The Children's Hospital of Philadelphia®

Informed Consent Form and HIPAA Authorization

Study Title:	Intranasal oxytocin to reduce excess weight gain in children, adolescents, and adults with brain tumors and hypothalamic obesity syndrome
Version Date:	July 25, 2018
Consent Name:	Main Study Consent

Principal Investigator: Dr. Shana McCormack, MD Office: (215) 590-3174
Emergency: (617) 596-9067

You, or your child, may be eligible to participate in a research study. This form provides important information and describes the purpose of this research study, including the risks and possible benefits of participating.

If there is any information in this form that you do not understand, please ask questions. Please take your time. You do not have to participate in this study if you do not want to. If you participate, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research team members. If you are a parent or legal guardian who is providing permission for a child, please note that the word "you" refers to your child.

Why are you being asked to participate in this study?

You are being asked to participate in this research study because you have had treatment for a brain tumor and have also struggled with easy weight gain. This condition is called "hypothalamic obesity syndrome".

What is the purpose of this research study?

The purpose of this research study is to determine if intranasal oxytocin (the hormone oxytocin delivered through a nasal spray solution) will promote weight loss in children, adolescents, and adults with brain tumors and hypothalamic obesity syndrome.

The hypothalamus is a part of the brain involved in the production of hormones in the body, including oxytocin. In individuals with hypothalamic obesity syndrome, the production of oxytocin may be too low. Oxytocin is important for the body's metabolism, or use of energy. Low oxytocin could be a cause of easy weight gain in people with hypothalamic obesity syndrome.

In previous studies, oxytocin seems to promote weight loss. It also has been studied in other health problems without major side effects in either children or adults when used appropriately. Therefore, we are determining if using an intranasal spray of synthetic oxytocin will safely promote weight loss compared to placebo (no oxytocin).

We will be administering an investigational drug called "Syntocinon", a synthetic form of oxytocin. Although it is not currently approved by the FDA, Syntocinon was previously approved for a different indication in the United States and there were no major safety

concerns. Syntocinon is currently approved in Europe for a different indication, from where it will be imported for this study. Syntocinon has not been used previously in hypothalamic obesity syndrome.

How many people will participate?

About 30 individuals will participate in this treatment study at the Children's Hospital of Philadelphia. We anticipate we will need to screen around 150 individuals to enroll this number of eligible participants. Children and adolescents will be enrolled along with their parents. Adult participants, living independently, may enroll individually.

What is involved in the study?

How long will you be in this study?

If you agree to participate, your participation will last for about 7 months and will involve 9 study visits. If there are safety concerns, extra visits may be required.

What are the study procedures?

The study involves the following tests and procedures. Although some procedures will occur at every study visit, some procedures will occur only once or twice during the study period. Prior to each study visit, we will carefully review your upcoming procedures.

Screening Visit: We will conduct an in-person screening visit to confirm your eligibility. If you are determined ineligible, you will not be able to continue with study procedures.

Pre-Test Fasting: You will be asked to fast overnight prior to some study visits with fasting tests. While fasting, you can drink water and take prescribed medications.

Medical Interviews/Questionnaires: A study team member will review and record your medical history, along with a listing of your current medications.

In addition, you will complete study questionnaires and surveys—they will be related to your mental and emotional health, quality of life, cognitive function, level of appetite, and eating behaviors.

Physical Examination: A routine physical examination will be completed at each study visit (i.e., listening to your heart and lungs, feeling your abdomen, testing brain and nerve function, etc.). We will also measure weight, height, abdominal dimensions, and vital signs (blood pressure, heart rate, respiration rate, etc.). Finally, a study doctor will perform Tanner staging, which is a physical examination method to measure sexual development. Tanner staging is not required, and will not be performed, on adult participants.

Blood Test: During the study, blood samples will be collected from you for laboratory testing by safely drawing blood from your arm—we will draw no more than 90 mL (approximately 18 teaspoons), or 3 cc/kg, whichever is less, of blood over the entire study period. By agreeing to participate in the study, you agree to provide these blood samples to CHOP for research purposes.

In addition, at certain study visits, blood samples will be obtained for pharmacokinetic (PK) analysis. We will safely place an intravenous line to draw your blood over a period of time during your visit.

