

PARENTAL PERMISSION FORM
CONSENT FORM: Ages 18 and up
ASSENT FORM: Ages 14-17

**Study Title: "Treatment with the Specific Carbohydrate Diet, for
Children with Clostridium Difficile Infection"**

Principal Researcher: David Suskind, MD

The Research Team:

Name/Degree	Title	Department	Phone Number
David Suskind, MD	Principal Investigator	Gastroenterology	206-987-2521

If you have questions about your rights as a research study participant, you can call the Institutional Review Board at (206) 987-7804.

24 hour Emergency Contact Number(s): 206-987-2000, ask for the on-call gastroenterologist

1. Researchers' Statement:

You have the option to take part in a research study. The goals of this form are to give you information about what would happen in the study if you choose to take part and to help you decide if you want to be in the study.

Feel free to take notes, write questions or highlight any part of this form.

Potential Participants 18 years and older: This is a consent form. It provides a summary of the information the research team will discuss with you. If you decide that you would like to take

part in this research study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy of this form for your records.

Potential Teen Participants: This form also serves as an assent form. That means that if you choose to take part in this research study, you would sign this form to confirm your choice. Your parent or guardian would also need to give their permission and sign this form for you to join the study.

Parents/Guardians: You have the option of having your child or teen join a research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

The word "you" in this form refers to your child/teen.

2. What you should know about this study:

- This form explains what would happen if you join this research study.
- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to be in the study, it will not affect your care at Seattle Children's.
- If you say 'Yes' now, you can still change your mind later.
- You can quit the study at anytime.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

3. What is the goal of this study?

The goal of any research study is to answer questions. We (the research team listed on the front of this form and our staff) are doing this research study to answer questions about a nutritional therapy called the Specific Carbohydrate Diet (SCD) for children with active Clostridium Difficile Infection. The SCDiet is a diet where all grains such as wheat, barley, corn, rice are restricted. Most dairy products (except certain yogurt) are also restricted. The diet mainly consists of meat, fruits, vegetables, nuts, oils and honey, and is offered to individuals with active Crohn's and Ulcerative Colitis disease, as part of standard of care at Seattle Children's.

For this study, we will be looking at a specific carbohydrate diet specifically, we want to know:

- **Is the SCD well tolerated?**
- **Is SCD effective for the treatment for Clostridium Difficile Infection?**

4. Why do I have the option of joining the study?

You have the option to take part in this research study because you are between the ages of 18 months -21 years of age with mild to moderate Clostridium Difficile Infection.

5. How many people will take part in the study?

We think that about 5 people will take part in this research study at Seattle Children's.

6. If I agree to join this study, what would I need to do?

A Chef knowledgeable in the SCD diets will prepare your meals. Recipes will be predetermined and you will be able to decide the meals you eat based upon menus that will be provided. We will give you a cookbook and an education book about the SCD study. We will also help you manage your diet at each visit.

If you join the study, you would also have some tests and exams. All the visits you would need to make are listed in the chart below.

These tests and exams help us find out if being in this study causes any effects that are important to know about. We use them to check on the safety of people in the study. We also use them to learn if an experimental treatment is helping or not. There are no extra research visits for this study. All visits listed are part of your normal clinical follow up.

Explanation of Research Tests or Procedures:

The tests that will be completed during the study, are as follows:

- **Blood collection** - We will collect clinical labs with a needle poke at the screening visit to assess how you are doing. All of these labs are collected for research purposes.
- **Stool collection** - We will collect stool at each visit. Stool will be collected for research purposes, while some will be used to better understand your gut microbiome and proteins in your stool. We will provide a collection hat with a specimen cup for the collection. Stool can be collected at home and brought to the clinic.
- **Nutritional assessment** - At the initial screening visit you will meet with a dietitian. The dietitian will review your nutrition diary and help make adjustments to your diet as needed.
- **Physical Exam** - At each visit, you will have a physical exam completed by a doctor. The physical exam is part of your clinical care and is not part of the research study.
- **Diaries** - You will need to keep a nutritional diary for the three days prior to your clinic visit. During this time, you will need to keep a detailed record of what and how much you have been eating. The dietitian will use this information during the visit.
- **Questionnaires** - At each visit, you will be asked to complete questionnaires about your quality of life and sleep habits. These questionnaires will be administered as part of research.
- **Medical History** - We will collect information about your medical history and your current medications.

Research Study Visits:

Visit #	Procedures	Location	How much time the visit will take
ALL visits (initial evaluation, week 1, week 2, week 4, and week 12	<ul style="list-style-type: none"> • Blood tests- approximately 2 teaspoons will be collected • Stool test • Nutrition Assessment including providing books on SCD • Review of diet • Physical Exam, including height, weight and vital signs • Questionnaire completion 	Seattle Children's	1-2 hours

7. How long would I be in the study?

If you choose to take part in all the study visits, you would be in the study for approximately 12 weeks.

