**FORM 5.2B- REPORTING EMERGENCY USE OF A TEST DEVICE**

**SPECIFIC INFORMATION**

Regulations pertaining to emergency use of a test article (investigational drug, biologic or device) are those involving greater than greater than minimal risk as may be determined by the IDI REC. Emergency use of a test article in a life-threatening condition is not considered research; nevertheless, it is under the purview of the IDI REC, because the use of an investigational test article not yet approved by the NDA is involved. The investigational drug or biologic must have received NDA approval, or the investigational device have received Investigational Device Exemption from the NDA for clinical testing, to be eligible for use in an emergency setting. Usually, IND or one that has received exemption from NDA, acquisition is conducted by the manufacturer. If approval by the NDA is not available, the Investigator must contact the NDA on an emergency basis.

For emergency use of a test article, all of the following criteria must be met:

1. The participant is facing a life-threatening condition, for which there is no conventional treatment, or conventional treatments have failed.
2. The physician has access to a test article, and believes that there is a reasonable likelihood that the article will help save the participant’s life, and that there is no approved treatment that has equal or greater likelihood of helping the participant.
3. Comprehensive written informed consent is to be executed prior to initiation of the administration of the test article.

Certain emergency circumstances may not permit the execution of the standard informed consent process prior to administration of the test article. National regulations and guidelines provide an exemption from the informed consent requirement, if the participant is unable to provide effective consent, and there is insufficient time in which to obtain consent from the participant’s legal representative. Under these circumstances, the opinion of another impartial physician is required on the expected benefit from the use the test article; please refer to the “Definitions and interpretations of the NDA and the National Guidelines for Research Involving Humans as Research Participants on Emergency Use of an Investigational article.

The test article is expected to be administered to a single participant as a single course (may involve multiple dosing to achieve maximal efficacy). The participant to receive the test article should not be enrolled in a research study related to the test article. If subsequent use of the test article is contemplated in the same participant or in others, a new project application to the IDI REC is required in advance of that use.

The use of a test article in an investigation designed to be conducted under emergency conditions *(e.g.* emergency room research) usually does not qualify for the emergency use exemption.

Emergency use is defined as the use of a test article on a human participant in a life-threatening situation, in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain REC approval for the use. The Investigator is still required to obtain informed consent under these circumstances.

National Guidelines for Research Involving Humans as Research Participants exempts from REC review the emergency use of a test article so long as the emergency use is reported to the REC within five working days of its occurrence. Any subsequent use of the test article is participant to REC review. "Subsequent use" means any use of the test article that occurs after its initial emergency use. When an IDI REC receives a report by a clinical Investigator of an emergency use, the IDI REC must examine each case to assure itself and the institution that the emergency use was justified.

Although exemption from REC review is designed to permit only a single emergency use of a test article for the treatment of one patient by one physician within an institution, the regulation is not intended to limit the authority of a physician to provide emergency care in a life-threatening situation. Should a situation arise which would require the emergency use of the test article for a second patient, either by the same or a second physician, subsequent emergency use should not be withheld for the purpose of gaining IDI REC approval If it appears probable that similar emergencies will require subsequent use of the test article at the institution, every effort should be made either to sign on to the Sponsor's protocol or to develop a protocol for future emergency use of the article at the institution.

Either of these protocols would need to be prospectively reviewed and approved by the IDI REC for future use of the test article.

In emergency circumstances, it may not be feasible to obtain informed consent prior to using the test article. The regulations therefore provide an exemption from the informed consent requirement for such situations. Emergencies qualifying for this exemption are defined as:

* 1. life-threatening situations necessitating use of the test article;
  2. where the participant is unable to provide effective consent;
  3. there is insufficient time in which to obtain consent from the participant's legal representative; and
  4. there is no available alternative method of approved or generally recognized therapy of equal or greater likelihood of saving the participant's life (Section 4.5.3 b) of the National Guidelines for Research Involving Humans as Research Participants).

**Special procedures for documenting the unfeasibility of obtaining consent apply as follows:**

1. The Investigator and another physician, who is not participating in the clinical investigation, must certify in writing the existence of all four conditions listed above before use of the test article [Section 4.5.3 b) of the National Guidelines for Research Involving Humans as Research Participants].
2. If in the Investigator's opinion,
   1. immediate use of the test article is necessary to save the life of the participant; **and**
   2. there is insufficient time to obtain informed consent to the test article required by Section 4.5.3 before using the test article;
   3. the Investigator is to make his or her own written determinations, then obtain the written review and independent evaluation of a physician who is not participating in the clinical investigation within five working days after the use of the test article [Section 4.5.3 b)].

The documentation required by Section 4.5.3 must be submitted to the IDI REC **within five working days** after the use of the test article Section 4.5.3 b)