Urine Testing: During the study, we will collect urine samples from you in a clean cup for laboratory testing. By agreeing to participate in the study, you agree to provide these urine samples to CHOP for research purposes.

Stool Sample Collection (Optional): We will ask you to collect a teaspoon-size amount of fresh stool in a clean container.

3-Day Diet Log: We will ask you to write down every item you have to eat or drink for 3 days prior to four of the study visits.

Pregnancy Test: A pregnancy test will be administered to all female study participants. These confidential results will be shared with you but not your parents/legal guardians. We strongly recommend that you share the results with your parents/legal guardians. If you become pregnant, you will not be able to continue participating in this study.

You will need to practice safe methods (such as not having sexual intercourse, or using a medically accepted form of contraception) to prevent pregnancy while you are using oxytocin. If you have questions about how to avoid pregnancy, talk with your study doctor or the research team and they will provide you with information regarding contraceptive options. You should inform your study doctor at once if you become pregnant during this study.

Study Medication: Syntocinon, a brand of synthetic oxytocin, and a placebo will be administered *via* intranasal spray during the study period. The placebo is a similar-looking intranasal spray, but has no oxytocin.

This is a randomized crossover study—participants will be randomly assigned to first take oxytocin (Group 1, below) or to first take placebo (Group 2, below).

Each participant holds an equal 50-50 chance of taking oxytocin first or placebo first.

Once you are assigned, you will undergo 8 weeks of intranasal oxytocin treatment (Group 1) **or** 8 weeks of placebo (Group 2).

After the first 8 weeks, you will then enter a 4-week "washout" period, when you will stop taking either oxytocin or placebo.

After the 4-week washout period, you will "crossover" into the other group for another 8 weeks. In other words, if you started taking oxytocin, you will then take placebo (Group 1). If you started taking placebo, you will then take oxytocin (Group 2).

Group 1: Oxytocin	→	*Washout (No Treatment)*	→	Placebo
Group 2: Placebo	→	*Washout (No Treatment)*	→	Oxytocin

Over the course of the study, each participant will receive both oxytocin and placebo, but at different times.

Hand-Grip Dynamometry: Muscle strength will be measured using a hand-grip strength dynamometer. You will squeeze the handle on the device with each hand and the strength of the "squeeze" will be measured. This measure will take approximately 5 minutes to complete and does not involve any radiation.

Resting Energy Expenditure (REE) and Respiratory Quotient (RQ) Test: REE measures the amount of calories burned while at rest, and RQ measures how much carbon dioxide and oxygen are being used. After an overnight fast and sitting comfortably, participants will complete a 60-minute REE/RQ test. This involves sitting still in a large hood and breathing in regular, clean room air while watching a movie or listening to music.

DXA Scan: A special x-ray of the body called a "DXA scan" will be completed to measure body composition (i.e., the amount of muscle, fat, and bone) and bone mineral density. During the DXA scan, you will be asked to lie flat on your back on a table as the machine scans your body. The scan occurs for less than 5 minutes. If there is any reason that you cannot have a DXA scan, you may still participate in the study.

Electrocardiogram (ECG): ECG measurements will be completed to check if there are any problems with the electrical activity of your heart before and during treatment. Extra ECG measurements may be recommended if any concerns develop during the study period.

MRI: Over the entire study, we will ask you to complete 2 MRI scans during two separate study visits to measure how your muscles are using energy. There is no contrast substance and no sedation. An MRI scan session may last between 2 to 3 hours, but you will spend no more than 90 minutes in the MRI machine. During the session, we will ask you to perform a brief light leg exercise. You will be asked to press down on a pedal, similar to a car accelerator or piano foot pedal, approximately 90 times, or as many as you are able, over a 2 minute period. If there is any reason that you cannot or do not wish to have an MRI scan, you may still participate in the study.

Stop-Signal Task: This consists of two short tests (together, about 25 minutes) completed on a computer where you are asked to press buttons according to test instructions. It tests how your brain responds to different signals.

