

Explanations of Procedures and their Associated Risks Acceptable Language for Informed Consent Forms

The examples in this document have been culled from informed consent forms and edits made to those forms by members of the IRB. These are examples; alternative wording is acceptable provided that it is written in language understandable to the subject – plain language (non-technical), written at Grade 6 - 8.

This document is a work in progress. Investigators who have suggestions for improving the wording of any of the example descriptions/risks or for inclusion of additional procedures/risks, should forward their suggestions to the IRB Office.

TABLE OF CONTENTS

Table of Contents	2
Activity Monitor (SAM)	5
Actigraphy	5
Apheresis	5
Audio Recording	6
Behavioral Testing	6
Blood Tests	6
Blood Pressure Monitoring (continual):.....	6
Bone Marrow Aspirate and Bone Marrow Biopsy:	7
Bone Marrow Harvest	7
Blood Transfusion	7
Brain Blood Flow	8
Breach of Confidentiality	8
Cell Mobilization (for apheresis.....	8
Central Line Placement	9
Certificate of Confidentiality	9
Continuous Glucose Monitoring.....	10
Contrast Agent.....	10
DXA Scan or pQCT Scan	10
Diary.....	11
Dose Escalation	11
Drug Interactions	11
Drug Testing	11
Echocardiogram (Echo)	12
Electrocardiogram (ECG or EKG).....	12
Electroencephalogram (EEG):.....	12
Employee Participation	13
Eye Exam.....	13
Eye tracking tests	13
Fasting	13
Fingerstick.....	13
Fluoroscopy	14
Focus Group	14
Fundus Photography	14

Gene Transfer.....	14
General Anesthesia (GA).....	15
Genetic Testing.....	15
GI Biopsies (additional biopsies)	16
Sharing Genetic Results with NIH	16
HIV Testing	16
Hypothermia.....	17
Incidental Findings.....	17
IV Catheter.....	17
IV Glucose Tolerance Test (IVGTT)	18
Ionizing Radiation	18
Liver Biopsy	18
Long-term Follow-up.....	18
Lower GI Endoscopy	19
Lumbar Puncture	19
MEG.....	19
MRI	19
MRI (non-FDA approved sequences).....	20
Medical Record Review	20
Medical Records from Outside Hospital or Physician.....	20
Mixed Meal Tolerance Test (MMTT).....	20
Motor Function Testing	21
Muscle Biopsy.....	21
Nasal Potential Difference (NPD) Test	21
Near-Infrared Spectroscopy (NIRS).....	21
Neurological Exam.....	22
Neurocognitive Testing	22
Optical Coherence Tomography (OCT).....	22
Oral Glucose Tolerance Testing	22
Pharmacokinetic (PK) Blood Sampling.....	23
Photographs	23
Physical Examination.....	23
Pregnancy Testing and Birth Control.....	24
Pulmonary Function Testing	24
Questionnaires.....	24

Randomization	25
Resting Energy Expenditure (REE)	25
Saliva or Buccal Swab	25
Sedation.....	25
Sharing of Specimens.....	26
Six-Minute Walk Test.....	26
Skin Biopsy	26
Skin Testing for Allergies	26
Skin Tests for TB	27
Sleep Study	27
Stool Sample Collection.....	27
Phone Survey	28
Sweat Test.....	28
Tear Collection.....	28
Telephone Follow-up	28
Timed Function Tests	28
Tissue Collection (additional specimen)	28
Transcranial Doppler (TCD).....	29
Transport Under General Anesthesia	29
24 Hour Urine Collection.....	29
Ultrasound	29
Unknown Risks	30
Upper GI Endoscopy	30
Urinalysis	30
Video Recording	30
Visual Evoked Potentials	31
Visual Field Testing	31

Activity Monitor (SAM)

Activity Monitor (SAM)

Activity Monitor (SAM): The SAM is a small device that tracks the number of steps you take. It is light and easy to wear. You wear it on your ankle from the time you wake up in the morning until bedtime. Remove the SAM before you get into any water or take a bath. You should wear it for a total of X days before you start taking the study drug. (modify the last sentence as applicable or include something like it)

Risks associated with activity Monitor

There is a potential for skin irritation.

Actigraphy

Actigraphy: This is like a watch worn around your child's ankle, designed to monitor periods of rest and activity. It is similar to a 'fitbit' which many adults use to track their activity over time. Your child will wear the actigraphy band for X days.

Risks associated with Actigraphy

There is a potential for skin irritation.

Apheresis

Aphereis: means separating the blood cells from the other parts of the blood.

- To have apheresis you will need a central venous catheter (CVC). If you do not already have a CVC, an intravenous needle will be placed in each arm.
- Blood will be collected from the catheter and sent to machine that separates the cells.
- After the cells are removed the rest of the blood will be returned to you.
- We may need to complete this process several times in order to get enough cells.

Risks associated with apheresis

Leukapheresis is not painful, but some people find it uncomfortable to stay sitting or lying down in the same place for 2 or 3 hours.

To prevent clotting in the machine, a blood thinner is added.

- This sometimes causes temporary numbness or tingling of the fingertips or around the mouth. It can also sometimes cause painful muscle spasms.
- Very rarely, changes in the heart rhythm can occur.
- If you have any of these side effects, please let us know. They can be prevented or made milder by giving calcium supplements, either by mouth or IV.

Other side effects can include nausea, vomiting, fainting or dizziness, becoming chilled during the procedure, seizures, skin rash, hives, flushing (redness and warmth of the skin, usually the face), blood loss, and infection.

Pain, bruising, bleeding and infection could occur at the needle sites. However, infection and severe bleeding are rare.

For smaller patients, it may be necessary to place a temporary central line called a leukapheresis catheter. Central lines have risks too. Those risks will be explained by the surgeon or radiologist.

You will be given a separate informed consent form to read and sign prior to having the central line inserted. The central line procedure may require sedation or general anesthesia.

Audio Recording

Audio Recording: The interview will be recorded. Your answers and information will also be written down (if applicable). No one other than the research team and the person who writes down the answers will hear the recordings. [add as applicable] If someone's name is mentioned, it will not be included on any notes made by the researchers.

Risks associated with audio recording:

The main risk to you is that someone could find out you were in this study. But we will do our best to keep your information confidential, so we think this risk is very low. Some people may feel uncomfortable having the interview recorded. You may skip any question or stop the interview at any time.

Behavioral Testing

Behavioral Testing: You will complete XXXX (computer/paper/etc.) tests. Each test lasts about 30 minutes. (Example explanation) Each test asks you to look at different pictures. The computer will measure your reaction to these pictures. This is done by watching your body language and by seeing if you answer the questions quickly and correctly.

Risks associated with behavioral testing:

There are no physical risks but you might experience momentary embarrassment or discomfort. The exam is similar to those that are performed as part of routine medical care.

Blood Tests

Blood Tests: We need to collect blood to measure (blood chemistries, blood counts, DNA, etc.). (If blood tests are repeated, explain the frequency – e.g. at each study visit, before starting the study, etc.) (Explain the amount in simple terms, e.g., Depending on the study visit we will collect between X and Y teaspoons of blood.) We will do our best to collect the samples at the same time as a clinic blood test. We will try not to stick you more than once.

Risks associated with blood tests:

Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection.

