Prevention of non-alcoholic fatty liver disease (NAFLD) in Hispanic Children

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STUDY00002076

You Are Being Asked to Be in a Research Study

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 300 people who are being studied at Emory and Children's Healthcare of Atlanta.

Why is this study being done?
The purpose of this study is to find out whether eating a diet with a better balance of nutrients helps protect children from developing liver disease, specifically non-alcoholic fatty liver disease (NAFLD), compared to eating a regular diet. For reasons not yet clearly understood, Hispanic children are at a higher risk of developing NAFLD than other kids. You are being asked to be in this research study because you are a Hispanic child between the ages of 6 and 9 years.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, please read the information below to learn about the study and be sure that any questions that you have are answered.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate in 9 study visits over 2 years. You will also be asked to: do your best to follow the diet related instructions given, have blood tests, complete an MRI and do a sugar response test each year. All of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. Being in the study may or may not help you by reducing the possibility that you will develop liver disease. It will help doctors and others learn the best way to prevent liver disease in others in the future.

What are the risks or discomforts I should know about before making a decision?
The study will take time. The intervention that is being tested may not work any better than what is usually done to keep children healthy, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include loss of privacy and breach of confidentiality. A full list of possible risks and information about how likely and serious they are can be found in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
It is your choice whether or not to be a part of this study. Choosing not to is OK.

Costs
You will not have to pay for any of the study procedures. There is more information in the cost section below.

What Should I Do Next?

Read this form or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Make sure you understand which parts are research and which parts are care that you would receive even if you did not join the study. Take time to consider this and talk about it with your family and others as needed.

Emory University and Children's Healthcare of Atlanta
Consent to be a Research Subject / HIPAA Authorization

Title: Prevention of NAFLD in Hispanic Children

IRB #: STUDY00002076

Principal Investigators: [redacted], MD, MSPH and [redacted], PhD, RN

Study-Supporter: National Institutes of Health (NIH)

If you are the legal guardian of a child who is being asked to participate, the term "you" used in this consent refers to your child

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

What is the purpose of this study?

The purpose of this study is to find out whether eating a diet with a better balance of nutrients prevents the onset of non-alcoholic fatty liver disease (NAFLD) compared to eating a regular diet.

To be in this study, you must be between the ages of 6 and 9 years. You will not be allowed to join this study if you have diabetes or a number of other medical conditions. If you are eligible and agree to join this study, you will be one of about 300 children enrolled in this study at Emory and Children's Healthcare of Atlanta.

During the first visit, the criteria for being in the study will be examined. Bloodwork will be checked to see if your liver is working as expected and that you have normal liver enzymes. If the liver enzymes are high, you will not be able to continue in the study. A copy of the liver enzymes results will be given to you to share with your doctor.

What will I be asked to do?

If you meet all the entry criteria, you will be assigned by chance to be either a part of the group asked to make some changes to your diet or to continue your usual diet over the course of the two years of this study. After your baseline (first) visit the research team will open a sealed envelope to randomly choose which group you will be assigned to. It will be like flipping a coin (50/50).

There is a possibility of you having elevated ALT. In case that happens, the research team will automatically put you in the intervention arm if you still want to participate in the study.

You will be asked to participate in the study for about 2 years. You will need to come to some of your study visits after not having eaten for several hours (fasting) for labs and MRIs, so the study team will do their best to schedule morning appointments. The study team will give you a call to remind you about your upcoming appointments and will go over the specifics of fasting prior to each visit. The following table shows what is involved with each study visit.

Procedure	**Baseline**	**Month 1**	**Month 3**	**Month 6**	**Month 9**	**Month 12**	**Month 18**	**Month 24**
Location: R=research unit, H=home visit, V = Virtual, L = lab	**R**	**H / V**	**H / V**	**V / L**	**H / V**	**R**	**V / L**	**R**
Length of Time	*2-7 hours*	*1 hour*	*1 hour*	*1 hour*	*1 hour*	*2-7 hours*	*1 hour*	*2-7 hours*
Informed Consent	X							
Medical History Review	X	X	X	X	X	X	X	X
Physical Exam	X					X		X
MRI	X					X		X
Liver Ultrasound (Velacur)	X					X		X
Oral Sugar Test	X					X		X
Blood draw	X			X		X	X	X
Saliva collection	X					X		X
Questionnaires	X			X		X	X	X
Intervention Counseling	X	X	X	X	X	X		
Fasting (12 hour fast)	Yes	No	No	No	No	Yes	No	Yes

Learning about the Study

Today we will review the study with you and you can decide whether or not to participate. We will also ask about video-conference capabilities to conduct visits through video (on your phone or computer) if necessary. The study team will review the study visits with you and schedule your first appointment.

