PI WORKSHEET: Emergency Use

The purpose of this worksheet is to provide support for investigators conducting an emergency use of unapproved drug, biologic, or device in a life-threatening situation, and to provide support Designated Reviewers reviewing such uses. For more information, visit: [Expanded Access to Unapproved Drugs or Biologics](https://research.uci.edu/human-research-protections/clinical-research/expanded-access-to-unapproved-drugs-or-biologics/) or [Expanded Access to Unapproved Devices](https://research.uci.edu/human-research-protections/clinical-research/devices-used-in-clinical-research/expanded-access-to-unapproved-medical-devices/).

Attach this worksheet and other supplemental documentation to a Reportable New Information (RNI) submission in ZOT IRB. Do not submit an IRB application.

**1. Submission Information**

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| **Basic Information**  |  **Submission Details**  |
| 1.1 IRB Number:  | ​​ Click or tap here to enter text.  |
| 1.2 Short Title:  | ​​ Click or tap here to enter text.  |

1. Research Must Meet One of the Following Sets of Criteria (Complete 2.1 or 2.2.)
	1. Emergency Use of an Unapproved Drug or Biologic[[1]](#endnote-2)

**2.1.1** **Emergency Use Criteria:** (Check if “Yes”. All must be checked.)

☐ The patient is (was) confronted by a disease or condition that is (was) either:

☐ Life-threatening[[2]](#endnote-3) (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).

☐ Severely debilitating (diseases or conditions that cause major irreversible morbidity).

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ The situation necessitates (necessitated) the use of the investigational drug or biologic.

[ ]  This is the first emergency use of this test article at UCI. [See list of prior Emergency Uses](https://research.uci.edu/human-research-protections/clinical-research/expanded-access-to-unapproved-drugs-or-biologics/#single-patient-emergency). Subsequent use of test article in the same or different patient requires a new IRB application for Committee review. [[3]](#endnote-4) [[4]](#footnote-2)

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ No generally acceptable alternative for treating the patient is (was) available.

[ ]  The patient does not meet the criteria of an existing study protocol, or an IRB approved protocol does not exist.

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ There is (was) insufficient time to obtain IRB approval. Specify the date the test article will be (was) administered.

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ The treating physician will document (has documented) in the medical record that the above findings were met.

☐ The treating physician will report (has reported) the use to the IRB within 5 working days with documentation that the above findings were met.

☐ The FDA has (had) issued an IND or ☐ will authorize (has authorized) shipment of the test article in advance of the IND submission. Attach supporting documentation.

☐ The use is (was) **NOT** subject to DHHS regulation See HRP-310 - WORKSHEET - Human Research Determination. 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.

**2.1.2 Consent Process:** (Check the option that applies.)

☐ **Consent Obtained:** Informed consent will be (was) sought from the patient or the patient’s Legally Authorized Representative (LAR), in accordance with and to the extent required by 21 CFR §50. See HRP-314 - WORKSHEET - Criteria for Approval.

☐ Informed consent will be (was) documented using HRP-506 - CONSENT - Expanded Access in accordance with and to the extent required by 21 CFR §50.27. See HRP-314 - WORKSHEET - Criteria for Approval.

[ ]  The patient’s signed HIPAA Research Authorization will be (was) obtained.

[ ]  If this study includes a non-English-speaking patient, the English version of the consent/HIPAA materials will be (was) translated for non-English speaking participant or their LAR.

☐ **Exception of Consent:** (Check if “Yes”. All must be checked.)

☐ The patient is (was) confronted by a life-threatening situation necessitating the use of the test article.

☐ Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient.

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ Time is (was) insufficient to obtain consent from the patient’s LAR.

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ There is (was) no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ The treating physician will document (has documented) in the medical record that the above findings were met.

☐ The treating physician will report (has reported) the use to the IRB within 5 working days with documentation that the above findings were met.

☐ A physician uninvolved in the clinical Investigation (i.e., independent physician) will certify (has certified) in the medical record that the above findings were met.

[ ]  Review and sign the Physician Attestation - Emergency Use of an Unapproved Drug or Biologic. See section 6 of the form.

☐ If certification took place after the use of the drug or biologic, all of the following are true: (“NA” if certification took place before the use.)

☐ N/A

☐ Immediate use of the test article is (was), in the investigator's opinion, required to preserve the life of the patient.

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ Time is (was) insufficient time to obtain the independent determination a physician uninvolved in the clinical Investigation.

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ The treating physician will document (has documented) in the medical record that the above findings were met.

☐ The treating physician’ report to the IRB within 5 working days will document that the above findings were met.

