

**Informed Consent Form and HIPAA Authorization**

* **Single Patient Experimental Treatment or**

**Drug Treatment or Device Treatment –**

**Title:** Single PatientExpanded Access for XXX (*Drug/Biologic or Device Treatment of Disease or Condition)*

Version Date: Month, Day, 20XX

**Principal Investigator:** Add Investigator Name Telephone: (xxx) xxx-xxxx

**Emergency Contact**: Add Name Telephone: (xxx) xxx-xxxx

Before you can begin treatment under this Single Patient Expanded Access (called “the study” in this consent form), we want to give you some information so you can make an informed decision. This process is known as “informed consent”.

This consent form tells you about the study that you may wish to take part in. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word “we” means the study doctor and other research staff. In the sections that follow, the word “you” means the patient.

## Study Overview

*Include a concise statement explaining the research. This example is relevant for studies that involve an investigational drug.*

You are being asked to take part in this study because you have XXXX. *Briefly include the major reasons why the subject is being approached to participate. For example, “…you have cancer which has not responded to treatment”*

The purpose of this study is to treat you with investigational drug XXXX (called ‘the study drug’ in this form). This study drug is not approved by the FDA *(If it is approved, discuss whether it is approved for its proposed use (i.e., for children, for specific disorders, etc.).*

If you agree to take part, your participation will last for XXXX and will involve XXXX study visits. You will need to take the study drug for YYY weeks. There are differences between this study and your usual care. As a participant in the study you will *(this listing of procedures should be limited to the most burdensome and/or main procedures that a reasonable person would want to know)*:

* Receive the study drug.
* Have study procedures to monitor the effect of the study drug *(such as ECGs, blood tests and imaging etc.)*

The main risks of this study are from the study drug. These include: death, stroke, hemorrhage, infection, etc. *(include risks pertinent to the drug, device, or other major procedures e.g. general anesthesia, liver biopsy)*

You may benefit if the study drug works to improve your symptoms *(slows the growth of your tumor, improves your immune system etc.)*.

Please see below for additional details about the study.

Please read the information carefully and discuss it with anyone you want. This may include your family or a friend.

If there is anything in this form you do not understand, please ask questions. Please take your time. Once you know about the study and the procedures that will be done, you will be asked to sign this consent form to receive treatment. You do not have to take part in this study if you do not want to. Joining or not joining will not affect your medical care. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor.

## What is involved in the treatment?

### How long will you be in this study?

Depending on how you respond, doses may be given as long as your disease doesn’t worsen and you don’t have serious side effects from the study drug.

### What are the study procedures?

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed. Additional tests may be performed if any of your initial test results are not normal.

### Experimental Procedures:

Study Drug or other Intervention: You will need to take the study drug by mouth twice a day for XXXX weeks.

Routine Clinical Trial Procedures (these include exams, tests or procedures that are needed to administer the study drug *(device – edit as applicable)*, monitor the effects of the study drug, and prevent or treat complications):

Blood tests: We need to collect blood to measure XXX *(blood chemistries, blood counts, etc.)*. Depending on the study visit we will collect between X and Y teaspoons of blood. We will do our best to collect the samples at the same time as a clinic blood test. We will try not to stick you more than once.

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

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

**Tests/procedures that are or may be done, if clinically indicated**:

Pregnancy Tests: If you are a woman able to have children, a pregnancy test will be performed. If you are pregnant, you will not be able to get this treatment.

X-Rays, Scans, Imaging Studies: You will be treated with a XXX *(drug/biologic)*, and you will need the following imaging studies: *List here*.

### Samples used for research purposes

### During the study, we will collect blood [urine, tissue etc., include as applicable] samples from you. By agreeing to participate in the study, you

### *[if stored at CHOP]* agree to give these samples to CHOP for research purposes. *AND/OR*

### *[if collected for a sponsor, include the language relevant to the sponsor’s storage and use]*

### Will I receive any results from the tests done as part of this study?

Results that could be important for your clinical care will be shared with you. We will not share other results with you.

## What are the risks related to XXX *(drug/biologic/device)* treatment?

You may have side effects from the drug/biologic/device. You will be watched carefully for any side effects. However, doctors don’t know all the side effects that could possibly happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects may be temporary. In some cases, side effects can be serious, long lasting, may never go away, or possibly result in death. If you have any questions about any of the possible risks listed below, you should talk to your doctor.