Before (and/or during) your first research appointment you will be contacted and asked to complete a total of one to two 24-hour food recalls by phone. Someone from the study team will call you and ask you what foods you consumed the previous day.

Screening and Baseline Visit

When you come to the research center for your screening and baseline visit, we will review the study with you again and you can decide whether to participate. Your parent will be asked to sign permission forms allowing us to look at your medical records.

We will ask you questions about your health and medical history and ask you to complete a few questionnaires. At this visit we will measure your height and weight and check your blood pressure, pulse, etc. (vital signs). We will also measure your hips, waist circumference, and thighs. The study physician may feel your abdomen to check your liver size. A picture of the skin on your neck will be taken. Labs will be drawn at this visit. Approximately 1 tablespoon (20 mL) of blood will be drawn for lab tests. You will be asked to spit into a funnel to collect saliva (2mL). We will ask you questions about your current diet and food preferences.

At this visit you will undergo a Magnetic Resonance Imaging (MRI). The MRI is a way to look inside the body without x-rays. This test will measure the amount of fat in the liver and provide a number with an estimate of the amount of fat. If the images from the MRI are not adequate, we may ask you to repeat the scan.

Also, you will undergo a Liver Ultrasound (Velacur), which is an imaging procedure that uses sound waves to collect imaging of the inside of your body. Your liver will be examined to assess if there is any fatty liver.
You will be asked to come to the visit with an empty stomach. This means not eating or drinking anything for 12 hours (in most cases this will be since 7pm the night before). At the visit you will meet with the study nutritionist. The nutritionist will ask you questions about what you usually eat and provide you with information.

Researchers will ask you about how you want to be contacted throughout the study, whether by text, phone calls, emails, mail, or all of these. They will use your preferred method as much as possible.

Intervention

If you are in the study diet group, it will take place for the whole 2-year study and may involve changing some of the foods and drinks that your family typically has. A nutritionist will first work with you and your family to make sure that the research diet is as close as possible to what you all usually eat. The nutritionist will also work with you to remove foods that aren't part of the study diet from the home. In their place, the researchers will provide all the food needed for breakfast, lunch and dinner for your entire family for the first 4 weeks of the study. Everyone in the family needs to be willing to eat the foods provided as much as possible for the 4 weeks. It is very important that you only eat the study diet.

After the first month, the study nutritionists will continue to work with your parent and you to select the best foods for your family within the diet plan. This includes working with your parent to do grocery shopping 3 times, approximately every 3 months in the first year. This will be done either in person in the grocery store or virtually via grocery store websites. The study team will contact you approximately monthly to discuss how things are going with the diet throughout the first year and to help you make adjustments where needed.

If you are in the usual diet group, you will continue to eat how your family normally eats. You will be provided money to assist with the cost of your food up to 7 times during the first year. The study coordinator will provide information about healthy activities that you can do at home.

Home Visit - About 10 days after the first (baseline) visit, the study nutritionist or coordinator may visit your home or contact you by phone to review your study instructions with you and assess your current diet.

Month 1, 3, 6, 9 and 18 Phone calls
We will ask you questions about any changes to your health. We will talk to you about the study intervention and provide additional counseling.

Month 6 and 18 Visits
At this visit we ask you to have a lab test done to check to see if blood markers related to the study are changing. Approximately 2 teaspoons (10 mL) of blood will be drawn for lab tests.

Month 12 and 24 visits
At this visit we will measure your height and weight, blood pressure, and other vital signs. The study physician will also conduct a physical exam. We will ask you questions about your health and medical history and ask you to complete a number of questionnaires. Labs will be drawn at this visit. Approximately 3 tablespoons (47 mL) of blood will be drawn for lab tests. You will be asked to spit into a funnel to collect saliva (2mL). We will ask you questions about your current diet and food preferences. You will undergo an MRI, liver ultrasound and an Oral Sugar Test plus a meal test (blood after eating breakfast). You will need to not eat (fast) for 12 hours before these appointments.

Before each of these visits we will conduct one to four 24-hour food intake assessment by phone. Someone from the study team will call you and ask you what foods you consumed the previous day.

Virtual Visits
Some visits will be done virtually, if possible. We will discuss your teleconference capabilities with you. Some visits may be partially conducted over the phone as an alternative.

Who owns my study information and samples?

If you join this study you will be donating your samples and study information. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.

The most common risks and discomforts expected in this study are:

- *Blood draws* – Blood drawing is mildly painful and can cause bruising. Very rarely, dizziness or fainting, blood clots, bleeding or an infection can occur. If numbing cream is used for blood draws, it may cause pain or irritation. The skin could temporarily turn red, white, or develop a rash. This usually doesn't last very long.
- *MRI* - this machine uses a large magnet and radio waves but no x-rays. You will lie quietly on a table for approximately 15-30 minutes. The machine makes a loud, banging noise while it is taking pictures. You will be

given a set of ear plugs to help with the noise. There are no known side effects from exposure to magnetic fields. You may experience: claustrophobia (fear of confined areas), anxiety, discomfort and fatigue (tiredness) from lying still in a confined space. If you have metal clips or plates in your body or a pacemaker (for your heart) you should tell the study staff. The MRI staff will review special conditions for safety.

- *Saliva collection* – You may experience minimal discomfort during the saliva collection. If your mouth is dry, we will have pictures of foods, such as lemons to help you produce more saliva.
- *Incidental findings* –There is a possibility that while reviewing your MRI we may see an abnormality that we did not expect to see in this study. This is called an “incidental finding”. If there is an incidental finding, your study doctor will discuss this with you. You do not have an option to decline information about an incidental finding. If you want, we will give information about this incidental finding to your primary doctor. An incidental finding may cause you to feel anxious. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.
- *Loss of privacy or breach of confidentiality* – there is a small risk of loss of confidentiality. The study team will follow all procedures required to protect you. Efforts will be made to ensure that all personal information remains confidential. All data will be stored in locked offices and password-protected computers. Your personal identity will be protected in any publication.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is designed to learn more about ways that diet may or may not influence the onset of liver disease, particularly NAFLD. There is a possibility that being in the study may delay or prevent the onset of NAFLD. You may benefit by learning of any incidental findings found by lab results or the MRI. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will get up to $100 in gift cards for each completed study visit to compensate you for your time and effort. We will provide you with transportation to and from your research clinic visits, unless you prefer to come on your own. Cost related to parking will be covered by the study. If you do not finish the study, we will compensate you for the visits you have completed. You will get $300 total, if you complete all study visits.

If you are in the diet intervention you will receive food for your entire family for 4 weeks. You will also have groceries provided during guided grocery events with the nutritionist at 3 points throughout the first year of the study. If you are withdrawn from the study you will not receive any food after the date of withdrawal. The total value of the food that you will receive during this study will total up to $1,400.

If you are in the control arm you will receive $400 in gift cards in the first month of the study for groceries. Additionally, you will receive $100 every 3 months 3 times for additional groceries. The total value of gift cards for groceries is up to $700. If you are withdrawn from the study you will not receive the gift cards any more. Gift card amounts will be pro-rated based on participation in the study.

Emory may be required to report your payment(s) to the IRS depending on how much you receive in a year. You must give the researchers a valid Social Security number or Taxpayer Identification Number for IRS reporting purposes. If you do not, your amount may be reduced because taxes are taken out. Please talk to your study team for more details.

A company called Greenphire is working on behalf of the study to compensate participants. Greenphire will need to collect certain personal information about you to set up your account. The company will see this study title, but will not any research-related information about you

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. The study doctor will discuss these with you. Taking part in this study, however, may make you unable to participate in some other research studies if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like Clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases
- Giving law officials information about abuse of a child, elderly person, or disabled person
- Giving out information to prevent harm to you or others
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data. Although your genomic information is unique to you, you do share some genomic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genomic information from them could be used to help identify you. Similarly, it may be possible that genomic information from you could be used to help identify them. If your genomic information is linked back to you, someone might use this information to learn something about your health.

