The purpose of this worksheet is to provide support for investigators conducting an emergency use of an unapproved drug, biologic, or device in a life threatening situation, or a compassionate use of an unapproved device that does not have an IDE, and to provide support for Designated Reviewers reviewing such uses. This worksheet is to be used when overseeing such uses. It does not need to be completed or retained.

### Emergency Use of an Unapproved Drug or Biologic

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: (Check box that is true.)
     - 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 treatment for the patient is (was) available.

   - There is (was) NOT sufficient time to obtain IRB approval.

   - The FDA has (had) issued an IND.

   - The research is (was) NOT subject to DHHS regulation. See WORKSHEET: Human Research Determination (HRP-309).

2. **Consent Criteria** (Check if “Yes”. All must be checked.)

   - 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 WORKSHEET: Criteria for Approval and Other Considerations (HRP-311).

   - Informed consent will be (was) documented using TEMPLATE CONSENT DOCUMENT: Emergency Use (HRP-506) in accordance with and to the extent required by 21 CFR §50.27. See WORKSHEET: Criteria for Approval and Other Considerations (HRP-311).

3. **Exception Criteria for Consent** (Check if “Yes”. All must be checked.)

   - The patient is (was) confronted by a life-threatening situation necessitating the use of the investigational drug or biologic.

   - 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 method of approved 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 the medical record that the above findings were met.

   - A physician uninvolved in the clinical investigation will certify (has certified) in the medical record that the above findings were met.

   - A physician uninvolved in the clinical investigation will certify (has certified) to the IRB within 5 working days 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” is certification took place before the use.)
     - Immediate use of the drug or biologic is (was), in the investigator’s opinion, required to preserve the life of the patient.
     - Time is (was) insufficient to obtain an independent determination from a physician uninvolved in the clinical investigation.
     - The treating physician will document (has documented) in the medical record that the above findings were met.
     - A physician uninvolved in the clinical investigation will certify (has certified) to the IRB within 5 working days that the above findings were met.

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1 Emergency use of an unapproved drug or biologic is a clinical investigation and must comply with 21 CFR §50 and 21 CFR §56.
**WORKSHEET: Emergency Use of a Test Article**

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### Emergency Use of an Unapproved Device

**Exemption Criteria for Emergency Use of an Unapproved Device** (Check if “Yes” or “N/A”. All must be checked.)

- [ ] The patient is (was) confronted by a life-threatening disease or serious condition requiring immediate use of the device.
- [ ] The situation necessitates (necessitated) the immediate use of the device.
- [ ] No generally acceptable alternative treatment for the patient is (was) available.
- [ ] There is (was) NOT sufficient 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.
- [ ] A physician uninvolved in the emergency use will certify (has certified) in the medical record that the above findings were met.
- [ ] A physician uninvolved in the emergency use will certify (has certified) to the IRB within 5 working days that the above findings were met.

**Consent Criteria** (Check if “Yes”. All must be checked.)

- [ ] Informed consent will be (was) sought from the patient or the patient’s legally authorized representative.

**Exception Criteria for Consent** (Check if “Yes”. All must be checked.)

- [ ] Immediate use of the device is (was), in the investigator’s opinion, required to preserve the life of the patient.
- [ ] Time is (was) insufficient to obtain consent from the patient’s legal representative.
- [ ] 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.
- [ ] A physician uninvolved in the emergency use will certify (has certified) to the IRB within 5 working days that the above findings were met.


**Notes:**

- "N/A" is certification took place before the use.
- This may take place before or after the use.
- FDA does not require the consent process to follow the informed consent requirements at 21 CFR §50.
- FDA does not require the documentation of consent to follow the informed consent requirements at 21 CFR §50.27.