Eye Tracking and EEG Measures: This is a short test (about 15-20 minutes) where you will be asked to wear both eye-tracking glasses (Tobii Pro Glasses or Pupil Eye Tracking Headset) to track your eye movements and the EPOC+ device, whenever possible, to record your brain waves. If you are not able to wear both devices, then we will ask you to wear only the eye-tracking glasses. Information collected from these devices, for example eye gaze information (where and how fast you look) and EEG (brain waves, EEG rhythms), will supplement behavioral data collected from questionnaires and other study activities. This is an optional procedure at the 3 visits

during the study. If you do not wish to complete this procedure, you may still participate in the study.

Mixed Meal Test: We will ask you to order a free study meal before the study visit. We will give you this meal to eat during the visit after a dose of either oxytocin or placebo.

Adverse Events Assessment: Our study team will contact you by telephone and see you at in-person visits throughout the study to discuss how you are feeling on the medication. This is to help make sure you stay safe during your participation.

Some of the procedures in this study will be repeated several times. Tests that are part of your usual medical care will continue to be completed. We will do our best to coordinate any blood draws for your clinical care with our study blood draws. Additional tests or procedures may be recommended if we have any concerns about your safety during the study, including to follow-up on abnormal results, for example.

What are the other study procedures (for parents)?

The study also involves the following procedures for parents, when enrolled with children or adolescent participants.

Questionnaires: You will complete questionnaires related to your child's current health status and factors that affect quality of life at 7 in-person visits, plus any additional safety visits that are needed.

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The following visit schedule table describes the schedule of key study procedures for individuals with hypothalamic obesity syndrome:

Study Visits*	Day	Study Procedures	Duration
Visit 0: Screening	-28	Informed consent, medical history review, physical examination, questionnaires, ECG, laboratory tests, pregnancy test, eye-tracking/EEG	6 hours
Visit 1: Block Start	0	Randomization, medical history review, physical examination, ECG, 3-day diet log, laboratory tests, pregnancy test, PK analysis or Stop-Signal, ***study medication dispensed***	8 hours
Safety Check	2 (-1/+2)	Review Safety Monitoring Uniform Report Form, Facilitate laboratory test	30 minutes
Visit 2: Dose Escalation	14 (± 3)	Medical history review, physical examination, questionnaires, ECG, laboratory tests, pregnancy test, PK analysis or Stop-Signal, ***study medication dispensed***	6 hours
Safety Check	16 (-1/+2)	Review Safety Monitoring Uniform Report Form, Facilitate laboratory test	30 minutes
Visit 3: Interim	28 (± 4)	Medical history review, physical examination, questionnaires, ECG, laboratory tests, pregnancy test, ***study medication dispensed***	6 hours

Safety Check	42 (± 5)	Review Safety Monitoring Uniform Report Form, Facilitate laboratory test	30 minutes
Visit 4: Block End	56 (± 6)	Medical history review, physical examination, 3-day diet log, questionnaires, ECG, REE/RQ, DXA scan, MRI, pregnancy test, eye-tracking/EEG	6 hours
Washout Period, then Group "Crossover"			
Visit 5: Block Start	84 (+ 6)	Medical history review, physical examination, 3-day diet log, questionnaires, ECG, laboratory tests, pregnancy test, PK analysis or Stop-Signal, ***study medication dispensed***	6 hours
Safety Check	86 (-1/+ 2)	Review Safety Monitoring Uniform Report Form, Facilitate laboratory test	30 minutes
Visit 6: Dose Escalation	98 (±3)	Medical history review, physical examination, questionnaires, ECG, laboratory tests, pregnancy test, PK analysis or Stop-Signal, ***study medication dispensed***	6 hours
Safety Check	100 (-1/+ 2)	Review Safety Monitoring Uniform Report Form, Facilitate laboratory test	30 minutes
Visit 7: Interim	112 (± 4)	Medical history review, physical examination, questionnaires, ECG, laboratory tests, pregnancy test, ***study medication dispensed***	6 hours
Safety Check	126 (± 5)	Review Safety Monitoring Uniform Report Form, Facilitate laboratory test	30 minutes
Visit 8: Block End	140 (± 6)	Medical history review, physical examination, 3-day diet log, questionnaires, ECG, REE/RQ, DXA scan, MRI, laboratory tests, pregnancy test, eye-tracking/EEG	6 hours
Unscheduled Study Visit**		Medical history review, physical examination, ECG, laboratory tests, pregnancy test	6 hours

*Telephone calls will occur throughout the study period to complete adverse event assessments
**Unscheduled study visit if needed

Your Current Medications:

During the study, you will be allowed to continue with your current medications. It is very important that you tell us at the beginning of the study which medicines you are currently taking (both prescription and non-prescription drugs), including dietary supplements, herbs, and vitamins. Any changes in medications during the study period must be reported to the study team.

