**EXPANDED ACCESS FOR SINGLE PATIENT EMERGENCY USE**

**WITH AN INVESTIGATIONAL DRUG/BIOLOGIC**

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| **INSTRUCTIONS:**  Use this form for use of an investigational drug or biologic in an EMERGENCY (there is no time for IRB review or the use has already taken place) as outlined in FDA's [Emergency Use of an Investigational Drug or Biologic - Information Sheet.](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-investigational-drug-or-biologic)  **Note**: Immediate life-threatening situations typically occur with short notice although occasionally the planned use can be foreseen 3 or 4 weeks in advance. When there is sufficient time, please submit the required documents outlined in this form for the IRB to review the proposed single patient use and to request IRB Concurrence BEFORE administration of the test article.  When there is insufficient time for IRB review, the Investigator may exercise the Emergency Exemption from prior IRB review and administer the investigational drug and seek IRB Concurrence after the use.  The Emergency Exemption is for a single patient use. If the investigator anticipates the need to use the same drug for a second individual, then they must prepare a protocol for IRB approval for the proposed use.  Questions? Contact Heather Ferreri [uzs6wf@virginia.edu](mailto:uzs6wf@virginia.edu)  **For questions about and requests for emergency use and expanded access for drugs, biologics or to get an emergency IND, contact FDA at:**  **• During Normal Business Hours (8 a.m. - 4:30 p.m. ET, weekdays):**  **○Drugs: 301-796-3400 [CDER's Division of Drug Information]**  **○Biologics: 800-835-4709 [CBER's Office of Communication, Outreach and Development]**  **• Nights/Weekends: (866) 300-4374 [Office of Crisis Management & Emergency Operations Center]** |

**STEP 1. Review Criteria for Emergency Use of an Investigational Drug/Biologic**

*Check all applicable items*

Disease is immediately life-threatening or will lead to severe disability

No approved therapeutic alternative is available

Risk of complications from the disease is higher than the risk of toxicity from this investigational treatment

IND supplier (e.g., product’s manufacturer) agrees to supply the drug and to provide Letter of Agreement (LOA)

Drug/biologic is not available by other means (approved drug, ongoing trial, another expanded access program)

There is insufficient time to obtain IRB approval and a report is provided to the IRB within five working days of the Emergency Use.

*Life-threatening* means diseases or conditions where the likelihood of death is high unless the course of the

disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life threatening or to immediately result in death. Rather, the patients must be in a life-threatening situation requiring intervention before obtaining FDA approval.

*Serious disease or condition* means a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.

Serious disease or condition includes sight-threatening and limb-threatening conditions as well as other situations involving risk of irreversible morbidity.

**STEP 2. Obtain authorization from the Manufacturer/Sponsor and FDA**

**When a Drug or Biologic is used an IND is required:**

Contact the manufacturer and determine if the drug or biologic can be made available for the emergency use under the manufacturer/sponsor held IND. If there isn’t time to apply for an IND, the FDA may authorize shipment of the test article in advance of the IND submission. Requests for such authorization may be made by telephone or other rapid communication means to the FDA (see contact below).

Obtain a letter of authorization (LOA) to use the drug/biologic from the manufacturer. You will ask:

* For permission to use the drug/biologic under the emergency mechanism
* Whether the manufacturer has an existing IND they will allow to be amended for this emergency use:
* If NO, you will submit an application to the FDA for Emergency IND held by the UVA PI.
  + - Refer to [FDA instructions to obtain Physician sponsored emergency IND](https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use)
* Arrange for shipping of the drug/biologic
* **IF THE MANUFACTURER/SPONSOR DISAGREES WITH THE EMERGENCY USE, YOU CANNOT USE THE DRUG/BIOLOGIC.**

***NOTE: FDA authorization is required PRIOR to use of an Emergency IND***

***For single patient emergency use,*** submit [Form FDA 3926](https://www.fda.gov/media/98616/download) to the FDA. Further instructions and help about [how to submit](https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use) available online.

**STEP 3. Coordinate with UVA Investigational Drug Services (IDS)**

For IND: Contact IDS as soon as possible to inform them of the planned use and shipment of the drug or biologic. Do not wait until you have obtained authorization from the FDA and/or the manufacturer. IDS is a valuable source of guidance and assistance for emergency situations. Provide them with the following:

1. Name of the drug/biologic
2. The source from which you are obtaining it (manufacturer/drug companies name)
3. Any information regarding administration, preparation instructions and dispensing instructions (dose, route, frequency etc.)
4. Estimates date and time of use
5. You must comply with IDS policies and procedures about receipt, storage, and dispensing of the drug/biologic.

Note: A *copy of IDS approval notice* will be required for submission at the time or reporting to the IRB.

**STEP 4. Informed Consent**

If you will be able to obtain consent, begin the consent process as soon as possible by discussing the situation with the patient and/or patient's legal representative, even if you don't yet have a consent form ready.

1. The consent form is not the same as a standard clinical consent form.
2. The FDA requires the consent process to include all of the standard elements of a research consent.

* Whenever possible, obtain consent from the patient or the patient’s legally authorized representative.
  + If a consent is not provided to the UVA study team, you must complete and use the [**TEMPLATE:** Emergency Use or Expanded Access Consent for Investigational Drug/Biologic or Device.](https://research.virginia.edu/sites/vpr/files/2020-04/Emergency%20Use%20or%20Expanded%20Access%20Consent%20Investigational%20Drug%2C%20Biologic%2C%20Device.docx)
  + Retain a copy (redacted) to send to the IRB **after** the emergency use and place a copy in the patient’s medical record.

If it is not possible to obtain consent, the EMERGENCY USE may still proceed if the treating physician AND an independent physician agree that all the following four (4) conditions apply (21CFR 50.23.(a)):

1. The patient is confronted by a life-threatening situation necessitating the use of the investigational drug/biologic.
2. Informed consent cannot be obtained from the patient because of an inability to communicate with or obtain legally effective consent from the patient.
3. Time is insufficient to obtain consent from the patient’s legally authorized representative.
4. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.

If immediate use of the drug/biologic is, in the physician's opinion, required to preserve the life of the subject and time is not sufficient to obtain the concurrence of an independent physician in advance as described above, the physician may proceed if all of the conditions described above are met. Within 5 business days after the use, the physician must obtain an independent physician's assessment as to whether the above four conditions were met.

***NOTE: The independent physician is required to concur and sign this document.***

**STEP 5. Proceed with Single Patient Emergency Use of the Drug/biologic**

**STEP 6. Notification of the IRB.**

**This is an FDA requirement.**

UVA investigators are required to submit this form AND all accompanying documentation with any follow-up information within 5 days AFTER the use of the test article for emergency use. If the sponsor requires acknowledgment from the IRB Chair *before* it will ship the drug, the UVA investigator should complete all applicable sections of this form and submit to the IRB-HSR **via IRB PRO-Expanded Access**

***-COMPLETE ALL QUESTIONS ON THE FOLLOWING PAGES-***

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| **PART 1: Select Reporting time:** | |
| The emergency use has **ALREADY** occurred, and I am reporting this for the first time to the IRB. The emergency use **HAS NOT** occurred, and I need acknowledgment from the IRB Chair/Designee that the use of the test article constitutes an emergency use before the manufacturer will ship the test article. | |
| **PART 2: Informed Consent:** | |
| **\*Select one:**  Informed consent has or will be obtained from the patient.  Informed consent has or will be obtained from the patient's legally authorized representative.  Informed consent of the patient or representative is or was not possible because:   * The patient is confronted by a life-threatening situation necessitating the use of the drug or biologic. * Informed consent cannot be obtained from the patient because of an inability to communicate with or obtain legally effective consent. * There is insufficient time to obtain consent from the patient’s LAR. * An alternative method of approved or generally recognized therapy that provides equal or greater likelihood of treating the patient is unavailable.   If informed consent of the patient or legal representative is or was not possible, **select one:**  Before the use of the drug or biologic, the treating physician will have an independent physician who is not otherwise participating in the treatment evaluate in writing the treating physician's justification for not obtaining informed consent.  Within 5 working days after the use of the drug or biologic, the treating physician will have an independent physician who is not otherwise participating in the treatment evaluate in writing the treating physician's justification for not obtaining informed consent.  If informed consent of the patient or legal representative is or was not possible, **confirm that**:  Within 5 working days after the use of the drug or biologic, the treating physician will provide the IRB with a copy of the treating physician's written certification justifying not obtaining informed consent and a copy of the independent physician's written evaluation of the treating physician's justification for not obtaining informed consent. | |
| **PART 3: TEST ARTICLE INFORMATION**:  Drug  Biologic | |
| 1. **Name of test article:** | **IND#** |
| 1. **Manufacturer:** | |
| 1. **Indication for Use (including patient’s condition):** | |
| 1. **Location of Treatment:** | |
| 1. **Course of Treatment and Dose** | |
| 1. **Date test article WAS administered:**   **If reporting AFTER emergency use of the drug or biologic, describe the outcome of the treatment, including any adverse events and/or unanticipated problems. Any subsequent developments must be reported to the IRB in a timely fashion.** [**Follow UVA IRB-HSR reporting requirements**](https://research.virginia.edu/irb-hsr/serious-adverse-events)**.** | 1. **Date test article TO BE Administered:**  N/A   **IMPORTANT:** If you have not yet administered the drug/biologic and you are submitting this fpr, PRIOR to emergency use, you are required to submit the [**Single Patient Treatment Follow up**](https://research.virginia.edu/sites/vpr/files/2020-04/Single%20Patient%20Treatment%20Follow-up%20%28RB%29.docx) document within 5 days of emergency use. |

