UnityPoint Health-Des Moines

CONSENT FOR USE OF EMERGENT USE DRUG OR DEVICE

Sponsor (holder of IND or IDE): _____

Physician: _____

Purpose:

The purpose of this form is to explain the option for you to receive a drug or device called _____ . _____ is investigational, which means it has not been approved by the Food and Drug Administration (FDA) for use in humans. Usually, patients can only receive an investigational drug or device by participating in a research study. However, in an emergency, when patients meet specific criteria, the FDA sometimes allows patients to receive an investigational drug or device without being in a study. This type of use is called Emergency Use when used outside a study protocol and when the hospital's Institutional Review Board (IRB) has not given approval of this drug or device's use.

Dr _____ will be overseeing the use of this drug or device.

The expected duration of use of the drug or device is _____.

Possible Risks:

List out potential risks

There may be a risk or side-effect that we don't know about yet. You might develop a new condition or suffer an injury. If you do, you should alert the physician right away.

Possible Benefits:

You may or may not benefit from receiving this drug or device, however, ***possible*** benefits include _____

Alternatives:

The alternative to receiving this drug or device is not to receive it. In order to qualify for this use, it has been determined you do not have any other acceptable standard treatment options available to you.

Your decision to receive this drug or device is voluntary and you may refuse to receive it, or withdraw its use at any time without penalty or loss of benefits.

Confidentiality:

The hospital employees assisting with this drug or device will collect information about you and your medical condition. This information is called **Protected Health Information**. The Health Insurance Portability and Accountability Act (HIPAA) requires that institutions have a Policy to protect your Health Information. The Privacy Policy of this institution is described in a booklet distributed to all patients. We are asking your permission to use your Protected Health Information and share it with others for the purposes of this use.

Governmental agencies that have the right to see or review your health information, such as the Office of Human Research Protections and the Food and Drug Administration

The persons who may use your Protected Health Information include Dr. _____ and those assisting with the use of this drug or device, the Institutional Review Board and its staff, legal counsel, audit and compliance staff, officers of UnityPoint Health System – Des Moines and other people who need to see the information to make sure it is being used correctly. These persons may disclose your Protected Health Information to staff of the entities listed in the next section.

Information that can be Disclosed:

- Your name, address, telephone number, date of birth, Social Security number and other details about you.
- Your health history
- Results of tests carried out to determine whether you can receive this drug or device
- Information in your medical record at Iowa Methodist Medical Center, Methodist West, Iowa Lutheran Hospital or Blank Children's Hospital that may be necessary for you to receive this drug or device.

If your health information is disclosed to someone who is not required by law to keep it confidential, then that information may no longer be protected, and it may be used or disclosed without your permission.

The Sponsor of the Study has voluntarily agreed to be bound by the provisions of the Privacy Rule of the Health Insurance Portability and Accountability Act.

Use and Disclosure of Protected Health Information:

You do not have to authorize the use or disclosure of your Protected Health Information. However, if you do not give this authorization, then you cannot receive this drug or device. Your regular medical care will not be affected if you do not participate in this study.

Authorization:

You may revoke your authorization to allow your Protected Health Information to be used or disclosed at any time by sending a written notice to Dr _____or the Institutional Review Board Office, 1415 Woodland Avenue, Suite 218, Des Moines, IA 50309. If you revoke your authorization, no health information about you will be gathered after that date. However, information gathered before that date may be used or disclosed if it is needed for any follow-up for the drug or device use.

The authorization to use and disclose your Protected Health Information does not have an expiration date. Your Protected Health Information will be used as long as it is necessary for the purposes of the drug or device use.

Financial Information:

Will patient be charged for medication or device? Will patient be billed for administration fees? Describe this here

Injury or Illness:

If you are injured or harmed, emergency care will be available through UnityPoint Health Des Moines. However, UnityPoint Health Des Moines does not have a policy to pay you if you are injured by this drug or device.

You do not waive any legal rights by signing this consent form.

If you think you have been injured because of this drug or device, you should call _____ at _____ .

Concerns and Complaints:

If you have questions about your rights or any concerns or complaints please feel free call the physician at the number listed above.

If you would like to talk to someone who is not associated with the use of this drug or device, please feel free to call any of the following.

Kathryn Karpowicz	**Research Subject Advocate**	**515-241-5711**
Jane Coy	Director of Corporate Compliance Privacy Officer UnityPoint Health - Des Moines	515-241-6039
UnityPoint Health – Des Moines Institutional Review Board Office		**515-241-5790**
UnityPoint Health – Des Moines Compliance HelpLine		1-800-548-8778

All calls will be kept confidential.

Required Signature Section:

You are not giving up any legal rights by signing this form.

You will receive a signed copy of this form to keep.

For Adults Subjects Capable of Giving Consent & Authorization on their Own Behalf

I consent to the emergent use of this drug or device
and
I authorize the use and disclosure of my Protected Health Information as described in this form.

Name of Subject:		
Signature:		Date:
Person Obtaining Consent and Authorization:		
Signature:		Date:

For Adult Subjects not Capable of Giving Consent & Authorization on the their Own Behalf

I consent to _____'s emergent use of this drug or device as described in this document
and
I authorize the use and disclosure of _____'s Protected Health Information as described in this form.

Name of Subject:		
Legally Authorized Representative		
Relation of Representative to Subject:		
Signature of Representative:		Date:
Person Obtaining Consent and Authorization:		
Signature:		Date:

For Minor Subjects not Capable of Giving Consent & Authorization on the their Own Behalf

I consent to my child's emergent use of this drug or device
and
I authorize the use and disclosure of my child's Protected Health Information as described in this form.

Name of Subject:		
Name of Parent or Legal Guardian:		
Relationship to Subject:		
Signature of Parent or Legal Guardian:		Date:
Person Obtaining Consent and Authorization:		
Signature:		Date: