***INSTRUCTIONS – PLEASE READ FIRST:***

*Many sections of this document include instructions to provide the user with a general overview of information required in the section. These instructions are shaded so that you can tell the difference between the instructions and required information. Additionally, there are headings or brief instructions through the document that are in italics and not meant to be included in the final document.*

*Many sections include required language. If this section applies to your study, you will need to use the language provided. There may be words or phrases within the required language that you will need to edit to fit the specifics of your study. These words will be indicated in italics. Sections labeled as “suggested wording” can be edited any way you wish.*

*Use lay terms. Avoid long or complex sentences and excessive technical language or jargon. Define any words or terms that may be unfamiliar to lay persons (i.e. clinical trial, Phase 2 study, focus group) and always define (write out) acronyms or abbreviations the first time you use them. Err on the side of simplicity.*

*Please delete all shaded and italicized instruction areas prior to submitting this form to the IRB.*

This consent form gives you important information about a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care.

Please read this consent form carefully and take your time making a decision. The first section gives you an overview of the key information you should know about the research study. More detailed information about these topics may be found in the pages that follow.

The form may contain words that you do not understand. Please ask questions about anything you do not understand. We encourage you to talk to others (for example, your friends, family, or other doctors) before you decide to participate in this research study.

***Include if study will enroll both children and adults***

Please check one of the following:

\_\_\_\_\_ You are an adult participant in this study.

\_\_\_\_\_ You are the parent or guardian granting permission for a child in this study.

If the participant is a child the use of "you" refers to "your child"

**Summary of Important Information**

***INSTRUCTIONS:***

*The informed consent statement must begin with a concise and focused summary of key information about the study. The intention of this section is to provide potential research participants with a quick overview of the study. The information presented in this section may be discussed in greater detail later in the consent form.*

We are asking you to participate in this research study. Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not impact the clinical care you receive at Boston Children’s Hospital.

In this research study we want to learn more about\_\_\_\_\_.

It is important to consider reasons why you would or would not want to participate in this research.

***Include if treatment/intervention study:***You do not have to be in this research study to be treated for *[medical condition].* Your healthcare provider has discussed with you what your clinical treatment options are and which clinical treatment(s) might be right for you considering your medical history. These clinical treatment options include *[provide a brief summary of the typical treatments available]*. Each of the clinical treatment options has known rates of being effective, known risks, as well as possible drawbacks.

The study treatment has not yet been proven to be safe and/or effective for the treatment of *[medical condition].* The study treatment may work better, the same, or worse and may have less, more, and/or other risks compared to the clinical care options. It is important to consider the trade-offs of the clinical care options as well as this research study before you decide whether you take part or not take part in this research study.

***Required for all studies:***If you decide to join this research study, the following things will happen: (*briefly discuss study design and provide a short high level summary of the main research activities.)*

The most important potential risks to know about are: *(Summarize the reasonable foreseeable risks and/or burden of the main study procedures – risks that are detrimental in the subject’s first consideration on why they may or may not participate in the study. For treatment studies, this might include side effects that are different from those associated with standard treatment. It could be those risks a clinician would consider essential to discuss with a patient.)*

The most important potential benefits to know about are: *(Summarize the potential benefits. If there are subjects who may not receive any benefit you should state this. You can also indicate whether there will be any potential benefits and the possibility of improvement through extra monitoring as part of the study.)*

It will take you about *[X days/weeks/months/years]* to complete this study. During this time, we will ask you to make *[X]* study visits. *[Include if applicable:* You will have *[how long/how many]* overnight visit(s) in the *[location]*.

***If applicable - (choose what applies to your study):*** The research funds will cover cost associated with the study. We may bill your health insurer for routine items and services you would receive even if you did not take part in this research. You will receive up to *[$ amount]* for the completion of the study. Some of travel related costs may be covered by the study.

***INSTRUCTIONS:***

*At the end of the “Summary of Important Information,” leave the remainder of the page blank and add a page break if needed. The next section of the consent form should start on a new page.*

**How are individuals selected for this research study?**

***INSTRUCTIONS:***

*Explain why the participant is being invited to participate in this study and how the investigator obtained their name (e.g. You are being asked to participate in this study because you have type 1 diabetes and are a patient at Boston Children’s Hospital) DO NOT include inclusion/exclusion criteria.*

*You do not need to repeat information in summary but can expand in more detail if necessary. If all information is included in the summary this section may be deleted.*

You are being asked to participate in this research study because \_\_\_\_\_.

**Why is this research study being conducted?**

***INSTRUCTIONS:***

*What are you trying to learn with this research? Explain the purpose in brief (a few sentences) clear language. Bullets may make the purposes of multiple-aim studies clearer to participants.*

*Clearly explain what is experimental/new about this study. Explain why the knowledge to be gained from this study is important or useful. When drugs or devices are used, describe their function, purpose, and means of use in lay terms.*

*You do not need to repeat information included in the summary. Rather use this section to provide more detailed information including the topics below.*

## *****If i******nvestigational drug or device included in study – SUGGESTED WORDING:*

This study involves testing an investigational drug [*OR device*], [*insert name of drug/device*]. This means the drug [*OR device*] has not yet been approved by the Food and Drug Administration (FDA) and has not yet been proven to be safe and effective for the purpose we are studying. Information from this research may help decide whether the study drug/device should be approved by the FDA.

***If drug/device is approved for another use – SUGGESTED WORDING:***

[*Name of drug/device*] is approved by the Food and Drug Administration (FDA) for \_\_\_\_\_\_\_\_\_\_.

In this study, the use of [*insert name of drug/device*] is investigational. This means the drug [*OR device*] has not yet been approved by the FDA for the purpose we are studying, the treatment of \_\_\_\_\_\_\_\_\_.

***If includes use of a drug that is FDA approved – SUGGESTED WORDING:***

[*Name of drug/device*] is approved by the Food and Drug Administration (FDA) for \_\_\_\_\_\_\_\_\_\_.

***If includes Phase 1 drug studies – SUGGESTED WORDING:***

In this study we want to find out more about the side effects (problems and reactions) of a new drug [*drug name*], for [*X condition*], and what doses of [*drug name*] are safe for people to take. Everyone in this study will receive [*drug name*] which is investigational and is not approved by the FDA. We do not know all the ways that this drug may affect people. This study is not intended to help you, but we hope the information from this study will help us develop a better treatment for [*X condition*] in the future.

**Who is conducting this research study, and where is it being conducted?**

***INSTRUCTIONS:***

*Name the Principal Investigator from Boston Children’s Hospital.*

*State where the research will be conducted. State whether the research is multi-center or single site; nationwide or international, when applicable. If multi-center, you do not need to specifically name all the other sites, just give a general idea of where the study is being conducted.*

*Identify the sponsors of the research, including any organization that is providing funding, or other resources for the study (devices, drugs, software, equipment, etc.).*

*If a corporate sponsor – SUGGESTED WORDING:*

This study is being done at (*Location*). (*PI Name and affiliation*) will conduct the study and it is funded by (*Sponsor Name*).

*If a research grant – SUGGESTED WORDING:*

A grant from the *(insert sponsor)* will provide funding for this study.

*If the investigator is also the participant’s health care provider – SUGGESTED WORDING:*

Your health care provider may be a research investigator for this research study and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another health care provider who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your health care provider. If you choose not to participate or not to allow your child to participate, your care or your child’s care at Boston Children’s Hospital and/or with your health care provider will not be affected in any way at all.

How many people will participate in this research study?