Blood Pressure Monitoring (continual):

Blood Pressure Monitoring (continual): We will send you home with a monitor that will take your blood pressure many times a day. Your blood pressure will be monitored for XX hours/days. Your blood pressure will be monitored while you are awake and when you are sleeping.

Risks associated continual blood pressure monitoring:

When blood pressure is taken, the blood pressure cuff may cause discomfort or bruising to the upper arm. When measurements are taken at night, this may wake you up.

Bone Marrow Aspirate and Bone Marrow Biopsy:

Bone Marrow Aspirate/Biopsy: We may/will need to test your bone marrow cells during the study. To do this, we will need to do a bone marrow biopsy. You will receive a numbing medicine before the special needle is inserted into your hipbone. The needle will be used to collect the bone marrow.

Risks associated with bone marrow aspirate/biopsy:

This test may be painful. The pain normally lessens within minutes to hours. Local anesthetic medications will be used to decrease the pain. (Include the former, only if applicable) There is also a small risk of infection or bleeding.

Bone Marrow Harvest

Bone Marrow Harvest: You may/will need to have a bone marrow harvest to collect blood stem cells. To do this, a special needle will be inserted into your hipbone. Bone marrow will be collected through the needle.

This takes about 1 to 2 hours.

Risks of bone marrow harvest:

You may have soreness, bruising, and aching at the back of the hips and lower back for a few days. Over-the-counter or pain drugs such as acetaminophen (Tylenol®), aspirin, ibuprofen, or naproxen are helpful. Some people may feel tired or weak, and have trouble walking for a few days. We may tell you to take iron supplements until the number of red blood cells returns to normal. Most people are back to their usual schedule in 2 to 3 days. But it could take 2 or 3 weeks before you feel completely back to normal.

Rare complications could include anesthesia reactions, infection, transfusion reactions (if a blood transfusion of someone else's blood is needed), or injury at the needle insertion sites. Problems such as sore throat or nausea may be caused by anesthesia.

Blood Transfusion

Blood Transfusion: Blood cells or plasma will be given through an IV catheter. It will take from 1 to 4 hours to complete the transfusion.

Risks associated with a blood transfusion:

Blood products come from voluntary donors who are carefully selected and tested. There are still some risks to blood transfusion. These risks are uncommon and are usually mild, but may be severe or life threatening.

- Occasional risks include: fever and allergic reactions due to the formation of antibodies (formed by the body to fight infections).
- Less common risks include: infections with viruses, such as hepatitis and fluid overload
- Very rare but serious reactions include: reactions due to a mismatch between the donor's blood and the recipient's and serious infections including HIV (the virus that causes AIDS)

(Include this statement if applicable) The alternative to volunteer donor blood is directed donor blood donated by a family member or friend, if appropriate for your disease.

Brain Blood Flow

Brain Blood Flow Measurements: A special device will be used to measure how much blood is flowing in your brain. The device is not FDA-approved (*if applicable*). (Include the next sentence if the study involves assessing the safety and efficacy of the device, i.e., an investigational device.) It is considered experimental. You will be asked to lie down in a hospital bed. The device will be attached with two special stickers – one on either side of your forehead. The stickers will stay in place the entire time. The procedure will take X minutes/hours.

Risks associated with brain blood flow measurements:

The research device uses similar laser-lights as the pulse-ox sensors placed on your hand or foot. The laser sources will be maintained in “off” mode until the probe is placed in contact with the skin. There is no more of a risk than pulse-oximeter sensors. However, the sensors may heat up and have rarely caused small burns.

The tape used to hold the probes in place may cause reddening or whitening of skin, or an allergic reaction. Please let the study team know if you have had any reactions to duoderm or other adhesive tapes in the past. If you have, we will either not use tape or will use a different tape.

(if device is considered investigational) Because these techniques are experimental, there may be other side effects we do not know about yet.

Breach of Confidentiality

Risks associated with breach of confidentiality:

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

At the time of participation, each participant will be assigned a study identification number. This number will be used on (*include items as applicable*) data collection forms, blood samples, tissue specimens and in the database instead of names and other private information. A separate list will be maintained that will links each participant's name to the study identification number for future reference and communication.

Cell Mobilization (for apheresis)

Cell Mobilization (for apheresis): Before we collect your blood stem cells, you will need to take several medicines. You will have injections of a medicine called filgrastim or G-CSF for 5 or 6 days. You will also receive a medicine called plerixafor or Mozobil for 1 or 2 days. These medicine cause blood stem cells to leave the bone marrow and move into the bloodstream. This is called “mobilization”.

Risks associated with filgrastim or plerixafor: (whichever applies)

Filgrastim can cause some side effects, the most common being bone pain and headaches. This can be treated with over-the-counter pain medicines like acetaminophen (Tylenol®), aspirin or ibuprofen. Other possible side effects include nausea, sleeping problems, mild fevers, and tiredness. These go away once the injections are finished and collection is completed.

Plerixafor may cause nausea, diarrhea, and sometimes, vomiting. There are medicines to help treat these symptoms. Rarely the spleen can enlarge and even rupture. Rupture can cause severe internal bleeding and requires emergency medical care. You should tell the doctor right away if

you have any pain in your left shoulder or under your left rib cage. These can be symptoms of this emergency.

Central Line Placement

Central Line Placement (central line): Because of the number of blood draws and treatments, we will place a central venous catheter to make it easier on your veins. The catheter goes into a neck vein or a vein under the collarbone. You will have the catheter placed while you are under anesthesia. The catheter will be held in place by stitches.

Risks associated with central line placement:

Some discomfort or pain is common for a few days at the site of the catheter placement. Other possible complications from placement of this catheter are: bruising or bleeding around the catheter, which rarely results in a need to operate to stop the bleeding; collapse of the lung, which can result in severe breathing difficulty; infection which require antibiotics or catheter removal; clot in the catheter, which may require medication or removal.

You will be required to sign a separate consent for the placement of the central venous catheter and anesthesia that will be used during the procedure.

Certificate of Confidentiality

Certificate of Confidentiality

A Certificate of Confidentiality (CoC) issued by the NIH covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your information or biological samples could be shared for: [\(restate what will be disclosed if there are other purposes listed in the consent form\)](#)

- other scientific research;
- [XXXXX other purposes;](#)
- your medical treatment [\(Since CHOP Policy requires all clinically relevant data to be stored in EPIC, this statement will rarely be applicable\).](#)

The CoC does not prevent some disclosures.

- [\(Only include the next statement if a US federal or state government agency is funding the research\)](#) The researchers can't refuse requests for information from those funding this research. The [Funding Agency] may need information to assess this project. [\(if applicable add\)](#) Also, the US Food and Drug Administration (FDA) may need information.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Conflict of Interest: (conflict of interest statements are not in this document.)

Continuous Glucose Monitoring

Continuous Glucose Monitoring: You will need to wear a continuous glucose monitor (CGM) for up to XXX days before starting the study. The CGM that will be used is called the XXXXX, which is made by a company called XXXXX. The CGM has a sensor called the XXXXX. The sensor is inserted under the skin using an insertion device called the XXXXX that contains a small needle. Once inserted, the needle is removed and the sensor remains.

The CGM tests blood sugar every X minutes and then saves the information. The CGM can be connected to a computer to retrieve the blood sugar readings. The CGM will provide important information about the effects of the study medication and the number of times you have low sugar.

