**Single Patient Expanded Access Application**

**(Emergency or Compassionate Use)**

TITLE**:**

*Note: Please provide a title for IRB Documentation purposes. E.g., Single Patient Compassionate Use of Drug X in Patient YZ for Disease A.*

TREATING CLINICIAN**:**

***NOTE: This individual will serve as the “Principal Investigator” for IRB Documentation purposes.***

DATE**:**

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| **INSTRUCTIONS**   1. **Read the IRB guidance for** [**How to Submit : Expanded Access**](https://irb.upenn.edu/how-submit-penn-irb/single-patient-expanded-access) 2. **Complete this form** 3. **Please attach required and supporting documents**   **DOCUMENTS REQUIRED FOR APPROVAL: Please provide one copy of the following:**   * Completed copy of this form * *Unsigned* consent form   + See www.upenn.edu/IRB/forms for the Single Patient Expanded Access Consent template * Regulatory documentation from FDA for the IND or IDE, **OR** notice that documentation is pending receipt from FDA and will be provided to the IRB upon receipt. * **Drugs/Biologics Only:**   + FDA form 3926. *If expedited IRB review is requested, box 10b must be checked on form 3926*   + Drug Investigator’s Brochure / Package Insert * **Devices Only**:   + Documented independent assessment from an uninvolved physician. The name of the physician should be clearly printed.   + Device Brochure / Manual   **The following are also required with your submission *when applicable*:**   * Clinical Protocol (i.e., if available from and provided by manufacturer) * Manufacturer authorization for the treating physician to utilize the device / drug (when required) * If appropriate: Reference a published protocol or journal article to support proposed treatment. * **If you require a letter:** A complete list of documents being submitted for review as they should appear in your determination letter (document name, version #, date)  1. **Please email the completed form and supporting documents to the IRB Director Team:** [**https://irb.upenn.edu/directory**](https://irb.upenn.edu/directory)   Note: This form is not for the use of expanded access applications in more than 1 patient.  **NOTE: PLEASE DO NOT SEND PROTECTED HEALTH INFORMATION (PHI) TO THE IRB** |

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| 1. **Who should the IRB contact with questions?** | |
| Name(s): | Telephone #(s): |
| Email(s): | |

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| 1. **What type of submission is this? (Select 1)** | |
| Emergency Use  By checking the box, I confirm the following are true:   * The patient has a life-threatening or serious disease or condition that **needs immediate treatment**; * No generally acceptable alternative treatment for the condition exists; and * **Because of the immediate need to use the device, there is/was no time to use existing procedures to obtain prospective FDA and IRB approval for the use.**   **Date product was administered:** | Compassionate Use  By checking the box, I confirm the following are true:   * The patient has a life-threatening or serious disease or condition; and * No generally acceptable alternative treatment for the condition exists.   Note: It is strongly recommended that submission to the FDA and IRB occur simultaneously to improve the efficiency of the submission process.  **Planned Date(s)/Timeline for product administration:**  *Please provide context regarding the planned date of administration including any special circumstances related to the patient (e.g., from out of town), etc.*  **Is the product currently available?**  Yes  No: when will it be available: |

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| 1. **What type of product has been or will be administered?** | |
| Drug/Biologic  Device | |
| Product Name |  |
| Product Manufacturer |  |
| Please describe how the product was or will be obtained. |  |

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| 1. **Brief Clinical History of the patient**   Note: If this information is available in a separate document (e.g., clinical protocol, an application or cover letter to the product manufacturer or FDA), you may refer to that document in this section. | |
| Diagnosis |  |
| Disease Status |  |
| Prior Therapy and Response |  |
| Rationale for Investigational Treatment. This should include an assessment of the risks in relation to the potential benefit. |  |
| Please describe the available therapeutic options that would ordinarily be tried or an explanation of why use of the investigational product is preferable |  |
| **Note**: Single Patient Use of an investigational **device** also requires an independent assessment from an uninvolved physician. **Please include this documentation with your submission.** | |

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| 1. **Proposed Treatment Plan**   Note: If this information is available in a separate document (e.g., clinical protocol, an application or cover letter to the product manufacturer or FDA), you may refer to that document in this section. | |
| Drugs/Biologics: Please describe the dosage, route of administration, and duration of administration  Devices: Please describe any necessary procedures to administer device (e.g., surgery) |  |
| Please describe monitoring procedures |  |
| Please describe any modifications or interventions (e.g. dose reduction or treatment delay) for drug toxicity or adverse device effects |  |
| \*If a clinical protocol is available and provided with this submission, please identify any deviations that may be necessary in order to treat the patient. *If no clinical protocol is available, please indicate Not Applicable in the box to the right.* |  |

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| 1. **Consent Process and Documentation:**   Informed consent must be obtained before initiating treatment, including in the case of emergency use, UNLESS the exception from informed consent requirements [21 CFR 50.23(a)] are met. Please describe the consent process and documentation. | |
| Written informed consent /HIPAA authorization will be obtained **prior to** the administration of the test article from the patient or the patient’s legally authorized representative (LAR)  Please describe the consent process:   * How informed consent will be obtained, including how, when, where, and by whom it will be obtained; * From whom consent will be obtained. If the patient’s LAR will provide consent prospectively and the patient may be capable after the article is administered, please describe the plan to seek informed consent from the patient retrospectively; * A plan for translating the consent or obtaining an interpreter, if the participant / LAR does not speak English. | |
| **OR** | |
| An exception from informed consent requirements is requested (**usually only applies to emergency use notifications**)  **Note**: Exception from informed consent requirements **in an emergency** requires an independent assessment from an uninvolved physician *prior to or within 5 working days of the use of the article*. **Please include this documentation with your submission.**  Please provide rationale for all of the following: | |
| 1. The patient is confronted by a life-threatening situation necessitating the use of the test article: |  |
| 1. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the patient: |  |
| 1. Time is not sufficient to obtain consent from the patient's legal representative: |  |
| 1. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the patient's life: |  |
| 1. **If the patient may be capable after the article is administered, please describe the plan to seek informed consent from the patient retrospectively:** |  |

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| 1. **IND/IDE Sponsor Information** |
| Who is the IND or IDE Sponsor? Please select one answer.  The treating physician submitted the paperwork to FDA and is/will be listed as the sponsor of the IND /IDE [i.e., the FDA Form 1571 (drugs) or Investigator Agreement (devices) lists the treating physician as the sponsor]  The product manufacturer submitted the paperwork to FDA and is/will be listed as the sponsor of the IND /IDE |

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| 1. **Financial Donation**   *Note: Contact the Office of Planned Giving to ensure that the patient in question has not given a gift to the Institution.* |
| Did the patient or his/her family member provide a financial donation to the institution that is related to the experimental therapy being provided?  No  Yes |
| If yes, please contact Jessica Yoos at [jessyoos@upenn.edu](mailto:jessyoos@upenn.edu). Please provide a plan to address this below. |
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| **Completion of Submission: (This section not required if submitting via HSERA or if the treating physician emails the submission to the IRB. If a wet signature is obtained and this document is scanned, please submit a unsigned version as well.)**  By signing this form, the principal investigator and the person completing the form (if other than the investigator) certify that he/she has disclosed to the IRB all relevant information that might affect the risk-benefit to this patient. |

Name of person completing this form:

Signature of person completing the form*:*

Principal Investigator Name:

Principal Investigator Signature:

Date: