Emergency Use of a Test Article

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1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the policy/procedure for Emergency Use of a Test Article.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the Health Sciences Institutional Review Board. All FDA regulated research is reviewed by the Health Sciences IRB.

3.0 Policy/Procedure

The FDA regulations for the protection of human subjects and patients allow for an investigational drug or device to be used in emergency situations without prior IRB approval [21 CFR 56.102(d), 21 CFR 56.104(c)]. The emergency use

provision in the FDA regulations is an exemption from prior review and approval by the full IRB.

All the following conditions for emergency use must be met:

- Subject is facing a life-threatening condition, for which there is no conventional treatment;
- There is insufficient time to obtain IRB approval prior to administration;
- The subject to receive the test article will not be enrolled in a research study involving the test article; and
- The physician has legitimate access to a test article and believes that there is reasonable likelihood that its use may be advantageous to the life-threatening condition.

Approval of an emergency use of a test article will be granted for **only one (1) patient**. If subsequent use of the test article is contemplated on the same subject or others, a complete IRB application must be submitted for full board review prior to any additional use of the test article. An investigator cannot carry out a research project on a case-by-case basis under an emergency use premise.

Procedure to Obtaining Emergency Use approval

1. If the Chair or IRB administrative office cannot be contacted in advance, the investigator may administer the drug or device as long as s/he obtains informed consent from the subject and submits the Emergency Use of a Test Substance Form within five (5) days of the test article administration.

2. If possible, prior to administration of the test article, the investigator must notify the IRB of the request for Emergency Use approval and the intention to use an investigational test article, by submitting the Emergency Use of a Test Substance Form. The investigator will be asked to submit a new research application if future requests to use the test article is likely to occur.

3. The IRB will direct the investigator to submit the Emergency Use of a Test Substance Form that contains the following information:
   a. Written request outlining the necessity for Emergency Use;
   b. Subject's name;
   c. Name and IND # (investigational new drug identification number) of test article;
   d. Explanation of subject's history and rationale for use of drug; and
   e. Informed consent document.

4. No review or action will occur until receipt of the items requested in 3.

5. The Chair (or physician designee if the chair is not a physician) and IRB administrative office will review the request for emergency use and the consent document for acceptability.

6. If the request is accepted, a memorandum documenting the determination will be sent to the investigator through the eCompliance system.

7. The investigator will be required to complete a PI assurance statement signifying their understanding and agreement of the reporting requirements.

8. A copy of the completed memorandum and consent document will be provided to the investigator and documented in the eCompliance system.

9. To be exempt from the requirement for IRB review for the emergency use of a test article in a life threatening situation, an investigator must not use the data in a systematic investigation designed to develop or contribute to generalizable knowledge. To comply with this limitation, investigators must follow these three rules as outlined in the determination letter:

    1. Do not use the emergency use exemption to circumvent the general requirement for prior **IRB** review;

    2. Do not use data from an emergency in a prospective research study; and

    3. Do not report data from an emergency use in a retrospective research study, unless granted specific approval by the IRB.

Reporting Requirements

As stated in the determination letter sent to the investigator, a Misc Reporting Form must be received in the IRB office within 5 days of issuance of the determination. The report must be a written status of the emergency use including information on the administration of the test article. If a report is not received within 5 days, a member of the IRB staff will contact the investigator on day 5 to obtain the status of the emergency use and reiterate reporting procedures to the investigator.

A full report is due again by 30 days. If a report has not been received in the IRB office within 30 days of issuance of the approval, a member of the IRB staff will contact the investigator on day 30 to obtain the status of the emergency use and reiterate reporting procedures to the investigator.

All unanticipated problems associated with the emergency use exemption must be reported to the IRB within 5 days of the occurrence.

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