(if a new sensor is being studied) The new XXXX sensor will be used. It is not FDA approved yet, but is in the process of being reviewed by the FDA. The XXXX sensor is smaller in size and has a smaller needle that is inserted under the skin compared with other XXXXX sensors that have received FDA approval. Therefore, we decided to use it in the study instead of an older sensor.

Risks associated with continuous glucose monitoring:

The risks of wearing the CGM are minimal. Bruising can occur. Mild skin irritation is common. Rarely an infection can occur at the site of CGM sensor needle placement. An allergic reaction to the tape used to hold the sensor in place is possible.

Contrast Agent

Contrast Agent: During the [*name the procedure*], you will receive a solution through an iv catheter. This solution is called gadolinium [*edit as appropriate*]. It improves the quality of pictures taken.

Risks associated with IV contrast agent :

Add this statement to ionizing radiation or MRI section when a contrast agent will be used:

You will receive a contrast agent as part of your *name of procedure*. Contrast agents can cause allergic reactions and kidney damage. Allergic reactions can include mild itching associated with hives and can be as serious life-threatening emergency from difficulties breathing. If this occurs, it is treatable.

DXA Scan or pQCT Scan

DXA Scan and pQCT Scans: A XXXXX scan will be done. The scan uses a very low dose of X-rays to determine the thickness of your bones and the amount of fat and muscle tissue.

Risks associated with DXA scan or pQCT scan:

This research study involves exposure to a small dose of radiation from a name of procedure. 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 unlikely that you will see any effects at all.

Diary

Diary:

(Example 1) We will give you a diary. You will be asked to record _____ that occur between study visits. You will also be asked to write down _____. You should bring the completed diary with you to each study visit.

(Example 2) You and your parent will be asked to keep a diary during the study. Each time you take the study drug, you should record the date and time of your dose in the diary. We will review this diary with you during your visits to the clinic.

Please bring your completed diary and all of your pills to each of your clinic visits. We will need to count the unused pills and review your diary as part of the study.

Risks associated with keeping a study diary:

The risks of keeping a study diary are no more than minimal.

Dose Escalation

Dose Escalation: We do not know the highest safe dose of the study drug. To find out, we will give the study drug to [number] participants at one dose level. If that is safe we will raise the dose given to the next group of participants. The dose you will get will depend on how many subjects get the drug before you and how they react. Since the study drug is experimental, it is not yet known what effects, good or bad, will happen at each of the doses being tested.

Risks:

The risks should be part of the study drug risks and should mention that lower doses may have fewer side effects than higher doses but might be less likely to prove effective.

Drug Interactions

Drug Interactions: A team member will take your medical history, along with a listing of any medications you are taking.

Risks associated with drug interactions:

Some medications may cause unwanted effects when combined with XXX or may make it difficult to tell whether or not XXX is working. Please tell the study doctor about all of the medicines you are taking. This includes prescription and over-the-counter drugs, supplements, homeopathic, alternative, or herbal medicines, and vitamins. You should also contact the study doctor before starting a new medicine or stopping or changing any of your current medicines. It is important to maintain stable doses of the medications you take.

We will go over which medicines you are allowed and which you are not allowed to take during the study.

(Example additional information for 3A4 inhibitors) Please avoid eating grapefruit, starfruit, and Seville oranges or drinking the juices of these fruits while in the study. The juices in these fruits can change the way the body breaks down XXX.

Drug Testing

Drug Testing: We will ask you for a small urine sample to test for the presence of several drugs, including cocaine, heroin, methamphetamine, and marijuana. If you test positive for one of these

drugs you cannot be in the study. (Generally should add the following) We will share the results with you and not with your parents.

[add as applicable] The results of these tests will not be shared with the sponsor, or police, even if you test positive for a drug.

Risks associated with drug testing:

Note: Unless there is a Certificate of Confidentiality, the test results could expose the subjects to some risk to reputation, insurability, and criminal liability.

Echocardiogram (Echo)

Echocardiogram (Echo): An Echo uses sound waves to create a moving picture of your heart. It can find problems with heart function. You will lie on a padded table or a bed. A technician will glide a special device called a transducer across your chest to take pictures of your heart. A small amount of clear gel will be applied to your chest to help the transducer work better.

Risks associated with an echocardiogram:

Echos are very safe. The gel may feel cold when it is first placed. Some people with sensitive skin can develop a rash from the gel.

Electrocardiogram (ECG or EKG)

Electrocardiogram (ECG or EKG): An ECG is a test that measures the electrical activity of the heart. It is used to examine the heart's rhythm to see if it is steady or irregular. It can also help tell how well the heart pumps blood. Several small pads will be attached to your chest, shoulders and legs. They are attached to a machine that traces your heart activity.

Risks associated with an ECG:

There is a small risk that redness or swelling could develop from the ECG electrodes (pads) that will be placed on the skin.

Electroencephalogram (EEG):

Electroencephalogram (EEG): (modify as needed) An EEG measures the electrical activity in the brain. You will wear a mesh cap with many small holes in it. Small pads (sensor electrodes) will measure the brain signals. They are fitted into each hole, along with a gel (similar to hair gel). The sensors measure electrical activity and do not deliver any electrical impulses.

During the measurement, you will sit in front of a computer screen. We will ask to you to perform simple tasks on the computer

You can take breaks if you need to. During the EEG a video recording will be made so we can study the activity.

Risks associated with an EEG:

There are no risks of physical injury associated with EEG. However, wearing the EEG cap can be a bit uncomfortable. Sitting in a chair for up to 2 hours can also become uncomfortable. You may dislike washing the electrode gel out of your hair afterward. Sometimes it can itch where the EEG sensors were attached. We will make every effort to reduce any discomfort.

Employee Participation
<p>Risks associated with employee participation:</p> <p>Your decision to participate in or withdraw from this study will not be shared with your supervisor and will not affect your employment status or performance evaluation.</p>
Eye Exam
<p><u>Eye Exam</u>: We will look at your eyes using different instruments. The light from the instruments used may seem very bright. The exam will take about XX minutes.</p>
<p>Risks associated with eye examinations:</p> <p>There is very little risk of harm from eye examination. (Add this statement if applicable) Eye drops will be needed to make the pupils larger. This may make your vision temporarily blurry and very sensitive to light. You will be given dark glasses to wear.</p> <p>(Include this statement if applicable) Some types of glaucoma may be made worse by dilating drops. If you have high blood pressure or a history of heart disease, in rare instances, dilating drops may make irregular heartbeats or high blood pressure worse. All of these side effects can be treated, if necessary.</p>
Eye tracking tests
<p><u>Eye tracking tests</u>: You will look at pictures and short movies on a screen, and listen to sounds. While watching the screen, your eye movements will be recorded by a special camera. This allows researchers to learn where you were looking during the tasks.</p>
<p>Risks associated with eye tracking tests:</p> <p>There is very little risk of harm from eye tracking tests.</p>
Fasting
<p><u>Fasting (before study visit)</u>: You will need to not eat for at least X hours before coming for certain visits. You will be reminded prior to those visits. You may have water during the fasting period.</p>
<p>Risks associated with fasting:</p> <p>You may feel uncomfortable, dizzy, or faint.</p> <p>The risks should be customized based on the subjects underlying condition and age.</p>
Fingerstick
<p><u>Finger stick Blood Sample</u>: A needle will be used to make a tiny hole in your finger. The blood will be used to check your sugar level.</p>
<p>Risks associated with finger stick:</p> <p>A finger stick is a bit uncomfortable and may cause some soreness and bruising. Very rarely, the site can become infected.</p>

