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| The purpose of this checklist is to provide support for reviewing an emergency use of an unapproved drug, biologic, or device in a life-threatening situation, when there is insufficient time for IRB review and approval at a convened meeting (i.e., the “5-day follow-up” report). This checklist may also be used as a guide to determine the criteria for emergency use if email notification was received by the IRB prior to administration of the test article.  This checklist is to be completed by the IRB Analyst and the Designated Reviewer upon receipt of the 5-day Follow-up Report and retained in IRBManager. | | | |
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| Treating Physician: | | |  |
| Emergency Use of an Unapproved Drug or Biologic[[1]](#footnote-1) | | | |
| 1. Criteria for Emergency Use of an Unapproved Drug or Biologic: The Investigator is to verify and provide documentation that the required criteria below was met prior to use. Check all that apply. | | | |
|  | A description of the patient’s disease including the rationale for the use / why the treatment with this investigational agent was necessary is provided. | | |
|  | A description of the administration of the drug/biologic and duration of therapy is provided. | | |
|  | The patient is (was) confronted by a disease or condition that is (was) either:   * Life-threatening (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); or * Severely debilitating (diseases or conditions that cause major irreversible morbidity). | | |
|  | No generally acceptable alternative for treating the patient is (was) available, including an existing study protocol. | | |
|  | Insufficient time to obtain IRB approval at a convened meeting based on the date of administration of the drug/biologic. | | |
|  | Confirmation that the treating physician has documented in the medical record that the criteria for emergency use were met. | | |
|  | The FDA has authorized the use of the test article (via phone or email) in advance of the IND submission and this communication has been provided. | | |
|  | The treating physician obtained Sponsor/Manufacturer approval to ship the investigational drug/device and communication with the Sponsor/Manufacturer is provided (e.g., email communication/approval or Letter of Authorization (LOA)). | | |
|  | The treating physician will (has) reported the use to the IRB within 5 business days of administration/use. | | |
|  | The use was **NOT** a Clinical Investigation[[2]](#footnote-2):   * It is not an experiment that involves a test article and one or more human subjects, in which the results are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. | | |
| 1. Consent Criteria: Check all that apply. | | | |
|  | Informed consent will be (was) sought from the patient or the patient’s legally authorized representative. | | |
|  | Informed consent will be (was) obtained from the patient or legal representative using SH IRB TEMPLATE CONSENT for Treatment Use (HRP-583) and the process documented in the medical record. | | |
|  | Confirm the consent form includes the following[[3]](#footnote-3):  The name and description of the investigational drug/biologic, treatment plan, and monitoring plan.  A statement that the drug/biologic is not-FDA approved, that this involves research and the identification of any experimental procedures (beyond the administration of the drug).  A statement that the treatment is an option for the patient’s life-threatening condition and any benefits to the patient.  A description of any reasonably foreseeable risks or discomforts to the patient.  A statement describing the extent, if any, to which confidentiality of records will be maintained and notes the possibility that the FDA may inspect the records.  An explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained, and whom to contact in the event of injury.  An explanation of whom to contact for answers to questions about the treatment and their rights.  A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the patient is otherwise entitled, and that the patient may discontinue participation at any time without penalty or loss of benefits to which the patient is otherwise entitled.  The following elements may be included in the consent form. When appropriate:  Anticipated circumstances under which the patient’s participation may be terminated by the investigator without regard to the patient’s consent.  N/A  Any additional costs to the patient that may result from participation in the treatment.  N/A  A disclosure of appropriate alternative procedures or courses of treatment, if any.  N/A  A statement that the particular treatment or procedure may involve risks to the patient (or to the embryo or fetus, if the patient is or may become pregnant) which are currently unforeseeable, if applicable.  N/A  The consequences of a patient’s decision to withdraw from the treatment and procedures for orderly termination of participation by the patient.  N/A  A statement that significant new findings developed during the course of the treatment which may relate to the patient’s willingness to continue will be provided to the patient.  N/A | | |
|  | Informed consent will not/was not obtained prior to the administration of the investigational drug/device. **Confirm the following (Skip if N/A)**: | | |
|  |  | All criteria for Emergency Use in Section 1 have been met. | |
|  |  | The treating physician has documented that 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. | |
|  |  | The treating physician has documented that time is (was) insufficient to obtain consent from the patient’s legal representative (LAR). | |
|  |  | A physician uninvolved in the clinical care will certify (has certified) in writing the following, and a copy has been/will be provided to the IRB:   * The patient is/was confronted by a life-threatening situation necessitating the use of the test article. * Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the patient. * Time is not sufficient to obtain consent from the patient’s legal representative. * No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life. | |
|  |  | If the independent physician certification took place after the use of the drug/biologic, confirm that this review was completed and documented in writing within 5 business days after administration/use. | |

