Statement of Volunteer Consent and Health Insurance Portability and Accountability Act (HIPAA) Authorization for Research Study

Study Title: Effect of Curcumin Food Supplement on Gut Microbiota in Children with Irritable Bowel Syndrome

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Sponsor: Clinical & Translational Science Institute

Name: _____ **Medical Record Number:**_____

Date of Consent Discussion:_____

"You" refers to you or your child throughout the consent form.

- **We are asking you to be in a research study.**
- **You do not have to be in the study.**
- **If you say yes, you can stop the study at any time.**
- **Your health care will not change in any way if you say no.**
- **Feel free to ask questions.**
- **Take as much time as you need to make your choice.**
- **Only sign this form if you want to be in the study.**

Effective Date: January 12, 2019
Expiration Date: November 7, 2019
Children's Hospital of Wisconsin IRB

A. Why are we asking you to be in this research study?

We invite you to take part in this research study to learn more about people like you who have stomach pain with diarrhea.

This study will help us learn more about the food supplement called curcumin (used in Asian cooking and gives yellow color to the curry) and its effect on bacteria which live inside the bowel. We are also interested in understanding if curcumin affects your symptoms such as stomach pain and diarrhea.

About 50 children, ages 10-18 years old, will be recruited from Children's Hospital of Wisconsin.

B. What happens if you say yes, you want to be in this study?

If you agree to help with this study, you will answer some questionnaires about how you feel during your visit today. You may skip any question that you do not want to answer. These questionnaires include the following: Irritable Bowel Syndrome-Symptom Scale, ROME IV Diagnostic Questionnaire, Pediatric Quality of Life, Functional Disability Index, Pain Frequency Severity Duration, State-Trait Anxiety Inventory for Children, Children's Depression Inventory, Symptom Response Scale, and Block Kids Food Frequency Questionnaire. You may also have your heart rate and temperature collected during this visit.

You will be randomized to receive either the supplement or a placebo (fake supplement) for 8 weeks. Randomized means that you are put into a group by chance. It is like flipping a coin. Which group you are put into is decided by a computer. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in either group. Using randomization helps to improve the chance of determining which (if either) treatment is better. You may continue taking your usual medication for your stomach pain and diarrhea. You will be given a tracking calendar to check off which days you take the study pills and collect your poop samples.

A pregnancy test will be performed (if applicable) before you complete any study procedures. If we discover you are pregnant, you will not be able to participate in this study. Please let the researchers know if you become pregnant while you are helping with this study. This treatment may involve risks to you (or to the embryo or fetus, if you are or may become pregnant), which are currently unknown.

Before you start taking the supplement, you will collect a poop sample that you will provide on the day of your clinic visit or mail back to the research team. The researchers will provide you with a poop collection kit and instructions that you can use to collect this sample. You will also receive the supplies needed to mail back the sample by FedEx. You will collect two other poop samples, one at Week 4 and one at Week 8.

You will receive three phone calls; these calls must be answered. At all three calls we will ask you a few questions to see how you are feeling, to see if anything has changed and to check in with how you are doing with taking your pills.

Call #1: within one week of beginning the study, we will call you within 1 week to ask what day you collected your first poop sample and what day you began taking the study capsules. If you have not yet collected your sample or begun taking the capsules, this call will be used to schedule this follow-up phone call within 1 week of starting them We will also schedule a day and time for you to come into the pTRU for your Visit #2.

Call #2: prior to Week 4, we will call to remind you to complete two questionnaires (Irritable Bowel Syndrome- Severity Scale and Block Kids Food Frequency Questionnaire) and to collect your Week 4 poop sample. You will be reminded to mail back the poop sample and two questionnaires by FedEx.

Call #3: prior to Week 8, we will call to remind you about your upcoming appointment in the pTRU and also to collect your Week 8 poop sample which you will need to bring in for your appointment.