What are the risks of this study?

Participating in a research study involves inconveniences and risks. If you have any questions about the possible risks listed below, you should talk to your study doctor or your primary care provider/family physician.

Like all medicines, the active medication may cause side effects in some people.

For this specific indication and route of administration, the risks associated with oxytocin:

- Irritation of the nose (nasal mucosa)
- Uterine contractions in females
- Nausea, vomiting, headache
- Cardiac arrhythmias (abnormal heart rhythms)
- Fluid retention, low sodium levels
- Skin rashes, allergic reactions
- Induction of labor in pregnant women
- Changes in blood pressure- high blood pressure

In addition, if you have diabetes insipidus and are taking a form of desmopressin, oxytocin may have some of the same effects as desmopressin. This could increase the chances of your body holding on to extra water and developing low sodium levels. Low sodium levels, if left untreated, can cause very serious health consequences, including seizures and hospitalization, even death. For this reason, we will be monitoring symptoms and sodium levels closely. You may need to reduce the amount of desmopressin you are taking while also taking oxytocin. We will carefully review your response to oxytocin by telephone and at in-person visits, including with testing of sodium levels, so we can help you and your usual endocrinologist adjust the dose of desmopressin, if needed. Desmopressin may be administered in an intranasal form. In order to avoid any confusion with study medication we will provide guidance regarding identifying medication containers and will review administration instructions at each visit when study drugs is dispensed.

If oxytocin is administered along with medications known for potential QT interval prolongation, there is an increased risk of abnormal heart rhythms associated with drug-induced long QT syndrome. Your current medications will be reviewed by the study team. If you have any questions about medications that you are taking, please ask the study doctor.

Because this drug is experimental, there may be other side effects that we do not know about yet. If you experience any other side effects, inform your physician or our study team. All clinically significant side effects will be immediately treated. **At any time during your participation, if you feel that you are experiencing ANY side effects from the study medication contact a member of the study team immediately.**

If you are prescribed any new drugs during the study, you must notify the study doctor. Also notify the study doctor of any new over-the-counter drugs, supplements, herbal products, and vitamins.

If you require a clinical blood test, inform the doctor or nurse that you are actively on an oxytocin regimen, as it may affect clinical test results.

Reproductive Risks

For **female** participants, if you are pregnant or nursing, you cannot participate in the study due to the study drug and exposure to radiation. All female participants, will be given a pregnancy test before starting this study and at each study visit (9 times) during your participation. The results will be shared with you (the child) and not with your parent(s). We encourage you to tell your parent(s) the results. If you are found to be pregnant, then you will not be able to continue participation in the study.

You and your partner will need to practice safe methods (such as abstaining from sexual intercourse or using a medically accepted form of contraception) to prevent pregnancy through the duration of the study. If you have questions about preventing pregnancy, the study doctor, Dr. Shana McCormack, will be able to discuss your choices and methods. In addition, if you become pregnant during the study, you must immediately contact Dr. McCormack.

Risks associated with other study procedures:

Medical Interviews/Questionnaires: There are no physical risks, but in-person and telephone interviews may cause temporary discomfort or embarrassment. You do not have to answer any questions that cause you to feel uncomfortable. These will be performed in private. In addition, if your mental and emotional health surveys reveal serious mental health problems, we may require or recommend mental health services.

Fasting: Fasting may cause discomfort and hunger. We will schedule the study procedures as to reduce the amount of fasting time. If you feel unwell fasting before the study, you can stop fasting at any time.

Physical Examination: Potential risks include fatigue, feelings of anxiety and frustration, and discomfort. Tanner staging will be completed in a private room to protect your privacy.

Blood Test: Arm pain, bruising, bleeding, blood clot formation, and in rare instances, an infection might occur at the site where blood is drawn. There is also the possibility of dizziness or fainting while your blood is drawn.