Fluoroscopy
Fluoroscopy: A fluoroscopy is an x-ray exam that captures internal parts of the body in motion. You will be asked to lie down on a padded table in the cardiac cath lab to obtain these images; this exam will take X minutes.
Risks associated with fluoroscopy: This study involves exposure to radiation from fluoroscopy. You will therefore receive a radiation dose. This dose is not necessary for your medical care. You will get the radiation only because you are taking part in this study. Radiation can increase the risk of cancer after many years but at a dose much higher than you will get. Because of the low dose of radiation, it is very likely that you will see no ill effects.
Focus Group
<u>Focus Group</u> : You will be asked to take part in a group discussion with other participants.
Risks associated with participation in a focus group: The risks of focus groups are not more than minimal. (Explain whatever measures will be employed to decrease risk of breach of confidentiality and to protect subject privacy. Example use of first names, asking people not to share comments made by others, etc.)
Fundus Photography
<u>Fundus Photography</u> : We will take photographs of the back of your eyes. At times, the flash of light during the photograph may seem bright. The procedure will take approximately X minutes.
Risks associated with taking photographs of the fundus of the eye: There is very little risk of harm from eye examination
Gene Transfer
<u>Gene Transfer</u> : Gene transfer inserts new genes into a person's cells. Many scientists and health care providers think gene transfer might be a good way to treat some diseases. Gene transfer is still a new area of science. We need to learn more about it to make sure it's safe to use in people and to see if it works. (if applicable) We will use virus called XXXX that has been changed in the laboratory. New genes have been added to the virus. A virus modified to deliver a gene is also called a vector. The changes made to the virus make it unlikely to reproduce or cause an infection once it is in your body. It is hoped that the virus will deliver the genes to the target cells.
Risks associated with a gene transfer: Risks are specific to the gene transfer procedure and need to be customized. Risks associated with the viral vector: The viral vector, which carries the gene into your cells, is considered harmless in humans. Your immune system is expected to reject (kill) the vector in [time amount]. Thus, the vector should not be able to survive and grow in your body. However, there is a small chance that the vector may enter the normal tissue surrounding the tumor, or other sites in the body. There is also a very small chance that the vector might stay in your body and cause cancer or other diseases.

Although some vectors have caused cancers, no cancers have yet been found in any of the experiments in which genes have been transferred into monkeys and humans using this vector.

General Anesthesia (GA)

General Anesthesia (GA): You may need medication to make you fall asleep for [*name of procedure*]. You will receive the anesthesia medicine through an IV (or however it will be administered). A doctor or nurse will monitor you while you are asleep. You will be monitored until you are ready to return to your everyday activities.

Risks associated with general anesthesia (GA):

You (may) will need GA in order to have a (**name of procedure**). There are very rare but serious side effects associated with general anesthesia including: irregular heartbeat, increases or decreases in blood pressure, rare reactions to medications used in the anesthesia, and blockage of breathing passages. Other rare complications include nerve injury, lung injury, heart attack and brain damage. An extremely rare but serious complication is rapid increase in body temperature. All of these complications are treatable but might lead to coma or even death. You will have an opportunity to discuss these risks with the anesthesiologist.

Genetic Testing

Genetic Testing: Thousands of genes are found in every cell in your body. Each of these genes contains a set of instructions that are read by the cell. This allows your body to make proteins. Genes are passed on from both parents to their child. Sometimes, the instructions aren't written properly and can result in disease. These differences are called variants. Everyone has variants in their genes. The meaning of most variants is not yet known. By looking at your genes we hope to learn about the causes of your disease (**or whatever applies**).

Risks associated with genetic testing:

The risks will need to be modified based on the plans for coding the specimens and return of results.

The risks related to genetic analyses can be to individuals or groups. These harms include stigmatization and insurability. (**if applicable add**) To reduce this risk, your samples will be stored and labeled with a code number. (**if applicable add**) If the results are used for future research, the researchers will not be able to identify you. Information about this study will not be recorded in your medical record.

There is a Federal law, called the Genetic Information Nondiscrimination Act (GINA), which 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 may 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 by companies that sell life insurance, disability insurance, or long-term care insurance.

There may be other risks that are not known at this time. Tell the study investigator or study staff right away if you have any problems.

Add the following if applicable:

New information about parentage may be discovered by this research. This could include unknown adoption and paternity (fatherhood). These types of findings will not be shared with you unless there are medical concerns. We will not reveal this information to any third party, including other family members.

GI Biopsies (additional biopsies)

Gastrointestinal (GI) Biopsies (additional biopsies for research purposes): When you undergo a GI endoscopy as part of your clinical care, we will collect extra tissue samples specifically for this study. We will collect no more than X from each area for a total of Y additional tissue samples during one endoscopy. No more than Z samples will be collected per year (no matter how many research studies you are participating in).

Risks associated with having additional GI biopsies:

Taking biopsies may lead to bleeding or infection. Very rarely, this may lead to perforation (hole) of the gut, which would require surgery and could be life-threatening.

Sharing Genetic Results with NIH

Risks associated with sharing genetic results or specimens: (applicable to GWAS, WGS or WES)

We may wish to share your data or DNA samples with other investigators or national databases. The NIH maintains a national database for genetic material. They collect samples for future research. The shared information will not include information that can identify you. The shared information will include information about your diagnosis and genes. If you withdraw consent for sharing, your information or samples that are still at CHOP will be removed and will no longer be used for future research. However, data and samples that have already been shared with other researchers cannot be taken back.

HIV Testing

HIV testing: The screening blood tests include a test for HIV. A counselor will explain the testing and the meaning of the possible results. We will inform you of your test results. Your results will be disclosed to the sponsor in a way that does not identify you by name (you will be identified only by your study ID number). Pennsylvania state law requires that all positive HIV test results be reported to the state.

Risks associated with HIV testing:

Being tested for HIV may cause anxiety. A positive test means that you may have been infected with the HIV virus. Receiving positive results may make you very upset. If other people learn about your positive test results, this may affect your ability to get insurance or employment. If your test is positive we will refer you to someone who can explain what this means for your future medical care. If your test is negative, there is still the possibility that you could be infected with the HIV virus and test positive at some time in the future. Also, it is always possible that the test results could be wrong.

Hypothermia

Hypothermia: Hypothermia means cooling the body. Describe the methods that will be used to induce and maintain hypothermia

Risks associated with hypothermia:

The following are the most common side effects of hypothermia:

- slow and irregular heartbeat;
- less oxygen supplied to the heart muscle;
- problems with clotting of blood;
- infections, especially pneumonia;
- high blood sugar levels;
- shivering;
- skin changes; and
- rapid changes in the blood levels of salts.

These side effects are most common when body temperature is lowered below 32 degrees Celsius or 92.3 degrees Fahrenheit. This is cooler than the body temperatures that will be used in this study. These side effects are also common whenever a person is very ill and needs intensive care.

Your child will be monitored closely for these problems and will be treated promptly if they occur. While your child is being treated, their heart rate and breathing will be closely monitored. We will frequently check blood sugar and salt levels. We will administer sugar (glucose) in the iv fluids to help him/her recover and we will also monitor for infection.

At the end of the hypothermia treatment, your child will be warmed slowly back to normal temperature. Some reports suggest that seizures and low blood pressure may be more likely to happen during this time of re-warming.

