

If you do need an Oral Glucose Tolerance Test, you will receive $60 for the Oral Glucose Tolerance Test. If you qualify to get the MRI done or if you get the MRI done before we know the result of the Oral Glucose Tolerance Test, you will receive an additional $15. This is a total of $75 for the Oral Glucose Tolerance Test and MRI.

You will be given a parking pass.

Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the

following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate

against you based on your genetic information. This law generally will protect you in the following ways:

• Health insurance companies and group health plans may not request your genetic information that we get from this research

• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign

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Principal Investigator: Katherine Kutney MD

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Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later. (614) 256-0640

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
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Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	5-6-17
Signature of Participant	Date
X [redacted]	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x [signature]	5-6-17
Signature of person obtaining informed consent	Date
x Katherine Kutney	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

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IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 04/21/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

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Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

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Study Procedures

As a study participant you will be asked to have blood drawn and an **MRI** of the liver done. We will also collect information from your past and current medical records.

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If you have **not had an Oral Glucose Tolerance Test in the last six months**

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MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

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Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

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There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

If you do not need an Oral Glucose Tolerance Test, you will receive $30 for this research study.

If you do need an Oral Glucose Tolerance Test, you will receive $60 for the Oral Glucose Tolerance Test. If you qualify to get the MRI done or if you get the MRI done before we know the result of the Oral Glucose Tolerance Test, you will receive an additional $15. This is a total of $75 for the Oral Glucose Tolerance Test and MRI.

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following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate

against you based on your genetic information. This law generally will protect you in the following ways:

• Health insurance companies and group health plans may not request your genetic information that we get from this research

• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign

regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	5/30/17
Signature of Participant	Date
X [redacted]	
Printed name of minor if used to obtain assent	
x [redacted]	5/30/2017
Signature of Parent/Legal Guardian	Date
x [redacted]	
Printed name of Parent/Legal Guardian	
x [redacted]	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x Allyson Tidball RN	05/30/2017
Signature of person obtaining informed consent	Date
x	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

IRB NUMBER: 09-16-01
IRB APPROVAL DATE: 01/10/2017
IRB EXPIRATION DATE: 09/12/2017

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

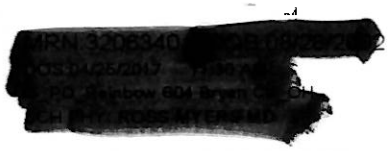
The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes-** this is also called Normal glucose tolerance
- **Borderline diabetes-** this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study.

We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.



UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hour and have one blood draw

If you have **not had an Oral Glucose Tolerance Test in the last six months**

- You will be asked to fast overnight for 10 hours and have an oral glucose tolerance test
- If this test is normal, your information will be used for this study
- If this test is abnormal, you are not eligible for this study. We will inform you and your doctor and you will still be compensated.

As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
Funds are given directly to the study participant regardless of age.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

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- Health insurance companies and group health plans may not request your genetic information that we get from this research

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

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Disclosure of your study records

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Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

614-256-0640

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

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Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[X] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	4-25-17
Signature of Participant	Date
X [redacted]	
Printed name of minor if used to obtain assent	
x [redacted]	4-25-17
Signature of Parent/Legal Guardian	Date
x [redacted]	mom
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x Katherine K MD	4-25-17
Signature of person obtaining informed consent	Date
x K Kutney	

Witness if required

x	
Signature of witness	Date
x	

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Please note: The use of "you" in this consent form refers to the person participating in the study—either you or your child.

If you are 18 years or older: This is a consent form. It explains a research study. If you decide that you want to be in this research study, then you will sign below to show that you agree.

Parents/Guardians: You have the option of having your child join this research study. This consent form is to obtain parental permission. It explains the research study. If you decide that your child can be in this research study, you will sign this form to show that you agree. Children 14-17 will also sign this form to show that they agree. Children 10-13 will sign a separate assent form to show that they agree.

Introduction/Purpose
You are being asked to participate in this study because you have cystic fibrosis.

The purpose of this research study is to learn more about fatty liver in patients with cystic fibrosis. Fatty liver is a condition where the liver has extra fat in it. Fatty liver is very common in obese people with type 2 diabetes. Fatty liver is usually not harmful, but sometimes does progress to severe liver disease. Studies have shown that many people with cystic fibrosis also have fatty liver but we do not know what this means. Most Cystic Fibrosis patients with fatty liver do not have problems from it. We want to see if people with CF related diabetes are more likely to have fatty liver than CF patients with no diabetes. This could lead to better treatments for CF diabetes or liver disease. One test for liver fat is called the "hepatic fat fraction" which is measured by an MRI scan.

People with cystic fibrosis have a diabetes test done each year called an Oral Glucose Tolerance Test. This test involves two blood draws and drinking a sugary beverage.
Based on the result of this test, patients can be separated into three groups:

- **No diabetes**- this is also called Normal glucose tolerance
- **Borderline diabetes**- this is also called Impaired glucose tolerance or impaired fasting glucose
- **CF related diabetes**

Only people with **No diabetes** or **CF related diabetes** will be included in this study.

