**EMERGENCY USE** **PATHWAY CRITERIA**

1. The patient has a **life-threatening** or serious disease or condition that needs immediate treatment;
2. No generally acceptable alternative treatment for the condition exists; and
3. Because of the immediate need to use the drug/device, there is no time to use existing procedures to obtain FDA approval for the use.

*\*****Life threatening*** *is defined as:*

* *The likelihood of death is high unless the course of the disease is interrupted;*
* *A disease or condition with a potentially fatal outcome, where the end-point is survival.*
* *The disease or condition causes major irreversible morbidity.*

***If the above 3 criteria are not met, refer to the Compassionate Use Pathway Criteria***

**SUBMISSION GUIDANCE AND STEPS FOR OBTAINING APPROVAL:**

* **BEFORE USE:**

1. The investigator should contact the drug/device manufacturer of the product to determine if the product can be provided, and if it can be administered under an existing IND/IDE. The investigator should also consult with the manufacturer regarding any manufacturer specific requirements (e.g., IRB chair concurrence prior to shipping a product). If it is not available through an existing IND/IDE, the investigator should:
   1. **Drugs/ Biologics**:
      1. Call FDA to obtain FDA authorization for the expanded access use. Refer to FDA Guidance Information:
      * [www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm)
      * [www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm597130.htm](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm597130.htm)
   2. **Devices**:
      1. Obtain an independent assessment by an uninvolved physician. FDA Guidance Information:
      * <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#emergency>
2. Determine whether informed consent can be obtained from the patient or the patients legally authorized representative (LAR), and whether there is time to obtain informed consent.
   1. If there is time, submit a consent form for the patient (or LAR) to sign before the test article is used. The patient (or LAR) must understand the investigational nature of the product being used. A template Single Patient Treatment Use consent form can be found here: [www.upenn.edu/IRB/forms](http://www.upenn.edu/IRB/forms).
   2. If consent cannot be obtained because the situation meets the requirements for Exception from Informed Consent Requirement (as outlined below) the investigator must:
      * Certify how this determination was made by completing Section F on the Expanded Access form.
      * Have the determination reviewed and evaluated by a physician who is not otherwise participating in the clinical investigation. This should occur preferably before the emergency use but no later than 5 working days after the use of the article.

|  |
| --- |
| *Exception from Informed Consent Requirements [21 CFR 50.23(a)]*   * *The subject is confronted by a life-threatening situation necessitating the use of the test article,* * *Informed consent cannot be obtained because of an inability to communicate with (or obtain legally effective consent from) the subject,* * *Time is not sufficient to obtain consent from the subject's legal representative, AND* * *No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.* |

1. If the clinical situation allows, notify the IRB (by telephone or email) as soon as possible about the emergency use of the investigational product.

* **AFTER USE:**

1. **Within 5 working days**, a written notification must be sent to the IRB describing the emergency use in the patient. The written notification to the IRB must include the completed Single Patient Expanded Access (Emergency/Expanded Access) Use Application, along with supplemental documentation (see form for details). This form can be found online here: [www.upenn.edu/IRB/forms](http://www.upenn.edu/IRB/forms).
   1. **Drugs/ Biologics**:
      * **Within 15 days**: Submit the expanded access IND to the FDA
      * If you need assistance with submitting an IND, please reach out to the Office of Clinical Research Sponsor Support Unit: [www.med.upenn.edu/ocr/sponsor-support-unit.html](http://www.med.upenn.edu/ocr/sponsor-support-unit.html).
      * Additional Guidance: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm597130.htm>
   2. **Devices:** 
      * Within 5 working days, a written notification must be sent to the FDA describing the emergency use in the patient.
      * If submitted through a manufacturer’s IDE: Notify the manufacturer of the emergency use so they may notify the FDA.
      * If the Penn physician submitted the IDE information directly to FDA: notify FDA of the emergency use and provide FDA with a written summary of the conditions constituting the emergency, subject protection measures, and treatment results. If you need assistance with this, please reach out to the Office of Clinical Research Sponsor Support Unit: [www.med.upenn.edu/ocr/sponsor-support-unit.html](http://www.med.upenn.edu/ocr/sponsor-support-unit.html).