* 1. Emergency Use of an Unapproved Device[[5]](#endnote-5)

**2.2.1** **Emergency Use Criteria:** (Check if “Yes” or “N/A”. All must be checked.)

☐ The patient is (was) confronted by a life-threatening disease or a serious condition requiring immediate use of the device.

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ The situation necessitates (necessitated) the immediate use of the device.

[ ]  This is the first emergency use of this test article at UCI. [See list of prior Emergency Uses](https://research.uci.edu/human-research-protections/clinical-research/expanded-access-to-unapproved-drugs-or-biologics/#single-patient-emergency). Subsequent use of test article in the same or different patient requires a new IRB application for Committee review.

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ No generally acceptable alternative for treating the patient is (was) available.

[ ]  The patient does not meet the criteria of an existing study protocol, or an IRB approved protocol does not exist.

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ There is (was) insufficient time to use existing procedures to obtain FDA approval of an IDE. Specify the date the test article will be (was) administered.

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ There is (was) substantial reason to believe that benefits will (would) exist.

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

☐ The treating physician will document (has documented) in the medical record that the above findings were met.

☐ The treating physician will report (has reported) the use to the IRB within 5 working days with documentation that the above findings were met.

☐ A physician uninvolved in the emergency use will certify (has certified) in the medical record that the above findings were met.

☐ One of the following is true:

☐ There is (was) no IDE.

☐ The treating physician wants (wanted) to use the device in a way not approved under an existing IDE.

☐ The treating physician is (was) not part of the IDE study.

☐ One of the following is true:

☐ There is an IDE and the treating physician has (had) authorization from the sponsor.

☐ There is no IDE and the treating physician will notify (has notified) FDA of the emergency use within 5 working days. This include a description of device used, details of the case, and the patient protection measures that were followed. Send 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

☐ The treating physician will follow (has followed) the procedures below if time permits (check all that apply):

☐ Concurrence of the IRB Chair.

☐ Informed consent from the patient or LAR (use HRP-506 - TEMPLATE CONSENT DOCUMENT - Expanded Access).

[ ]  The patient’s signed HIPAA Research Authorization will be (was) obtained.

[ ]  If this study includes a non-English-speaking patient, the English version of the consent materials will be (was) translated for non-English speaking participant or their LAR.

☐ The use is (was) **NOT** subject to DHHS regulation See (HRP-310 - WORKSHEET - Human Research Determination. 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.

1. Financial Considerations for Patients

**3.1 Patient Cost:** If the patient will pay for the emergency use treatment, provide specific details.

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| Click or tap here to enter text. |

1. Treatment Plan

**4.1 Treatment Plan:** Specify the treatment plan including the dosage (as applicable) and duration of treatment. Do not include patient identifiable data nor protective health information (PHI).

[ ]  ***This is included in a separate treatment plan attached.***

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| Click or tap here to enter text. |

1. Follow-Up Report

**5.1 Follow-Up Report:** Provide a report to the IRB within 5 working days of the administration of treatment.

[ ]  ***This is included in a separate report attached or*** [ ]  ***will be included in a subsequent Reportable New Information submission.***

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| Click or tap here to enter text. |

1. Physician Attestation – Emergency Use of an Unapproved Drug or Biologic

[ ]  ***This section is not applicable.***

**6.1 Physician Attestation:** Complete this section to address the documentation requirements.Confirm the following information and provide both signatures below.

As the physician holding the Emergency IND or the physician uninvolved in the clinical investigation (i.e., independent physician), I have:

1. Confirmed that the patient is confronted with a life-threatening situation necessitating the use of the test article; and
2. Confirmed that informed consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from the patient; and
3. Confirmed that time is not sufficient to obtain consent from the patient's legal representative; and
4. Confirmed/ agree that 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.

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**Name of Physician Holding the Emergency IND**

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**Signature of Physician Holding the Emergency IND Date**

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**Name of Independent Physician**

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**Signature of Independent Physician Date**

1. 45 CFR §46.116(f) [↑](#endnote-ref-2)
2. **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 subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible. [↑](#endnote-ref-3)
3. Regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval. However, in guidance documents, FDA acknowledges that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the protocol. [↑](#endnote-ref-4)
4. FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval. However, in guidance documents, FDA acknowledges that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the protocol. [↑](#footnote-ref-2)
5. FDA does not consider the emergency use of an unapproved device to be clinical investigation, and FDA does not require compliance with 21 CFR §50 and 21 CFR §56. The requirements are based on FDA guidance at <http://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf>, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#compassionateuse>, and <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf>. [↑](#endnote-ref-5)