IRB SOP 1002
Emergency Use:
Investigational Drugs, Biologics or Devices

Purpose

4.2 The IRB will use the date of concurrence to initiate tracking to ensure the investigator provides a report to the IRB within five working days as required by 21 CFR 56.104(c) and again at one month after use of the test article.

5.0 For any emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following (21CFR50.23(a)):

5.1 The subject is confronted by a life-threatening or severely debilitating situation necessitating the use of the test article;
5.2 Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject;
5.3 Time is not sufficient to obtain consent from the subject's legally authorized representative; and
5.4 No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life or preventing a severely debilitating condition.

6.0 If, in the investigator's opinion, immediate use of the test article is required to preserve the subject's life or prevent a severely debilitating condition, and if time is not sufficient to obtain an independent physician's determination that the four conditions specified in Section 5.0 above apply, the clinical investigator should make the determination and, within **5 working days** after the use of the article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. The investigator must submit the written documentation regarding the decision to proceed without informed consent to the IRB within **5 working days** after the use of the test article [21 CFR 50.23(c)].

7.0 The investigator must provide an

9.0 After emergency use of a medical device, the investigator must notify the sponsor of the emergency use, if an IDE for the particular use exists. If an IDE does not exist, the investigator must notify the FDA of the emergency use and provide the FDA with a written summary of the conditions constituting the emergency, subject protection measures, and results. If the emergency use involves a humanitarian use device, the report should be submitted to the HDE holder. Copies of the correspondence should be submitted to the IRB.

10.0 If the emergency use of the test article has occurred without approval of the full Board, the Chair will review the documentation submitted, report to the full IRB at the next convened meeting after the documentation is received, and notify the physician seeking emergency use that the Board acknowledges its use.

11.0 If the emergency use of the test article has occurred without prior approval of the full Board or concurrence of the Chair, he/she will review the documentation submitted, report to the full IRB at the next convened meeting after the documentation is received, and notify the physician seeking emergency use whether the Board agrees that the conditions for emergency use were satisfied.

12.0 USA IRB will include in its correspondence to the investigator/physician a statement indicating that any subsequent use of the test article at the institution requires prospective IRB review and approval, unless in the investigator's opinion, immediate use of the test article is required to preserve the subject's life or prevent a severely debilitating condition.

13.0 If the emergency use involves a test article utilized in an IRB-approved study, a copy of all correspondence and documentation concerning the emergency use will be retained in IRBNet.

14.0 Exceptions from informed consent requirements for emergency research

able to give their informed consent as a result of their medical condition
- The intervention must be administered before consent can be obtained from the subject's legally authorized representative
- There is no reasonable way to identify prospectively individuals likely to become eligible for participation
- Participation in the research holds out the prospect of direct benefit to the subjects
- The clinical investigation could not practicably be carried out without the waiver

For each subject unable to provide informed consent, the clinical investigator participating in emergency research must commit to attempting to seek written informed consent within the therapeutic window, if feasible, from the subject's legally authorized representative. If no LAR is available, the clinical investigator must commit to attempting to contact a family member to provide an opportunity to object to the participation of an individual, before administering the test article without informed consent, if feasible.

The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, details of the investigation and other information contained in the informed consent document. The IRB shall also ensure that subjects may discontinue participation at any time without penalty or loss of benefits to which the subject is entitled. If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member is contacted, information about the study is provided to the subject's legally authorized representative or family member, if feasible.

If an IND or IDE already exists, protocols involving an exception to the informed

Regulated Documents

21 CFR 50(a)-(c); 21 CFR 56.102(d); 21 CFR 56.102(l); 21 CFR 56.104(c)

IRB Form:

Emergency Use Post-Use Report Form – Available in IRBNet, Forms and Templates

Guidance Documents