If you join the study, you can decide to stop **at anytime for any reason**. If you decided to stop, you would need to talk with Dr. David Suskind so you leave the study in a safe way.

The research study doctor could also decide to take you out of this study. This might happen if we find out that it is not safe for you to stay in the study. Alternatively, it might happen if you cannot come to enough of the study visits. If we ask you to leave the study, we would always explain why.

8. What are the potential harms or risks if I join this study?

Specific Carbohydrate Diet (SCD)

We anticipate that the Specific Carbohydrate Diet (SCD) will be well tolerated. However, changing the way you cook or shop, may involve more time. Additionally, you may not like all the food that is made for this study. The food that you purchase for snacks may be more expensive. You may feel uncomfortable discussing food with the dietitian. We will provide you with resources to help make this discussion comfortable. You may lose weight while on this dietary therapy. We will have you work closely with a dietitian to ensure you are receiving enough calories to support your needs.

Blood draws

You may have pain and/or bruising at the site of the blood draw. Rarely, some people feel faint or lightheaded during this procedure. These risks are considered minor and are temporary.

Stool collection (microbiome and protein analysis)

Stool collection is generally thought to be safe. We will provide kits for you to collect the stool. You may feel embarrassed at having to collect a stool sample. You can collect it at home for more privacy and bring with you to the research visit. If you have questions about collecting the stool sample, please ask the study staff.

Vital signs

We will be collecting your blood pressure, pulse, temperature, height and weight at each visit. These measurements are generally well tolerated. You may feel uncomfortable being weighed. We do not have to tell your weight if you do not want to know. Additionally, the cuff to measure your blood pressure may squeeze your arm tightly. These risks are considered minimal and temporary.

Social

You may feel sad or upset if your symptoms do not improve while you are on the SCD. You might feel uncomfortable answering some questions on the survey. You could skip any questions you did not want to answer.

Loss of Confidentiality

There is a risk that your confidentiality or privacy could be breached. This would mean that someone other than the research team or our collaborators might find out that you were in the research or see your answers or medical information.

9. What are the potential benefits if I join this study?

Potential Benefits for You:

We do not know if this study will be any benefit to you.

Being in this study may benefit you in the following ways:

- It may help reduce symptoms of your Clostridium Difficile Infection.
- It could be an active form of treatment for your Clostridium Difficile Infection.
- It may delay the need for additional therapies to treat your Clostridium Difficile Infection

Potential Benefits for Others:

- We hope to use information we get from this study to benefit others who have mild to moderate Clostridium Difficile Infection.

10. What other options do I have?

There are other options if you choose not to participate in this study. You may treat your Clostridium Difficile Infection, with antibiotics or receive a Fecal Transplant. You may also decide to start the SCD without being in this study. Please talk to the study doctor about these other options.

11. How would you keep my information confidential?

If you take part, we will make every effort to keep your information confidential.

We will store all of your research records in locked cabinets and secure computer files. We will not put your name on any research data. Instead, we will label your information with a study number. The master list that links a person's name to their study number is stored in a locked cabinet or on a secure computer file.

If results of this research are published, we would not use information that identifies you.

If you decide to take part in this study and have, your samples stored:

- We would store your stool samples at the University of Washington and the University of California, Irvine. We would keep them indefinitely. The samples will be coded with a unique study number and date of collection.
- We would share your stool samples with Dr. Sam Miller at the University of Washington for microbiome analysis and Dr. Katrine Whiteson at the University of California, Irvine for protein analysis.
- Your samples or information may be used in future research on protein analysis and the microbiome.
 - We would not be able to give you the results from research that is done using your samples.
 - Your samples could be used to make new products, tests or findings. These may have value and may be developed and owned by the research team and/or others. If this happens, there are no plans to pay you.

We would only use your information for research. These are some reasons that we may need to share the information you give us with others:

- If it is required by law.
- If we think, you or someone else could be harmed.
- Sponsors, government agencies or research staff sometimes looks at forms like this and other study records. They do this to make sure the research is done safely and legally. Anyone who reviews study records would keep your information confidential.
 - Agencies or sponsors that may look at study records include:
 - Seattle Children's Hospital
 - University of Washington
 - University of California Irvine
 - Others responsible for watching over the safety, effectiveness, and conduct of the research.

If you join this study, we would put information about this study in your medical record. We do this because the research study involves patient care.

We would keep your results indefinitely.