Incidental Findings

Risks associated with incidental finding:

There is a possibility that we may find something unexpected in your XXXX (MRI, genetic tests, etc.) test results.

If we find something unexpected (**explain the process**). For example, ... a qualified person will talk to you about the test result. You do/do not (whichever applies) have the option to decline receiving information about an incidental finding.

Note: Only tests performed in a CLIA- or CAP-certified lab and FDA-approved imaging sequences may be shared with subjects or their physicians.

IV Catheter

Intravenous (IV) Catheter: An IV is a small plastic tube placed into a vein in your hand or arm. The tube is inserted with a small needle. The IV will stay in for **XXX days/the duration of the study**.

Risks associated with an IV catheter:

Placing an IV may cause some pain, and bleeding or bruising at the spot where the needle enters your body. Rarely, it may cause fainting. The longer an IV catheter is left in place, the more common it is for redness or infection to develop.

IV Glucose Tolerance Test (IVGTT)

Intravenous Glucose Tolerance Test (IVGTT): The IVGTT tells us how well your pancreas makes insulin. After you have gone for a full night without eating glucose will be given through a vein in your arm. To make it less painful to collect your blood, we will place an IV in a vein in your arm. This IV will stay in your arm until XXXX.

Risks associated with an intravenous glucose tolerance test:

Some people may feel nauseated or flushed when they have the IVGTT.

Ionizing Radiation

Ionizing Radiation: You will have a *name of procedure* (e.g. chest x-ray, CT) in order to take pictures of your *heart, lungs, bones and/or tissues*.

Risks associated with ionizing radiation:

This study involves exposure to radiation from a *name of procedure*. You will therefore receive a radiation dose. This dose is not necessary for your medical care. You will get the radiation only because you are taking part in this study. Radiation can increase the risk of cancer after many years but at a dose much higher than you will get. Because of the low dose of radiation, it is very likely that you will see no ill effects.

Liver Biopsy

Liver Biopsy: A liver biopsy means removing a small piece of liver tissue through a needle. To keep you comfortable the area will be numbed with local anesthetic. You will be sedated/anesthetized so that you will not be awake.

Risks associated with having a liver biopsy:

Pain at the biopsy site is the most common complication after a liver biopsy. It is usually a mild discomfort but if the pain makes you uncomfortable, you may be given pain medication. Bleeding can occur. Excessive bleeding may require hospitalization for a blood transfusion or surgery to stop the bleeding. Rarely, the biopsy may cause an infection. Other possible complications include allergic reactions to the local anesthesia and bruising or swelling at the site of the biopsy. In addition, in rare instances, the needle may puncture another internal organ, such as the gallbladder or a lung, during a liver biopsy

Long-term Follow-up

Long-term Follow-up: You will be asked to continue to for the rest of your life. This is called long-term follow-up. Once a year (*modify as necessary*) you will be asked to have your blood drawn and answer questions about your general health and medical condition. We will ask you to report any recent hospitalizations, new medications, or the development of conditions or illness that were not present when you enrolled in the study. We will request that physical exams and laboratory tests be performed if necessary.

Risks associated with long-term follow-up:

The risks are those of the underlying procedures and need not be repeated.

Lower GI Endoscopy

Lower GI Endoscopy: A doctor will insert a small camera called an endoscope or “scope” via the rectum. The scope is used to look at the intestines, colon, and rectum.

Risks associated with a lower GI endoscopy:

The endoscope could puncture or pierce the intestines. This could require additional treatment or surgery. If biopsies are taken, this could lead to bleeding or infection.

Lumbar Puncture

Lumbar Puncture (LP): During the study you will (need to have/ may need to have) a lumbar puncture or LP. An LP is done by inserting a needle between two lower spine bones (vertebrae). A small amount of cerebrospinal fluid (CSF) is then removed. CSF is the fluid around the brain and spinal cord.

Risks associated with a lumbar puncture:

A lumbar puncture is generally a safe procedure. However, some people experience pain during the procedure. Headache, nausea, vomiting and dizziness are common after the procedure. Other side effects include back pain and bleeding. Infection, numbness, spinal hematoma and meningitis as potential rare but serious risks. Rarely, increased pressure within the skull, due to, for example, a brain tumor, can lead to compression of the brainstem after a sample of cerebrospinal fluid is removed.

MEG

Magnetoencephalogram (MEG): A MEG exam shows the pattern of brain activity. You will sit in a chair with the MEG helmet around your head. Pictures or videos are presented on a computer monitor. There is no radiation involved. A mock scan will be performed ahead of time so you will know what to expect. During parts of the testing you may be able to watch a movie on a video screen while the testing takes place. Your parent may accompany you into the room during the set up procedures at the beginning of the examination. The scan last about 1 hour.

Risks associated with a magnetoencephalogram:

A MEG scan can cause some feelings of claustrophobia or discomfort. If this happens, we will make every effort to reduce your discomfort.

MRI

Magnetic Resonance Imaging (MRI): An MRI scan takes picture of XXX. MRI uses a combination of a large magnet, radio waves and a computer to produce pictures. The MRI scan will take about XXXX hours.

Risks associated with having an MRI scan:

There are no known risks of physical harm associated with MRI. However, MRI machines produce loud banging noises, which cause some people to become stressed or upset. You may also feel uncomfortable inside the magnet if you do not like to be inside small places or have difficulty lying still.

The MRI magnet is always on and attracts certain metal objects. Any metal objects on or inside of your body may heat up, move, and/or not function properly within the scanning room. Metal

objects in the room can fly through the air toward the magnet and hit those nearby. There are many safety measures in place to reduce these risks. The staff will screen all persons and materials entering the scanning room for metal. When the study begins, the door to the room will be closed to minimize the risk of someone accidentally bringing a metal object into the scanner room.

MRI (non-FDA approved sequences)

Magnetic Resonance Imaging (MRI; non-FDA approved sequences): Some of the MRI sequences used in this study are not FDA-approved. They are for research purposes only (include the following if the sequences are being tested for their safety and efficacy) and are considered experimental. You will not receive any results from these sequences.

Risks associated with non-FDA approved sequences:

Same as for MRI. The sequences are widely used in research worldwide and there are no physical risks associated with them.

Medical Record Review

Medical Record Review: We will review your medical records throughout the study to collect information about your medical history, current health, diagnosis, treatments, medications, and results of clinical tests.

Risks

Risks are those of breach of confidentiality

Medical Records from Outside Hospital or Physician

Medical Records from Outside Hospital/Physician: We would like to get a copy of your medical records from your regular doctor. We will ask you to sign a Release of Information form. This will allow your doctor to send us the records.

Risks:

Risks are those of breach of confidentiality

Mixed Meal Tolerance Test (MMTT)

Mixed Meal Tolerance Test (MMTT): You will have a mixed-meal tolerance test which will involve drinking a liquid meal. The liquid meal looks like a milkshake. This drink will raise your blood sugar and cause your body to try to produce insulin.

You will be asked to fast from all food and drinks except for water for about 10 hours prior to the scheduled visit.

You will need to finish the drink over no more than 5 minutes.

An IV catheter will be placed in a vein to take blood samples during the test.

Blood will be drawn from an IV before the drink and then 9 more times over a 4-hour period.

