Emergency Use Checklist

Unless use was required to preserve the life of a patient, IRB policy requires the IRB Chair, Vice Chair or Physician Member to concur with the Emergency Use determination based on review of:

- Written memorandum, email or telephone call of explanation which justifies administration of the test article; and
- Copy of the informed consent form.

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 required conditions for use, either with or without informed consent:

WITH INFORMED CONSENT

☐ Not Applicable

☐ Human subject is confronted by a life-threatening situation necessitating use of test article;

☐ There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the subject's life; AND

☐ In which there is not sufficient time to obtain IRB approval.

WITHOUT INFORMED CONSENT

*Notation regarding * below: Requires an independent evaluation by nonparticipating physician (in advance if available, or with 5-day report if insufficient time).*

☐ Not applicable

☐ Human subject is confronted by a life-threatening situation necessitating use of test article;

☐ There is available no alternative method of approved or generally recognized therapy 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*; AND

☐ Time is not sufficient to obtain consent from subject's legal representative*.

Reviewer Comments:

ORI E-IRB Instruction: Physician researchers may initially submit emergency use requests external to E-IRB or via E-IRB submission. The following outlines the ORI E-IRB Process when request is initially submitted in E-IRB:

If application is FULL (FL) Protocol Process Type, to avoid returning the application to the researcher after Primary Reviewer (PR) concurrence:

- Take measures to ensure the Primary Reviewer (PR) does not complete his/her IRB Review task* (e.g., make yourself required reviewer);
- In the Select Reviewer task window, assign the Emergency Use Checklist to the Primary Reviewer;
- Inform the PR in advance (e.g., application comment; email; whatever works best to get his/her attention) that (s)he should **NOT** click the “Complete Review” button in the IRB Review task window -- only complete the Emergency Use Reviewer Checklist and write applicable review notes about concurrence (or not) in his/her IRB Review task window, date them, and click **Save**.
  Note: to view PR's "determination", in the ORI Dashboard select "IRB TASKS AND MAINTENANCE-->Tasks in Progress", and click on the Primary Reviewer's IRB Review task button (you might need to ask for the task to be released first).
- Use the Re-select Reviewer tool to add all the other committee members to review the application (removing ‘required reviewer’ in the process);
- Manually add the application to an agenda.

*If the PR completes his/her IRB Review task, getting the application full reviewed without returning to the PI first is no longer an option.

Note: if study comes in as XP Protocol Process Type, the reviewer can complete his/her task with determination of “Full Review Required” and the application does not get returned to the PI – ORI immediately has option to schedule on meeting via the “Screen Revision” task button.