Stool Sample Collection (Optional): Providing a stool sample may cause embarrassment and discomfort.

Urine Test: You may feel embarrassment or discomfort.

Pregnancy Test: Potential risks include feelings of discomfort and anxiety.

Hand-Grip Dynamometry: The hand-grip dynamometer test may result in mild, temporary hand or forearm discomfort.

REE/RQ Test: There are no known risks associated with the measurement of resting energy expenditure.

DXA Scan: You will be exposed to minimal radiation during the DXA scan. However, this is a very minimal dose of radiation. This radiation dose is not necessary for your medical care and will occur only as a result of your participation in the study. At doses much higher than you will receive, radiation is known to increase the risk of developing cancer after many years. At the doses you will receive, it is very likely that you will see no effects at all.

ECG: There is a risk of skin irritation, redness, or swelling developing from the placement of ECG electrodes on your chest if you are allergic to adhesives. Hypoallergenic electrodes can be used.

MRI Scan: There are no known physical risks associated with MRI scanning. However, MRI machines produce loud noises, which may cause discomfort and irritation. We will provide you with earplugs or earphones to quiet the noise. You may also feel uncomfortable lying inside the magnet due to claustrophobia or inability to lie still. If you become anxious, you can tell us and we will remove you from the machine.

The MRI magnet is always activated and attracts certain metal objects. Any metal object on or inside of your body may heat up, move, and/or improperly function within the scanning room. Metal objects in the room can fly through the air toward the machine (magnet) and hit those in the area. However, there are many safety measures to prevent or reduce these risks.

Stop-Signal Task: There are no known physical risks for this procedure, but you may experience temporary embarrassment, frustration, anxiety, or discomfort.

Eye Tracking and EEG Measures: There are minimal physical risks for this procedure. Wearing the Tobii Pro eye glasses and/or the EPOC+ device may cause some temporary discomfort.

Mixed Meal Test: The study meal could cause allergic reactions if you eat something to which you are allergic. We will carefully screen for food allergies prior to the study visit to ensure that the meal is prepared without known allergens. If you feel ill during your meal, we will remove the meal and observe you for any symptoms.

Incidental Findings: It is possible that during the course of the study we will find new health problems. If this happens, we will discuss them with you and help to review your best options with your usual physicians.

Actionable Findings: If your mental and emotional health surveys reveal indications of serious mental health problems or suicidal ideation, we may require or recommend mental health services.

There may be other risks that are not known at this time. Immediately inform the study doctor or a research team member if you experience any problems.

Are there any benefits to participating in this study?

This research study includes procedures that may change the treatment you would otherwise receive. The study drug may help reduce excess weight gain. It may also improve cognitive and emotional health and quality of life, independent of weight changes. Although your condition may improve while participating in this study, this

cannot be guaranteed. Future patients with hypothalamic obesity syndrome may benefit from the knowledge gained from this clinical trial.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be provided to you for your personal records.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a study participant when deciding about your participation in this clinical trial. You will need to follow the study doctor's directions, attend all study visits, and take the study drug as instructed.

What happens if you decide not to participate in this study?

Participation in this study is voluntary. You do not have to participate in order to receive care at CHOP.

If you decide not to participate or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop participating in the study at any time. You do not have to provide a reason.

Can the study doctor remove you from the study early?

The study doctor may remove you from the study if:

- Your condition worsens.
- The study is stopped.
- The study drug is no longer available.
- You no longer meet all the requirements of the study.
- New information suggests participating in this study may not be in your best interests.

What choices do you have other than this study?

There are options for you other than this study including:

- Continuing to receive your usual clinical care
- Not participating in this study
- You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Personal Health Information (PHI), and confidentiality?

As part of this research, your health information will be collected. This will include information from past and present medical records, study procedures/tests, and interviews that are part of this research. Information related to your medical care at CHOP will go in your medical record. This could include laboratory test results, ECG results and some MR images, except for tests that are performed for this research only. Medical records are

available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to maintain your privacy and confidential status. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at academic and medical meetings and published in scientific journals to inform other doctors and health professionals. We will not reveal your identity in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- People from agencies and organizations that perform independent accreditation and/or oversight of research, such as the Department of Health and Human Services, Office for Human Research Protections;
- Doris Duke Charitable Foundation who is funding this research; and
- The Food and Drug Administration

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the federal Food and Drug Administration. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains

your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that they are required by law to disclose to government authorities. For example, researchers must comply with laws requiring the reporting of suspected child abuse and neglect, intent to hurt self or others, and communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To revoke your permission, it is preferred that you inform the investigator in writing.

