# Worksheet: Emergency Use

| NUMBER | HRP-322 |
|---|---|

| | |
|---|---|
| IRB NUMBER | |
| PROTOCOL NAME | |
| INVESTIGATOR | |

## Emergency Use of an Unapproved Drug or Biologic[1]

1. Exemption Criteria for Emergency Use of an Unapproved Drug or Biologic. (Check if "Yes". All must be checked.)

| | | |
|---|---|---|
| ☐ | 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) |
| | ☐ | Severely debilitating (diseases or conditions that cause major irreversible morbidity). |
| ☐ | The situation necessitates (necessitated) the use of the investigational drug or biologic. | |
| ☐ | No generally acceptable alternative for treating the patient is (was) available. | |
| ☐ | There is (was) insufficient time to obtain IRB approval. | |
| ☐ | 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 | |
| ☐ | The use is (was) NOT research subject to DHHS regulation see CHECKLIST: Human Research Determination (HRP-310). | |

## NOTE: Section 2 or 3 must be met

2. Consent Criteria (Check if "Yes". All must be checked, if approving for an ICF.)

| | |
|---|---|
| ☐ | Informed consent will be (was) sought from the patient or the patient's legally authorized representative, in accordance with and to the extent required by 21 CFR §50. See CHECKLIST: Criteria for Approval (HRP-314). |
| ☐ | Informed consent will be (was) documented in accordance with and to the extent required by 21 CFR §50.27. See CHECKLIST: Criteria for Approval (HRP-314). |

3. Exception Criteria for Consent (Check if "Yes". All must be checked, if approving for an EXCEPTION to an ICF.)

| | | |
|---|---|---|
| ☐ | 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. | |
| ☐ | Time is (was) insufficient to obtain consent from the patient's legal representative. | |
| ☐ | There is (was) no available alternative method of approval or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient. | |
| ☐ | The treating physician will document (has documented) in medical record that the above findings were met. | |
| ☐ | The treating physician will report (has reported) the use to the IRB within 5 days with documentation that the above findings were met. | |
| ☐ | If certification took place after the use of the drug or biologic, all of the following are true: ("N/A" if certification took place before the use) ☐ N/A | |
| | ☐ | Immediate use of the test article was, in the investigator's opinion, required to preserve the life of the patient. |
| | ☐ | Time was insufficient time to obtain the independent determination a physician uninvolved in the clinical investigation. |
| | ☐ | The treating physician will document (has documented) in the medical record that the above findings were met. |
| | ☐ | The treating physician's report to the IRB within 5 working days will document that the above findings were met. |

[1] Emergency use of an unapproved drug or biologic is a clinical investigation and must comply with 21 CFR §50 and 21 CFR §56.

| Emergency Use of an Unapproved Device[2] | |
|---|---|
| 4. Criteria for Emergency Use of an Unapproved Device (Check if "Yes" or "N/A". All must be checked, if approving for a Device.) | |
| ☐ | The patient is (was) confronted by a life-threatening disease or a serious condition requiring immediate use of the device. |
| ☐ | The situation necessitates (necessitated) the immediate use of the device. |
| ☐ | 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. |
| ☐ | There is (was) substantial reason to believe that benefits will (would) exist. |
| ☐ | 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. |
| ☐ | 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 an 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. |
| ☐ | The treating physician will follow (has followed) the procedures below if time permits (check all that apply): |
| | ☐ Concurrence of an IRB Chair. |
| | ☐ Informed consent from the patient or legally authorized representative. |
| | ☐ Clearance from the institution as specified by policy. |
| ☐ | The use is (was) NOT research subject to DHHS regulation. See CHECKLIST: Human Research Determination (HRP-310). |

[2] 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.