Your data and specimens from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we *do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.*

We will use your sample and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

In general, we will not give you any individual results from the study of the samples you give us except for the clinical blood work such as the liver enzymes and glucose measurements. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Genetic Information

The saliva and part of the blood we will obtain may be used for future genetic research. DNA specimens will be stored in the Emory Health Science Research Building in a repository. The repository collects, stores, and distributes DNA and study data from people with many kinds of disorders, from unaffected family members, and from other healthy people. The purpose of this collection is to make DNA and data available for use in health research. Your DNA and data will be used by the researchers carrying out this study, but it also may be used by other researchers, both during the study and after it ends. Your DNA and data may be stored indefinitely.

Your saliva and blood samples and data will be labeled with a code number. Your name, address, social security number, date of birth and other personal identifiers will not be included in the repository, and hence the repository will not be able to give out your name or other information that identifies you to the researchers who use your DNA and data.

How is my Genetic Information Protected? What are the Risks?

The Genetic Information Nondiscrimination Act (GINA) is a federal law that 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 deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, Medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

It is possible that we will discover that you have a gene variant/medical issue that is unrelated to the purpose of this study. If we believe that the information is of urgent medical importance, we will share this information with you. You should not assume that if you are not contacted, that you do not have any gene variants that might be related to a disease.

Privilege

In the State of Georgia, in some circumstances your genetic information has may have special legal protections called "privilege." This means that the information cannot be used as evidence in a court. By allowing us to use and disclose your genetic information for this research study along with other information about you, that genetic information used in the research may no longer have that legal protection. Other protections described in this form will still apply. There are also other confidentiality protections for research data in general under Georgia state law.

Medical Record

If you have been an Emory and Children's Healthcare of Atlanta patient before, then you already have an Emory and Children's Healthcare of Atlanta medical record. If you have never been an Emory and Children's Healthcare of Atlanta patient, you do not have one. An Emory and Children's Healthcare of Atlanta medical record will be made for you if an Emory and Children's Healthcare of Atlanta provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Children's Healthcare of Atlanta medical record you have now or any time during the study.

Emory and Children's Healthcare of Atlanta may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Children's Healthcare of Atlanta medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: the results of some laboratory tests, the oral sugar test, as well as some of the MRI measurements.

You will be getting a scan for research purposes only. The research does not require the scan to be read for healthcare purposes, however we will do our best to have a reading by a healthcare profession and place this in your medical record. The information in your medical record will be available to you and to your other doctors.

In this study, some of the blood work will be available in your medical record including tests like liver enzymes and glucose levels. Some tests and procedures done at non-Emory and Children's Healthcare of Atlanta places may not become part of your Emory and Children's Healthcare of Atlanta medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

The sponsor may choose not to pay for Subject Injury Costs for any subject, no matter if the subject is insured, or how he/she is insured. *If you believe you have become ill or injured from this research, you should contact* [redacted] *at telephone number:* [redacted]*. You should also let any health care provider who treats you know that you are in a research study.*

If you get ill or injured from being in the study, Emory and Children's Healthcare of Atlanta *will help you to get medical treatment. Neither* Emory, Grady Health System, Children's Healthcare of Atlanta *nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.*

For Emory and Children's Healthcare of Atlanta*, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an* Emory or Children's Healthcare of Atlanta *employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.*

Costs

There are no costs to you, research or standard of care related, associated with the study. There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done, specifically:

- The study team will ask you to complete an Early Termination visit. This visit will be similar to the Baseline visit.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

- You are not complying with the study requirements or visit schedule.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures, and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study.
- Emory and Children's Healthcare of Atlanta may use and disclose your PHI to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The National Institute of Health is the Supporter of the study. The Supporter may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Supporter may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- AMRA
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Children's Healthcare of Atlanta offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory and Children's Healthcare of Atlanta IRBs, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study
    - Government agencies that regulate the research including: Office for Human Research Protections; National Institute of Health
    - Public health agencies
    - Research monitors and reviewer
    - Accreditation agencies
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: [redacted]

At that point, the researchers would not collect any more of your PHI, but they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact the study team at [redacted]

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at [redacted] or [redacted] or [redacted]:

- if you have questions about your rights as a research participant
- if you have complaints about the research or an issue you rather discuss with someone outside the research team

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke**.