***INSTRUCTIONS:***

*State the number of participants from Boston Children’s Hospital you expect to participate. If multicenter, also give the total number of participants you expect to participate in this study at all sites, including BCH.*

***SUGGESTED WORDING:***

Approximately \_\_\_ people will take part in this study at \_\_\_ (*if multicenter, add number of hospitals/medical facilities*) different hospitals and medical facilities, and approximately \_\_\_ people will take part at Boston Children’s Hospital.

**What do I have to do if I am in this research study?**

***INSTRUCTIONS:***

*This section needs to clearly describe all research related procedures/assessments, including screening procedures. It should not address assessments and procedures necessary for clinical care.*

*State what procedures will be done at each study visit, what the procedures entail, where each study visit will occur, and the length of each study visit. When describing what is involved in the study, consider*

1. *Laying out a timeline. For example, on Day 1, you will have an EKG and two tablespoons of blood will be drawn from your arm by needle stick for blood tests. On Day 2, you will receive the study drug intravenously (into your vein) for two hours (and so forth). You can also create a timeline using visits. For example, on Visit 1, you will receive study drug to take daily until Visit.*
2. *Including a schema, schedule, table, etc. to give a visual representation of procedures. This helps simplify what participants need to know. The schemas can also be attached as an appendix.*

*State the total time commitment for the study. State how many months or weeks (or until a certain event) the participant will be asked to participate, including length of follow-up.*

*When samples are taken from participants state the volume of each sample and site of sample removal.*

*When questionnaires are given, state what type of questions will be asked.*

*If medical records will be reviewed please indicate whether this is once, during the study or for an ongoing period.*

*When a medical record review will take place for collection of study data, list this as a procedure.*

*When scientific terms such as “placebo,” “randomization” or “investigational” are being used, please define in lay terms. Please see the lay language glossary on the IRB website for further guidance.*

*If drugs are being administered, explain how often they are given and how they are given (see IRB glossary).*

*If MRIs, X rays, or Scans are performed*

*• State what parts of the body will be imaged.*

*• State how long the scans will take.*

*• Warn participants that scans may need to be repeated if movement occurs.*

*Explain what additional commitment or responsibilities will be expected of the participant and/or parent(s) or guardian(s).*

*After reading this section, the potential participant/family should have an idea of exactly what will be done during the study.*

***Each of the following sections should be included if they are relevant to your study. Please edit the statements where indicated to make them specific to your study.***

***Time Commitment – SUGGESTED WORDING (does not need to be repeated if described in summary):***

You will be in this research study for about [*estimated length of time of participant’s involvement*] or

You will [*take the study drug or be followed*] for \_\_\_ months/weeks.

***If includes screening for eligibility – SUGGESTED WORDING:***

If you decide to join the research study, some screening tests will be done first to see if you are eligible to participate. [*Describe screening procedures*].

If the screening information shows that you meet the requirements, then you will be able to start the study. If the screening information shows that you cannot be in the research study, the research investigator will discuss other options with you and/or refer you back to your regular health care provider.

***If includes randomization – SUGGESTED WORDING:***

Because no one knows which of the [*drugs/devices/interventions*] is best, you will be “randomized” into one of the [*two / three / etc.*] study groups. [*One group will receive drug and one group will receive placebo or one group will receive drug [X] and the other group will receive drug Y]*. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have a (n) [*equal / one in three /explain weighting, etc.*] chance of being placed in [*either / any*] group. Neither you nor the research investigator can choose what group you will be in.

***If includes blinding – SUGGESTED WORDING:***

Since the expectations of patients and doctors can influence the results of a study, neither you nor the research investigator will know which drug you get until the study is over. But, if there is an emergency, the research investigator will be able to get this information.

***If a placebo may be used – SUGGESTED WORDING:***

You should know that the placebo is a pill [*or infusion, etc.*] that does not contain any medicine and we do not expect it will do anything for your health. We use a placebo so we do not know whether you are receiving the drug or not.

***EXAMPLE SCHEMA/SCHEDULE/TABLE: (Please use when possible)***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study Visit****Timeline** | **Visit 1****Screening** | **Visit 2****3 Month** | **Visit 3****6 Month** | **Visit 4** **12 month** | **Visit 5****18 Month** |
| **Consent /Assent** | **X** |  |  |  |  |
| **Physical/Neurological Exam** |  | **X** |  |  | **X** |
| **Blood Draw** | **X** |  |  |  |  |
| **MRI** |  | **X** |  |  |  |
| **Quality of Life Questionnaires** | **X** | **X** | **X** | **X** | **X** |
| **Medication Diary** |  | **X** | **X** | **X** | **X** |

***If cell lines will be created – REQUIRED WORDING:***

The blood or tissue collected in this research may be used to create a “cell line” that can be grown in the laboratory. A cell line can continue to grow and make more cells indefinitely. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you. The researchers will use these cells to try to learn more about [*disease/condition*].

***If iPS cells will be created – REQUIRED WORDING:***

We may use the cells taken from your [*specify source of cells, e.g. skin*] to create a type of cell known as a pluripotent stem cell. Stem cells can be used to create other types of cells and tissue, including [*specify type of cells, e.g. cardiac, muscle, etc.*] cells. Your cells might be used to study genetic changes. The researchers will use your cells to try to learn more about [*disease/condition*].

***If cells will be used in animal models include the following sentence – REQUIRED WORDING:***

Your cells [*will/may*]be mixed with other human cells, mixed with animal cells, or grown in lab animals like mice. [*Provide a brief explanation, in lay terms, as to why cells will be used in animal models for the purposes of this study*].

***INSTRUCTIONS:***

*State whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.*

***If*** ***whole exome or whole genome sequencing studies will be done for this research – REQUIRED WORDING:***

We *(may/will)* perform a whole genome or whole exome analysis on your sample. Some research involves just studying a few genes that are linked to a disease or condition. In whole genome or whole exome analysis, all or most of your genes are studied and used by researchers to find causes of [*signify here whether the sequencing data will be limited to the disease under study and related disorders or "many diseases or conditions."* *Note if your research is subject to the NIH Genomic Data Sharing policy and submitted to dbGaP you must indicate “many diseases and conditions*” *and cannot limit uses*].

**What are the risks of this research study? What could go wrong?**

***INSTRUCTIONS:***

*This section should include the* ***reasonably anticipated*** *risks/inconveniences/discomforts of all interventions and procedures being performed as part of the research. Risks of standard care procedures* *such as clinically indicated radiology studies, MR, CT etc., should not be included in the consent form. Be sure to include both emotional/mental physical and privacy risks. Present risks with a consistent categorization of severity and frequency.*

*For medication side effects, differentiate between most and least common, as well as anticipated and potential severity. Consider using a visual table. Clarify which side effects may be temporary/reversible and which, if any, are permanent. Describe what can or will be done beforehand to minimize these risks.*

*Describe what actions will be taken to counteract the occurrence of side effects as applicable.*

*If there are potential risks from multiple sources, use subheadings to label the different risk sources with their specific risks. For example: “Risks related to the study medication”; “Risks related to MRI”; “Risks related to blood draw.”*

***When appropriate, the following information should also be included:***

*If the research includes participants of child bearing potential or who are pregnant, and the risk profile of any research interventions or interactions on embryos and fetuses is not well known, then disclose that the particular treatment or procedure may involve risks to the embryo or fetus, if the participant is or may become pregnant, which are currently unforeseeable.*

*If there are any adverse consequences of a participant's decision to withdraw from the research, disclose the consequences of a participant's decision to withdraw from the research. If there are any adverse consequences of a participant's decision to withdraw from the research, disclose procedures for orderly termination of participation by the participant.*

## *If Greater than Minimal Risk – REQUIRED WORDING:*

Some procedures or treatments used in this research may present risks that are not well-known or understood. Therefore, there may be unforeseeable risks associated with participating in this research.

