**EXPANDED ACCESS FOR SINGLE PATIENT EMERGENCY USE**

**WITH AN INVESTIGATIONAL MEDICAL DEVICE**

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| **INSTRUCTIONS:**  Use this form for use of an investigational device in an emergency (there is no time for IRB review or the use has already taken place) as outlined in [Expanded Access for Medical Devices](https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices). This document is also used for Emergency Use of a Humanitarian Use Device.    **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 enough time, please submit the required documents outlined in this form for the IRB-HSR to review the proposed single patient use.  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 and is NOT research. If the investigator anticipates the need to use the same device for a second individual, then they must prepare a protocol for IRB-HSR approval for the proposed use.  Questions? Contact Eileen Sembrowich (434-243-6542)/ [ecs3b@virginia.edu](mailto:ecs3b@virginia.edu)) or Susie Hoffman (434-924-9634 )/[srh@virginia.edu](mailto:srh@virginia.edu))  **For questions about and requests for emergency use and expanded access for devices or to get an emergency IDE contact FDA: During normal business hours (8 a.m. - 4:30 p.m. ET, weekdays) at 301-796-7100 [CDRH's Division of Industry and Consumer Education]**  **During Nights/Weekends call (866) 300-4374 [Office of Crisis Management & Emergency Operations Center]** |

**STEP 1. Criteria for Emergency Use of a Medical Device**

Emergency use of an unapproved device to save a patient’s life may occur when:

* An IDE does not exist (IDE: Investigational Device Exemption. The FDA requires an IDE when doing research with an unapproved medical device. For more information, please follow this [link](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm?utm_campaign=Google2&amp;amp%3Butm_source=fdaSearch&amp;amp%3Butm_medium=website&amp;amp%3Butm_term=investigational%20device%20exemption&amp;amp%3Butm_content=1)) OR
* The patient does not qualify for the IDE protocol or the treating physician wants to use the device in a way not approved under an IDE OR
* The physician is not an investigator under an IDE protocol

For the use of an unapproved medical device to qualify for Emergency Use, the UVA physician must confirm that ALL of the following conditions exist:

The patient has a life-threatening condition that needs **immediate** use of the device;

No generally acceptable alternative treatment for the condition is available; and

Because of the immediate need to use the device, there is no time to use existing procedures to obtain FDA approval for an IDE.

*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**

**When a Device is used, an IDE# is required:**

Contact the manufacturer and determine if the device can be made available for the emergency use under the manufacturer/sponsor held IDE. If there is not time to apply for an IDE, the FDA may authorize shipment of the device in advance of the IDE submission. Requests for such authorization may be made by telephone or other rapid communication means to the FDA.

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

* For permission to use the device under the emergency mechanism
* Whether the manufacturer has an existing IDE they will allow to be amended for this emergency use:
* If NO, you will submit an application to the FDA for Emergency IDE held by the UVA PI.
  + - Refer to [FDA instructions to obtain Physician held IDE](https://d.docs.live.net/a77e78f3ee212751/Desktop/Request%20for%20IRB%20Concurrence-4%20forms/Obsolete)
* Arrange for shipping of the device
* If the manufacturer requires a letter from the IRB before entertaining your request or shipping the device, contact either Eileen Sembrowich (434-243-6542)/ [ecs3b@virginia.edu](mailto:ecs3b@virginia.edu)) or Susie Hoffman 434-924-9634 /[srh@virginia.edu](mailto:srh@virginia.edu))
* **IF THE MANUFACTURER/SPONSOR DISAGREES WITH THE EMERGENCY USE, YOU CANNOT USE THE DEVICE**

**NOTE: Treatment use of a device, in an emergency situation, does not need prior IRB Concurrence or FDA approval.** However, the emergency use is required to be reported to the FDA and IRB after within 5 working days after treatment occurs. The report to the FDA should be submitted by the sponsor (IDE holder), if one exists, or by the UVA treating physician if there is no IDE.

**STEP 3. 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 4. Patient Protection Measures**

Before using the investigational medical device, the treating physician should follow patient protection measures including:

1. Obtain a written independent assessment from a licensed physician if the use of the device by an uninvolved physician (See Part 3 below)
2. Obtain authorization from the device manufacturer
3. If possible, obtain documented informed consent from the patient or the patient’s legally authorized. Use [Emergency Use or Expanded Access Consent Investigational Drug, Biologic or Device consent to](https://research.virginia.edu/sites/vpr/files/2020-04/Emergency%20Use%20or%20Expanded%20Access%20Consent%20Investigational%20Drug%2C%20Biologic%2C%20Device.docx) create this document.

* If consent was not obtained before use, the treating physician and a licensed physician who is not participating in the medical care protocol must certify in writing that:
  + The patient was under a life-threatening
  + There was an inability to communicate with or obtain legally effective informed consent from the patient
  + There was not sufficient time to obtain informed consent from the legally authorized representative
  + There was no available alternative method of FDA-approved or generally recognized therapy that provided an equal or greater likelihood of saving the patient’s life.