Your blood sugar level will be adjusted with insulin as necessary after these samples are taken. (if applicable)

We will also need to collect 3 urine samples as part of the test. The first sample will be collected during the 24 hours prior to the MMTT. The second sample will be collected the morning of the MMTT, and the third urine sample will be at the end of the 4-hour MMTT.

Risks associated with having a mixed meal tolerance test:

You may not like the taste of the Boost drink, and you may also experience nausea. Boost contains milk and soy products. Please inform the staff if you are allergic to these ingredients so they may ensure your safety by excluding you from the study.

If your blood glucose is high at the end of the test we will help you with your insulin dosing to get it back to a desirable level.

Motor Function Testing

Motor Function Testing: These tests evaluate the level of muscle function. We will observe you performing simple movements, such as rolling, sitting, crawling, climbing, standing, timed walking, and strength.

Risks:

Same risks as for a physical exam

Muscle Biopsy

Muscle Biopsy: A muscle biopsy involves inserting a special needle into the biceps muscle in your arm. A small piece of muscle tissue is then removed. The area will be numbed up with local anesthetic first.

Risks associated with having a muscle biopsy:

There will be pain at the muscle biopsy site. There is also a small risk of bleeding and infection.

Nasal Potential Difference (NPD) Test

Nasal Potential Difference (NPD) Test: This test measures how well salt flows across the lining inside your nose.

A small needle will be placed under the skin of your forearm. A sticky pad will be placed on your arm. A wire will connect the pad to a computer. A very small catheter will be placed inside the nose and taped to the outside.

Approximately 10 to 20 teaspoons of different solutions will be dripped into one side of your nose over about 10 minutes. The computer will take measurements while this is being done. The test will be repeated on the other side of your nose. The test will take about an hour.

Risks associated with having the nasal potential difference test:

You may experience pain in your nose, mild discomfort with the small needle stick in your forearm, and mild discomfort from having to hold your head in place for about 45 minutes. There may be tearing, sneezing, coughing, nosebleeds, temporary skin irritation under the sticky pad, and infection from the needle stick. Less than 1% of the subjects experience bronchospasm (wheezing caused by tightening of the airways).

The doses of amiloride and isoproterenol used for this test are much lower than those typically used in patients for other reasons. We do not expect these doses of drugs to have side effects. The usual (higher) dose of amiloride typically does not produce side effects,

Near-Infrared Spectroscopy (NIRS)

Near-Infrared Spectroscopy (NIRS): Near-infrared spectroscopy (NIRS) measures the amount of oxygen in the blood in organs. The NIRS instrument shines a light through the skin and measures the amount that returns. The NIRS sensors pad(s) will be placed on your forehead to

measure the level of oxygen in your brain. They will be attached using a medical grade adhesive similar to those used for infants. (State how long the sensor will remain in place.)

Risks associated with NIRS testing:

There are no known physical risks associated with the use of near-infrared spectroscopy. Because it is a Class I laser product, the levels of laser radiation are considered to be safe by the FDA. There are safety features that minimize the possibility of exposure to the laser light.

It is usually not uncomfortable to place or remove the NIRS sensors. The sensor can cause your skin to warm up but this will be less than 1 degree Fahrenheit. The skin may be red for a few hours following removal of the sensors.

Neurological Exam

Neurological Exam: We will test your movements, speech, balance, alertness, and coordination.

Risks associated with a neurological exam:

There are no physical risks but you might experience momentary embarrassment or discomfort. The exam is similar to those that are performed as part of routine medical care.

Note: These risks can be combined with the risks of physical exams.

Neurocognitive Testing

Neurocognitive Tests: You will be asked to complete assessments that test your behavior, thinking, memory and development. The tests may take up to X hours.

Risks associated with neurocognitive testing:

There are no physical risks but you might experience momentary embarrassment or discomfort.

If the results of the neuropsychological assessments suggest that you might need further evaluation or care, we can help refer you to appropriate services.

Optical Coherence Tomography (OCT)

Optical Coherence Tomography (OCT): An OCT uses light to capture images of the eye. A dim light beam will scan back and forth, measuring different regions of the eye. You will be required to sit still during the brief scanning procedure. Each scan takes a few seconds but many scans will be made. The entire procedure will take about 15 minutes.

Risks associated with optical coherence tomography:

OCT is not a painful procedure. There may, however, be some mild discomfort in your eye.

Oral Glucose Tolerance Testing

Oral Glucose Tolerance Test (OGTT): The OGTT measures the amount of sugar (glucose) and insulin (the chemical that controls sugar) in the blood after a drink of sugar. Before this test you must not eat or drink anything other than water for at least 10 hours. An IV will be inserted into a vein. After the IV is in place, you will receive a sugar drink. A blood sample will then be taken from the IV every 30 minutes for 2 hours.

When the test is finished, the IV will be removed. You will then be allowed to eat.

Risks associated with an oral glucose tolerance test:

The risks associated with the OGTT are the same as those for having blood drawn. The OGTT may cause low blood sugar. You may feel a little sick to your stomach for a few minutes after drinking the sugary drink.

Pharmacokinetic (PK) Blood Sampling

Pharmacokinetic (PK) Testing: PK tests involve taking blood samples at different times to measure the amount of study drug in your blood. This test shows how the body handles the drug. The blood samples will be taken from an IV catheter inserted in a vein. (if applicable) X blood samples will be taken over a period of Y hours. (or whatever the schedule is).

Risks associated with PK blood tests:

You will have an intravenous (IV) catheter (a small tube) inserted into a vein in your arm or hand to collect blood samples. The risks of an intravenous catheter include discomfort, bruising and, rarely, infection. No more than three attempts will be made to place the IV. After each failed attempt, you have the option to refuse further attempts.

Photographs

Photographs: Photographs of your (face/skin/XXXXX) will be taken. They will be used to XXXXXXXX.

Risks associated with taking photographs:

Many individuals have physical features or functional characteristics that reflect their diagnosis, making photographs and video recordings useful for research and teaching purposes. If you are willing, we may wish to obtain photographs or video recordings of your physical features or functional characteristics. These may show your face, your body, or specific areas of your body.

A number of different groups of people could see these photographs and video recordings, including members of the general public, scientists and medical researchers. Although these photographs and video recordings will be used without your name, it is possible that someone might recognize you.

If images or recordings are shared with or released to other individuals or organizations, the recipients could use, distribute, broadcast and/or publish them in ways that do not protect your privacy and that CHOP cannot control. If you change your mind about taking part in this study after photographing, recording or filming is done, images or recordings that were released outside of CHOP may continue to be used. You will not be paid for the use or release of the images.

Physical Examination

Physical Exam: Exams will be conducted before and during the study. The exam will include measurements of weight, height, temperature, blood pressure, heart rate and respiratory rate, etc. (whatever is applicable).

Risks associated with physical exams:

There are no physical risks but you might experience momentary embarrassment or discomfort. The exam is similar to those that are performed as part of routine medical care.

When blood pressure is taken during physical exams, the blood pressure cuff may cause discomfort or bruising to the upper arm.

Pregnancy Testing and Birth Control

Pregnancy Testing: If you have already started having periods, you will be asked to take a urine pregnancy test XX times during the study. The results will be shared with you and not with your parent(s). If you are found to be pregnant, you will not be able to participate/continue participating in the study. We encourage you to share the results of a positive pregnancy test with your parents but we cannot make you do that.

If subjects will need to use birth control also include procedures for doing so.

