**Emergency Use of a Test Article without Informed Consent**

**Background:** Even for an emergency use, the investigator is required to obtain informed consent of the participant or the participant’s legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following [21 CFR 50.23(a)]:

(1) The participant is confronted by a life-threatening situation necessitating the use of the test article.
(2) Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the participant.
(3) Time is not sufficient to obtain consent from the participant's legal representative.
(4) 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, in the investigator's opinion, immediate use of the test article is required to preserve the participant's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions above apply, the clinical investigator should make the determination and, within 5 working days after the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. The investigator must notify the IRB within 5 working days after the use of the test article [21 CFR 50.23(c)].

**Instructions:** This template may be used prior to the use of a test article without informed consent.

1. The principal investigator must complete and sign Section A.
2. The principal investigator must arrange for the review of Section A by an independent physician who must then complete and sign Section B.

NOTE: If time was not sufficient to obtain the independent determination of a physician prior to the use of the test article, Section A must still be completed prior to the use of the test article. After administration of the test article, the principal investigator must arrange for the review of Section A by an independent physician who must then complete Section C.
3. Attach signed form to the Notification/Report of Emergency Use of a Test Article in the ERICA system. **This form must be completed and submitted to the IRB within 5 working days of emergency use of a test article without informed consent.**

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| **SECTION A: Principal Investigator Certification** |

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| Principal Investigator: |       |
| Name of Test Article and IND/IDE number, if applicable: |       |
| Date of Use of Test Article: |       |

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| **I certify that the following statements are true:** |
| [ ]  | **1. The participant is confronted by a life-threatening situation necessitating the use of the test article.** |
|  | Explain the nature of the life-threatening situation and why use of the test article is necessary:      |
| [ ]  | **2. Informed consent cannot not be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from the participant.** |
|  | Explain why the participant is unable to provide informed consent:       |
| [ ]  | **3.** **Time is not sufficient to obtain informed consent from the participant’s legal representative.** |
|  | Explain why there is insufficient time, and efforts made (if any) to contact the participant’s legally authorized representative and obtain informed consent:      |
| [ ]  | **4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the participant’s life.** |
|  | Describe available alternative treatment methods:      |

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| **Principal Investigator Name** |  | **Signature** |  | **Date** |

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| **SECTION B: Independent Physician Certification Prior to Emergency Use** |

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| **I have reviewed the information provided and certifications made by the Principal Investigator prior to the use of the Test Article and certify that:** |
| [ ]  | 1. The participant is confronted by a life-threatening situation necessitating the use of the test article. |
| [ ]  | 2. Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant. |
| [ ]  | 3. Time is not sufficient to obtain consent from the participant’s legal representative. |
| [ ]  | 4. There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the participant’s life. |
| [ ]  | 5. I am not otherwise participating in the clinical investigation. |

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| **Physician Name** |  | **Signature** |  | **Date** |

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| **SECTION C: Independent Physician Certification After Emergency Use** |

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| **I have reviewed the information provided and the certifications made by the Principal Investigator within 5 working days of the use of the test article and certify that:**  |
| [ ]  | 1. The participant was confronted by a life-threatening situation necessitating the use of the test article. |
| [ ]  | 2. Informed consent could not be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant. |
| [ ]  | 3. Time was not sufficient to obtain consent from the participant’s legal representative. |
| [ ]  | 4. There was no available alternative method of approved or generally recognized therapy that provided an equal or greater likelihood of saving the participant’s life. |
| [ ]  | 5. I am not otherwise participating in the clinical investigation. |

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| **Physician Name** |  | **Signature** |  | **Date** |