**INSTRUCTIONS**

*(1) If the patient is under 18 years of age and parental consent will be required, this consent document should be written in the “your child” format.*

*(2) Language NOT in blue is MANDATORY and should not be changed.*

*(3) Blue shaded areas indicate required specification of information, and/or instructions*

*(4) Establish and maintain* ***grammatical second person*** *throughout form*

*(5) Establish and maintain Q & A format throughout form*

*(6) DELETE blue shading and instructions boxes when finalizing ICF*

*(7) Providers are expected to conduct informed consent procedures according to FDA regulations set forth at 21 CFR part 50*

# **INFORMED CONSENT AND HIPAA AUTHORIZATION**

# **for SINGLE PATIENT EXPANDED ACCESS TO INVESTIGATIONAL DRUG/BIOLOGIC**

**Protocol Title**: *Use ONLY for protocol expanded access. Delete line if not applicable*

**Sponsor/Manufacturer:** *Use ONLY for protocol expanded access. Delete line if not applicable*

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

**Emergency Contact:***Required 24-hour contact information*

1. **What should you know about this Expanded Access use?**

* Your condition is very serious, and regular (standard of care) ways of treating your condition are not working.
* A possible way to treat your condition is to use a drug or device in a way that has not been tested/approved for use to treat your condition. Using an untested/unapproved drug or device in an untested/unapproved way is called “expanded access use.”
* Your doctor wants your permission to use the following drug/device to treat you: *name drug or device*.
* *Name drug or device* is not approved by the federal Food and Drug Administration (FDA) for your condition, which means this use is investigational (we don’t know if it will help you).
* This Informed Consent Form (ICF) gives you the information you need to make a thoughtful decision about allowing your doctor to treat you with *name drug or device*.
* Please read this ICF carefully and take as much time as you need. If you want, then you should talk with others about this information and your decision. Ask your doctor to explain any words or information in this ICF 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 the following bullet if cognitively impaired adult or minor/child will take part in this compassionate/emergency use:*

* The patient for this Expanded Access use may not be able to give consent for this use because of medical condition or legal condition (i.e., child/minor). You are being asked to give permission for patient as his/her decision maker (i.e., legally authorized representative).

1. **Why is your doctor offering this Expanded Access use of** *name drug or device***?**

*This section should include, but not be limited to the following elements:*

*(1) An introductory sentence describing the primary purpose of the single patient Expanded Access use of this investigational drug or device;*

*(2) A statement on the emergent or extreme seriousness of the patient’s condition; and*

*(3) A statement that the treating physician will answer questions about your condition and this treatment.*

*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.

1. **What will happen if you agree to this Expanded Access use?**

*Describe IN DETAIL all components of the treat regimen, including, but not limited to:*

*(a) Dosing*

*(b) Means of administration*

*(c) Frequencies*

*(d) Data collection activities*

*(e) Labs*

*(f) Other relevant activities for which patient must give consent*

1. **What are the risks or discomforts that may occur with the use of** *name drug or device***? *[Note: Limit this section to CONCISE description. You may add elaboration as an appendix.]***
2. **Are there risks related to pregnancy?**

* *DO NOT DELETE! Add “Not Applicable” when not applicable to patient.*
* *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.*
* *Birth control language must comply with* [*OSF-approved language*](https://www.osfhealthcare.org/media/filer_public/f4/5a/f45acc59-1735-4b42-af43-d24029cd8176/osf_template_icf_language.docx)*.*

1. **Are there benefits to taking part?**

There is no guarantee that you will benefit from allowing this Expanded Access use.

1. **What are your options if you do not want to allow the Expanded Access use?**

Your doctor is offering this Expanded Access use as an option for you to choose. You do not have to choose this option. If you don’t choose this option, then your doctor will talk with you about other possible treatment options. Whatever you choose, your choice will NOT affect the care OSF will give you.

1. **Will it cost you anything?**

*This section* **must** *include the following:*

* *Description of procedures, tests, drugs or devices that are provided at NO COST to patient.*
* *Description of procedures, tests, drugs, or devices for which OSF will charge the patient’s insurance company.*
* *The following statement must be added when billing is involved:* **If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.**

1. **Will you be paid?**

No.

1. **Can you decide not to allow this Expanded Access 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*.*

1. **Why would we stop your Expanded Access 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.

1. **How will your privacy be protected? (HIPAA Authorization)**

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 Expanded Access 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 Human Immunodeficiency Virus (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 OSF, 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 OSF may need to see or receive your information about this Expanded Access use. Examples include government agencies [such as the Food and Drug Administration (FDA)] and safety monitors.

We cannot give you this Expanded Access use without your authorization to use and give out your information. You do not have to give us this authorization. **If you do not give us your authorization, 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 OSF 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 doctor who is treating you with this Expanded Access use. You should notify your doctor by phone or writing a letter. If you contact the doctor by phone, then you must follow-up with a letter that includes your contact information AND the name of the drug or device you want to stop. The doctor’s name, address, phone and fax information are on the front (first page) of this

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.

1. **Will we require any of your other health care providers to share your health information with us for this Expanded Access use?**

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

1. **What treatment costs will be paid if you are injured?**

OSF does not have plans to pay you if you are hurt or have other bad results from taking part in this Expanded Access use. However, medical care at OSF 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 Expanded Access 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 Expanded Access use.
* It is important for you to follow your physician’s instructions including notifying your physician as soon as you are able of any complication or injuries that you experience.

**You are not waiving any legal rights thereby freeing sponsor, Principal Investigator, or hospital of any malpractice, negligence, blame or guilt by participating in this Expanded Access use.**

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

1. **What other things should you know about this Expanded Access use?**
   1. **What is the Institutional Review Board (IRB) and how does it protect you?**

The 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 Peoria IRB office number is 309-680-8630. You may also call this number for other questions, concerns or complaints about the research.

* 1. **What do you do if you have questions about the Expanded Access use?**

Call your doctor, Dr. \_\_\_\_\_\_\_ at insert telephone number. If you wish, you may contact your doctor by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the Peoria IRB office at 309-680-8630.

* 1. **What should you do if you are injured or become ill as a result of this Expanded Access use?**

*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 a paging system is used, then you must include clear instructions for using the system.*

* 1. **What happens to Data and Biospecimens that are collected during this**

**Expanded Access use?**

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

OSF and our research partners work to understand, treat, and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you allow this Expanded Access use, then you need to know that you will not own your biospecimens or data. Also, if researchers use your biospecimens and/or data to create a new product or idea, then you will not benefit financially.

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

With appropriate protections for privacy, OSF may share your biospecimens and information with our research sponsors and partners.

1. **How do You Support/Affirm Your Child’s Decision (Assent) to Receive this Expanded Use?**

*Add this section if the Expanded Access 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.*

If you give your permission/consent to allow you child to receive this Expanded Access use, then you are agreeing that:

* Expanded Access use has been explained to your child in your presence in language your child can understand, and
* Your child has been encouraged to ask questions now and at any time in the future.

1. **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 Expanded Access 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

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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.*

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

**For ADULTS NOT CAPABLE of GIVING CONSENT** (Per current Illinois law, p*ersons from* *the following categories* **in order of priority** *may be a Legally Authorized Representative: (1) the patient's guardian of the person; (2) the patient's spouse; (3) any adult son or daughter of the patient; (4) either parent of the patient; (5) any adult brother or sister of the patient; (6) any adult grandchild of the patient; (7) a close friend of the patient; (8) the patient's guardian of the estate; (9) the patient's temporary custodian)*

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Relationship of LAR to Participant Date/Time

Explain why the LAR has authority to act as a surrogate health care decision-maker under Illinois Law:

**For CHILD PARTICIPANT**

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Signature of Parent (Print Name) Date/Time

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Description of LAR’s authority under Illinois Law to act as surrogate health care decision-maker for child research participant (e.g., Legal Guardian, court-ordered representative)

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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

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

(optional unless IRB or Sponsor required)

**NOTE**: **THE DOCTOR ADMINISTERING THE EXPANDED ACCESS USE MUST RETAIN THIS SIGNED AND DATED ORIGINAL. THE DOCTOR MUST GIVE A COPY TO THE PATIENT.**