PRINCIPAL INVESTIGATOR: Stephanie T. Chung, M.B.B.S.

STUDY TITLE: Prebiotics and Metformin Improve Gut and Hormones in Type 2 Diabetes in Youth (MIGHTY-fiber)

STUDY SITE: NIH Clinical Center

Cohort: Adult affected patient OR Parent of a minor patient

Consent Version: 03/16/2021

WHO DO YOU CONTACT ABOUT THIS STUDY?

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KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

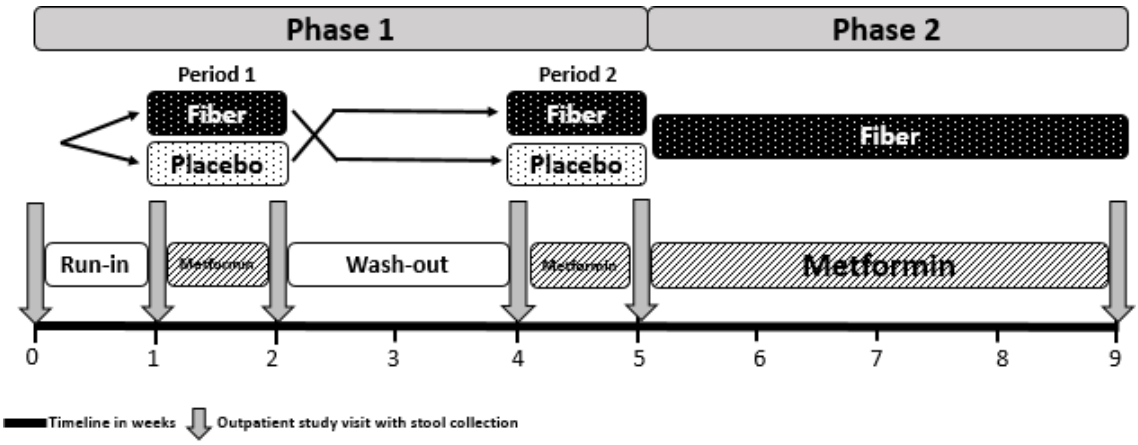
You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you to in making your decision about participating in this study. Additional information that may help you make a decision can be found in other sections of the document. Taking part in research at the NIH is your choice.

You are being asked to participate in this study because you have type 2 diabetes. Metformin is a pill taken by mouth and is the first-line treatment. At present, it is the only treatment that is taken by mouth approved by the United States Food and Drug Administration (FDA) for diabetes in youth. Metformin is thought to work by decreasing excess sugar made by the liver, but it may also increase the gut hormones, change the bacteria in the gut and its action may be affected by certain genes in our body. Metformin also commonly causes side effects such as

diarrhea, upset stomach, or other discomforts in the gastrointestinal (GI) tract that are not typically dangerous, but are unpleasant for many patients.

Some people have used fiber and other supplements derived from natural sources to improve their overall health, specifically decrease the common gut side effects. This study will use a natural prebiotic (fiber) supplement with metformin to determine if this combination will help to decrease the side effects in youth and young adults with type 2 diabetes. This study will also help us learn more about whether this prebiotic fiber supplement can help younger patients with diabetes to have fewer GI side effects with metformin and also improve their blood sugars.

This is a 9-week double-blinded placebo-controlled outpatient study with 2 parts: A 6-week Phase 1 and a 4-week Phase 2. During Phase 1 participants will be asked to stop their metformin during a 1-week run-in period. Then study participants will be divided by chance into two groups – everyone will take metformin, but half will receive the prebiotic fiber supplement, and the other half will receive a placebo for 1 week. Participants will then be taken off metformin and all treatments for 2 weeks (wash-out period). After the wash-out, the participants will restart metformin the groups will switch receive to the other product (for example, if you received placebo during the first period, you will receive the prebiotic fiber supplement during the second period). The blinded study means that you and the investigators will not know the order of the treatment and this will help to reduce study bias.