Shana McCormack, MD
The Children's Hospital of Philadelphia
The Division of Endocrinology and Diabetes
34th Street and Civic Center Boulevard
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

You will be informed if changes to the study are needed to protect your health. You will be informed of any new information that could affect your willingness to remain in the study, such as new risks, benefits or alternative treatments.

Financial Information

While you participate in this study, the cost of your usual medical care – clinical procedures, medications and doctor visits – will continue to be billed to you or your health insurance.

Will there be any additional costs?

There will be no additional costs to you by participating in this study.

The Doris Duke Charitable Foundation will provide financial support for the following research procedures, medications, and study visits:

- The study drug and placebo
- Study procedures performed at each visit
- Cost of travel, parking and meals

Will you be paid for participating in this study?

The compensation provided at each visit, is designed to cover the cost of travel, parking, and meals as well as your time and effort. Additional compensation will be provided, if

Unscheduled Visit(s) or Additional Safety Check Assessment(s) are required during your participation. You and your parent/legal guardian will be compensated according to the following study visit schedule:

Study Visits	Participant Dollar Amount	Parent/Legal Guardian Dollar Amount	Total
Visit 0: Screening	$75	$25	$100
Visit 1: Block Start	$100	$50	$150
Safety Check	$25	-	$25
Visit 2: Dose Escalation	$50	$25	$75
Safety Check	$25	-	$25
Visit 3: Interim	$50	$25	$75
Safety Check	$25	-	$25
Visit 4: Block End	$100	$50	$150
Visit 5: Block Start	$100	$50	$150
Safety Check	$25	-	$25
Visit 6: Dose Escalation	$50	$25	$75
Safety Check	$25	-	$25
Visit 7: Interim	$50	$25	$75
Safety Check	$25	-	$25
Visit 8: Block End	$100	$50	$150
Total	**$ 825**	**$325**	**$1,150**
Unscheduled Visit or Additional Safety Check	**$25**	**-**	**$25**

If you are below 18 years of age (age 10-17), your family will be compensated according to the above schedule, however all funds will be placed on a single bank card for you and your family.

If you are 18 years of age or older (age 18-35), you will receive a bank card for yourself. A separate bank card will be issued to your parent/legal guardian, if applicable

Adults who enroll individually will receive the compensation amounts as outlined in the "Participant Compensation" column above and will not receive the additional "Parent/Legal Guardian" compensation.

If you receive payment with a bank card, the bank will have access to identifiable information. The bank will not have access to any medical information.

If you have any questions regarding the payment schedule, we can provide additional details in regard to the allocation of family costs, parent/legal guardian compensation, and/or subject compensation.

For non-local participants/families, travelling from outside a 100 mile radius of CHOP, we will reimburse eligible travel expenses up to a maximum of $1,500 during the course of your participation in the study. We can provide additional details about eligible expenses and travel reimbursement guidelines.

Who is funding this research study?

The Doris Duke Charitable Foundation will provide funding to support this study.

Please contact Dr. McCormack if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about the study, contact the study doctor, Dr. McCormack at (215) 590-3174. You may also talk to your own doctor if you have any questions or concerns.

The Institutional Review Board (IRB) at the Children's Hospital of Philadelphia has reviewed and approved this study. The IRB reviews research studies to protect research subjects' rights and welfare. If you have questions about your rights or if you have a complaint, you can contact the IRB Office at (215) 590-2830.

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 study's results. You can search this website at any time.

What happens if you are injured during the study?

If you become hurt or sick from any procedure that was done as part of this study, doctors at the clinic or hospital can arrange for emergency medical care. The hospital does not offer financial compensation or payment for injuries due to participation in this research.

You and your health insurance company will be billed for the costs of any care or injuries.