At your follow-up visit, about 8 weeks later, you will answer the same questionnaires and you will be asked to bring in your Week 8 poop sample and pill bottle(s).

At Visit #1 and Visit #2 we will collect information about your temperature, heart rate, height, weight, heart rate and blood pressure.

If you want to stop being in this study, we will ask you to complete the final questionnaires and stool sample at that time.

If we do not receive your poop samples, we may call you to see if you were able to collect and mail your poop sample and pill bottles.

	Week 0 (Visit#1)	**Week 4**	**Week 8 (Visit#2)**
IBS-SS	x	x	x
ROME IV	x		
Peds QL	x		x
FDI	x		x
PFSD	x		x
STAI-C	x		x
CDI	x		x
SRS	x		x
Food Frequency Questionnaire	x	x	x
Stool specimen	x	x	x
Pregnancy test (if applicable)	x		
Phone call	x[1]	x	x
Clinic or pTRU visit	x		x

x[1] Week 0 phone call will be completed within one week of beginning the study.

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How long will the study take?
The study will take about 2 ½ hours of your time. The questionnaires will take you about 30-45 minutes to complete on Week 0 and 8, and about 15 minutes to complete on Week 4.

If you turn 18 years old while you are participating in this study, you will be re-consented.

Please note that because of Wisconsin and federal law and your child's age, the researchers are not able to share some of your child's test results, such as pregnancy tests, with you during the study without your child's permission.

The researchers are required by law to report child abuse or neglect (or suspicion of abuse or neglect) if you or your child mention it to the researchers or if it is suspected.

C. Can anything bad happen to you because of this study?
Yes, there is a chance that the supplement will not help you. In some cases, people have complained of an upset stomach, nausea, dizziness or diarrhea when taking curcumin. If you have any of these symptoms, please contact Dr. Sood at 414-266-3690.

The questions could make you sad or upset. If you become upset, please talk to the researchers. They will make a plan to help you feel less upset. The researchers are required by law to report child abuse or neglect (or suspicion of abuse or neglect) if you or your child mention it to the researchers or if it is suspected.

Someone could find out that you are in the study and learn something about you that you did not want others to know. We will do our best to protect your privacy.

D. Will this study help you in any way?
Being in this study may help you, but we cannot promise this. It may help you to have less symptoms. It may help people who have stomach pain with diarrhea in the future too.

E. Will you be paid for being in this study?
You, the child participant, will receive a total of $60 for completing this study. You will receive a $15 check after completing the first set of questionnaires and after we receive the first stool sample. You will receive the second check of $15 after completing the second set of questionnaires and after we receive the second stool sample. You will receive a third check of $30 after coming in for Visit #2, completing questionnaires and after we receive the third stool sample and pill bottle(s).

Your Social Security Number is required to process these payments.

F. Will it cost you anything to be in this study?
You will not be charged for participating in this study. The supplement, analysis of the stool collection and questionnaires will be provided by the research team. You or your insurance company are responsible for all other costs, including any clinic visits during your participation in the study. If you seek medical help for an injury that you believe is related to this study, you or your insurance company will be responsible for these costs.

G. Do you have to participate in this study?

No, you do not have to be in this study**.** You can stop being in the study at any time. Just let Dr. Sood know by calling him at 414-266-3690.If you say no, your health care will not change in anyway.

If you stop being in this study, we will still use the study information we have already collected.

Participation in the study may be terminated by your study doctor without your consent if he/she thinks this is in your best interest. Your participation may also be terminated without your agreement if your symptoms do not improve or if they get worse.

H. What if you have questions?

If you have questions or there is something you do not understand, please call the Principal Investigator, Dr. Sood. Please call if you have any questions or concerns about the study. You should contact him in case of a research related injury too.

You can also call the Institutional Review Board (IRB) if you have any questions about your rights as a research subject. The IRB is the committee that has reviewed this study. A member of this committee can talk to you if you have any questions or complaints at 414-337-7133.

