Conflict of Interest (CoI) Disclosure

Yes
No
Clear

Do you have a conflict of interest (personal, financial, academic or other interest) in reviewing this protocol that would prevent you from conducting a fair and objective review?

If No, please continue with your review by completing all areas of the checklist.

If Yes, please contact your IRB Coordinator immediately. You will be provided with specific instructions should your conflict of interest be valid. Please complete this COI section only and save this checklist in the appropriate study within the ERICA system.

- *Example of personal COI – your spouse, an immediate family member, your advisor*
- *Example of academic COI – your student, my research partner/colleague*
- *Example of financial COI – income from stock in etc. the Sponsor or company whose business is substantially related to the subject matter of the research.*

Reviewer Description of Conflict of Interest:

Exemption from IRB Review Requirements for Emergency Use of a Test Article

This checklist is used to determine if the emergency use of a test article meets regulatory requirements [21 CFR 56.102(d)].

Is the activity being reviewed a proposed emergency use or a reported emergency use?

- ○ Proposed Emergency Use (notification to the IRB prior to emergency use of a test article.)
- ○ Reported Emergency Use (report to the IRB after emergency use of a test article.)

Clear

All of the following must be "Yes" for the test article to be administered without prospective IRB review and approval.

- ○ Yes
- ○ No

Clear

The investigators notified the IRB before the use of the test article. If immediate use of the test article was required to save the life of the subject and there was not sufficient time to contact the IRB, the investigator notified the IRB within 5 working days.

- ○ Yes
- ○ No

Clear

The investigator has documented that the participant is (was) confronted with a disease or condition that is (was) either:

- Life threatening meaning the likelihood of death is high unless the course of the disease is interrupted or a disease or condition with a potentially fatal outcome, where the end-point of clinical trial analysis is survival. (The criteria for life threatening do not require the condition to be immediately life threatening or to immediately result in death. Rather, the participants must be in a life threatening situation that requires intervention before review at a convened meeting of the IRB is feasible.)
- Severely debilitating meaning the disease or condition causes major irreversible morbidity. (Examples of severely debilitating conditions include blindness, loss of arm, leg, hand, or foot, loss of hearing, paralysis or stroke.)

- ○ Yes
- ○ No

Clear

The investigator has documented no standard acceptable treatment is (was) available.

- ○ Yes
- ○ No

Clear

There is (was) **NOT** sufficient time to obtain IRB approval (i.e. convened meeting with quorum).

- ○ Yes
- ○ No

Clear

The investigator has documented that the situation necessitates (necessitated) the use of the investigational article.

- ○ Yes
- ○ No

Clear

The research involves (involved) an investigational drug, and the FDA will issue or has issued an IND or the research involves (involved) an investigational device.

- ○ Yes
- ○ No

Clear

The research is (was) **NOT** subject to DHHS regulation.

NOTE: The research must not be subject to DHHS regulation since DHHS has no corresponding exemption from prospective IRB review. The activity must not meet the DHHS definition of "research" and involve "subjects" as defined by DHHS regulations. In other words, the data from an emergency use may not be reported in a way that implies that the activity was a prospectively planned systematic investigation designed to develop or contribute to generalizable knowledge. The PI will be notified of this restriction in the notification letter.

DETERMINATION: Does the proposed or reported activity meet the FDA requirements for exemption from prospective IRB review for emergency use of a test article?

- ○ Yes
- ○ No

Clear

If the proposed or reported activity meets the FDA requirements, the PI will be notified of the determination. The PI will also be notified that any subsequent use of the investigational product at the institution must have prospective IRB review and approval.

*If the **proposed activity** does NOT meet the FDA requirements, the research will be referred to a convened board meeting.*

*If the **reported activity** does NOT meet the FDA requirements, the activity will be handled according to the IRB Non-Compliance Policy.*

Informed Consent Requirement

Has the investigator indicated that informed consent will be (was) obtained and documented from the participant or the participant's legally authorized representative?

- ○ Yes
- ○ No

Clear

Exception from Informed Consent Requirement (21 CFR 50.23)

At least one of the following options must be "Yes" to meet the FDA requirements for the exception from the informed consent requirement.

Before the use of the test article both the investigator and a physician who is not otherwise participating in the clinical investigation certified in writing all of the following:

1. The participant is confronted by a life-threatening situation necessitating the use of the test article;
2. Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant;
3. Time is not sufficient to obtain consent from the participant's legal representative;

There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the participant.

○ Yes
○ No
Clear

All of the following are true:

- Immediate use of the test article was, in the investigator's opinion, required to preserve the life of the participant;
- Time was not sufficient to obtain the independent determination of a physician who was not otherwise participating in the clinical investigation;
- **Before** the use of the test article the investigator certified in writing all of the following:
  1. The participant is confronted by a life-threatening situation necessitating the use of the test article.
  2. Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant.
  3. Time is not sufficient to obtain consent from the participant's legal representative.
  4. There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the participant.
- **After** the use of the test article a physician who is not otherwise participating in the clinical investigation certified in writing within 5 working days after the use of the article all of the following:
  1. The participant is confronted by a life-threatening situation necessitating the use of the test article.
  2. Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant.
  3. Time is not sufficient to obtain consent from the participant's legal representative.
  4. There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the participant.
- The above documentation required was submitted to the IRB within 5 working days after the use of the test article.

○ Yes
○ No
Clear

DETERMINATION: Does the reported activity meet the FDA requirements for the exception from informed consent requirements for emergency use of a test article (at least one of the above options is "yes")?

○ Yes
○ No

Clear

If the reported activity meets the FDA requirements for exception from informed consent for emergency use of a test article, the PI will be notified of the determination.

If the reported activity does NOT meet the FDA requirements for exception from informed consent for emergency use of a test article, the activity will be handled according to the IRB Non-Compliance Policy.