Date:
Principal Investigator:
Application No.:

*If the patient in this compassionate/emergency use is under 18 years of age and parental consent will be required, this consent document should be written in the your child" format.*

# INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

## Compassionate/Emergency Use for Single Patient

**Protocol Title**:

**Application No**. :

**Sponsor:** *Delete line if not applicable*

**Principal Investigator**: *Include name, address, phone and fax information*

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### *1.* What you should know about this compassionate/emergency use:

- You are being asked to allow the compassionate/emergency use of *name drug or device*.
- *Name drug or device* is not approved by the Food and Drug Administration (FDA) for your condition and therefore this use is investigational.
- This consent form explains how *name drug or device* will be used.
- Please read it carefully and take as much time as you need. Ask your doctor to explain any words or information in this informed consent that you do not understand
- While you are taking *name drug or device,* we will tell you if we learn any new information that may cause you to change your mind about allowing this compassionate/emergency use.

*Include this bullet if cognitively impaired adult will take part in this compassionate use:*

- The person being asked to take part in this compassionate/emergency use may not be able to give consent for this use. You are therefore being asked to give permission for this person as his/her decision maker.

*Start with an introductory sentence describing the primary purpose of the single patient compassionate/emergency use of this investigational drug or device:*

### 2. Why is this use of *name drug or device* being offered?

This investigational *name drug or device* is being offered to....

*If the investigational drug or device is currently being studied in a clinical trial, include the following language:*

*Name drug or device* is currently being studied in a clinical trial sponsored by *Sponsor name*. You will not be enrolled in the study; however, information about your experience with *name drug or device* will be shared with the sponsor and possibly others as explained in Section 13 (How will your privacy be protected?) of this consent form.

## 3. What will happen if you agree to this compassionate/emergency use?

**How long will this use of *name drug or device* last?**

*Insert the expected duration (days, weeks or months) of the patient s participation*

## 4. What are the risks or discomforts that may occur with the use of *name drug or device* ?

## 5. Are there risks related to pregnancy?

- *Insert this heading and section if applicable.*
- *Describe foreseeable risks to a fetus.*
- *Describe any required pregnancy testing and actions that may be taken if the participant or a participant s partner becomes pregnant. This should also include the requirement of adequate birth control measures for women capable of having children.*

This compassionate/emergency use may hurt an embryo or fetus in ways we do not currently know.

## 6. Are there benefits to taking part?

There is no guarantee that you will benefit from allowing this compassionate/emergency use.

## 7. What are your options if you do not want to allow the compassionate/emergency use?

You do not have to allow this compassionate/emergency use. If you decide not to allow the use of *name drug or device*, your care at *name your institution* will not be affected.

## 8. Will it cost you anything?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this compassionate use. The Sheet will include whether you or your health insurer will be charged for the investigational drug or device. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

## 9. Will you be paid?

No.

## 10. Can you decide not to allow this compassionate/emergency use?

- If you wish to stop, please tell us right away.
- Stopping the use of *name drug or device* will not stop you from getting regular medical care.

## 11. Why might we stop the compassionate/emergency use?

Your use of *name drug or device* may be stopped if:

- Continuing with the treatment would be harmful.
- You need treatment not allowed while using *name drug or device*.
- You fail to follow instructions.
- You become pregnant.
- There may be other reasons to stop *name drug or device* that we do not know at this time.

## 12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The medical team working on this compassionate/emergency use will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The medical team will know your identity and that you are receiving this compassionate/emergency use. Other people at *name of your institution*, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of *name of your institution* may need to see or receive your information about this compassionate/emergency use. Examples include government agencies (such as the Food and Drug Administration), safety monitors.

We cannot do this compassionate/emergency use without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not take part in the compassionate/emergency use.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside *name of your institution* who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the application number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this compassionate/emergency use will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

## 13. Will we require any of your other health care providers to share your health information with us for this compassionate/emergency use?

As a part of this compassionate/emergency use, we may ask to see your health care records from your other health care providers.

## 14. What treatment costs will be paid if you are injured?

*Name of your institution* does not have a program to pay you if you are hurt or have other bad results from taking part in this compassionate/emergency use. However, medical care at *name of your institution* is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of this compassionate/emergency use will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of an injury from this compassionate/emergency use.

By signing this form you will not give up any rights you have to seek compensation for injury.

***The following section is required in this format on ALL consent forms.***

## 15. What other things should you know about this compassionate/emergency use?

### a. What is the Institutional Review Board (IRB) and how does it protect you?

The *name of your institution* IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is *insert telephone number*. You may also call this number for other questions, concerns or complaints about the research.

**b. What do you do if you have questions about the compassionate/emergency use?**
Call the principal investigator, Dr. _____ at *insert telephone number*. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form.

**c. What should you do if you are injured or ill as a result of this compassionate/emergency use?**

If you think you are injured or ill because of this study, call *Principal Investigator (If the Principal Investigator is not a medical doctor, include designated physician)* at *insert telephone number* during regular office hours.

*A 24 hour number must be included if the research is more than minimal risk to ensure participant has access to a physician for an urgent medical problem.*

**If you have an urgent medical problem** related to your taking part in this study, call *designated physician* at *insert telephone number* during regular office hours and at *insert phone or pager number available 24 hours* after hours and on weekends.

*If you insert a pager number, include the following instructions:* **After the tone, enter the phone number where you can be called, press the # key, and hang up.**

**d. What happens to Data and Biospecimens that are collected during this compassionate/emergency use?**

*If this compassionate/emergency use will not include biospecimens, you may delete that word from*

*Name of your institution* and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you allow this compassionate/emergency use, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

*If consent for biospecimens is part of this informed consent, include the following:*

With appropriate protections for privacy, *name of your institution* may share your biospecimens and information with our research sponsors and partners.

## 16. Assent Statement

*Insert this statement if the compassionate/emergency use includes children, except when (a) the child is incapable of understanding the explanation: or, (b) the study intervention offers the prospect of direct benefit to the child that is only available through this use.*

This compassionate/emergency use has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions now and at any time in the future.

***What does your signature on this consent form mean?***

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to allow the compassionate/emergency use

You will not give up any legal rights by signing this consent form.

**WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM**

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time

**Add any of the following that are applicable for this study and delete any that do not apply**

_____

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time

**For ADULTS NOT CAPABLE of GIVING CONSENT** (*Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)*

_____

Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker under Maryland Law) Date/Time

_____

Signature of Parent (Print Name) Date/Time

_____

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time

**For CHILD PARTICIPANT**

_____

Description of LAR's authority under Maryland Law to act as surrogate health care decision-maker for child research participant (for example, Legal Guardian, court-ordered representative) Date/Time

_____

Signature of Parent #2 (Print Name) Date/Time
(required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

_____

Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

_____

Signature of Witness to Consent Procedures (Print Name) Date/Time

Date:
Principal Investigator:
Application No.:
(optional unless IRB or Sponsor required)

**NOTE**: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD.**