# Indiana University Informed Consent Statement and Authorization for Treatment with [Name of Investigational Product]

**[Insert Protocol Title]**

**[Insert IRB Protocol Number]**

**[Insert Principal Investigator’s Name and Telephone Number]**

NOTE – this template would typically be used for a single, identified patient. In those cases, the language should be customized to that particular patient, e.g., include pregnancy language/risks only for female patient, include pregnant partner language/risks only for male patients, changing “you” to “your child” when the patient is a minor, etc.

## Introduction

* You are diagnosed with [insert name of disease/condition].
* [Insert applicable statement:] For your condition, there is no drug approved by the Food and Drug Administration (FDA) for use in medical care in the United States.

**OR**

The Food and Drug Administration (FDA)-approved drugs available for your treatment did not work for you.

**OR**

You cannot tolerate the side-effects of the drugs approved by the Food and Drug Administration (FDA) for treatment of your condition.

* Your doctor would like to treat you with [insert name of investigational product].
* [Insert name of investigational product] is an investigational drug. It is not approved by the FDA for the treatment of your condition. However, the FDA is allowing [insert doctor’s name] to treat you with [insert name of investigational product] under the FDA’s expanded access program. Expanded access is a way for patients with serious diseases or conditions who cannot participate in a clinical trial to gain access to a medical product that has not been approved by the FDA.
* Whether or not you take [insert name of investigational product] is up to you. If you choose not to receive [insert name of investigational product] or change your mind later, your doctors will still treat you.
* Read this form carefully. You may want to discuss your options with your doctors, family, friends, and others before deciding whether to receive this treatment.
* Please ask questions about anything you do not understand.

## What are the Procedures Associated with this Treatment?

[Insert explanation of all procedures/tests that will be performed as a part of the investigational treatment using language understandable to the subject. For example: You will receive [investigational product] approximately every 2 months (6–8 weeks) for up to 1 year at the clinic. [Investigational product] will be administered in your vein. The initial treatment will take three hours. After your initial treatment, other visits will take about 90 minutes.

After you complete this treatment, you will still need to come to the clinic for follow-up visits every 4 months for about one year. We will collect blood samples and take a CT scan of your chest at these visits. This is to continue to monitor your health. These visits will last about 90 minutes.]

## What Are the Potential Benefits of this Treatment?

[Insert a statement of potential benefits. For example: We would like to treat you with the investigational drug because we believe it may help you. There is a chance it will improve symptoms caused by [X] or reduce [Y]. However, there is no guarantee that you will benefit from this treatment.]

## What Are the Potential Risks of this Treatment?

[Include a list of reasonably foreseeable risks and side effects of the investigational product. Include frequency, if known. Also, describe any potential risks from the medical procedures necessary to administer the investigational product.

For example: The investigational drug needs to be administered via [W] route of administration during [Z procedure]. Risks of [Z] may include pain or numbness in the legs and lower back and bleeding into the spinal canal where the main nerve that goes down your back is located. The doctors who will perform the [Z] are specifically trained and experienced in performing this procedure.

The following are serious side effects that have been reported for [X]:

* Serious injury to your kidneys that could lead to kidney failure
* Significant disability

The following are side effects that are more likely to occur when taking [X]:

* Headache
* Vomiting
* Dizziness

There may also be risks that are unknown, including risks to a fetus if you become pregnant while taking part in the investigational treatment.

There is also a possibility that someone outside your care team could get access to your treatment or medical information.]

## If I Do Not Choose this Treatment, What are my Other Options?

[Describe any other treatment options. Example language if no alternatives: There are no other drugs approved for your disease, and you are currently not eligible to enroll in any clinical trials. However, you can discuss other treatment options, with may include [insert options] with [doctor’s name].]

## Will it Cost Me Anything to Receive this Treatment?

Taking part in this treatment may lead to extra costs to you or your insurance company. You or your insurance company will be charged for [insert a detailed list of the procedures, tests, office visits, medications, etc. for which the subject or the subject’s insurance is responsible].

You will not be billed for [insert a list of the procedures, tests, visits, medications, etc. for which the study will pay]. You should check your medical bills to be sure you are billed correctly.

[If appropriate, include the following:] If [name of investigational product] is approved by the FDA during the study and becomes commercially available, you or your insurance company may have to begin paying for the drug.

## Who Will Pay if I Am Injured by the Treatment?

[If a source of funds for payment of treatment costs is available:

Insert a description of the source and conditions for payment of those costs. IU expects industry sponsors to compensate subjects for research-related injury. Language used should be detailed and consistent with the contract with the sponsor but should be phrased in a way that is understandable to subjects. Note that if the sponsor is providing compensation for injury, and the subject has government payor insurance, the government payor cannot be billed. The sponsor must directly cover these costs.] Signing this form won’t take away any of your legal rights if you are injured.

[If a source of funds for payment of treatment costs is NOT available, insert the following:]

If you have an injury or illness as a result of participating in the study, [insert one of the following: necessary medical treatment will be provided to you and billed as part of your medical expenses OR you will be responsible for seeking medical care and for the expenses associated with any care received]. Any costs not covered by your medical insurance will be your responsibility. We don’t have money set aside to pay for these types of injuries. However, signing this form won’t take away any of your legal rights if you are injured.

## How Will My Information [and Specimens] be Used?

The care team assisting with this treatment will collect information about you from your medical records. This may include information that can identify you, such as your name, contact information, and medical record number. Information from your medical records will be used to make sure you meet the criteria to receive this treatment, review how you are responding to the treatment, and make decisions about your ongoing medical care and treatment.

The information released and used related to your treatment will include all of your medical records. This may include information about mental health, alcohol or substance abuse, HIV/AIDS, sexually transmitted diseases, and/or results of genetic testing.

