VUMC Institutional Review Board
Parental Informed Consent Document for Research

Study Title:	Impact of a Low-Carbohydrate Diet on Glycemic Control and Lipids in Pediatric Type 1 Diabetes
Version Date:	11/01/19
PI:	Sara H. Duffus, MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

What is the purpose of this study?
Your son or daughter is being asked to be part of this research study because he or she has type 1 diabetes (T1DM).

The purpose of this research study is to learn how different aspects of diabetes management affect your adolescent's health. These factors include diabetes self-care tools, what he or she eats, exercise, and other factors. As a participant in this study, we may ask your child to follow a certain exercise or nutrition plan or learn more about helpful ways to manage his or her diabetes. All of these factors have an impact on blood sugar, cholesterol, and how your child feel about how hard or easy it is to take care of diabetes. We will be studying how these factors impact his or her blood sugar (we will measure HbA1c and use your child's continuous glucose monitor data), cholesterol, and quality of life. We are also interested in how these factors affect how you feel about caring for your child's diabetes.

Your child is being asked to take part in a 14-week study. If you decide to be part of the study, there will be three study visits and three phone calls. The study visits will happen in the Vanderbilt Eskind Pediatric Diabetes Clinic. Two of the three clinic visits will be part of your child's regular diabetes follow up visits. At the beginning of the study, you and your child will meet with a member of the research team to discuss his or her current exercise and diet in addition to learning more about other ways to help manage diabetes at home.

We will draw blood at the beginning and end of the study to measure your child's HbA1c, cholesterol, and ketones. We will also ask your child to use his or her insulin pump and continuous glucose monitor (CGM) during the entire study. We will also ask your child to take 3 surveys about his or her symptoms and how he or she feels at the beginning and end of the study. Additionally, we will ask you to complete 2 surveys at the beginning and end of the study.

We plan to enroll 45 participants at Vanderbilt University Medical Center in this study.

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Your child does not have to be in this research study. You may choose for him or her not to be in this study and get other treatments without changing your child's healthcare, services, or other rights. Your child can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want your child to be in this study. Your child's medical record will contain a note saying he or she is in a research study and may contain some research information about you. Anyone you authorize to receive your child's medical record will also get this information.

Side effects and risks that you can expect if your child takes part in this study:
It is possible that your child will not directly benefit from this study.

It is unlikely that participating in the research will make your adolescent sick. There are some things that could cause temporary discomfort. Here are the things you should know about:

- Blood draw: drawing blood can possibly cause bruising, bleeding, discomfort, and infection. Sometimes people may feel sick to their stomach, be lightheaded, or even faint during this procedure. We will attempt to minimize these possibilities by cleaning the skin and having your child lie down or sit during this procedure.

There are several other potential risks to changing the way your adolescent eats that you should know about:

- Slow growth and low blood sugar: if your adolescent changes the way he or she exercises too much or what he or she eats in a way that does not give enough calories, it could cause him or her to have trouble gaining weight and growing taller or make blood sugars become too low. However, the lifestyle changes we will recommend will include the right amount of calories for your child's weight and activity level.
- Diabetic ketoacidosis: insulin helps stop the body from making ketones. If there is a significant increase in activity level or decrease the amount of carbohydrates eaten so much that your child does not need to give as much insulin, his or her body could possibly start to make more ketones. This could possibly lead to diabetic ketoacidosis, where lots of ketones build up in the body. However, we will not ask your child to exercise so much or eat so few carbohydrates that he or she does not need insulin at meals. So we anticipate that your child will not be making more ketones than usual.

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Good effects that might result from this study:
The benefits to science and humankind that might result from this study:
Many lifestyle factors, including diet and exercise, affect blood sugar in patients with diabetes. Long periods of time with high blood sugars lead to increased risk of heart disease for patients with diabetes. This study will help us better understand how the lifestyle of patients with diabetes affects their blood sugar. We hope that this will help us know how to advise patients with diabetes to help improve their blood sugar. There is no guarantee that your child will directly benefit from being in this study.

Procedures to be followed:
For 12 weeks of the study, we may ask your child to make changes to his or her lifestyle, including changes to activity level, dietary intake, or other ways of taking care of diabetes at home. We may ask your child to track some of these practices on a smart phone app. We will also ask your child to wear his or her CGM and use the insulin pump for all insulin administration and recording of carbohydrates during the entire 12 week study period.

Payments for your time spent taking part in this study or expenses:
Your child will be compensated for his or her participation in the study. We will ask for your child's social security number and address before he or she is compensated. You will be mailed a check equal to the dollar amount below.

- **Study Visits:** The initial screening visit will last approximately 2-3 hours. Each of the additional 2 study visits will last approximately 1-2 hours. Participants who complete these visits and complete all required pre-visit tasks will be compensated $25 for each visit (total of $75 if all three study visits are fully completed).
  - For study visit 1, participants will receive $25 for attending the visit.
  - For study visit 2, participants will receive the following:
    - $10 for attending the visit
    - $10 if he or she has tracked 2 or more meals per day in the smartphone app on 6 or more of the 7 days preceding the study visit
    - $5 if he or she has photographed 2 or more meals in the smartphone app in the 24 hours preceding the study visit
- **Phone Calls:** Each phone call will last 30-60 minutes. Participants who complete these phone calls will be compensated $10 for each phone call if all required pre-phone call tasks are completed (total of $30 if all three phone calls are fully completed).
  - For each phone call, participants will receive the following:

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- $5 for participating in the phone call
- $5 for uploading both pump and continuous glucose monitor data via online portal for study personnel to review

Costs to you or your child if you take part in this study:

There is no cost to you or your child for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then your child and/or your child's insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care your child would normally receive for treating your child's illness or the costs of any additional care. There are no plans for Vanderbilt to give you or your child money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel your child has been hurt by being a part of this study, please feel free to contact Dr. Sara Duffus at 615-322-7427. If you cannot reach the research staff, please page the study doctor at 615-835-0218.

For additional information about giving consent or your child's rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
- Your child becomes pregnant
- If there is concern that staying in the study might be harmful to your child
- Your child no longer meet the requirements of the study

If you are taken out of the study, you will be told why.

What will happen if you decide to stop being in this study?
If you or your child decide to stop being part of the study, you should tell your child's study doctor.

Clinical Trials Registry:

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

Confidentiality:
Only research associates in our laboratory or individuals directly involved in the study will have access to data or protected health information. Research records and data with personal identifiers will be stored in our locked offices or on a secure data collection program (REDCap). Only the study doctor and key personnel on the research team will be able to access study patients' names or other identifying data. Data from the study will be maintained in HIPAA-compliant, password-protected databases. Urine samples from the pregnancy test will be immediately discarded.

Vanderbilt may share your adolescent's information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Duffus, and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you or your adolescent for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, your child's study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if your child needs medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that your child makes him or herself are also not protected.

Privacy:
Any samples and information about your child may be made available to others to use for research. To protect your privacy, we will not release your child's name. Your child will not receive any benefit as a result of the tests done on his or her samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

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Study Results:
A summary of the study results will be made available via https://clinicaltrials.gov/ once the project is complete.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your child's private health information. By signing this document, you agree that your child's health care providers (including both Vanderbilt University Medical Center and others) may release his or her private health information to us, and that we may use any and all of his or her information that the study team believes it needs to conduct the study. Your child's private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your child's private health information include the researchers and their staff. Additionally, we may share your child's information with other people at Vanderbilt, for example if needed for his or her clinical care or study oversight. By signing this form, you give permission to the research team to share your child's information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your child's information keeps it confidential, but we cannot guarantee that his or her information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, your child may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your child's information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

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You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you or your child decide not to take part in this research study, it will not affect your child's treatment, payment or enrollment in any health plans or affect your child's ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to allow my child take part in this study.

_____ _____

Date Signature of consenting parent

Consent obtained by:

_____ _____

Date Signature

_____

Printed Name and Title

Time: _____