Birth Control and Pregnancy Prevention

- If you are pregnant or nursing, you will not be allowed to participate in this study. You will need to take safety measures to prevent pregnancy (such as not having sexual intercourse, or using a medically accepted form of contraception) for a minimum of ____ (time period before, during and after the study). If you have questions about how to avoid pregnancy, talk to your doctor or the researcher and they will provide you with information on contraceptive choices. You should contact Dr. XXXXX at once if you become pregnant during this research study.
- You should not get anyone pregnant for a minimum of ____ after administration of STUDY DRUG. You need to take safety measures to prevent pregnancy (such as not having sexual intercourse or using contraception) for a minimum of ____ after administration of _____. If you have questions about how to prevent pregnancy, talk to your doctor or the researcher and they will provide you with information on contraceptive choices.

Reproductive Risks:

This risk section should go as a sub-section under the procedure associated with that risk. For example, it should go as a subsection in the Risks of Study Drug.

The effects of the study drug/radiation/etc. on the developing fetus are unknown. It is possible that it may harm the fetus. (Explain the potential harms, if known of the study drug, radiation, etc. on the fetus.)

Pulmonary Function Testing

Pulmonary (Lung) Function Tests (PFTs): PFTs measure how well your lungs can move air in and how fast you can breathe out. You will wear a nose clip and be asked to blow as hard and as fast as you can into a tube three or more separate times. (modify as needed)

Risks associated with pulmonary function testing:

You may experience shortness of breath or chest tightness while performing the breathing tests. You will be treated if this occurs. This treatment (a medication called albuterol) may cause an increase in the heart rate.

Questionnaires

Questionnaires: You will be asked to complete questionnaires about XXX (e.g. your quality of life, your mood and how you have been feeling, and your daily activities; some of the questions will ask whether you have thought about or tried to hurt yourself or others).

(if applicable) Your parent and teacher (if applicable) will also be asked to complete questionnaires about you.

NOTE: If parents complete questionnaires about themselves, they are subjects. If this is the case, there should be a separate entry for Parent Questionnaires or Teacher Questionnaires

Risks associated with completing questionnaires:

There are no physical risks but you might experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable. (Add a statement, if applicable, to discuss any counseling that may be available as a result of concerns that are raised.)

Randomization

Randomization: You will be randomly assigned (like the flip of a coin or drawing lots) to one of two groups: the experimental group or control group. You will have a X in Y chance of being assigned to either group. (modify the names of the groups as applicable – study drug, low dose, high dose, placebo etc. Explain placebo, if applicable).

[edit as applicable and insert where most logical] It is not known which treatment works best. The treatment group you are assigned to may prove less effective or have more side effects than the other study group(s) or other available treatments.

Risks :

There are no risks from randomization per se. The risks are all attributable to the risks of the various treatment assignments.

Resting Energy Expenditure (REE)

Resting Energy Expenditure (REE): REE is determined by measuring the amount of oxygen and carbon dioxide that is in the air you breathe. The test will be done shortly after you wake up in the morning. You must not eat or drink anything except water for 12 hours before the test. The test lasts about 60 minutes.

Risks associated with resting energy expenditure measurement:

The risks of REE are no more than minimal.

Saliva or Buccal Swab

Saliva or Buccal (Cheek) Swab: You may be asked by your doctor to spit some saliva into a cup or to have a swab of your cheek done.

Risks associated with a cheek swab:

There are no physical risks but you might experience momentary discomfort.

Sedation

Sedation: You may need medication to make you sleepy for [name of procedure]. You will receive the sedative medicine through an IV (or however it will be administered). A doctor or nurse will monitor you while you are sedated. You will be monitored until you are ready to return to your everyday activities.

Risks associated with sedation:

Sedative medicines may make you sleep for several hours and sometimes can have prolonged effect. Uncommon but serious complications include: irregular heartbeat, increases or decreases in blood pressure, rare reactions to medications used, and blockage of breathing passages. All of these complications are treatable but rarely, may lead to coma or even death. Emergency personnel and equipment will be available in the event of a serious adverse reaction to sedation. You will have an opportunity to discuss these risks and the specific drugs that will be used with the nurse or doctor who will supervise the sedation.

Sharing of Specimens

Insert a statement in the Financial Section regarding sharing profits from commercialization

Examples:

Your specimens, DNA, and their derivatives may have significant therapeutic or commercial value. If they result in a commercial product (for example, a genetic test to predict kidney damage,) you will not benefit financially.

We may share your specimens and data with researchers at other institutions or for profit companies. If there are patents or products that result from the research, CHOP, the researchers and the companies may make money from the research. You will not receive any financial benefit from research done on your specimens or data.

Six-Minute Walk Test

Six-Minute Walk Test: You will be asked to walk back and forth at a comfortably quick pace in order to go as far as you can in 6 minutes. Your heart rate will be monitored during the test.

Risks associated with the Six-Minute Walk test:

You may feel tired during or after this test. The walk test will be supervised, but there is still a minor risk of a fall.

Skin Biopsy

Skin Biopsy: After numbing up your skin with local anesthesia, a needle will be inserted to remove a small piece of skin.

Risks associated with a skin biopsy:

Skin biopsy may cause some pain, bleeding or bruising at the spot where the skin is taken. There may also be a tiny scar. Rare side effects include infection at the biopsy site, allergic reactions to the numbing medicine, and excessive scarring.

Skin Testing for Allergies

Skin Testing for Allergies: This test involves pricking your arm with a small needle to introduce allergy extracts under the skin. If you are taking antihistamines, you will need to stop taking them for X days prior to each skin prick test.

Risks associated with allergy skin testing:

The skin prick test usually does not hurt and does not bleed. However, it is possible that you may experience pain or discomfort.

If you are allergic to the allergens that are introduced under your skin, you may get a bump on your skin called a wheal. The wheal might be red, itchy or swollen. This usually goes away within 30–60 minutes after the skin test, although it can last for up to 24–48 hours. After the skin testing, you may receive an antihistamine by mouth or an anti-itching cream to help stop any itching if you wish.

While very rare, serious or life-threatening reactions known as anaphylaxis can occur with allergy skin testing. These reactions may include swelling of the throat or other body parts, blood pressure drops, difficulty breathing or swallowing, loss of consciousness, or death. Skin tests may also bring on an asthma attack, especially if you have active asthma symptoms on the day of testing. However, this is also very rare. A study physician will be available to treat any reactions, if one should occur when you are having skin testing.

Skin Tests for TB

Skin Test for Tuberculosis: At the screening visit, you will have a skin test to be sure you don't have tuberculosis (TB). If you have TB, you will not be allowed to participate in the study.

Risks associated with tuberculosis skin tests:

You may experience tenderness, swelling, itching or a rash at the site of injection for a few days. Cold packs can be applied to the area for comfort.

Sleep Study

Sleep Study: A sleep study involves observing you while you sleep. You will wear EEG leads (long, thin plastic-covered wires) on your head and your chin (EMG leads) to measure your brain waves. This will allow us to observe you as you go through all the stages of sleep. If you wish, your parents will be allowed to stay with you overnight.

Risks associated with a sleep study:

You may feel uncomfortable staying overnight in the sleep lab and wearing wires on your head and chest. You may not sleep as well as you would at home.

There is a small risk that redness or swelling could develop from the sensors (pads) that will be placed on the skin.