***If Psychological/Emotional Risk (surveys, interviews, etc. use sections that are appropriate) – SUGGESTED WORDING:***

You may be asked questions that make you uncomfortable or cause you to remember situations that were upsetting to you. You may become frustrated if you are asked questions during the (*survey/interview*) that you do not know how to answer. You may not be able to answer all the questions and you do not need to answer any questions that you do not wish to answer. If you become upset at any time, you can stop the *(survey/interview*). We will also offer to have you speak to someone about how you are feeling.

## *If Phlebotomy Risk – SUGGESTED WORDING:*

**Risks associated with a blood draw may include minor discomfort, bruising, fainting, and infection. When possible, we will draw blood at the time of a clinically-indicated procedure to reduce the number of needle sticks.**

## *If greater than usual chance of uncovering child abuse risk – REQUIRED WORDING:*

If, during your participation in this research, there is reason to believe that child abuse is of concern, the research team must follow state law by filing a child abuse report with the Department of Children and Families (DCF). Research records might be court ordered for use in court hearings. The research team will make every reasonable effort to protect the confidentiality of research data, though it is possible that a court might demand the release of information gathered during this research.

## *If greater than usual chance of uncovering Suicidal Risk or risk of harming others (greater chance of uncovering than usual) – REQUIRED WORDING:*

**If, during your participation in this research, there is reason to believe that you are at risk for being suicidal or otherwise harming yourself, *(or risk of harming* *others)* the research team is required by law and Hospital policy to act on this suspicion. This may include notifying your parent(s), your therapist(s) if applicable, or other individuals. If this were to occur, we would not be able to assure confidentiality, but we would let you know that we plan to disclose this information because we felt it best for your safety *(or the safety of others*).**

## *If study drug is dispensed in packaging that is not child resistant – REQUIRED WORDING:*

The drug to be used in this research study will not be given to you in a child resistant package.  It must be stored out of the reach of children.

I understand that the drug is not in a child resistant package and understand that I must make sure that it is stored safely and out of the reach of children. \_\_\_\_\_\_ (initials of /parent/guardian)

***If there are potential Risks to Fetus /Pregnancy Testing – Participant who has the ability to get pregnant– required wording FOR participants under 18 (CHILD):***

***FOR Adolescent – to be included in a separate Assent Form:***

Because participation in this research study could result in harm to a fetus, you cannot be pregnant while you are in the study. To be a part of the research, you must not have sex or you must use birth control. Before you start this research, you will be tested for pregnancy. One of the research nurses or doctors will meet privately with you to tell you your pregnancy test results. We will not tell your parent(s)/guardian(s) your results without your permission, except under certain circumstances, for example, if your life was at risk, or if the pregnancy was the result of suspected abuse. In these instances, we may need to tell your parent(s)/guardian(s) or relevant authorities.

Even if we do not tell your parent(s)/guardian(s) about the positive results, they may guess that you are pregnant because we may need to tell them you cannot participate in the research. During the research, if you become pregnant, or if there is a chance that you are pregnant, you or your parent(s)/guardian(s) should contact the research personnel immediately so that we may provide assistance and counseling. If you become pregnant during the research, we must remove you from the research.

***FOR PARENT – to be included in Consent Form:***

The effects of the drug being studied on the reproductive system (sperm, eggs) or to the developing fetus are unknown. For this reason, participants taking the drug should not become pregnant. All participants must agree to not have sexual intercourse or use a reliable, effective birth control during the study. Pregnancy testing will be performed before the research begins. The results of the pregnancy test are confidential and will be given to your child by one of the study nurses or doctors in private. We would not tell parent(s) or guardian(s) without your child's permission. However, under certain circumstances, we might be compelled to reveal this information. For example, if your child's life was at risk or if abuse was suspected, it may be necessary to inform you as parent(s) or guardian(s) or relevant authorities.

If we believe it's necessary to tell a parent or guardian about a positive pregnancy test, we would ask permission from your child. However, if we feel it is necessary to tell a parent/guardian without your child’s permission we would first meet with your child in private to discuss our concerns before divulging any information regarding pregnancy. During research, if your child has a positive pregnancy test, we must withdraw your child from the research. This means that even if we do not reveal the results, parent(s) or guardian(s) may suspect that their child is pregnant despite our best efforts to maintain confidentiality. If your child becomes pregnant or if there is any chance that your child is pregnant (late menstrual period), please contact the research investigator immediately so that we may provide medical assistance and counseling.

***If there are potential risks to Fetus /Pregnancy Testing – REQUIRED WORDING FOR PARTICIPANTS OVER 18 (ADULT):***

The effects of the research drug on the reproductive system (sperm, eggs) or to the developing fetus are unknown. For this reason, participants taking the drug should not become pregnant.

Because it is unknown if participation in this research could result in harm to a fetus, you cannot be pregnant while you are in the research. To be a part of the research, you must not have sexual intercourse or you must use reliable, effective birth control during participation. Before you start this research, you will be tested for pregnancy. One of the research nurses or doctors will meet with you privately to tell you your pregnancy test results. During the research, if you become pregnant, or if there is a chance that you are pregnant, you should contact the research investigator immediately so that we may provide medical assistance and counseling. If you become pregnant during the research, we must withdraw you from the research.

## *If there are potential risks to Fetus – Participants who can produce sperm – REQUIRED WORDING:*

***For CHILD or ADULT – to be included in Consent and/or separate Assent Form:***

The effects of the research drug on the reproductive system (sperm, eggs) or to the developing fetus are unknown. Because it is unknown if participation in this research could result in harm to a fetus, you should not have a baby while taking part in this research. If you have a partner who is able to become pregnant, one or both of you must use some form of effective birth control. During the research, if your partner becomes pregnant, or if there is a chance that your partner is pregnant, you should contact the research investigator immediately so that we may provide medical assistance and counseling.

## *If the study includes Focus Groups – SUGGESTED WORDING:*

The investigators will ask you and the other people in the focus group to use only first names during the group session. They will also ask group members not to tell anyone outside the group what was said during the focus group discussion. However, the investigators cannot guarantee that everyone will keep the discussions private.

***If the study will use Audio and/or Video Recordings – SUGGESTED WORDING:***

Only the research team will have access to your (*audio, video*) recordings. After the information has been transcribed from the recordings, the recordings will be destroyed. No names, images or other identifiers will be used in any reports or publications that may result from this research.

***If the research includes Genetic Research – SUGGESTED WORDING:***

Our testing might find a gene which may put you or a relative at risk for a genetic disorder in the future. There might be social and economic disadvantages associated with genetic information. For example, genetic information provided to the wrong source could affect you and your family. A U.S. law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Under this law, health insurance companies, group health plans, and most employers may not request your genetic information that we get from this research. For more information about GINA, please see: <http://www.eeoc.gov/laws/types/genetic.cfm>. This law does not protect information for being used when applying for life or long term care insurance. We will do our best to keep all information confidential and only with your permission would we share this information with others.

Some people involved in genetic studies feel anxious about the possibility of carrying a gene that places them at risk or that may be passed on to children. If these feelings arise at any time during the research, you may contact us and we will arrange for you to speak with a genetic counselor.

***If the research includes genetic testing (involving proband and family members) and non-paternity could be discovered – REQUIRED WORDING:***

You should be aware that because we are testing family members, we may find out that someone else might have parented a child, or that a child had been adopted. If you wish, you may let us know in confidence if this is a possibility. In all cases, this information will be kept in the strictest confidence and will not be shared with you or anyone outside of the research staff.

