Emergency Use Checklist: Guidance for IRB Chair, Vice Chair or Physician Member

PI: _____ Date: _____

Test Article _____ Condition: _____

The following conditions must be met to confirm that use of a test article in a single subject meets FDA requirements for administration without prior IRB review and, if applicable, without Informed Consent. Please check applicable items:

With Informed Consent

- ☐ Human subject is confronted by a life-threatening situation necessitating use of test article
- ☐ There is no alternative method of approved or generally recognized therapy available that provides an equal or greater likelihood of saving the subject's life
- ☐ In which there is not sufficient time to obtain IRB approval

Without Informed Consent

- ☐ Human subject is confronted by a life-threatening situation necessitating use of test article
- ☐ There is no alternative method of approved or generally recognized therapy available that provides an equal or greater likelihood of saving the subject's life
- ☐ In which there is not sufficient time to obtain IRB approval
- ☐ Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject
- ☐ Time is not sufficient to obtain consent from subject's legal representative

IRB policy requires the following be obtained at the time the Emergency Use determination is made, unless requirement is waived by the IRB Chair, Vice Chair or Physician Member:

- Written memorandum, email or telephone call of explanation which justifies administration of the test article;
- Copy of the informed consent form (unless conditions listed above in "Without Informed Consent" are met); AND
- Completed General Information Sheet.

Comments:

_____ _____

Name of IRB Chair, Vice Chair or Physician IRB Member Date