If you agree to participate, you authorize the following to disclose your medical record information:

* Indiana University Health
* Indiana University Health Physicians [include specialty]
* IUMG – Primary Care Physicians
* Eskenazi Health
* Indiana Network for Patient Care (INPC)
* [Insert name of health care organization(s) or provider(s) not listed above]
* Other: [blank space for participant to complete]

The following individuals and organizations may receive or use your identifiable health information:

* Your care team providing the treatment
* The Institutional Review Boards (IRB) or its designees that review research and investigational treatments
* Indiana University
	+ [If treatment will be provided at the ICRC:] The Indiana Clinical Research Center (ICRC)
* State and Federal government agencies as permitted by law, including but not limited to:
	+ The United States Food and Drug Administration (FDA)
* Data safety monitoring boards and others authorized to monitor the conduct of your treatment
* The following research sponsors or product manufacturers: [list]
* Contract research organization(s): [list]

After your medical record information is released for purposes of this research study, your information may no longer be protected under federal privacy laws, such as HIPAA. However, your identifiable information will still be stored securely and only used as described in this consent. We will do our best to keep your personal information private, but we cannot promise complete confidentiality. We won’t share any information that we think could be used to identify you in publications about this treatment. However, your personal information may be shared outside your care team as described in this document and/or if required by law.

Information related to your treatment [and specimens collected] may be used for research studies or shared with other researchers who are conducting research studies. This may include sharing with researchers outside Indiana University and sharing with private companies. It may also include making the information available in public and private databases of research data so that other researchers can use the information to answer research questions.

If we share your information [or specimens] in this way, we will remove information that could identify you, such as your name and contact information, before any information [or specimens] are shared. Since identifying information will be removed, we will not ask for your additional consent for this sharing. [If re-identification is possible (i.e. more than a theoretical risk), insert a statement to that effect and describe any risks.]

## What if I Do Not Want to Receive this Treatment or Change my Mind?

After reviewing this form and having your questions answered, you may decide to receive this treatment. Or, you may choose not to receive this treatment. This decision is up to you. If you choose not to receive this treatment or change your mind after signing this form, it will not affect your usual medical care or treatment or relationship with [IU Health, Eskenazi Hospital, Riley Hospital for Children, etc.].

If you change your mind and decide to stop receiving the treatment in the future, your care team will help you stop treatment safely. If you decide to stop treatment, [explain the procedure for withdrawal from the protocol]. [If withdrawal from the protocol prior to completion could pose risk to the subject, insert a description of what those risks might be and how orderly termination will occur.]

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying [name and mailing or email address]. If you withdraw your authorization, you may not be able to continue to receive this treatment. Please discuss this with your care team before withdrawing your authorization. Otherwise, this authorization remains valid until your treatment and required monitoring of your treatment has been completed [OR insert date or description of a specific event or circumstance].

You will be told about new information that may affect your health, welfare, or willingness that may affect your decision to continue to receive this treatment.

## Can the Treatment be Stopped without my Permission?

In certain situations, your doctor may need to stop the treatment without your permission. This may happen if:

* Your condition gets worse.
* [Insert name of investigational product] is no longer safe for you.
* New information suggests that [insert name of investigational product] does not work.
* [If applicable] You become pregnant.
* New information suggests that another investigational drug may be better.
* The FDA tells your doctor that your treatment should be stopped. This may happen if the FDA receives new information about [Insert name of investigational product].
* [Insert name of investigational product] is no longer available from the manufacturer.

If your doctor needs to stop your treatment, we will tell you as soon as possible.

## Who Should I Call with Questions or Problems?

For questions about your treatment or an injury from the treatment, contact [insert name of investigator], at [insert telephone number]. [You may also include an email address.] After business hours, please call [insert alternate number and person/title the subject should request (e.g., on-call physician)].

In the event of an emergency, you may contact [insert name of investigator] at [insert 24-hour emergency number].

[If this is an investigational drug study using IU Health IDS, insert the following:]If you are unable to reach the doctor at the above numbers in an emergency, you may contact the University Hospital pharmacy at 317-944-0362 and ask them to page the IDS pharmacist on call.

For questions about your rights, to discuss problems, complaints, or concerns about your treatment in this expanded access program, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

## Patient’s Consent and Authorization

I agree to receive this investigational treatment.

**Patient’s Printed Name**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Patient’s Signature**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**:\_\_\_\_\_\_\_\_\_\_\_

**Patient’s Address**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
*(include street address, city, state, and zip code)*

**Printed Name of Person Obtaining Consent**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Person Obtaining Consent**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**:\_\_\_\_\_\_\_\_\_\_

**[FOR RESEARCH INVOLVING CHILDREN, USE THE FOLLOWING SIGNATURE BLOCKS, AS APPLICABLE]**

**Printed Name of Child**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Child’s Address**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(include street address, city, state, and zip code)*

**Printed Name of Parent**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Parent**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**:\_\_\_\_\_\_\_\_\_\_

**[If a 2nd parent signature is NOT required, REMOVE the 2nd parent signature block below]**

**Printed Name of 2nd Parent**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of 2nd Parent**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**:\_\_\_\_\_\_\_\_\_\_

**[If the child participant will NOT sign this form, REMOVE the child signature block below]**

**Signature of Child**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**:\_\_\_\_\_\_\_\_\_\_

**[FOR RESEARCH INVOLVING INDIVIDUALS LACKING CONSENT CAPACITY, USE THE FOLLOWING SIGNATURE BLOCK]**

**Patient’s Printed Name**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Patient’s Address**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
*(include street address, city, state, and zip code)*

**Printed Name of LAR**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
*(Legally authorized representative)*

**Signature of LAR**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**:\_\_\_\_\_\_\_\_\_\_