***If Radiological Procedures will be used – REQUIRED WORDING:***

 ***If the radiological procedures involve only DEXA scan, Chest X-ray, Bone age X-ray:***

Your participation in this research study may include the use of additional imaging scans that use radiation. The scans are the same as those currently used for routine clinical care however for the purposes of the research some additional scans may be added that otherwise would not be performed. The amount of radiation used for the additional diagnostic scans is below the levels that are thought to likely cause harm.

 ***If other than the above radiological procedures AND the estimated effective dose and/or effective dose equivalent as defined by the ICRP is < 620 millirem (mrem):***

Your participation in this research involves exposure to radiation. We are exposed to radiation on a daily basis from both natural and manmade sources. Radiation exposure is measured in millirem. The average amount of radiation a person in the U.S. is exposed to from these sources is about 620 millirem per year. The amount of radiation you will receive when participating in this research is less than this amount and is well below the levels of radiation that are thought to have a high risk of causing harmful side effects. The amount of radiation that you will be exposed to if you participate in this research is approximately [*insert number* here] millirem.

 ***If other than the above radiological procedures AND the effective dose and/or the effective dose equivalent as defined by the ICRP is > 620 millirem (mrem) but < 5000 mrem:***

Your participation in this research involves exposure to radiation. We are exposed to radiation on a daily basis from both natural and manmade sources. Radiation exposure is measured in millirem. The average amount of radiation a person in the U.S. is exposed to from these sources is about 620 millirem per year. The amount of radiation that you will receive in this research is greater than the average amount that a person living in the U.S. receives from natural and manmade sources, but well below the levels of radiation that are thought to have a high risk of causing harmful side effects and less than the amount of exposure legally allowed for those people whose jobs require work with radiation (for example, X-ray technologists, etc.). The amount of radiation that you will be exposed to if you participate in this research is approximately [*insert number here*] millirem.

## *If Magnetic Resonance Imaging will be used – REQUIRED WORDING:*

Magnetic resonance imaging (MRI) is generally considered a harmless imaging technique because it does not involve exposure to ionizing radiation such as x-rays.

There are some risks associated with MRI:

* MRI uses a powerful magnet to make images; therefore, persons with metal implants, such as certain types of surgical clips or pacemakers should not have an MRI.
* Other metal objects such as keys, pocketknives, and some types of cosmetics or jewelry must be removed prior to entrance to the magnet room. The MRI scanner also uses radio frequency waves that can, on rare occasions, cause a mild warming sensation similar to what you feel on a warm day.
* The MRI scanner makes loud banging noises during the scanning session, but you will be provided with earplugs to reduce the noise heard from the scanner.
* It is also possible, but rare, that the magnetic fields in the scanner can cause mild twitching in the arms and legs.
* Some people feel uncomfortable and/or claustrophobic when lying inside the MRI scanner. If you feel nervous or upset during the MRI, the procedure may be stopped.
* Although there are no known long-term harmful effects from having an MRI, it is possible that there are long-term effects that we don’t know about yet.

Before your MRI, staff will ask your questions to make sure that you can safely undergo the procedure and an MR screening form will be completed.

***If sedation will be used for an Imaging that is not part of usual clinical care required:***

* *Describe the agent used for sedation and any risks/contraindications of this agent*
* *State how the agent will be administered*
* *State how long participant will be under sedation*
* *State who will monitor the participant and how*
* *State the plan for recovery and an estimate of the time for full recovery and how recovery will be assessed*

***If sedation will be used for an MRI – REQUIRED WORDING:***

Some research studies require sedation so that the patient sleeps during the MRI scan. When sedation is given, wires are attached to the participant for monitoring their breathing and heart rate during the procedure. On very rare occasions these wires have caused burns where they touched the skin, but this risk is rare and staff has been trained to take the proper precautions to avoid this risk.

***If a research portion will be added onto a clinical scan when sedation is to be used – REQUIRED WORDING:***

 *(State how long sedation will be prolonged for the added research procedure)*

***If the research includes CT or MRI with Contrast – REQUIRED WORDING:***

During this MRI (or CT) you will be given an IV (a needle inserted into your body with a tube attached to a bag of liquid) with contrast medium (liquid that shows up inside your body during imaging).

 *(Specify the name and active ingredient of contrast media to be used in this study [i.e. gadolinium].)*

Rarely, participants may have a reaction to the contrast medium, such as an allergic reaction causing hives, or difficulty breathing. There is also a possibility that the injected contrast medium may leak into the surrounding tissue, which can cause reddening or burning. If a substantial amount leaks into the surrounding tissue, further medical evaluation or treatment may be required. Please tell research staff if you have chronic kidney disease, as patients with this illness should not have MRI with contrast.

## *If the research involves Cardiac MRI – REQUIRED WORDING:*

For cardiac MRIs, additional devices are used in order to generate high quality images of the heart. These devices require wire attachments to your body, primarily on your chest. On very rare occasions these wires have caused burns where they touched the skin, but this risk is rare and research staff has been trained to take the proper precautions to avoid this risk.

***Research Imaging Study Results in Medical Records***

All Imaging Studies performed at Boston Children’s Hospital are placed in the BCH medical record of participants. If a research participant is not already a BCH patient, a BCH medical record is generated for that research participant

***Incidental Finding on Imaging – SUGGESTED WORDING:***

Your research *(insert name of imaging. i.e. MRI)* will be reviewed by a radiologist, as a safety measure. If any unexpected abnormality is noticed, the research investigator will notify you or your physician and recommend next steps for you and your healthcare providers to take. *(You may also want to include additional information as pertinent to your study.)*

***TWO SAMPLE RISK CHARTS:***

|  |  |  |  |
| --- | --- | --- | --- |
| **Possible Risk/Side Effect** | **How often has it occurred?** | **How serious is it?** | **Can it be corrected?** |
| Headaches | may occur just after drug administration | usually of short duration  | Yes |
| Rash | occasionally occurs | usually involves the face and arms and may cause scratching | Yes, it will go away with treatment. |
| Skin discoloration | uncommon | will not impact your overall health | It can be permanent. |
| Liver damage | extremely uncommon  | very serious | The damage is permanent and can affect the rest of your health. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Possible Side Effects** | **Common** Happens to >21 children out of every 100  | **Occasional** Happens to 5-20 children out of every 100  | **Rare** Happens to <5 children out of every 100  |
| **Drug 1** | * Stomach pain
* Nausea or vomiting
* Dizziness
* Drowsiness
* Headache
 | * Back pain
* Blurred vision
* Constipation
* Diarrhea
* Dryness of the mouth
* Heartburn
* Increased sweating
* Trouble sleeping
 | * Chest pain
* Hives or itching
* Joint pain
* Swelling of the legs
* Flu like symptoms
* Memory loss
 |
| **Drug 2** | * Stomach pain
* Nausea or vomiting
* Dizziness
* Drowsiness
* Headache
 | * Back pain
* Blurred vision
* Constipation
* Diarrhea
* Dryness of the mouth
* Heartburn
* Increased sweating
* Trouble sleeping
 | * Chest pain
* Joint pain
* Flu like symptoms
* Memory loss
* Acute liver failure
 |

**What are the benefits of this research?**

***INSTRUCTIONS:***

*This section should explain both the potential direct/immediate benefit from the research for the participant*

*and how the research might benefit others in the future.*

*Do not list compensation in this section. Compensation must be described in the costs/payments section of the consent form and not the benefits section.*

*Do not feature “extra medical supervision” as a benefit unless participant will receive medical testing which they might not otherwise receive and which could provide potentially useful clinical information.*

*If the drug is investigational, do not suggest that the drug is beneficial.*

*Please note that there does not need to be a direct benefit to every study. If there is none, please be sure to state this.*

*SUGGESTED WORDING FOR NO BENEFIT:*

Being in this research may not help you right now. When we finish the research, we hope that we will know more about (*disease/condition*). This may help other children/adults with (*disease/condition*) in the future.