If you think you have been injured from participating in this study, contact Dr. McCormack at (215) 590-3174. She can review any concerns with you, inform you of resources that may be available, and provide information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

Optional Consent for Disclosure of Participation and Results to the Participant's Personal Physician for Clinical Use

Please indicate whether you grant permission to have the study disclose your participation and results to your personal physician for clinical use by signing next to one of the following choices:

_____ (Initials) I agree to the disclosure of my participation and results to my personal physician for clinical use.

_____ (Initials) I **DO NOT** agree to the disclosure of my participation and results to my personal physician for clinical use.

Optional Consent for MRI Scan

Please indicated whether you wish to participate in the MRI scans for the study:

_____ (Initials) I agree to complete the study MRIs.

_____ (Initials) I **DO NOT** agree to complete the study MRIs.

Optional Consent for Eye Tracking and EEG Measures

Please indicated whether you wish to participate in the Eye Tracking and EEG Measurements for the study:

_____ (Initials) I agree to complete the Eye Tracking and EEG.

_____ (Initials) I **DO NOT** agree to complete the Eye Tracking and EEG.

Optional Consent for Stool Sample Collection and Storage for Future Research

With your permission, we will collect a teaspoon-size amount of fresh stool in a clean container.

We may wish to use these samples for analysis in the current study and for future microbial testing. The samples will be given a unique code and will not include information that can identify you. Coded samples will be stored in a secured laboratory freezer at CHOP. Information that can identify you or your stool samples may be kept permanently on a secured shared drive at CHOP. Only the study doctors and authorized CHOP personnel will have access to information that could identify you.

Results will not be disclosed to you, but they may contribute to knowledge for future research studies. If you leave the study, you can ask to have your samples destroyed. You can also ask us to remove information that identifies you from the samples.

Please indicate whether you grant permission to have the study collect and store your stool sample for future microbial testing by signing next to one of the following choices:

_____ (Initials) I agree to the collection and storage of my stool sample for future research.

_____ (Initials) I **DO NOT** agree to the collection and storage of my stool sample for future research.

Optional Consent for Blood Sample Collection and Storage for Future Research

As a part of the study, we will collect blood samples. We may wish to use these samples for future analysis related to energy balance and metabolism research studies. The samples will be given a unique code and will not include information that can identify you. Coded samples will be stored in a secured laboratory freezer at CHOP. Information that can identify you or your blood samples may be kept permanently on a secured shared drive at CHOP. Only the study doctors and authorized CHOP personnel will have access to information that could identify you.

Results will not be disclosed to you, but they may contribute to knowledge for future research studies. If you leave the study, you can ask to have your samples destroyed. You can also ask us to remove information that identifies you from the samples.

Please indicate whether you will allow your blood samples for future research by signing next to one of the following choices:

_____ (Initials) I agree to the collection and storage of my specimens for future research.

_____ (Initials) I **DO NOT** agree to the collection and storage of my specimens for future research.

Optional Consent to be Contacted for Future Research Studies

Please indicate whether you grant permission to be contacted for future research studies by signing next to one of the following choices:

_____ (Initials) I agree to be contacted for future research studies.

_____ (Initials) I **DO NOT** agree to be contacted for future research studies.

Consent to Participate in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

If you, the subject and are consenting to participate in the study:

By signing this form, you are indicating that you have had your questions answered and you agree to take part in this research study. You are also agreeing to let CHOP use and share your health information as explained above.

If you, the parent or legal guardian, you are consenting for yourself and to allow your child/adult to participate in the study:

By signing this form, you are indicating that you have had your questions answered, you agree to take part and to allow your child or the adult to take part in the research study, and you are legally authorized to consent to your child's or the adult's participation. You are also agreeing to let CHOP use and share the health information that will be collected for this study, as explained above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Name of Subject	
Signature of Subject (18 years or older)	Date
Name of Authorized Representative (if different than subject)	Relation to subject: ☐ Parent ☐ Legal Guardian ☐ Legally Authorized Representative
Signature of Authorized Representative	Date

Child/Adult Assent to Participate in this Research Study

For children (or adults with diminished capacity) capable of providing assent:

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

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to participate.

_____ _____
Signature of Subject Date

For children (or adults with diminished capacity) unable to assent:

I certify that _____ was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

_____
Person Responsible for Conducting Assent

_____ _____
Signature of Person Responsible Date