**STEP 5. Proceed with Single Patient Emergency Use of the Device**

**STEP 6. Notification of the FDA—*REQUIREMENT***

**This is an FDA requirement.**

If the manufacturer holds an IDE for the device, the UVA investigator is required to report to the manufacturer, who will then report to the FDA. Submit this form AND all accompanying documentation with any follow-up information within 5 working days AFTER the use of the test article for emergency use.

**STEP 7. Notification of the IRB-HSR -*REQUIREMENT***

**Submit all of the following to the IRB-HSR prior to or within 5 working days after emergency use to IRBHSR@virginia.edu:**

1. This form completed: *Expanded Access for Single Patient Emergency Use with* an *Investigational Medical Device*
2. Letter of Authorization (LOA) from the manufacturer
3. FDA Authorization AND Single Patient IDE#
4. [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)
5. Treatment plan/protocol
6. Investigator Brochure
7. New Medical Device application to UVA Health

***-COMPLETE ALL QUESTIONS on the FOLLOWING PAGES-***

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| **PART 1: MEDICAL DEVICE INFORMATION**: | |
| 1. **Name of Medical Device:**       **Manufacturer/IDE Holder:** | |
| 1. **Select one:**   If available, the device has the following IDE#    Emergency Use of [**HUD Device**](https://www.fda.gov/industry/developing-products-rare-diseases-conditions/humanitarian-use-device-hud-designation-program):  The device does not have an IDE, and the UVA treating physician will submit a follow-up report on the use of the device, details of the case, and the patient protection measures that were followed to:  Food and Drug Administration  Center for Devices and Radiological Health  10903 New Hampshire Ave Document Control Center  WO66 Rm G-609  Silver Spring, MD 20993  Emergency use has **ALREADY** occurred, and I am reporting this event for the first time to the IRB. Emergency use **HAS NOT** occurred, and I am requesting acknowledgment from the IRB Chair/Designee that the use of the investigational device constitutes an emergency use before the manufacturer will ship the medical device (\*rare): IRB Concurrence | |
| 1. **Provide the patient’s history sufficient to justify that:**  * The patient has a life-threatening or serious disease or condition that needs immediate treatment, diagnosis, or monitoring * NO generally acceptable alternative treatment, diagnostic, or monitoring for the condition exists. * There is insufficient time to use existing procedures to obtain FDA approval before the use. * There is substantial reason to believe that benefits will exist. | |
| 1. **Describe the treating physician’s schedule for monitoring the patient, taking into consideration the investigational nature of the device and the specific needs of the patient:** | |
| 1. **Indicate the patient protection measures will be or were used:** (*check those applicable at the time of this submission)*   Obtain IRB concurrence prior to use.  Obtain informed consent from the patient or the patient's legally authorized representative (LAR).  Obtain authorization from the device manufacturer (required)  Obtain approval for use of New Medical Device from UVA Clinical Engineering (required) | |
| 1. **Location of Emergency Use:** | |
| 1. **Date Medical Device WAS administered:**   **If reporting AFTER emergency use of the investigational medical device, 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 Medical Device TO BE Administered:**        N/A   Note: If you have no administered the investigational medical device AND you are submitting this form 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 business days of emergency use. |

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| **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 legally authorized representative (LAR) is or was not possible because:   * The patient is confronted by a life-threatening situation necessitating the use of the device. * 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 device, 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 device, 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. | |
| **PART 3: INDEPENDENT PHYSICIAN ASSESSMENT for EMERGENCY USE** | |
| 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 or serious disease or condition that need immediate treatment, diagnosis or monitoring  Has full awareness of the information within this form.  Certified the information within this form is accurate and complete.  Has or will document in the medical record that:   * The patient has a life-threatening or serious disease or condition that needs immediate treatment, diagnosis, or monitoring. * No generally acceptable alternative treatment, diagnostic, or monitoring for the condition exists. * There is insufficient time to use existing procedures to obtain FDA approval before the use. * There is substantial reason to believe that benefits will exist. |
| **NAME OF UVA TREATING PHYSICIAN:**  **SIGNATURE OF UVA TREATING PHYSICIAN**:  **DATE:** |

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| **FOR IRB-HSR ONLY:** |
| ***IRB CHAIR/DESIGNEE CONCURRENCE:*** |
| **By signing below, the IRB Chair/Designee confirms/understands that the (check all that apply):**  Patient was/is in a life-threatening situation for which no standard acceptable treatment is available;  There was/is insufficient time to obtain approval of the full board IRB for use of the test article. |
| **NAME of IRB CHAIR/DESIGNEE:**    **SIGNATURE OF IRB CHAIR/Designee:** **DATE:** |