In Phase 2, everyone will take the prebiotic fiber supplement for 1 month.

We will ask you to come to the NIH Clinical Center for 6 outpatient visits that will include blood work, collection of stool and urine samples, meal tests, questionnaires, and an x-ray. While you're at home, we will ask you to fill out daily short surveys online, to wear a continuous glucose monitor (CGM) and activity monitor daily, collect your stool and to eat the food provided.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs

that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

If the individual being enrolled is a minor then the term "you" refers to "you and/or your child" throughout the remainder of this document.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

This is a research study. The purpose of this research study is to see if a prebiotic fiber supplement will help improve the common gastrointestinal (GI) side effects that patients who take metformin often experience, and also to see if it will help with their blood sugars.

We are asking you to join this research study because you have type 2 diabetes and are a patient who either is taking or will be taking metformin to take care of your diabetes.

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this study, you will be followed for about 2-3 months and seen in a series of 6 visits at the NIH Clinical Center.

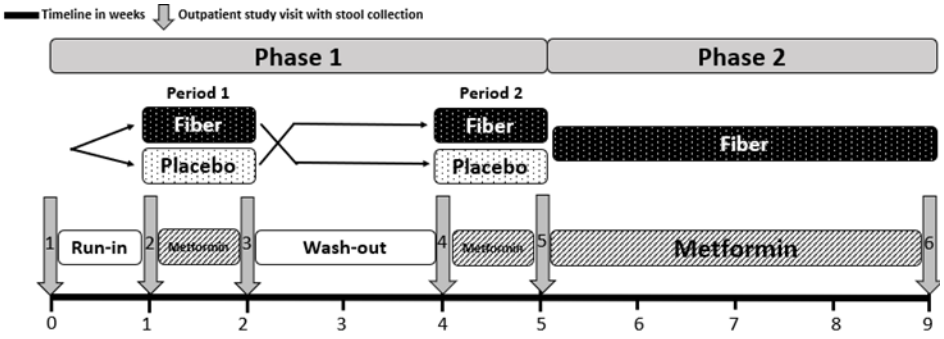
This is a summary of the exams and collections to be done at each study visit:

	Phase 1					**Phase 2**
	Visit 1	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**
		Period 1		Period 2		Prebiotic Fiber

		Prebiotic Fiber/ Placebo		Prebiotic Fiber/ Placebo		
Physical exam and meet with the researchers	X	X	X	X	X	X
Blood tests	X		X		X	X

		Prebiotic Fiber/ Placebo		Prebiotic Fiber/ Placebo		
Mixed Meal Tests			X		X	X
Urine pregnancy test for women	X	X	X	X	X	X
Questionnaires	X	X	X	X	X	X
Stool sample	X	X	X	X	X	X
Meet with dietician	X	X	X	X	X	X
X-ray (DXA scan)		X				
Continuous glucose monitoring	Continuously throughout study					
Accelerometer		X	X	X	X	X

Below is the overview of the study again, along with how often we will ask you to do things at home during the study:



Survey about stomach symptoms	2-3 times	Every day	4-5 times	Every day	4-5 times
Glucose Monitoring	Every day	Every day	Every day	Every day	Every day
Accelerometer	(no)	Every day	(no)	Every day	Every day
Food provided by the study	(no)	Every day	(no)	Every day	(no)

Visit One (Screening Visit):

The first visit will have four parts: (1) To explain the study to you (2) to see if you would like to participate (3) to see if you qualify and (4) to give instructions on how to monitor blood sugar levels. We will discuss the consent and assent forms and give you time to review the printed

material. If you agree to participate, we will ask you to sign the consent forms. During the visit, we will ask about your health history, perform a physical examination and take blood and urine to test for anemia, diabetes control, kidney and liver function, as well as a urine pregnancy test for women. We will have our nutritionist meet with you to discuss what you usually eat. Visit One will take about 3-4 hours.

After Visit One, all study participants will be taken off all diabetes medication, such as metformin, for one week (5-7 day). We will ask you to wear a Continuous Glucose Monitor (CGM) for the rest of the study to monitor your blood sugars regularly. We will instruct you how to use this device and share the data it gathers with us at least once daily while you are not taking medication. If very high blood sugars are noted or you feel ill (e.g. urinating a lot, very thirsty, tummy pain), please notify the study staff immediately and the principal investigator will determine if you can continue to participate in the study. During the drug-free period, you must wear your CGM and upload data daily OR monitor your fingerstick blood glucose at least twice daily and report the values to the study staff. If you are unable to check or report your blood sugars during this period, you will be withdrawn from the study.

After visit 1, you will be asked to fill out short surveys about how you are feeling, mostly related to your stomach and bowel habits (e.g. what your stools look like). We will review with you how to do this on your mobile device, computer or on paper.

At the end of this visit, our nutrition staff will meet with you to learn about what you usually eat. For the 1-week study periods 1 and 2 our study team will provide your food. You must agree to eat only the foods that we provide for the study.

Period 1 (Visit 2 and 3) Visit 2 (Start of period 1):

This study visit is designed to see what your microbiome looks like before starting any medication. It will last for about 3-4 hours during the day. When you arrive in the morning, we will obtain your height, weight and blood pressure. Detailed descriptions of tests to be done at the study visit are outlined below.

Blood test: A blood sample (~1 tablespoon) will be taken to assess your glucose, hormones and metabolites.

Urine pregnancy test: All girls will be asked to give a urine sample for a pregnancy test. The urine test will be done at every visit. This test must be negative in order to participate in the study.

Dual energy X-ray absorptiometry (DXA) scan: The DXA scan is a measure of total body fat and muscle. The scan is a quick X-ray in which you lie on your back for 10-15 minutes on the examination table.

Stool Sample

A research stool sample will be collected at home and brought to the visit or collected during the visit. The purpose of the stool tests is to study gut bacteria and if the treatment changes the types and number of gut bacteria.

Accelerometer

We will give you an activity tracker called an accelerometer to monitor your activity level and sleep patterns while you are on the study to see if the prebiotic fiber supplement may cause changes

to these things. You will be asked to wear this tracker every day during the study for periods 1 and 2 and phase 2 as outlined in the Figure.

Questionnaires

We will ask you to fill out a survey about your quality of life at each visit either online or on paper.

Study Medications and Diabetes Education

Study participants will be randomly assigned (by chance) to one of two groups:

1. Metformin and prebiotic fiber supplement
2. Metformin and Placebo

The prebiotic fiber product we are using is a dietary supplement that can be purchased through online retailers. Such supplements are not regulated by the government because they contain food products that are "generally considered as safe". We want to see if using this product, which contains fiber and fruit extracts, helps patients with diabetes.

Both the prebiotic fiber supplement and placebo are powdered substances that we will give to you in bottles, so you will not know which one you are getting; at home you will mix these powders with either a shake or a fruit juice, and you may also add ice and use a blender we will provide to make a smoothie. You will take the powder at the same time as your metformin – once daily for the first 1-3 days, then twice daily for the rest of the week. Our study staff will review the schedule for taking the medication as well as the medication side effects that may occur. It is important that you take the medication as prescribed so that the side effects are lessened and so that we are able to learn how the drug works.

Controlled diet

Our study team will provide all your food for period 1 and period 2. You must agree to eat only the food provided in order to participate in the study. We will give you this food in a cooler. You will have both frozen and non-perishable, to be eaten during the 1-week study period 1. You will be asked to not eat additional food outside of what our team provides you and we will ask you to bring back the items you don't eat during the week.

Visit 3 (end of period 1):

This study visit is designed to see how the supplement or placebo may have affected your ability to process sugar and your GI symptoms. You will arrive to the NIH Clinical Center in the morning (around 7am) and undergo meal testing until about 1pm. You will be asked to either bring from home or provide another stool sample. We will also ask you to bring in any medication, powder bottles, and a list of food that you did not consume during the week. During this visit we will ask you to fill out short questionnaires similar to the ones you completed at the screening visit. The mixed meal test is described below.

Mixed Meal Test

An intravenous catheter (IV) will be placed in the forearm for blood draws during the meal test. Before the needle prick, a cream can be used to numb the skin. Blood tests will be drawn for glucose control and hormone levels. The mixed meal test will help us learn about the way that blood sugar and hormone levels change when we drink a meal that contains a set amount of sugar,

fat and protein. This test will be done in the morning after the 8-10 hour fast and will last 3 hours. After the test, you will eat a meal.

Period 2 (Washout, Visit 4 and 5) Washout period

At the end of visit 3, we will ask you to stop taking diabetes medications for a 'washout' period for 2-3 weeks. During this time, you will not be taking any study products and we will ask you to continue wearing your CGM every day to monitor your blood sugars. We will ask you to complete the mobile surveys every 3-4 days before visit 4, and you will need to be in touch with the study team at least every week to monitor you for high blood sugars or any other symptoms.

Visit 4 (start of period 2):

After the 2-3 week washout period, you will return to the NIH clinical center to be started on the other powder. During this visit we will ask you to complete the same questionnaires either online or on paper, give blood (1 tablespoon) and stool sample. We will again provide you with all the food for you to eat for the week, the metformin pills, the bottles of powder with the juice or shake to mix it in, and food for you to eat during the next week. During this 1-week period you will need to monitor your glucose and wear the activity monitor as before.

Visit 5 (end of period 2):

After 1 week, you will come back and have a visit to assess your body's response on the study treatment. This visit that is identical to visit 3 and will start early in the morning at 7am. An IV catheter will be placed, and you will have another mixed meal test. After this test is completed, we will give you a 1-month supply of the prebiotic fiber supplement and metformin pills and instructions for administration.

Phase 2 (1-month open-label trial and Visit 6)

During this 1 month we will ask you to take the prebiotic fiber supplement and metformin twice per day. We will provide the 1-month supply of metformin and the supplement. We will also ask you to continue to wear the accelerometer and the continuous glucose monitor for the duration of this 1 month. You will be asked to contact the study team regularly (at least every 2 weeks) for blood glucose and symptom monitoring. We will NOT provide the food for this phase of the study.

Visit 6 (final visit):

After 1 month, you will come back to the NIH Clinical Center for the final visit 6. The procedures will be identical to visits 3 and 5 above. After the study is completed, you will re-start taking your home medications and return to your usual doctors to direct your diabetes management. Our team, including our nutritionist, will meet with you to discuss dietary recommendations and other lifestyle choices after the study.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last for 9 weeks. Each visit will last ~ 4-5 hours.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to enroll up to 50 people for this study at the NIH

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

1. Routine Blood Tests: The needle puncture of your vein can cause soreness, bruising, clot or infection at the site of needle entry and there is a very small risk of fainting. The risk of skin infection is minimal as all needles are sterile and used only once. The total amount of blood to be drawn from start to finish of the study is about 372mL (75 teaspoons), which is considered safe according to NIH guidelines.

2. Intravenous Catheter Placement: The placement of intravenous catheters can be uncomfortable and there is a minimal risk of bleeding, bruising and infection. The catheter will be placed under sterile conditions and universal precautions will be observed. Numbing cream can be used on the skin to decrease the pain of inserting the catheter. Intravenous catheters will be maintained to avoid repeated needle sticks. Should any complications occur, they will be addressed immediately.