Will I receive my study results?

***INSTRUCTIONS:***

*REQUIRED: State whether clinically relevant research results will be returned, and if so, under what conditions. If clinically relevant research results will NOT be returned, this needs to be specified.*

## *If clinically relevant results will be shared – REQUIRED WORDING:*

## During this research we may learn information from the study results which could be important for your health or your treatment. This information will be made available to *(insert you, your health care provider*). The information we may share is (*please insert statement as to what may be shared and the conditions of how it will be shared)*

***If not reporting research results – REQUIRED WORDING:***

During this research we may learn information from the study results which could be important for your health or your treatment; however, we will not share this information with you.

## *If the research will use a laboratory that is not CLIA-certified: Reporting of Research Results – REQUIRED WORDING:*

**Because we are using a research laboratory and not a laboratory with certified procedures for reporting results, we cannot directly give you the results from this research. However, if we learn information that we think might be important for your health, your treatment, or your family (e.g., discovering a gene that may cause a disease or condition) we may be able to have these results confirmed by a CLIA-certified clinical laboratory that is allowed to provide results. There may be costs for the lab to perform the tests. These tests may not be covered by your insurance and in that case you will be responsible for the costs of the tests. Most CLIA laboratories will ask for new blood or tissue in order to ensure the research results are correct. If your results are confirmed, they will be given to your doctor, who will arrange for these results to be discussed with you. The study will not cover the costs of any follow-up consultation or actions.**

**Please check and initial to indicate below whether or not you wish to be informed of research results that would require follow-up CLIA testing. If you choose to be contacted, we can only do so through your own health care provider. Please provide the contact information for the healthcare provider who we should contact to discuss these results and arrange for CLIA testing.**

**\_\_\_\_\_\_ [ ]  Please contact my health care provider if results become available in the future:**

**Doctor’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

## *If the research will use a laboratory that is CLIA-certified: Reporting of Research Results – SUGGESTED WORDING*

## *(Consider whether it is preferable to give results to a health care provider or directly to subject)*

For some tests we will use a laboratory with certified procedures for reporting results. If we learn information that we think might be important for your health, your treatment, or your family (e.g. discovering a gene that may cause a disease or condition), **they will be given to [*Pick the applicable statement:* “*you with the recommendation to discuss with your doctor” or “your doctor, who will arrange for these results to be discussed with you”*]*.* The study will not cover the costs of any follow-up consultation or actions.**

***(If results will be returned to the participant’s provider, include the following:)***

**\_\_\_\_\_\_ [ ]  Please contact my health care provider if results become available in the future:**

**Doctor’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Will my samples/information be used for research in the future?**

***INSTRUCTIONS:***

*If the research involves the collection of identifiable private information or identifiable biospecimens, you must address if information and/or biospecimens will be used for research in the future. In almost all studies conducted at BCH it is possible that information and/or biospecimens collected for one study will be used, shared and/or stored for future research. The informed consent documents must address the following key points:*

***1. Clear statement on whether information and/or biospecimens collected for the study may be shared and used for future research.*** *Language provided in this template references the common practice of sharing coded information and biospecimens for future research. This language can be modified based on the study and procedures for sharing information and/or biospecimens. If the study will share identifiable information and/or biospecimens the consent form must clearly state this and address safeguards for confidentiality (i.e. IRB review and approval).*

***2. Clear statement on whether information and/or biospecimens will be used broadly for future research use or whether the future research use will be limited to specific conditions or diseases.*** *The IRB encourages you to consider the broad sharing template language if information will be shared with a central repository or database. Limiting future research to specific conditions/diseases may require additional consent if broad uses are identified later.*

***3. Identification of who participants can contact with questions about the use of their information and/or biospecimens in future research and whether they can request their information and/or biospecimens be withdrawn.*** *Investigators who want to share information/samples are required to address who participants can contact with questions and the process for requesting information/samples be withdrawn. Template language can be modified based on the protocol.*

***4. Information on the sharing of information with a central registry, database or repository and whether that sharing will be through controlled access or unrestricted access.*** *Please note many funding agencies and journals now require data to be deposited in a database/registry/repository and made available broadly for future sharing. If data will be deposited in an NIH-designated Data Repository (e.g. dbGaP) the following language is required. Template language may be adjusted to contemplate biospecimens as needed.*

***1. Clear statement on whether information and/or biospecimens collected for the study may be shared and used for future research.***

 ***Recommended template language:***

We will gather information and/or samples about you as part of your participation in this research study. The information/samples may include personal information, such as your name, address, and birth date; information from your medical record; and results or findings from study-related tests and procedures.

To advance science, medicine, and public health, we may share your information/samples with other researchers and one or more scientific databases but only after personal information that may identify you has been removed. Your information/ samples will be labeled with a research code without identifiers so that you cannot be identified. These samples/information may be shared without getting additional consent from you.

***The IRB does not recommend in the below template language. Only select this option if you know for certain that information and/ or biospecimens will never be used or shared for future research. This would include the use and sharing of information /biospecimens which have been stripped of identifiers. The BCH IRB may request information on how the investigator plans to ensure that information/samples will NOT be used or shared in the future.***

Samples and private information collected from you during this study will NOT be used for future research studies or shared with other researchers for future research, even if the information identifying you are removed from the sample and/or private information

***2. Clear statement on whether information and/or biospecimens will be used broadly for future research use or whether the future research use will be limited to specific conditions or diseases.***

 ***Recommended template language: BROAD SHARING FOR ANY DISEASE/CONDITION***

The information/samples may be combined with other researcher’s data to help understand, why diseases develop, how to best diagnose and treat diseases, and how to develop new medicines or medical devices. Your information/samples may be made broadly available for general research for multiple conditions or diseases.

***LIMITED SHARING FOR SPECIFIC DISEASES/CONDITIONS***

The information/samples may be combined with other researcher’s data to help understand, why diseases develop, how to best diagnose and treat diseases, and how to develop new medicines or medical devices. Future use of your information/samples will be limited to the disease/condition and related disorders being studied as part of this research.

***3. Identification of who participants can contact with questions about the use of their information and/or biospecimens in future research and whether they can request their information and/or biospecimens be withdrawn.***

 ***Recommended template language:***

If you have questions about storing information/ samples or would like to request that information/samples be removed from storage, please let us know. It is not always possible to remove information /samples from storage or to retrieve information/samples from which identifiers have been removed and/or that have already been sent to other researchers.

***4. Information on the sharing of information with a central database, registry or repository and whether that sharing will be through controlled access or unrestricted access. Note this language is required for genomic information deposited in a NIH designated repository.***

 ***Recommended template language: CONTROLLED ACCESS DATABASE/REGISTRY/REPOSITORY***

As part of this research study, we will put your information (i.e. genetic data) in a large database for broad sharing with the research community. Your individual information will be labeled with a code and not with your name or other information that could be used to easily identify you. Only qualified researchers will be able to access your information from the database. These researchers must receive prior approval from individuals or committees with authority to determine whether these researchers can access this information.

 ***Recommended template language: OPEN ACCESS OR PUBLIC ACCESS DATABASE/REGISTRY/REPOSITORY***

As part of this study, we will put your information (i.e., genetic data) in a large database which will be freely available to the public. The information is intended for other researchers to use and learn from but anyone can gain access to them, including law enforcement. The information in this database will include but is not limited to genetic information, race, ethnicity and sex. If your individual information is placed in one of these databases, it will be labeled with a code and not with your name or other information that could be used to easily identify you. This information when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen.