The list of side effects below contains the most common or serious side effects of the drug/biologic/device. Please notify your doctor if you experience any of the described side effects. This treatment is experimental, so there may be risks that are currently not known. Please tell your doctor if you are experiencing any problems.

**Risks associated with study XXX *(drug/biologic/device)*:**

*Whenever possible, include the risks of drugs/biologis/devices in a table organized by frequency.*

**Very Common (greater than 10 out of 100 patients)**

**Common (from 1-10 out of 100 patients)**

### Less Common (from 1 out of 1000 to 1 out of 100 patients)

**Rare (less than 1 out of 1000 patients)**

### Reproductive Risks:

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

**Risks associated with blood draws:**

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

### Risks associated with an ECG:

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

## Are there any benefits to taking part in this study?

You might benefit by reduction or stopping of your symptoms of disease. *(edit as applicable)* However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study.

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

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

### What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

### What happens if you decide not to take part in this study?

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

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

### Can you stop your participation in the study early?

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

### Can the study doctor take you out of the study early?

The study doctor may take you off of the study if:

* Your condition worsens.
* The study is stopped.
* The study drug is no longer available.
* New information suggests taking part in the study may not be in your best interests.

### What choices do you have other than this study?

There are options for you other than this study including:

* Not participating in this study.
* You may discuss other options available to you with your doctor.

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

As part of this study, health information about you will be collected. This will include information from your medical record. Information related to your medical care at CHOP will go in your medical record. This could include tests done in the clinical lab. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

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

* Members of the study team and other authorized staff at CHOP;
* People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
* The Food and Drug Administration;
* XXX, the manufacturer of the drug *(if applicable)*.

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

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

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

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

Dr. XXXXXX
The Children’s Hospital of Philadelphia
Division/Department of XXXX
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

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

**Additional Information**

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

## Financial Information

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

### Will there be any additional costs?

There will be no additional costs to you by taking part in this study. The company that makes the study drug will provide it free of charge. *(as applicable)*

### Will you be paid for taking part in this study?

You will not receive any payments for taking part in this study.

### Who is funding this study?

The Children’s Hospital of Philadelphia is funding this study *(as applicable)*.

## What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. XXXX at xxx-xxx-xxxx. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children’s Hospital of Philadelphia has reviewed this study. If you have questions about your rights or if you have a complaint, you can call the Institutional Review Board (IRB) Office at 215-590-2830.

## What happens if you are injured during the study?

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

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

If you think you have been injured from taking part in this study, call Dr. XXXX at xxx-xxx-xxxx. They can go over things with you, let you know of resources that may be available and give you information on what you need to do.

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

## What will be done with my data and specimens *(if applicable)* when this study is over?

*(Use one of the following options regarding the use of data and/or specimens for future research.):*

*NO secondary (future) research with or without identifiers:*

Your data and/or samples *(include as applicable)* will not be used for any future research after this study is complete.

*Secondary (future) research without identifiers:*

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

**Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research**

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

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Obtaining Consent |  | Signature of Person Obtaining Consent |
|  |  |  |
|  |  | Date |

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

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| --- | --- | --- |
|  |  |  |
| Name of Subject |  |  |
|  |  |  |
| Signature of Subject (18 years or older) |  | Date |
|  |  |  |
| Name of Authorized Representative (if different than subject) |  | Relation to subject:[ ]  Parent [ ]  Legal Guardian |
|  |  |  |
| Signature of Authorized Representative |  | Date |

## Child Assent to Take Part in this Research Study

### For children capable of providing assent:

I have explained this study and the procedures involved to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in terms he/she could understand and that he/she freely assented to take part in this study.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Obtaining Assent |  |  |
|  |  |  |
| Signature of Person Obtaining Assent |  | Date |

This study has been explained to me and I agree to take part.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of Subject (optional) |  | Date |

Delete the following if all subjects will assent.

### For children unable to assent:

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

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Responsible for Obtaining Assent |  |  |
|  |  |  |
| Signature of Person Responsible |  | Date |

**COMMENTS**

1) Delete assent lines if none of the children will be old enough to assent (e.g., neonates) or if the study only involves subjects capable of consenting for themselves.

2) If some may be old enough and some not, include both statements so that the investigator can document on the Assent page, why a particular subject was unable to assent.