We plan to enroll up to 30 people with CF related diabetes and 30 people with no diabetes.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

Study Procedures

As a study participant you will be asked to have blood drawn and an MRI of the liver done. We will also collect information from your past and current medical records.

If you have **CF related diabetes** OR you had **no diabetes on an Oral Glucose Tolerance Test in the last six months**

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As a study participant you will also be asked to have an MRI of the liver done.

Prior to having the MRI done, you will answer an MRI safety questionnaire to ensure the MRI is safe for you. The questionnaire will take several minutes to complete, however for example questions include details about allergies, surgical history, implanted devices (such as pacemakers) and tattoos. If you meet the MRI safety and eligibility criteria, you will be asked to lay flat and still on the MRI table for approximately 15 minutes.

Sometimes there are unforeseeable errors performing the MRI test or with the MRI equipment. If there are errors with any of the MRI tests performed during the study, you may be asked to return for an extra visit to complete an acceptable MRI.

MRI Results: If any clinically meaningful findings result from the MRI, the investigators will share this information with you and your treating physician.

We will ask whether you want to be in a separate study to develop MRI technology. That study involves taking MRI images of the liver, lungs, and kidneys. That MRI could be done at the same time that the liver fat fraction is done if you want. You do not have to be in that study to participate in this study. If you agree to also be in the MRI technology study, you will be asked to sign a separate consent form for that.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

We will collect information from your current and past medical records including height, weight, pulmonary function tests, medications, lab results, duration of diabetes and CF causing mutations.

Risks

Blood test: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting. The blood test will take about 15 minutes if you do not need an oral glucose tolerance test and 2 hours if you do need an oral glucose tolerance test. You will be asked to fast for 10 hours before the blood work which is inconvenient.

Magnetic Resonance Imaging: The MRI scan is painless. The only discomforts involved are that it is noisy and it could be uncomfortable lying in one position in a small space while the pictures are being taken. Some people experience nervousness or claustrophobia during an MRI. The MRI is open on both ends of the tube, which helps reduce claustrophobia. To minimize the noise from the MRI, you will be provided with headphones to wear during the exam and music is played in the MRI room. There is also a "panic" button that you can push at any time during the scan (for any situation including nervousness, claustrophobia, and/or from being uncomfortable from lying in the same position) and the scan will be stopped. The technician administering the MRI test will communicate with you using a two-way speaker and can also address any concerns that you may have during the exam. As with the standard MRI examination, there are no known side effects or risks associated with undergoing an MRI examination.

There is a small risk that your personal information could be breached.

Benefits

There is no direct benefit to you by your participation in this research study.
Your participation in this study may aid in our understanding of cystic fibrosis related diabetes and cystic fibrosis liver disease.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Hepatic Steatosis and Cystic Fibrosis Related Diabetes

Principal Investigator: Katherine Kutney MD

You can still participate in the study of MRI technology without participating in this study.

Financial Information

The study funds will cover the cost of all blood work.

You will receive 30 dollars for participation in this research study if you do not need an Oral Glucose Tolerance Test.
You will receive 75 dollars for participation in this research study if you do need an Oral Glucose Tolerance Test.
You will be given a parking pass.
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To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.

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If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

Any information or test results gathered for the purpose of this study will be stored on a secure password protected database. It will be accessed only from secure computers at University Hospitals Cleveland Medical Center. Your name, date of birth, and any other identifying information will be removed when the information is transferred off of the database for interpretation.

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CONSENT FOR INVESTIGATIONAL STUDIES

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Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent if you are found to not meet criteria for the study after the oral glucose tolerance test. You will still be compensated.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled " Hepatic Steatosis and Cystic Fibrosis Related Diabetes" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Kutney and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Name, Age, Date of Birth, Height, Weight, Pulmonary Function Test Results, Type of CFTR mutations, Screening blood test result, Medications and doses, Insulin Doses and diabetes duration (if applicable) This PHI will be used to find factors associated with fatty liver. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Katherine Kutney, Dr. Beth Kaminski, Dr. Kim McBennett, Dr. Thomas Sferra, Dr. Rose Gubitosi-Klug, Dr. Chris Flask, Shannon Donnola, and other staff from the Principal Investigator's medical practice group; University Hospitals, including

the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Katherine Kutney, Department of Pediatric Endocrinology, Rainbow Babies and Children's Hospital, 11100 Euclid Ave, Suite 737 Cleveland OH 44106. If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research

- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

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• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

Dr Kutney has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Katherine Kutney can also be contacted at 216-844-3666. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

(614)256-0640

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If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Future Research Studies

Please check one box below to indicate if we can contact you for future research studies.

[✓] YES, you may contact me for future research studies
[ ] NO, you may not contact me for future research studies

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Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X [redacted]	
Signature of Participant	Date 4-13-17
X [redacted]	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian	Date
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x [signature]	
Signature of person obtaining informed consent	Date
x KATHRINE KUTNEY	4-13-17

Witness if required

x	
Signature of witness	Date
x	

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