***REQUIRED WORDING FOR ALL PROTOCOLS THAT DEPOSIT Information/ Samples INTO database/registry/repository***

We will do everything we can to protect your privacy before sharing your de-identified information/samples with other researchers but, despite best efforts, there is still a very small chance that you could be re-identified. To minimize this risk, we will follow all relevant data protection laws.

Are there costs associated with this research? Will I receive any payments?

***INSTRUCTIONS:***

*This section should clearly state who is responsible for paying the costs associated with each of the tests/procedures/ interventions described above. If applicable, separate and explain costs related to research procedures from other regular costs participants might incur Explain whether participants will be remunerated for participation. Include reimbursement for meals, parking, monetary compensation, etc. Specify the overall amount, schedule of payment(s) and any plan for prorating payments if participant does not complete the study. Please also explain how remuneration will be given (i.e. gift cards, check in the mail, etc.) and to whom (parent/guardian vs. participant). If participants will not be remunerated, please state this*.

*Remember to include who is responsible for the costs associated with the treatment of side effects and to clarify the difference between routine medical care and the research. Also, clarify who is responsible for the costs of any referrals that might result from the research (e.g. additional scans, follow-up for suicidal thoughts, counseling.*

*If there are known or likely potential costs to the participant, state these costs.*

*If you state that there are no costs, then the participant (or their insurance) should never be billed for anything related to the study.*

***SUGGESTED WORDING:***

***If there is monetary compensation for participation – SUGGESTED WORDING***

You will be paid **$***XX.XX*for each research visit that you complete. *(If the amount will vary from visit to visit, state the different amounts and visit types.)*

This will add up to a total of **$***XXX.XX*if you complete all of the research visits. *(If some participants may get a particular procedure while others may not, break this into different amounts and explain.)*

If you leave the research early, or if we have to take you out of the research, you will only be paid for the visits you have completed.

***If Monetary Compensation for Time will be greater than $600/year – required wording:***

You will be paid (*insert X amount*) for your time spent in the research. Since this amount will be greater than the minimum reporting requirements set by the Internal Revenue Service or IRS (>$600/year), Boston Children’s Hospital must report this to the IRS and will give you a 1099 form because the payment you receive for this study will be considered taxable income. Boston Children’s Hospital will not deduct taxes from this payment. You will be responsible for reporting this payment when you file your tax return. We will ask for your social security number for tax reporting purposes, but it will not be stored with any other research data.

***If some procedures may be billed to insurance – REQUIRED WORDING:***

Although research funds will pay for some research-related items and services, we may bill your health insurer for routine items and services you would have received even if you did not take part in this research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the research staff.

***Injury Language for greater than minimal risk research – required wording:***

We will offer you the care needed to treat any injury that directly results from taking part in this research. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

[*The sponsor may request to include a statement about the injury coverage the sponsor will offer. When the sponsor requests to include such a statement, the statement may be entered here, after the institution's commitment to provide care for the injury. For example, "In this study, [Sponsor] will pay for medical treatment for any injury that is not paid for by your health insurer if the injury is a direct result of your taking part in the study."*]

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form. If you think you have been injured or have experienced a medical problem as a result of taking part in this research, tell the person in charge of the research as soon as possible. The researcher's name and phone number are listed in this consent form.

If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

***If you plan to use ClinCard to reimburse participants – REQUIRED WORDING:***

This research study will use a service called ClinCard® by the company Greenphire, www.greenphire.com, to manage all payments associated with your participation in study visits, your time and travel related to participation in the study. ClinCard/Greenphire will provide documentation for filing your taxes (1099 form), to the hospital, and may ask for your name and social security number using a secure website to meet that federal requirement. Boston Children’s Hospital or the sponsor has contracted with ClinCard/Greenphire to provide this service but Boston Children’s Hospital and ClinCard/Greenphire are separate entities and have no other relationship. ClinCard/Greenphire is solely responsible for the security of any information you provide to them.

You will be issued a ClinCard, which is a specially designed debit card for clinical research onto which your funds will be loaded as appropriate. When a study visit is completed, funds will be loaded onto your card. The funds will be available within 1 day and can be used as you wish.

If I do not want to take part in this research, what are the other choices?

***INSTRUCTIONS:***

*There should be an explanation of the reasonable alternatives to participating in the research. For interventional studies, this might include things like palliative care, continuing current therapy or, alternate available treatments.*

*If there are no alternatives, or the alternative is to not participate in the research study you do not need to include this section.*

***SUGGESTED WORDING:***

If you do not join this research your doctor can discuss other healthcare choices with you.

Your other choices may include *(list examples relevant to specific study or condition, for example)*:

* *List/describe the different kinds of routine care for this condition or symptoms.*
* *Joining a different research study.*
* *The procedure or drug offered in this study also may be available without being in any research.*

**Are there other things I should know about?**

***INSTRUCTIONS:***

*This section is meant to include any other important information that does not fit within the headers the IRB has have provided throughout this template Please note: This section should not refer to returning individual participant results. This topic is already covered in the “will I receive my study results” section of this template.*

***SUGGESTED WORDING:***

As this research progresses we may learn new information from data we have collected through other participants or from outcomes from other research studies. If this information could affect your health, safety or willingness to stay in this research, we will let you know as soon as possible.

***DISCLOSURE- If collection of human specimens that potentially may be used for development of diagnostic tools/therapies or commercial products – REQUIRED WORDING:***

It is possible that the samples we collect or what we learn or create from the samples, may be made available to other hospitals, universities, and businesses for further research or to create commercial products, research tools, or inventions that have value. If this were to occur, Boston Children's Hospital and/or the research investigator might receive financial benefits. Any commercial profits generated from your samples and/or information collected in this study *[will/will not]* be shared with you *(If commercial profit will be shared with the participants, provide details)* As in all research studies, the hospital has taken steps designed to ensure that this potential for financial gain does not endanger research participants, or undercut the validity and integrity of the information learned by this research.

***FINANCIALINTEREST DISCLOSURE: If Boston Children's Hospital owns equity in the company sponsoring the trial or the investigator has financial interest or owns a patent on the technology being studied – Required WORDING – SELECT the paragraphs as they pertain to your research:***

**Sometimes Boston Children's Hospital licenses some of its research inventions, discoveries, and technologies to for profit companies for further research and/or commercial development. Boston Children’s Hospital may receive equity (partial ownership of the company) in return for this license. We want you to know that Boston Children's Hospital has equity in the company that is sponsoring this research and may gain financial (monetary) benefits if the drug/device/technology being studied in this trial proves to be of benefit.** Any commercial profits generated from your samples and/or information collected in this study [*will/will not*] be shared with you. *(If commercial profit will be shared with the participant, provide details.)*

From time to time, Boston Children's Hospital licenses some of its research discoveries to for profit companies for further research and/or commercial development. Sometimes the inventor of the research receives equity (partial ownership of the company) in such licensing arrangements. It is also possible that a research investigator conducting a study may be paid for providing consulting services to a company that funds the research. In this research, [*please insert name*] has a financial interest in the technology that is used in this research or in the company that is funding this research. Any commercial profits generated from your samples and/or information collected in this study [*will/will not*] be shared with you. *(If commercial profit will be shared with the participant, provide details.)*

In the future it is possible that this technology will be sold commercially, and that the results of this research will be important in securing government approval or contracting with a business to manufacture or develop the technology. If this were to occur, Boston Children's Hospital and/or the researcher might receive financial benefits. As in all research studies, the hospital has taken steps designed to ensure that this potential for financial gain does not endanger research participants, or undercut the validity and integrity of the information learned by this research. Any commercial profits generated from your samples and/or information collected in this study [*will/will not*] be shared with you. *(If commercial profit will be shared with the participant, provide details.)*

**Why would I be taken off the study early?**

***INSTRUCTIONS:***

*If there are anticipated circumstances under which participation will be terminated by the research investigator without regard to the participant’s consent, disclose these anticipated circumstances.*

***SUGGESTED WORDING (include all those that may apply, you may add others as well):***

The research investigator [*or the study sponsor*] may take you out of this study at any time. This would happen if:

* ***The research is stopped.***
* ***You are not able to attend the research visits required.***
* ***You fail to follow the research requirements.***
* ***You need a treatment or medication that may not be taken while on the research or the research investigator feels it is in your best interest to be taken out of this research.***

**If this happens, the research investigator will tell you.**

**Other information that may help you:**

Boston Children’s Hospital is interested in hearing your comments, answering your questions, and responding to any concerns regarding clinical research. If you have questions or concerns, you may email IRB@childrens.harvard.edu or call (617) 355-7052 between the hours of 8:30 and 5:00, Monday through Friday.