12. Would it cost me money to be in the study?

This study is a clinical trial that involves two types of services. Some services are related to the research. Other services are related to your usual medical care.

Services related to the research are done only for the purpose of the study. These include:

Initial evaluation:

- Microbiome/protein analysis
- Stool testing(for C-Diff Antigen/Toxins)
- Blood tests(CBC w/differential and platelets, CRP, ESR, and Albumin)
- Books for SCD (including "Breaking the Vicious cycle" and "Recipes for the Specific Carbohydrate Diet")

Weeks1, 2, 4, and week 12 visits:

- Stool studies for microbiome/protein analysis
- Stool testing(for C-Diff Antigen/Toxins)

There would be no cost to you and no cost to your insurance company for these research services.

Services related to your usual medical care are part of your routine care. You or your insurance company would be charged for these services. If you join the study, costs to you would include your usual insurance deductibles and co-payments. All of your insurance company's usual rules would apply.

These services include:

- Clinic visit fees for all visits
- Nutrition Assessments
- All other lab and stool tests (not including the research labs listed above)

13. What if I were injured because I joined the study?




If you are injured, as the direct result of this research study, Seattle Children's Hospital would provide treatment. We would refer you for treatment if needed. No funds have been set aside for this treatment. You or your insurance company would be billed for the treatment.

It is important that you tell the Principal Researcher David Suskind, MD, if you think that you have been injured, as a result of taking part in this study. You can call him/her at 206-987-2521.

14. Would I be paid if I join this study?

You will not be paid to take part in this study. This has been decided, as all study food, minus snacks, will be provided at no charge to you.

15. Who do I contact if I have problems, questions or want more information?

 If I have questions or would like to know about ...	 You can call ...	 At ...
<ul style="list-style-type: none"> • Emergencies • General study questions • Research-related injuries • Any research concerns or complaints 	<p>David Suskind, MD</p>	<p>Phone: 206-987-2521</p>
<ul style="list-style-type: none"> • Emergencies • General study questions • Research-related injuries • Any research concerns or complaints 	<p>Mason Nuding</p>	<p>Phone: 206-987-0055 Pager: 206-998-8194</p>
<ul style="list-style-type: none"> • Your rights as a research participant 	<p>Institutional Review Board This is a group of scientists and community members who make sure research meet legal and ethical standards.</p>	<p>Phone: (206) 987-7804</p>

More Information:

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

16. If I join the study, can I stop?

Yes. Taking part in research is always a choice. If you decide to be in the study, you can change your mind at any time. We ask that you tell Dr. David Suskind. You can contact this person by telephone at 206-987-2521.

If you choose to leave the study, it will not affect your care at Seattle Children's. You will not lose any benefits or be penalized if you choose to leave the study.

17. Banking?

Storing samples for future research use is called "banking". The reason researchers' bank information or samples are to use it for later research studies of their own or to share it with other researchers. One optional part of the study is the storing or "banking" of your stool samples to use for future research use. These samples will be stored and processed at the University of Washington and the University of California, Irvine and used to understand more about the bacteria and proteins that are found in your gut. Banking of these stool specimens is optional and you can still participate in the study if you decide that you do not want your stool samples to be banked.

What if I changed my mind about banking my samples?

You could always tell us to stop storing your samples. We would destroy your samples and all the information that identifies you. However, we would not be able to destroy or get data if the samples have already been processed.

Please initial below:

_____ I agree to having my stool samples stored at the University of Washington and the University of California, Irvine

_____ I *do not* want my stool samples being stored at the University of Washington and the University of California, Irvine (you can still participate in the study if you do not want your stool samples to be stored)

18. What would my signature on this form mean?

Your signature on this form would mean:

- The research study was explained to you.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you may have about the study or your rights as a research study participant.
- **You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the study.**
- By signing this consent form, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
 - You agree to take part in the research study.
 - If the person reading this form is a parent/guardian, you agree to have your child take part in this research study.

Printed Name of Research Participant

Signature of Research Participant (required if 14 years or older)

Date

Time

Printed Name of Parent or Legal Guardian

Signature of Parent or Legal Guardian

Date

Time



IRB # (if known):15858

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Carbohydrate Diet, for Children with Clostridium
Difficile Infection"

Principal Researcher: David Suskind, MD

Revision Date: 06.14.2018 (v2.0)

Protocol Version:1.0

19. Researcher's Signature

I have fully explained the research study described by this form. I have answered the participant and/or parent/guardians questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

Printed Name of Researcher Obtaining Parental Permission or Consent

Signature of Researcher Obtaining Parental Permission or Consent

Date

Time

Original form to:

Research Team File

Copies to:

Participant; Parents/Guardians (if applicable); Medical Records (if applicable)