I. Will your information be kept private?

The only people allowed to see your information will be the people who work on the study and people who make sure the study is done the right way and hospital rules are followed. Groups or people who might look at and/or copy your research records are:

- The study Sponsor, Clinical & Translational Science Institute
- The research team
- The IRB at Children's Hospital of Wisconsin
- The Food and Drug Administration (FDA)

Your health information, and this form will be locked in our files. We will also upload a copy of this form to your medical record.

When we share the results of the study in medical journals, we will not include any information that identifies you. We will do our best to make sure no one outside of the study will know you are a part of the study.

A 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.

This Federal law does not protect you against genetic discrimination for companies that sell life insurance, disability insurance, or long-term care insurance.

A description of this clinical trial will be available in http://www.clinicaltrials.gov, as required by US 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.

J. Permission to collect, use and share your health information.

The health information we are asking for is called "Protected Health Information" (PHI). It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA).

A copy of this signed consent and HIPAA Authorization will be kept in your medical record.

Researchers are required to get written permission from you to use your health information in a research study, data registry bank, and/or a tissue bank.

How will your health information be used?

Your health information will be used to provide information needed for the research study.

What information will be used?

What we will use:

- Past and present treatment as an inpatient or an outpatient, clinic or physician office setting.
- History and identification of the problem/disease.
- Other medical conditions that may affect treatment.
- Laboratory, radiology and pathology test results.
- Information collected from the questionnaires you complete

How will your information be used:

- To decide whether you can take part in this study.
- To watch over your health while in the study.
- To make reports for the sponsor.

Who will use your health information?

The hospital or clinic that holds your medical records will share medical information with the researchers. The researchers may also share it with other people outside CHW, such as the study Sponsor or the FDA.

How long will the permission last?

This authorization will last until for 10 years after the study ends.

You can end this Authorization at any time by withdrawing your permission in writing. Beginning on the date your permission ends, no new health information from you will be used. Any health information that was shared before you withdrew your permission will continue to be used. After this Authorization ends, you can no longer actively take part in this research study.

Withdrawal of your permission should be made in writing to the person whose name is listed here:
Dr. Manu Sood
8701 W. Watertown Plank Rd., Suite B610, Milwaukee, WI 53226

How will your health information be protected?
Whenever possible, your health information will be kept confidential. Federal privacy laws, however, may not apply to some people outside of CHW who can share your health information without your permission. Researchers will assign you a code which will be applied to your study papers and data instead of your name.

Additional information.
You should take as much time as you need to make your decision about giving permission for the use of your health information for this research study. Please ask any questions you may have about this authorization.

K. Permission for you to participate in this study
This study, consent form and HIPAA Authorization has been explained to you by:

Name of Study Leader or Study Team Designee	**Signature of Study Leader or Study Team Designee**
Date	**Time**

Sign this document if:

- **You have read (or had it read to you) this entire consent form.**
- **We have talked with you about the information in this form and have answered your questions.**
- **You agree to let the study team use and share your health information for this study.**
- **You agree to let your primary care doctor share your health information with us.**
- **You agree to be in this study.**

After you sign this document, we will give you a copy of this form.

<u>Printed</u> Name of Study Participant or Authorized Representative	**Date**
<u>Signature</u> of Study Participant or Authorized Representative	

CHILD ASSENT TO TAKE PART IN A RESEARCH STUDY

I have explained this study and the procedures involved to _____ in terms he/she could understand and he/she freely assented to take part in this study.

_____ _____

Person Responsible for Obtaining Assent **Date**

This study has been explained to me and I agree to take part.

_____ _____

Signature or Printed Name of Child **Date**

If child's assent is not obtained above, please indicate reason below (check one):

- ☐ **Assent is documented on a separate IRB-approved assent form**
- ☐ **Child is under the required age range for assent**
- ☐ **The IRB granted a waiver of assent, please specify: _____**

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