**Who may see, use or share your health information?**

***INSTRUCTIONS:***

*Note that all consent forms should explain whether a copy of the consent form and research assessment results will be placed in the medical record.*

*Research consents must be placed in the medical record for studies that may be characterized by any of the three categories:*

*1) research involving medical procedures /testing for which medical care or support is required*

*2) research undertaken for the intervention, treatment, or diagnosis of a disease, disorder, or condition (e.g., drug and device trials; comparison of psychological interventions; testing new diagnostic techniques)*

*3) any testing or assessment relevant to the patient’s clinical care,*

*For all three categories any reports and results that bear on the care of the patient, including the proper interpretation of unrelated clinical tests that would otherwise be anomalous data also need to be placed in the consent and this needs to be specified in the consent.*

***If the participant does not have current medical record but one is created as a result of the research (i.e. normal participant undergoing MRIs or any other type of medical testing);***

If you are not currently a patient at Boston Children’s Hospital and do not have a medical record at Boston Children’s Hospital, one may be created for you for your participation in this research. You may also be required to register as a patient of Boston Children’s Hospital in order to participate in this research.

***If consent form will be placed in medical record – REQUIRED WORDING:***

A copy of this consent form will be placed in your medical record. If you do not have a medical record at Boston Children’s Hospital, one will be created for you.

***If consent form will NOT be placed in medical record – REQUIRED WORDING:***

A copy of this consent form will not be placed in your medical record.

***If research data will be placed in medical record – REQUIRED WORDING:***

Information collected during this research will become part of your medical record, if the information is related to the care you receive at Boston Children's Hospital. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Boston Children's Hospital and may be reviewed by Hospital staff when carrying out their responsibilities; however, they are required to maintain confidentiality in accordance with applicable laws and Hospital policies. Information contained in your medical record may not be given to anyone unaffiliated with Boston Children's Hospital in a way that could identify you without written consent, except as required or permitted by law.

***If research data will not be placed in medical record – REQUIRED WORDING:***

The results of the tests performed for research purposes will not be placed in your medical record. Because of this, it is unlikely that others within the hospital, an insurance company, or employer would ever learn of such results.

***If you have or will obtain a Certificate of Confidentiality – REQUIRED WORDING:***

*Please note that effective of October 1, 2017 certificates of confidentiality will be automatically issued to NIH-funded research that collects or uses identifiable, sensitive information.  This includes:*

* *Human subjects research if the recorded information is directly or indirectly linked to identifiers;*
* *Research involving the collection or use of biospecimens or information for which there is at least a very small risk that some combination of the biospecimens/information, a request for the biospecimens/information, and other available data sources could be used to deduce the identity of an individual;*
* *Research that involves the generation of individual level human genomic data regardless of the identifiability of the biospecimens.*

*The following required language is required to be in your consent form(s):*

The National Institutes of Health has issued (or we have applied to the NIH for) a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena unless you give permission.  However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research.  Any research information that is placed in your medical record would not be covered under this Certificate.   The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.  The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

***If your protocol will be registered on clinicaltrials.gov– REQUIRED WORDING – CANNOT BE CHANGED:***

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

***Use of Non-Secure Email and Text Messages***

***INSTRUCTIONS:***

*Non-secure email or text messaging may only be used for research in accordance with the IRB Policy and if approved for the protocol. Requests will be evaluated on a case-by-case basis. Certain studies may not be appropriate for non-secure email or text communications, e.g., certain mental health conditions, sexually transmitted disease, HIV, illicit drug use, illegal or abusive behaviors. Templated consent language is included below. Any other process or use of language outside of this language will be subject to review and approval by the Compliance/Privacy Office.*

***Email only******– SUGGESTED WORDING***

The Boston Children’s Hospital standard is to send emails securely by encryption. If you prefer, we can send you regular non-encrypted emails Unencrypted emails are sent directly to and can be opened from your personal email account. There is a potential risk of loss of confidentiality when using unencrypted email, as your email account is hosted by a third-party. Please be aware that email communication can be intercepted in transmission or misdirected.

You acknowledge that you have been informed and understand that we cannot guarantee that regular non-encrypted email will be confidential. Please check below if you wish to receive non-encrypted emails.

\_\_\_\_\_\_\_ [ ]  I wish to receive regular non-encrypted emails from the study team.

If, at any point, you no longer wish to receive unencrypted emails from us, you may indicate this by sending an email to [studyemail@childrens.harvard.edu] or calling this number [xxx-xxx-xxxx], and we will return to communicating via encrypted email.

***Text Message Only – SUGGESTED WORDING***

We would like to offer you the option of receiving study information and updates via SMS text message. Text messages are sent directly to the personal phone number you have provided. Text messages are sent from study-related Boston Children’s Hospital phone numbers.

There is a potential risk of loss of confidentiality when using SMS text messages, as text messaging is hosted by a third-party. Please be aware that text messages can be intercepted in transmission or misdirected.

You acknowledge that you have been informed and understand that we cannot guarantee that text messages will be confidential. Please check below if you wish to receive text messages.

\_\_\_\_\_\_\_ [ ]  I wish to receive text messages from the study team.

If, at any point, you no longer wish to receive text messages from us, you may indicate this by replying STOP to a study text message, sending an email to [studyemail@childrens.harvard.edu], or calling this number [xxx-xxx-xxxx], and we will no longer send you text messages.

***Email and Text Messages – SUGGESTED WORDING***

The Boston Children’s Hospital standard is to send emails securely by encryption. If you prefer, we can send you regular non-encrypted emails. Unencrypted emails are sent directly to and can be opened from your personal email account.

We would also like to offer you the option of receiving study information and updates via SMS text message. Text messages are sent directly to the personal phone number you have provided. Text messages are sent from study-related Boston Children’s Hospital phone numbers.

There is a potential risk of loss of confidentiality when using unencrypted e-mail and text messaging, as both are hosted by a third-party. Please be aware that these communications can be intercepted in transmission or misdirected.

You acknowledge that you have been informed and understand that we cannot guarantee that regular non-encrypted email or text messages will be confidential. Please check below if you wish to receive non-encrypted emails or text messages.

\_\_\_\_\_\_\_ [ ]  I wish to receive regular non-encrypted emails from the study team.

\_\_\_\_\_\_\_ [ ]  I wish to receive text messages from the study team.

If, at any point, you no longer wish to receive unencrypted emails from us, you may indicate this by sending an email to [studyemail@childrens.harvard.edu] or calling this number [xxx-xxx-xxxx], and we will return to communicating via encrypted email. If you no longer wish to receive text messages from us, you may also reply STOP to a study text message and we will no longer send study text messages.