3. High Blood Sugars: During the drug-free run-in, and the washout periods, you may have high blood sugars because you are not taking your usual diabetes medications. Very high blood sugars can make you feel thirsty, have blurry vision and urinate often. During this time, you must monitor your blood glucose values at home and report them to the study staff/ principal investigator. If you do not monitor and report your blood sugars, you may not be able to complete participating in this study. Drinking extra non-sugary fluids will help you stay hydrated if the blood sugars are high. You will be given instructions on how to monitor your blood sugars, how to treat, and who to call if you have high blood sugars. We will give you the telephone numbers of the study doctors and nurses so that you can call us at any time if you have problems or questions.

4. Metformin: Metformin is a commonly used oral medicine to treat type 2 diabetes in youth and adults. Metformin may be associated with nausea, vomiting, diarrhea, gas, abdominal discomfort and indigestion. These side effects are more common when starting the medicine for the first time at the highest dose. To decrease these side effects we will start you on half of the full dose for at least 1-3 days before increasing to the full dose, but will increase more slowly if needed. If you experience severe abdominal pain or vomiting, we will stop the medication and withdraw you from the study. Metformin is rarely associated with increased acid in the blood (lactic acidosis). The risk of lactic acidosis with metformin use is increased in individuals with kidney and heart failure or if an individual is dehydrated. To minimize the risk of lactic acidosis we will not enroll you in this study if you have kidney or heart dysfunction and you will be instructed to stop the metformin if you have persistent vomiting, diarrhea or dehydration.

5. Stool samples: Stool sampling is not associated with any health risk but may be uncomfortable for some individuals.

6. Activity and Sleep monitoring: There are no risk associated with these monitors, but participants may find them inconvenient to wear.

7. Continuous glucose monitoring system: According to the device manufacturer, there is minimal risk associated with the device. Possible side effects include but are not limited to local infection, inflammation, pain or discomfort, bleeding at the insertion site, bruising, itching. A medical provider will be available should any of these problems occur.

8. Risk associated with prebiotic fiber supplement: The prebiotic fiber supplement is a food supplement that can be associated with increased bloating and abdominal discomfort. In the small study in adults using the same formulation, no severe adverse effects were observed.

What are the risks related to pregnancy?

For girls, a urine pregnancy must be negative at every visit to take part in the study. If you are sexually active, you will need to use reliable birth control while in the study. If you are a minor age 10-17 years and your urine pregnancy test is positive, we will ask your permission to inform your family so that you can get optimal medical care. If you become pregnant at any time during this study, you will be withdrawn from the study. You will also not be able to participate if you are breastfeeding. This is because the changes of normal pregnancy affect the results of the tests of this study and the radiation involved in the study could put a developing child at risk.

What are the risks of radiation from being in the study?

During your participation in this research study, you may be exposed to radiation from one DEXA scan each year. This is considered a low exposure. The risk of this exposure is too low to be reliably measured.: The amount of radiation you will receive is less than the NIH Radiation Guidelines of 0.5 rem per year for participants less than 18 years old.

Every day, people are exposed to low levels of radiation that come from the sun and the environment around them. This type of radiation is called “background radiation”. No one knows for sure whether exposure to these low amounts of radiation is harmful to your body. The radiation you will get by participating in this study is less than the average yearly background radiation in the United States.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study. However, the potential benefit to you might be that the prebiotic fiber supplement may help reduce the side effects of metformin and/or slightly improve your blood sugars.

ARE THERE ANY POTENTIAL BENEFITS TO OTHERS THAT MIGHT RESULT FROM THE STUDY?

In the future, other people might benefit from this study because we may be able to help people taking metformin have fewer GI side effects and understand who is more likely to have stomach upset from taking metformin or for whom metformin may not work well.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Participation in clinical trials is completely voluntary. Refusal to participate will not affect a participant's ability to participate in other studies at NIH or elsewhere. Before you decide whether or not to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could continue your usual diabetes regimen as prescribed by your regular doctor, including metformin and/or other medications. Prebiotic fibers are available commercially for purchase but have not yet been shown to be effective in diabetes care.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

Once the study is complete you will receive a letter from the Principal Investigator, Stephanie T. Chung, MBBS, with clinically relevant information, for example hemoglobin A1c, lipid profile and blood pressure readings. You will have these results for your medical records and if you request we will send your results to your personal physician.

