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| **INFORMATION**  The FDA recognizes that there are circumstances in which use of an investigational drug is the appropriate option to diagnose, monitor or treat a patient’s disease or condition OR an investigational device is the only option available for a patient faced with a serious, albeit not a life-threatening condition.  **CRITERIA** **for Single Patient Non-Emergency Treatment Use:**   1. The patient has a life-threatening or serious disease or condition; and 2. No generally acceptable alternative treatment for the condition exists.   *\*****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.*   Questions: Eileen Sembrowich @ 434-243-6542 or [ecs3b@virginia.edu](mailto:ecs3b@virginia.edu)    [FDA Contact Info](https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use)  [FDA Guidance-Expanded Access Devices](https://www.fda.gov/medical-devices/device-advice-investigational-device-exemption-ide/expanded-access-medical-devices)  [FDA Guidance-Expanded Access Drugs](https://www.fda.gov/media/85675/download) |

**SUBMISSION GUIDANCE AND STEPS FOR OBTAINING IRB Concurrence**

1. The investigator should contact the drug/device manufacturer of the product to determine 1) if the product can be provided, and 2) if it can be administered under an existing IND/IDE. If it is not available through an existing IND/IDE, but the manufacturer is willing to provide the product, the investigator should:
   * 1. **Drugs/ Biologics**: Apply for expanded access to an investigational drug/biologic under a single patient (non-emergency) IND
        + [FDA Guidance Information](https://www.fda.gov/news-events/expanded-access/expanded-access-information-physicians)
        + **For IRB Concurrence: Box 10b must be checked on FDA form 3926**
     2. **Devices**: obtain an independent assessment by an uninvolved physician and work with the manufacturer to submit the required documentation or IDE supplement to the FDA

* [FDA Guidance Information](https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices#compassionate)
* Physicians can also contact [CDRHExpandedAccess@fda.hhs.gov](mailto:CDRHExpandedAccess@fda.hhs.gov) for assistance.

1. Complete the Request for IRB Concurrence for Single Patient (Non-Emergency/Compassionate Use) of an Investigational Drug or Device including any necessary supplemental documentation. (this form)
2. Draft an informed consent form. Written informed consent should be obtained from the patient or a legal representative. Consent template can be found [HERE](https://research.virginia.edu/sites/vpr/files/2020-04/Emergency%20Use%20or%20Expanded%20Access%20Consent%20Investigational%20Drug%2C%20Biologic%2C%20Device_0.docx)

**The physician should not treat the patient identified in the request until FDA and the IRB approves use of the drug/device under the proposed circumstances.**

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| **SUBMISSION OF DOCUMENTS TO THE IRB-HSR**  **PRIOR to the use of an Investigational Drug/Biologic or Device for NON-EMERGENCY TREATMENT, submit all of the following to the IRB-HSR requesting IRB Concurrence via** [**IRBHSR@virginia.edu**](mailto:IRBHSR@virginia.edu)  Subject line: *Request for IRB Concurrence: Single Patient Treatment (Non-Emergency)*   1. *Request for Single Patient Treatment (Non-Emergency) with Investigational Drug or Device Form* 2. For investigational drugs: Completed Form: 3926 (FDA) 3. Contact the manufacturer to obtain their approval 4. FDA Authorization PRIOR to treatment 5. For investigational Devices: Letter of support from a physician not involved in the patient’s care 6. Single Patient IND/IDE# 7. Consent Form: see [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 not provided by the sponsor 8. Treatment plan/protocol 9. For investigational drugs: IDS approval for investigational drugs 10. For Investigational devices: New Medical Device application from Clinical Engineering   **AFTER the use of the investigational drug or device for NON-EMERGENCY/Compassionate TREATMENT, submit the following to the IRB-HSR via** [**IRBHSR@virginia.edu**](mailto:IRBHSR@virginia.edu)   1. [Single Patient Follow-up Form](https://research.virginia.edu/sites/vpr/files/2020-04/Single%20Patient%20Treatment%20Follow-up%20%28RB%29.docx)  * Within 1 working day if a problem resulted in the death of the patient * Otherwise, within 5 working days * [**FDA follow up submission requirements**](https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-guide-non-emergency-single-patient-expanded-access-submissions) |

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

**IRB-HSR#:**        **DATE OF REQUEST:**

**Submitted by**:

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| **Name of UVA Physician/Email** |  |
| **Name of Drug/Biologic/Device** |  |
| **IND#** | **IDE#** |

1. Provide a description of the patient’s condition and the circumstances necessitating treatment.

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1. Describe why alternatives therapies are unsatisfactory and why the probable risk of using the investigational drug or device is no greater than the probable risk from the disease or condition.

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1. If there is an IRB-HSR approved protocol, describe what deviations or alterations from the protocol are necessary in order to treat the patient.

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1. Describe the plan to monitor the patient to address the specific needs of the patient and detect any possible problems.

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