**University of Vermont**

**Emergency Use of an Investigational Drug, Biologic, or Device Certification of Compliance Form**

NOTE: THIS FORM MUST BE COMPLETED FOR EVERY APPLICABLE SUBJECT. THE FORM MUST BE SUBMITTED WITHIN 5 WORKING DAYS AFTER THE USE OF THE TEST ARTICLE.

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| Date: | | |  | | PI: | | |  | | | | | | | | | |
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| Name of Test Article | | | |  | | | | | | | Date Test Article is to be (or was) used: | | | | | |  |
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|  | | Check here if the proposed use meets the following definition from the FDA regulations: | | | | | | | | | | | | | | | |
|  | "Emergency use means the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval." 21 CFR 56.102(d) | | | | | | | | | | | | | | | | |
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| Date and name of IRB Representative that you contacted: | | | | | | | | | | | |  | | | | | |
|  |  | | | | | | | | | | | | | | | | |
| Did you obtain consent? | | | | | | | | |  | Yes | | |  | No | | | |
|  | If yes, describe verbal or attach signed consent form. | | | | | | | | | | | | | | | | |
|  | If no, you must have an independent physician certify by signing below that the four conditions listed below are met. | | | | | | | | | | | | | | | | |
|  | “d. If obtaining informed consent is not possible from the subject or the subject's legally authorized representative, the investigator and a physician not otherwise involved, must certify in writing that the following four conditions have been met:  • the subject is 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 subject;  • time is not sufficient to obtain consent from the subject's legal representative; and  • no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life" (21 CFR 50.23(2)).” | | | | | | | | | | | | | | | | |
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| Signature of Independent Physician | | | | | |  | Date | | | | | | | |  | Printed Name of Physician | |
|  | | | | | | | | | | | | | | | | | |
| Describe the condition treated and the outcome below. | | | | | | | | | | | | | | | | | |
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| Signature of Principal Investigator |  | Date |  | Printed Name of Principal Investigator |