This consent form gives you important information about an individual patient expanded access treatment for your child. Expanded access is a way we can offer a drug/device that has not been approved yet by the Food and Drug Administration to an individual patient without the need to be enrolled in a research study

Participation in this individual patient expanded access treatment is voluntary. You are free to say yes or no and your decision will not impact the care your child receives at Boston Children’s Hospital. You can withdraw from the treatment at any time. A description of the expanded access treatment is voluntary and its risks, potential benefits and other important information are in this consent form. Please read this consent form carefully and take your time making a decision. 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 let your child participate.

**How are individuals selected for this expanded access treatment?**

Your child is being asked to participate in this expanded access treatment because your child ……..The drug/device we want to offer is considered an expanded access treatment and is voluntary because this drug/device has not been approved for treatment of your child’s condition. It is an investigational drug/device that we will administer.

**Why is this expanded access treatment is voluntary being offered?**

The purpose of this expanded access treatment is to >>>>

The drug/device has not yet been approved or cleared by the Food and Drug Administration (FDA) and has not yet been proven to be safe and effective for the purpose we are using it for.

**Who is recommending the expanded access treatment?**

This drug is being recommended by ……..

This expanded access treatment is being requested only for your child.

**What do I have to do if I am in this expanded access treatment ?**

Insert descriptions

**What are the risks? What could go wrong?**

Investigational (drugs/devices) have not yet been approved by the FDA and they have not been proven to be safe and effective. Therefore, they may be effective in treating this condition , or they may not. It is important to remember that the drug/biologic/medical device may have unexpected serious side effects and that patients need to consider all the possible risks when seeking access to an investigational medical product.

**What are the potential benefits of this expanded access treatment?**

Insert descriptions

Are there costs associated with this expanded access treatment?

(Add whatever necessary)

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.

We will offer your child the care needed to treat any injury that directly results from taking part in this expanded access treatment. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care your child gets 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.

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 your child has been injured or have experienced a medical problem as a result of taking part in this investigational treatment, tell the person in charge of the treatment as soon as possible. The physician’s name and phone number are listed in this consent form.

If I do not want your child to take part in this expanded access treatment, what are the other choices?

If your child does not receive this expanded access treatment, your doctor can discuss other healthcare choices with you. Other choices may include: …..

Insert descriptions

Participation is voluntary. Your child may withdraw from the treatment at any time and this will in no way affect the medical care received at Boston Children’s Hospital.

**Are there other things that are important to know about?**

If we find out about new information from this expanded access treatment that may affect your child’s health, safety or willingness to stay on this treatment we will let you know as soon as possible.

Insert descriptions

**Why would my child be taken off this expanded access treatment early?**

Your child may be taken off this drug/device at any time. This would happen if:……

**Insert descriptions**

**If this happens, we will tell you.**

**Other information that may help**

Insert description if applicable

Boston Children’s Hospital is interested in hearing your comments, answering your questions, and responding to any concerns regarding investigational treatments. 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?**

Your participation in this research study may be noted in your electronic medical record. If you do not have an existing medical record, one may be created. Information placed in your medical record may include the informed consent or the results of tests or assessments we collect during the research. This could be viewed by staff from Boston Children’s Hospital, study monitors and others who provide oversight of the study. Everyone who sees this information is required to keep it confidential in accordance with hospital policies and laws. Information about your research participation may not be given to anyone unaffiliated with Boston Children's Hospital in a way you can be identified unless we obtain your permission, or it is permitted or required by law.

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

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

* Research staff at Boston Children’s Hospital involved in investigational treatment
* Medical staff at Boston Children’s Hospital directly involved in your care that is related to the treatment or arises from it;
* Other researchers and centers that are a part of this study, including people who oversee expanded access treatment at that hospital;
* People at Boston Children’s Hospital who oversee, advise, and evaluate expanded access treatment and care. This includes the ethics board and quality improvement program;
* People from agencies and organizations that provide accreditation and oversight of expanded access treatment ;
* 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 expanded access treatment including the government or private sponsors.
* Companies that manufacture drugs or devices used in this expanded access treatment
* Federal and state agencies that oversee or review expanded access treatment 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 expanded access treatment at Boston Children’s Hospital, including services providers, such as laboratories and others;
* And/or your health insurer, for portions of the expanded access treatment 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 expanded access treatment is ongoing, we cannot give you an exact time when we will destroy this information. We may 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 treatment information we collect about you so identifying information will not remain with the data and will be kept separately. The results of this investigational treatment 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 expanded access treatment, 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 treatment; 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 physician team.

You may have the right to find out if information collected for this treatment 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: |  | ▪ General questions about the treatment ▪ treatment -related injuries or emergencies▪ Any treatment -related concerns or complaints |
|  | Pager: | 617-355-7243  |
| Contact | Phone: |  | ▪ General questions about the treatment ▪ Treatment-related injuries or emergencies▪ Any treatment -related concerns or complaints |
|  | Pager: |  |
| Institutional Review Board  | Phone: | **617-355-7052** | ▪ Rights of a participant ▪ Use of protected health information.▪ Compensation in event of treatment -related injury▪ Any treatment concerns or complaints.▪ If investigator/treatment contact cannot be reached.▪ If I want to speak with someone other than the Investigator, Treatment Contact or 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 expanded access treatment.
* This expanded access treatment has been satisfactorily explained to me, including possible risks and benefits.
* All my questions were satisfactorily answered.
* I understand that participation in this expanded access treatment is voluntary and that I can withdraw at any time.
* I am signing this consent form prior to participation in any expanded access treatment activities.
* I give permission for participation in this expanded access treatment and for the use of associated protected health information as described above (HIPAA).

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

**If the child to be involved in this expanded access treatment is a foster child or a ward of the state please notify the investigator or their staff who is obtaining your consent.**

 ◼ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 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 intreatment 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 expanded access treatment 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 expanded access treatment h escribed 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 treatment procedures or the risks and benefits during or after the course of the expanded access treatment
* 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 **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**