If you are a patient receiving care at Children's Healthcare of Atlanta and have a question about your rights, please contact the Director of Research Administration at [redacted]

If you are a patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at [redacted]

Optional Study – CGM:

Glucose (sugar) measurement is often done on an empty stomach but measurements after meals, snacks and throughout the day are also important. This optional study will use a small device called a "continuous glucose monitor" that attaches to the skin on the belly to measure glucose continuously for about 20 days after the baseline visit and about 10 days before the year 1 visit and year 2 visit. The CGM device is approved for use in children and is often used by people with diabetes to monitor their sugar levels.

If you decide to participate in this part of the study, the study staff will help you place the small CGM on your skin and you will wear it for 10 days after the baseline visit. During the home visit, it will be taken off and a second device will be placed for the next 10 days. We will ask you to mail us that device or we can pick it up from your house. At the end of year 1 and year 2 this will be repeated. The device will be mailed with instructions or a study staff will come to your house to help you put it on.

Optional Study- OGTT/MMT

The researchers would like to see whether the study diet improves your body's ability to break down sugar. In order to do this, they will do an optional sugar test at the Baseline, Month 12, and Month 24 research visits. This involves having you drink a sweet beverage within a few minutes and having your blood samples taken approximately 8 times over 4 hours from an access placed in your vein by a research nurse. Once placed, this will allow samples of your blood to be taken at multiple time points without discomfort. By taking several samples of your blood as your body processes the sugary drink the researchers will be able to tell how quickly your body can process sugar. This test will last 4 hours. Then you will be given breakfast. The breakfast will be measured to be about 1/3 of all of the food you typically need in a day. After you eat the breakfast, small blood samples will be collected from the IV approximately 4 more times for a total of about 2 tablespoon (2 mL) of blood. Then the IV will be removed and the research visit will be concluded.

What are the possible risks and discomforts?

We are using a device called the Dexcom G6 that is approved for children to use. It can cause a small amount of discomfort when putting it on and you can have some minor irritation or pain at the site. Rarely it can cause infection or inflammation at the site and very rarely the device could break. It is important to call the study staff if you notice any of these issues.

Additional Compensation:

If you participate in the CGM study, you will be compensated an additional $50 for each time you complete it (up to $200 max). If you participate in the OGTT/MMT you will get $100 per completed visit. This will be in the same form that you receive payment for your study visits.

Optional substudy – Elevated ALT

Researchers of this study would like to find out whether eating a diet with a better balance of nutrients helps protect children from liver disease progression. You will be part of this study if you consent for it and because you are a Hispanic child between the ages of 6 and 9 years with liver disease diagnosed by elevated ALT.

What are the possible risks and discomforts?

The risks and discomforts are the same as being part in the main study intervention arm, mention in page 5 of this consent.

Additional Compensation:

If you participate in these sub study, you will be compensated in the same way and schedule as intervention patients in the main study. There are no extra payments. This will be in the same form that you receive payment for your study visits.

PHI That Will be Used/Disclosed for Optional Studies:

- The PHI that we will use and/or disclose (share) for the optional research study includes: Medical information about you including your medical history and present/past medications
- Results of exams, procedures and tests you have before and during the study
- Laboratory test results

Purposes for which your PHI will be Used/Disclosed for Optional Study:

We will use and disclose your PHI for the conduct and oversight of the optional research study.

Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study:

You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study. You can still be in the main research study even if you don't participate in the optional study.

People Who Will Use/Disclose Your PHI for Optional Study:
The same people and groups who will use and disclose your PHI for the main study will also do so in connection with this optional research study.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact [redacted] at [redacted].

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Consent and Authorization

Consent and HIPAA Authorization for Optional Study/Studies:
Please check and initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

☐ Yes ☐ No **[Continuous Glucose Monitor (CGM) Sub-study]** ____________**Initials**

☐ Yes ☐ No **[OGTT/MMT Sub-Study]** ____________**Initials**

☐ Yes ☐ No **[Screen Fail ALT Sub-study]** ____________**Initials**

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

____

Name of Subject

____ ____________________

Signature of Subject (18 or older and able to consent) **Date** **Time**

____ ____________________

Signature of Legally Authorized Representative **Date** **Time**

____

Authority of Legally Authorized Representative or Relationship to Subject

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TO BE FILLED OUT BY STUDY TEAM ONLY

____

Name of Person Conducting Informed Consent Discussion

____ ____________________

Signature of Person Conducting Informed Consent Discussion **Date** **Time**