UCSF Institutional Review Board (IRB)
Emergency Use Compliance Checklist

The treating physician must fulfill specific requirements before, if at all possible, and after the emergency use of an investigational drug, biologic, or device (test articles). See the IRB website for more information.

PRIOR TO THE EMERGENCY USE:

- ☐ Contact the IRB office at (415) 476-1814 and ask to speak with the staff member trained in emergency use. The staff member will record the necessary information and direct the treating physician to the appropriate Chair.
- ☐ The treating physician must call the Chair/Vice Chair designated by the IRB staff member to discuss whether the case meets criteria for emergency use:
  - ☐ The test article is used one time per institution to treat a single patient, and
  - ☐ The patient has a condition that is life-threatening or severely debilitating, and
  - ☐ No standard treatment is available, and
  - ☐ There is not sufficient time to obtain prior IRB review and approval, and
  - ☐ The treatment is not part of a systematic investigation designed to develop or contribute to generalizable knowledge (does not meet the DHHS definition of research), and
  - ☐ Informed consent will be obtained, or a waiver of consent will be justified (see below), and
  - ☐ The IRB is notified of the emergency use within five working days. (The consultation with the IRB Chair/Vice Chair serves as notification of the IRB; however, as noted below, an additional written report should be submitted within five working days of the use.)
- ☐ If the Chair/Vice Chair agrees to the treatment, call the IRB office again to arrange preparation of a letter certifying that the requirements for emergency use have been met. The letter can be sent immediately if needed by the manufacturer/sponsor for test article release.
- ☐ If it is not possible to contact the IRB office or Chair/Vice Chair, treating physician should review the criteria above, proceed with treatment if the use meets the criteria, and submit a written report within 5 working days as detailed below.
- ☐ Contact the sponsor or FDA, as applicable, and obtain an IND or IDE.

☐ Obtain written informed consent, or waiver justification. For waiver justification, the treating physician and a physician not involved in clinical investigation of the test article certify in writing (preferably prior to the use, but in any case within 5 working days):

- ☐ The patient is confronted with a life-threatening situation, and
- ☐ The physician cannot communicate with the patient, and
- ☐ Time is not sufficient to obtain consent from the patient's surrogate (legally authorized representative), and
- ☐ No alternative method of approved or generally recognized therapy is available that provides equal or greater likelihood of saving the patient's life.

POST-USE REQUIREMENTS:

☐ Written report submitted to the IRB *within 5 working days* after test article use:
- ☐ Information as detailed in the Post-Use Form
- ☐ Copy of signed informed consent, or
- ☐ Copy of informed consent waiver, if applicable

☐ Complete any follow-up requirements:
- ☐ Written report on "results of use" (within 10 working days, if not submitted as part of the 5 working day reporting requirement)
- ☐ Items specified in the IRB letter (i.e., protocol submissions, etc.)

☐ If applicable, comply with reporting requirements for adverse events.