***Contact for Future Studies – SUGGESTED WORDING:***

**Contact for Future Studies:** Your participation in any research is completely voluntary and you should feel no pressure to participate if you are contacted about another research study.

**Please check and initial one** of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

­­\_\_\_\_\_\_\_ [ ]  Yes, I may be contacted about participating in other research projects studying (*insert category*) disease or related conditions. I give permission for my contact information (name and mailing address and/or phone number) to be given to other researchers working with the study investigator at Boston Children’s Hospital.

\_\_\_\_\_\_\_ [ ]  No, I do not want to be contacted about other research projects. **Do not** give my contact information to the staff of any other research studies.

***INSTRUCTIONS:***

*We have combined the required HIPAA privacy disclosure with the required section on privacy and confidentiality. Please do not include a separate confidentiality section. If there is additional information that you want to include please insert it below. If sponsors include a separate confidentiality section, it should be added to the language below and should not be repetitive. The rest of this text is mandated to be in all consent forms. Please be sure to update the signature section, as appropriate.*

**What should you know about HIPAA and confidentiality?**

Your health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research, including those funding and regulating the study, may see the data, including information about you. For example, the following people might see information about you:

* Research staff at Boston Children’s Hospital involved in this study;
* Medical staff at Boston Children’s Hospital directly involved in your care that is related to the research or arises from it;
* Other researchers and centers that are a part of this study, including people who oversee research at that hospital;
* People at Boston Children’s Hospital who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program;
* People from agencies and organizations that provide accreditation and oversight of research;
* People that oversee the study information, such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others;
* Sponsors or others who fund the research, including the government or private sponsors.
* Companies that manufacture drugs or devices used in this research;
* Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities;
* People or groups that are hired to provide services related to this research or research at Boston Children’s Hospital, including services providers, such as laboratories and others;
* And/or your health insurer, for portions of the research and related care that are considered billable.

If some law or court requires us to share the information, we would have to follow that law or final ruling.

Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of Boston Children’s Hospital, we cannot promise that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this, you may contact the Boston Children’s Hospital Privacy Officer at (857) 218-4680, which is set up to help you understand privacy and confidentiality.

Because research is ongoing, we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years, so it is not possible to know when they will be done.

We will also create a code for the research information we collect about you so identifying information will not remain with the data and will be kept separately. The results of this research may be published in a medical book or journal or be used for teaching purposes. However, your name or identifying information will not be used without your specific permission.

**Your privacy rights**

If you want to participate in this research study, you must sign this form. If you do not sign this form, it will not affect your care at Boston Children’s Hospital now or in the future and there will be no penalty or loss of benefits. You can withdraw from the study and end your permission for Boston Children’s Hospital to use or share the protected information that was collected as part of the research; however you cannot get back information that was already shared with others. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your health information, please contact the research team.

You may have the right to find out if information collected for this study was shared with others for research, treatment or payment. You may not be allowed to review the information, including information recorded in your medical record, until after the study is completed. When the study is over, you will have the right to access the information again. To request the information, please contact the Hospital’s Privacy Officer at (857) 218-4680.

**Contact Information**

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

|  |  |  |
| --- | --- | --- |
| 🚹 I can call… | **🕾** At | **❓** If I have questions or concerns about |
| Investigator: | Phone: | **[Insert Contact #]** | ▪ General questions about the research ▪ Research-related injuries or emergencies▪ Any research-related concerns or complaints |
| **[Insert PI Name]** | Pager: | 617-355-7243 **[Pager #]** |
| Research Contact | Phone: | **[Insert Contact #]** | ▪ General questions about the study▪ Research-related injuries or emergencies▪ Any research-related concerns or complaints |
|  | Pager: | 617-355-7243 **[Pager #]** |
| Institutional Review Board  | Phone: | **617-355-7052** | ▪ Rights of a research participant ▪ Use of protected health information.▪ Compensation in event of research-related injury▪ Any research-related concerns or complaints.▪ If investigator/research contact cannot be reached.▪ If I want to speak with someone other than the Investigator, Research Contact or research staff. |
|  |  |  |

**Documentation of Informed Consent and Authorization**

* I have read this consent form and was given enough time to consider the decision to participate in this research.
* This research has been satisfactorily explained to me, including possible risks and benefits.
* All my questions were satisfactorily answered.
* I understand that participation in this research is voluntary and that I can withdraw at any time.
* I am signing this consent form prior to participation in any research activities.
* I give permission for participation in this research and for the use of associated protected health information as described above (HIPAA).

**Parent/Legal Guardian Permission (if applicable)**

**Please let the researcher or staff know if the Massachusetts Department of Children and Families (DCF) has obtained temporary or permanent legal custody of the child to be involved in this research.**

 ◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 Date (MM/DD/YEAR) Signature of **Parent #1** or **Legal Guardian** Relationship to child

 ◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 Date (MM/DD/YEAR) Signature of **Parent #2**  (if required) Relationship to child

[ ]  CHECK if 2nd parent signature **not** obtained above. The PI must document in research records all attempts made to contact the second parent, as well as the reason why the 2nd parent signature was not obtained.

**Child Assent**

◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 Date (MM/DD/YEAR) Signature of **Child/Adolescent Participant**

◼ If child/adolescent’s assent is **not** documented above, please indicate reason below (check one):

[ ]  Assent is documented on a separate IRB-approved assent form

[ ]  Child is too young

[ ]  Other reason (e.g. sedated), please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Adult Participant (if applicable)**

◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 Date (MM/DD/YEAR) Signature of **Adult Participant (***18+ years)*

**Adult Participant: If decisionally impaired (if applicable)**

**Legal Authorized Representative/Guardian**

I give permission for the person I am authorized to represent to participate in this research and for the use of associated protected health information as described above (HIPAA).

 ◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 Date (MM/DD/YEAR) Signature of **Legal Guardian** Print Name

◼ Relationship to Participant \* *(This order must be followed. If there is a court appointed guardian, this is who needs to provide consent. If not, a health care proxy, followed by durable power of attorney and lastly, family members)*

 [ ]  Court-Appointed Guardian

[ ]  Health Care Proxy (Attach Proxy and ensure there is express authority to make health care decisions inclusive of research.)

[ ]  Durable Power of Attorney (POA) (Durable POA may be limited to specific areas. Attach Durable POA and ensure that it covers research.)

 [ ]  Family Member/Next of Kin, (in order of preference: spouses, parents, and adult children)

 Specify relationship\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Adult Assent** (if applicable)

◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Date (MM/DD/YEAR) Signature of **Adult Participant**

[ ]  CHECK if Adult Participant’s assent **not** obtained above, and specify reason below:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Research Investigator /or Associate’s Statement & Signature**

* I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
* I have answered and will answer all questions to the best of my ability.
* I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
* I have provided a copy of the consent form signed by the participant / parent / guardian and a copy of the hospital’s privacy notification (if requested).

◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 Date (MM/DD/YEAR) Signature of **Research Investigator or Associate**

**Witness Statement & Signature**

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

[ ]  The individual cannot read and this consent document was read to the participant or legal representative, **or**

[ ]  The individual has certain communication impairments that limit the participant’s ability to clearly express consent **or**

[ ]  Situations where the IRB requests a witness be present: please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 I confirm that the information in this consent form was accurately explained to the participant, parent or legally authorized representative, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date (MM/DD/YEAR) Signature of Witness

**Or**

[ ]  The individual is not English speaking and, through an interpreter, a short form consent document was presented orally to the participant or legal representative and this consent document serves as the summary for such consent.

I confirm that the information in this consent form was presented orally to the participant, parent or legally authorized representative, in a language they could understand and the individual had the opportunity to ask questions.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Date (MM/DD/YEAR) Signature of Witness