INSTRUCTIONS
Questions? Contact the IRB at 650-725-7258 or secure-irbemergencyuse@lists.stanford.edu
See guidance GUI-6 and HRPP Policy Manual Chapter 5.9.

Report to IRB
The protocol director must submit the following to the IRB within five (5) working days following the emergency use of the test article:
1. This form [APP-11m] completed as follows:
   - Sections A, B, C
   - arrange for an independent physician to complete Section D if informed consent was not obtained from the participant or their legally authorized representative.
2. If obtained: Signed Consent Form
Submit: Email to secure-irbemergencyuse@lists.stanford.edu; or FAX: 650-725-8013; or hardcopy to:
    IRB/RCO, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306 [Mail Code: 5579]

Report to FDA
- Drugs: Physician or sponsor is responsible for submitting a new IND, or an amendment to an existing IND, to FDA within 15 working days of FDA’s authorization of the use. Clearly mark as “Emergency IND”. See FDA website for Physician Request for a Single Patient IND for Compassionate or Emergency Use
- Devices when no IDE: the physician should submit a follow-up report on the use of the device (description of device used, details of the case, and the patient protection measures that were followed) to CDRH.
- Devices when IDE: The IDE sponsor must notify the FDA of the emergency use within 5 days through submission of an IDE Report (§812.35(a)(2)).

Section A

<table>
<thead>
<tr>
<th>Protocol Director</th>
<th>Degree: MD/PhD</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dept/Div</td>
<td>Mail Code</td>
<td>Phone</td>
</tr>
</tbody>
</table>

Protocol Title: include name of test article

Alternate Contact (e.g., Admin Contact) | Phone | Fax | E-mail |

Confirm: This emergency use of the test article was not a systematic investigation designed to develop or contribute to generalizable knowledge.

Subject Populations: check all applicable:
- [ ] Child (under 18)
- [ ] Pregnant Woman/Fetus
- [ ] Neonate
- [ ] Prisoner
- [ ] Other _____

Location:
- [ ] Stanford University
- [ ] Lucile Packard Children’s Hospital
- [ ] CTRU
- [ ] VA; Specify PI at VA: _____
- [ ] Stanford Hospital & Clinics
- [ ] Other _____

Will the drug or device be provided at cost or free of charge?
Section B

Investigational Drug or Biologic?

Name: ___
IND#: ___
Manufacturer: ___

1) Has sponsor agreed to the use of this drug or biologic for this subject? [ ] Yes [ ] No
2) Has FDA given permission for this use and this subject? [ ] Yes [ ] No
   If “yes”, provide FDA IND letter.

Investigational Device?

Has sponsor agreed to the use of this device for this subject? [ ] Yes [ ] No

If there is an existing IDE# for this device, please list: ___

[ ] If there is an IDE for the device, the IDE sponsor must notify the FDA of the emergency use
   within 5 days through submission of an IDE Report (§812.35(a)(2)).
[ ] If no IDE exists, the physician should submit a follow-up report on the use of the device
   (description of device used, details of the case, and the patient protection measures that were
   followed) to CDRH.

Section C

Protocol Director Certification: Emergency Use of a Test Article

Date of Use of Test Article: ___

1. I certify that all of the following statements are true:
   [ ] The participant was confronted by a life-threatening or severely debilitating situation necessitating the use of the
   Test article.
   Explain the nature of the life-threatening or severely debilitating situation and why use of the test article was
   necessary:
   
2. [ ] No alternative method of approved or generally recognized therapy was available that provides an equal
   or greater likelihood of saving the participant’s life.
   Describe available alternative treatment methods:

3. [ ] There was not sufficient time to obtain IRB approval in advance of the use of the test article.
   Explain why there was not sufficient time to obtain IRB approval of the Emergency Use of the Test Article

4. Do you intend to use this test article in the future? [ ] No [ ] OR [ ] Yes
   Any subsequent use of the test article at Stanford is subject to full and prospective IRB review.
   If you intend to use the test article in the future, you must submit a Protocol Application to the IRB.
Emergency Use of a Test Article
[Investigational drug, device, or biologic; FDA regulations 21 CFR 56.104(c)]

Notification to the IRB

Informed Consent

5. Was informed consent obtained from the participant or the participant’s legally authorized representative?
   - Yes  Date of Informed Consent Obtained: 
   - No  If informed consent was NOT obtained from the participant or the participant’s legally authorized representative, you MUST:
     - answer the following questions,
     - arrange for an independent physician to complete Section D below

6.  Informed consent could 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 was unable to provide informed consent:

7.  Time was not sufficient to obtain informed consent from the participant’s legal representative.
   Explain why there was insufficient time, and describe efforts made (if any) to contact the participant’s legally authorized representative and obtain informed consent:

Signature of Protocol Director __________________________ Date __________________________

Section D

Independent Physician Certification: Emergency Use of a Test Article Without Informed Consent

Certification of Independent Physician Who is Not Otherwise Participating in the Clinical Investigation of the Test Article:
I have reviewed the information provided and certifications made by the Principal Investigator (Protocol Director) and certify that all of the following statements are true:

- The participant was confronted by a life-threatening or severely debilitating situation necessitating the use of the test article
- Informed consent could not be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant
- Time was not sufficient to obtain consent from the participant’s legal representative.
- No alternative method of approved or generally recognized therapy was available that provided an equal or greater likelihood of saving the life of the participant.

Name of Independent Physician: ______

Signature of Independent Physician __________________________ Date __________________________