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| Emergency Use of an Unapproved Device[[4]](#footnote-4) | |
| 1. Criteria for Emergency Use of an Unapproved Device: The treating physician is to verify and provide documentation that the required criteria below was met prior to use. Check all that apply. | |
|  | A description of the patient’s disease including the rationale for the use / why the treatment with this investigational agent was necessary is provided. |
|  | A description of the administration of the drug/biologic and duration of therapy is provided. |
|  | The patient has a life-threatening condition that needs immediate treatment. |
|  | No generally acceptable alternative for treating the patient is (was) available. |
|  | There is (was) insufficient time to use existing procedures to obtain FDA approval of an IDE based on the date of administration of the device. |
|  | There is (was) substantial reason to believe that benefits will (would) exist. |
|  | Confirmation that the treating physician 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 business days with documentation that the above findings were met. |
|  | The treating physician has provided information regarding one of the following:  There is (was) no IDE for this device.  The treating physician wants (wanted) to use the investigational device in a way not approved under an existing IDE.  The treating physician is (was) not part of the IDE study. |
|  | The treating physician has provided information regarding one of the following:  There is an IDE and the treating physician has (had) notified the sponsor of the IDE of this emergency use.  There is no IDE and the treating physician will notify (has notified) FDA of the emergency use within 5 business days. |
|  | The treating physician has obtained clearance from the institution (i.e., clearance from ORI). |
|  | Select any additional patient protection measures the treating physician will follow (has followed) (check all that apply):  Concurrence of the IRB Chair prior to the use of the unapproved device.  Informed consent from the patient or Legally Authorized Representative using the SH IRB TEMPLATE CONSENT for Treatment Use (HRP-583).  An independent assessment from an uninvolved physician documented in the medical record that the criteria is (was) met.  Authorization from the device manufacturer is (was) obtained. |

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| 1. **Pre-Review Comments/ Contingencies to be Met:**   If the Criteria in Sections 2-3 cannot be determined, request further clarifications or documentation from the treating physician via email. Attach to the submission file all supporting documentation and email correspondence. Document short summary and/or relevant notes to the reviewer below. | | | |
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| Once the criteria for Emergency Use have been documented in the “5-day follow-up” report submission forward this completed checklist to the Designated Reviewer for review and acknowledgement. | | | |
| **Analyst Completing Checklist:** |  | **Date**: |  |

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| 1. **Designated Reviewer Acknowledgement**: This section is to be completed by the IRB Chair or Designated Reviewer when the IRB Analyst’s pre-review indicates that the criteria for Emergency Use with a Test Article is met. | | | |
| **5.1 Reviewer Criteria**: All must be “Yes”. If a conflict of interest exists, a different Designated Reviewer is to be selected. If pre-review contingencies are not met; return to IRB Analyst to obtain required information. | | | |
| Yes  No | I do **not** have a Conflicting Interest. | | |
| Yes  No | All pre-review contingencies noted above have been met. | | |
| **5.2 Designated Reviewer Acknowledgement:** | | | |
| Yes  No | The criteria for use of the investigational test article have been met and there was insufficient time to obtain IRB approval at the time of administration/use.  *If no, the treating physician is to submit a Reportable New Information (RNI) xForm outlining the use of this investigational test article when the criteria was not met.* | | |
| * 1. **Designated Reviewer Notes:** | | | |
| Designated Reviewer Completing Checklist: | |  | **Date:** |

1. 1FDA criteria for Emergency Use of a Drug/Biologic 21 CFR 56.102(d):

   <https://www.ecfr.gov/cgi-bin/text-idx?SID=bfb1a8cdf6f6050ed592e8075ee04d57&mc=true&node=se21.1.56_1102&rgn=div8>

   Emergency Use is a category of Expanded Access; 21 CFR 312, Subpart I:

   <https://www.ecfr.gov/cgi-bin/text-idx?SID=ab7e4caf5d7800b302a384d2fb9dec79&mc=true&node=pt21.5.312&rgn=div5#sp21.5.312.i> [↑](#footnote-ref-1)
2. HHS Letter re Emergency Treatment: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-medical-care-and-research/index.html> [↑](#footnote-ref-2)
3. FDA requires consent for treatment use of a drug/biologic to be compliant with 21 CFR 50; however, with modification related to this use as treatment, not research; 21 CFR 312.305 (c)(4): <https://www.ecfr.gov/cgi-bin/text-idx?SID=ab7e4caf5d7800b302a384d2fb9dec79&mc=true&node=pt21.5.312&rgn=div5#sp21.5.312.i> [↑](#footnote-ref-3)
4. 4FDA 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 criteria for emergency use of an unapproved device are in 21 CFR 812.35(a)(2) and 21 CFR 812.36(a) and are based on FDA guidance at <http://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf>, <https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices#emergency> and <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf>. [↑](#footnote-ref-4)