EARLY WITHDRAWAL FROM THE STUDY

If you are unable to communicate blood sugar information to us or complete the GI symptom questionnaires daily, we may remove you from the study. You may also need to be taken out of the study if you are having side effects from metformin that you cannot tolerate; in that case, we will see you within 1-3 days and monitor you frequently until symptoms stabilize. If your blood sugars are also too high during the study, you may need to be taken out of the study, and we can make recommendations about changing your diabetes treatment until you are able to see your regular doctor and monitor you frequently until then.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you.

We plan to use these specimens and data for studies going on right now, as well as studies in the future. These studies may provide additional information that will be helpful in understanding type

2 diabetes in youth or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

We may share your coded specimens and data with other researchers. If we share your coded data and/or specimens the other researchers will not have the code key to be able to identify you. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded specimens and data to be shared with other researchers and used by these researchers for future research as described above.

_____Yes Initials

_____No Initials

We will place coded information we learn from studying the microbial samples in an open access (public) scientific database available over the Internet; NCBI, NIH's Genebank. If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your samples. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw the specimens and data.

How Long Will My Specimens and Data be Stored by the NIH?

Your specimens and data may be stored by the NIH indefinitely. Blood, urine and stool samples obtained from this study will be divided up, some will be analyzed at NIH and some will be sent to our collaborators for specialized testing that is not available at NIH. Prior to sending these samples, all identifying information, including hospital medical number, will be removed. The sample will be labeled with a code number but no other identifying information. The key to the code number along with all other private information will be kept confidential and your privacy protected by keeping then in secure, locked places and/ or in a safeguarded database. You may request copies of your medical records at any time and may ask us to share these records with other medical professionals at your discretion. If at any time you would like your coded samples or data destroyed, you can notify the principal investigator and that will be done.

Risks of Storage and Sharing of Specimens and Data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information.

New methods may be created in the future that could make it possible to re-identify your data or samples.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will I receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines. If you take part of this study the method of payment will be by direct deposit or check.

How much you will be paid if you take part in this study:

Table: Compensation per Visit/ Procedure

	Compensation	Estimated repeats	Total
Visit	$ 40	6	$ 240
MMT	$ 50	3	$ 150
DXA	$ 30	1	$ 30
Stool collection	$ 20	6	$ 120
GI Symptom Questionnaire	$ 1	30	$ 30
Completion Bonus	$ 250	1	$ 250
Total			**$ 820**

If you are unable to finish the study, you will receive payment for the parts you completed. For example, if you do not complete daily GI symptoms questionnaires, you will be compensated only for each one that is completed. Compensation will be given in two installments: after Visit 5 and at the end of the study.

Total compensation for guardians accompanying minors for the entire study is $50 per visit x 6 visits = $300. The guardians will only receive payments for whatever visits were completed and will be paid as a lump sum at the completion of the study.

With few exceptions, study compensation is considered taxable income that is reportable to the Internal Revenue Service (IRS). A "Form 1099-Other Income" will be sent to you if your total payments for research participation are $600 or more in a calendar year. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically reduced to repay that debt on your behalf.

Will I receive reimbursement or direct payment by NIH as part of my participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

This study does not offer reimbursement for, or payment of, travel, lodging or meals.

Will taking part in this research study cost me anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

CONFLICT OF INTEREST (COI)

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The National Institute of Diabetes and Digestive Disorders and Kidney (NIDDK) and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

PRIVACY ACT

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Dr. Stephanie Chung, stephanie.chung@nih.gov, 301-402-2122. Other researchers you may call Lilian Mabundo, RN at 240-383-9379. You may also call the NIH Clinical Center Patient

Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research- related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date
Signature of Parent/Guardian	Print Name of Parent/Guardian	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only:

Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.