Stool Sample Collection

Stool Sample Collection: We will provide you with a stool collection kit for when you need to use the bathroom. The stool will be tested for XXX.

Risks associated with stool sample collection:

Any stool sample may contain germs that spread disease. It is important to carefully wash your hands and use careful handling techniques to avoid spreading infection.

Some people may feel uncomfortable or embarrassed using the stool collection kit. There should be no pain while collecting the stool sample. However, if you are constipated, straining to pass stool may be painful.

Phone Survey
<u>Phone Survey</u> : We will call you at a convenient time. We will ask about [edit as applicable]. The call will last about 30 to 60 minutes.
Risks: Risks of questionnaires and breach of confidentiality
Sweat Test
<u>Sweat Test</u> : This test measures how much salt is in your sweat. To collect the sweat, a sticky pad will be attached to the skin of your arm for about 5 minutes. The pads will then be removed and replaced by a disc to collect sweat for about 30 minutes. The entire procedure will be repeated on your other arm.
Risks associated with a sweat test: The skin may feel warm and tingly while the patches are in place. In some cases, blister-like welts may form. These usually disappear in 2-3 hours.
Tear Collection
<u>Tear Collection</u> : We will collect your tears by briefly placing a cotton-like swab just inside your eyelid. This procedure is painless and takes only a few seconds.
Risks associated with collection of tears: There are no physical risks but you might experience momentary discomfort.
Telephone Follow-up
<u>Telephone follow-up</u> : You will be contacted by telephone to ask about any side effects or illnesses you may have experienced and about any changes to your medications. (modify as needed)
Risks Risks of questionnaires and breach of confidentiality
Timed Function Tests
<u>Timed Function Tests</u> : These tests measure the time it takes to perform certain activities like arising from a lying position, walking or running 10 meters (about 30 feet), and climbing or descending a set of steps.
Risks associated with timed function tests: Although these tests will be supervised, there is a minor risk of a fall.
Tissue Collection (additional specimen)
<u>Tissue Collection</u> : <i>(if prospective specimens will be collected)</i> If you are scheduled for an operation, the surgeon will take a small extra piece of tissue from XXXX during surgery. <i>(if existing specimens will be used)</i> : Existing: If tissues and cells have already been collected from you in the past, we will ask your permission to use these samples.

<p>Risks associated with: collection of additional specimens:</p> <p>The risks depend on whether the biopsy is extra or leftover tissue or existing tissue.</p>
<p>Transcranial Doppler (TCD)</p>
<p><u>Transcranial Doppler (TCD)</u>: A TCD measures the speed of the blood flowing through the blood vessels in the neck and brain. You will be required to lie on your back while a small microphone is placed on various parts of your head. This test takes approximately 30 minutes and does not cause any discomfort.</p>
<p>Risks associated with transcranial doppler:</p> <p>There are no physical risks and the test is not uncomfortable.</p>
<p>Transport Under General Anesthesia</p>
<p><u>Transport under General Anesthesia</u>: Explain the process</p>
<p>Risks associated with transport under general anesthesia:</p> <p>During transport to and from “location #1” to “location #2” there is a small risk that the breathing tube or an intravenous catheter might come out. If either problem happens, it could result in serious breathing or bleeding problems. To minimize the likelihood of any harm, your child’s anesthetic care will be directed by experienced anesthesiologists with assistance from nurses and respiratory therapists during the scheduled procedure and transport. You will have an opportunity to discuss these risks with the anesthesiologist.</p>
<p>24 Hour Urine Collection</p>
<p><u>24-hour Urine Collection</u>: You will be asked to collect all of your urine over a 24-hour period. You will start when you wake up and empty your bladder for the first time and continue until the next morning.</p>
<p>Risks associated with 24-hour urine collection:</p> <p>There are no physical risks but you might experience momentary embarrassment or discomfort.</p>
<p>Ultrasound</p>
<p><u>Ultrasound of the XXXX</u>: Ultrasound uses sound waves to produce pictures of organs. A device that produces and receives sound waves will be moved back and forth over your belly/chest/head to produce images of your head/fetus/liver/heart/etc..</p>
<p>Risks associated with ultrasound:</p> <p>This procedure is associated with very little discomfort. The gel may feel cold when first placed on the body.</p>

Unknown Risks
<p>Unknown Risks:</p> <p>This should be a sub-section as part of the risks of the study drug or device</p> <p>Since the study drug is experimental, there may be side effects that we do not yet know about. There may also be unknown risks to a fetus or embryo.</p>
Upper GI Endoscopy
<p><u>Upper GI Endoscopy:</u> During an upper endoscopy, a doctor inserts an endoscope or “scope” into the mouth and passes it into the intestines. The scope has a small camera to look at the esophagus, stomach and first part of the small intestines. <i>(if biopsies will be taken, add explanation)</i></p>
<p>Risks associated with upper GI endoscopy:</p> <p>Possible risks and discomforts associated with the endoscopy procedure include gagging, nausea, vomiting, sore throat and possible reaction to the numbing medicine used during the procedure. There are other less common risks. The endoscope could puncture or pierce the intestines. This could require additional treatment or surgery. If biopsies are taken, this could lead to bleeding or infection. <i>(if GI endoscopy will be done by someone who isn't an investigator, add this statement)</i> The doctor performing the endoscopy will explain these risks to you in more detail before you have the procedure.</p>
Urinalysis
<p><u>Urine Test:</u> You will be asked to pee into a cup. You can do this in a bathroom without anyone watching you. <i>[add as applicable]</i> We will measure protein, sugars, blood and kidney function in your urine throughout the study.</p>
<p>Risks associated with urine tests:</p> <p>There are no physical risks but you might experience momentary embarrassment or discomfort. The test is similar to those performed as part of routine medical care.</p>
Video Recording
<p><u>Video Recording:</u> During XXX testing you will be video-recorded so that we can review your testing again later.</p>
<p>Risks associated with video-recording:</p> <p>Many individuals have physical features or functional characteristics that reflect their diagnosis, making photographs and video recordings useful for research and teaching purposes. If you are willing, we may wish to obtain photographs or video recordings of your physical features or functional characteristics. These may show your face, your body, or specific areas of your body.</p> <p>A number of different groups of people could see these photographs and video recordings, including members of the general public, scientists and medical researchers. Although these photograph and video recordings will be used without your name, it is possible that someone might recognize you.</p> <p>If images or recordings are shared with or released to other individuals or organizations, the recipients could use, distribute, broadcast and/or publish them in ways that do not protect your privacy and that CHOP cannot control. If you change your mind about taking part in this study after photographing, recording or filming is done, images or recordings that were released</p>

outside of CHOP may continue to be used. You will not be paid for the use or release of the images.

Visual Evoked Potentials

Visual Evoked Potentials (VEP): This test measures the brain's electrical activity to pictures and patterns. For this test you will sit in front of a screen that will display a checkerboard pattern.

Risks associated with visually evoked potentials:

Visual evoked potential cause little discomfort. The electrodes that are used only measure electrical activity and do not produce any sensation. The electrodes may have a slight odor from the materials used for attachment. The gel may feel cold when first placed on the body. Some people with sensitive skin develop rashes where the wires are taped to the skin. You will be asked to remove any metal from your jewelry or clothing.

Visual Field Testing

Visual Fields Testing: The visual fields testing examines peripheral or side vision.

Risks associated with visual field testing:

There are no physical risks but you might experience momentary embarrassment or discomfort.