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
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FDA regulations is an exemption from prior review and approval by the full IRB. All the following conditions for emergency 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
- 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 an investigational drug 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 can not be contacted in advance, the investigator may administer the drug as long as s/he obtains informed consent from the subject, and provided written notification to the IRB within five (5) days of the test article administration.

2. If possible, prior to administration of the test article, the investigator must notify the Chair and/or IRB administrative office of the request for Emergency Use approval and the intention to use an investigational test article. 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 provide the investigator with written information and procedures for obtaining approval for emergency use of a test article. (The instructions will be consistent with this SOP). Attachment 1 contains the written information and procedures. Required 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
   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 provided consent document for acceptability.
6. If the request is approved, a memorandum documenting the approval will be prepared for the investigator. (See Attachment 2)

7. The investigator will be required to sign the approval memorandum signifying their understanding of and agreement of the reporting requirements.

8. A copy of the completed memorandum and approved consent document will be provided to the investigator. A full copy of all documents and information will be kept in a file in the IRB administrative office.

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 or else the exemption no longer applies. To comply with this limitation, investigators must follow these three rules:

   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**

A report must be received in the IRB office within 5 days of issuance of the approval. 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.
Attachment 1:

REQUIREMENTS AND PROCEDURES FOR THE EMERGENCY USE OF AN UNAPPROVED INVESTIGATIONAL DRUG, BIOLOGIC OR DEVICE

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. Emergency use is defined as the use of a test article (e.g. investigational drug or biologic) on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is insufficient time to obtain IRB approval.

Requirements for Emergency Use

Each of the following conditions must exist to justify the emergency use of an unapproved investigational drug (including biologic) or device:

1) the patient has a life-threatening condition that requires immediate treatment

2) no generally acceptable alternative for treating the patient is available

3) because of the immediate need to use the drug or device, there is not sufficient time to submit for full IRB review and action

Exemption from full IRB approval for Emergency Use of an investigational drug will be granted for **only one (1) patient**. If subsequent use of the test article is contemplated on the same subject or others, a full application packet submitted for full board review will be required prior to any additional administration of the test article. An investigator can not carry out a research project on a case-by-case basis under an emergency use premise.

University policies require that the IRB chair or IRB administrative office be notified prior to the emergency use of an investigational drug or device, however, this notification should not be construed as IRB approval. Notification is required by the IRB to ensure that the conditions described in the respective FDA regulations are met and to reinforce the OHRP directives prohibiting the designation of such use as a research activity.

Procedure for obtaining exemption from full IRB approval for Emergency Use of a test article is as follows:

1) Prior to administration of the test article, the investigator should notify the Chair and/or the IRB administrative office of the request for Emergency Use exemption and the intention to use an investigational test article.

2) Written request of an exemption from full IRB approval for Emergency Use of a test article must be provided to the IRB administrative office outlining the necessity for Emergency Use including:
   a) Subject’s name
   b) name and IND # of test article
   c) explanation of patient’s history and rationale for use of drug
3) Proposed informed consent document must be submitted to the IRB administrative office for review.

4) No review or action will occur on the Emergency Use request until the IRB has received the items requested in 2) and 3).

5) The Chair and IRB administrative office will review the request for exemption from approval for Emergency Use and the informed consent document for acceptability.

6) If exemption from full board approval for an Emergency Use is granted, a memorandum documenting this action will be provided to the investigator. The investigator will also be required to sign this memorandum documenting that s/he has read and agrees to comply with the documentation and reporting requirements for Emergency Use of a test article.

The physician is required to notify the IRB administrative office within 5 days and again within 30 days of the date of approval for exemption from IRB approval. This notification must be a written report of the status of the emergency use including information on the administration of the test article.

Any unanticipated problems that are deemed reportable under the HS IRB Unanticipated Problems policy, associated with the Emergency Use of the test article must be reported to the IRB within five (5) days of their occurrence.

If the Chair or IRB administrative office can not be contacted in advance, the investigator may administer the drug as long as the criteria stipulating emergency use are met, informed consent is obtained from the subject, and the physician provides written notification to the IRB within (5) days of the test article administration.

Federal regulations require obtaining informed consent, if feasible, unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following: (20 CFR 50.23 (a)).

1) the subject is confronted by a life-threatening situation necessitating use of the investigational drug

2) informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject

3) there is insufficient time to obtain consent from the subject’s legal representative

4) no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the life of the subject

If there is insufficient time to obtain an independent physician’s determination that the above four conditions apply, and immediate use of the test article is required to preserve the patient’s life, the test article may be given to the patient. However, within five (5) working days of the administration of the test article, an independent physician must submit in writing
to the IRB a review and evaluation of the decision to use the test article complied with FDA regulations. An independent physician is a physician who is not otherwise participating in the treatment of the patient.

Prior notification of intent to invoke the exception to the requirement to obtain consent for the use of a test article on an emergency basis in a life-threatening situation without prior IRB approval must be reviewed to determine that the circumstances of the exception complied with FDA regulations.

Reports of the exception to the requirement to obtain consent for the use of a test article in a life-threatening situation without prior IRB approval must be reviewed to determine that the circumstances of the exception complied with FDA regulations.

These procedures apply only to clinical use of investigational drugs. Use of FDA-approved drugs for an unlabeled use in a treatment setting is considered part of clinical judgment and is not subject to regulation unless the investigator wishes to research an unlabeled use.

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 or else the exemption no longer applies. To comply with this limitation, investigators must follow these three rules:

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.
Attachment 2

MEMORANDUM

DATE: <current date>

TO: name of doctor

FROM: Chair
      Institutional Review Board

RE: emergency protocol

The Chair of the Institutional Review Board has reviewed the information provided regarding this patient’s condition and has approved the consent form provided by the physician. An Emergency Use exemption from full board approval has been granted after a review of the situation and the informed consent document. This approval is valid only for this patient in this situation at this time.

A full report is due back to the IRB by calendar date 5 days hence and again by calendar date 30 days hence.

Failure to submit reports as requested constitutes a breach in IRB compliance.

PHYSICIAN ASSURANCE

I agree to accept responsibility for the scientific conduct of this project.

I agree to report back to the IRB by calendar date 5 days hence and by calendar date 30 days hence.

I agree to report any unanticipated problems that are deemed reportable under the HS IRB Unanticipated Problems policy, to the IRB within 5 days of their event.

Signed: __________________________

Date: __________________________

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