**SUBMISSION OF DOCUMENTS TO THE IRB-HSR**

**Submit all of the following to the IRB-HSR within 5 working days after emergency use via IRB PRO-Expanded Access-Single Patient**

1. *This document: Expanded Access- Single Patient Emergency use of an Investigational Drug or Biologic)*
2. Completed [Form FDA 3926](https://www.fda.gov/media/98616/download) that was submitted to the FDA
3. Letter of Authorization (LOA) from the manufacturer
4. FDA Authorization AND Single Patient IND#
5. [Completed Consent Form Template](https://research.virginia.edu/sites/vpr/files/2020-04/Emergency%20Use%20or%20Expanded%20Access%20Consent%20Investigational%20Drug%2C%20Biologic%2C%20Device_0.docx) (if after use; redacted consent signed by the patient/LAR)
6. Treatment plan/protocol (if none provided, treatment plan should be documented in FDA 3926)
7. Investigator Brochure

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| **PART 4: IDEPENDENT PHYSICIAN ASSESSMENT for EMERGENCY USE**  (Only when written consent cannot be obtained)  N/A |
| In some emergency use circumstances, it may not be feasible to obtain informed consent prior to the administration or use of the test article. An exception to the informed consent requirements is acceptable if the Investigator AND a UVA physician who is not otherwise involved in the patient’s treatment, must certify in writing that the following four (4) conditions exist:   1. The patient is confronted by an immediately **life-threatening situation** necessitating the use of the test article. 2. **Informed consent cannot be obtained** because of an inability to communicate with, or obtain legally effective consent from, the patient. 3. **There is insufficient time** to obtain consent from the patient's legal representative. 4. **No alternative method** of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the patient’s life.   NOTE: If, in the investigator's opinion, immediate use of the test article is required to preserve the patient’s life, and if time is not sufficient to obtain an independent physician's determination that the four conditions above apply, the clinical investigator should make the determination and, within 5 working days after the use of the article, have the determination reviewed and evaluated in writing by an independent UVA physician who is not participating in the clinical investigation. The investigator must notify the IRB within 5 working days after the use of the test article (21 CFR 50.23(c)). |
| ***SIGNATURE OF INDEPENDENT UVA PHYSICIA*N:**  Assessment Before Emergency Use Assessment After Emergency Use  **By signing below, I certify that this emergency use meets all four (4) of the conditions listed above.**  NAME OF IDEPENDENT UVA PHYSICIAN: EMAIL:  SIGNATURE OF IDEPENDENT UVA PHYSICIAN: |

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***TREATING PHYSICIAN ACKNOWLEGMENT***

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| **SIGNATURE OF UVA TREATING PHYSICIAN**  **By signing below, the UVA Investigator (check all that apply):**  Certifies that this patient is in a life-threatening situation and severely disabling situation for which no standard acceptable treatment is available;  Certifies that there is insufficient time to obtain approval of the IRB full board for use of the drug/biologic;  Acknowledges that the patient may not be considered a research subject and any data generated may not be claimed as research. The outcome of this emergency use may not be included in any report of research activity, except possibly for case reports;  Acknowledges that any subsequent use of the drug/biologic in the same or different patient requires submission of an IRB application to the IRB for full board review. |
| **NAME OF UVA TREATING PHYSICIAN:**  **SIGNATURE OF UVA TREATING PHYSICIAN**:  **DATE:** |

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