SSH PROCEDURE:
Emergency Use of Investigational Drugs

PURPOSE

This procedure outlines the steps for emergency use of investigational drugs

DEFINITIONS

Emergency use is defined as the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)].

PROCEDURE INFORMATION

Emergency Use:
- Emergency use is defined as the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)].
- DHHS regulations do not permit data obtained from patients to be classified as human participants research, nor permit the outcome of such care to be included in any report of a research activity subject to DHHS regulations.
- FDA regulations require that any subsequent use of the investigational product at an institution have prospective IRB review and approval.

Investigators should take the following steps:
1. Determine if the proposed use meets the regulatory definition for emergency use of an investigational drug or biologic [21 CFR 56.102(d)]. Emergency uses must meet ALL of the following criteria:
   - The subject has a disease or condition which is life-threatening (e.g., the likelihood of death is high) or severely debilitating (e.g., may cause irreversible morbidity, such as blindness, loss of limb, loss of hearing, paralysis or stroke);
The subject's disease or condition requires intervention with the investigational drug or biologic before review at a convened meeting of the IRB is feasible; and

- No standard acceptable treatment is available.

2. The emergency use of an unapproved investigational drug or biologic requires an IND. If the intended subject does not meet the criteria of an existing study protocol, or if an approved study protocol does not exist, the investigator may contact the manufacturer and determine if the drug or biologic can be made available for the emergency use under the company's IND. The manufacturer must contact the FDA to obtain permission for the emergency use to occur using the existing IND. The IRB requires documentation of the FDA's permission for the emergency use.

3. The need for an investigational drug or biologic may arise in an emergency situation that does not allow time for submission of an IND. In such a case, FDA may authorize shipment of the test article in advance of the IND submission. Requests for such authorization may be made by telephone or other rapid communication means [21 CFR 312.310(d)]. The IRB requires documentation of the FDA's permission for the emergency use.

FDA Contacts for Obtaining an Emergency IND

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<thead>
<tr>
<th>Product</th>
<th>Office/Division to Contact</th>
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<tr>
<td>drug products</td>
<td>Division of Drug Information</td>
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<td></td>
<td>(888) 463-6332</td>
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<td>(301) 796-3400</td>
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<td>biological blood products</td>
<td>Office of Blood Research and Review</td>
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<td>(HFM-300)</td>
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<td>(301) 827-3518</td>
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<td>biological vaccine products</td>
<td>Office of Vaccines Research</td>
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<td>(HFM-400)</td>
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<td>(301) 827-3070</td>
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<td>On nights and weekends</td>
<td>Office of Crisis Management &amp; Emergency Operations Center</td>
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<td>(866) 300-4374</td>
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<td>(301) 796-8240</td>
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4. Contact the Office of Research at 781-624-4369 or 781-624-4035 to notify them of planned emergency use of a drug or biologic.
   - Important regulatory and reporting requirements with the FDA and IRB must be followed.
   - There must be a staff physician (i.e. not a fellow or resident) responsible for emergency uses; who oversees and is responsible for the emergency use and completes all reporting requirements.

5. Contact the Pharmacy as soon as possible to inform them of the planned use and shipment of drug.
   - If a protocol from any institution or manufacturer is being followed, or other reference information regarding the drug or biologic is available, a copy must be sent to the IRB and the pharmacy.
   - Any information regarding drug use, indication, administration, dispensing instructions (dose, route, frequency, etc), and preparation instructions must be sent to the pharmacy. The pharmacy needs to verify what is being prepared and the responsible physician should have something in writing to this effect.
   - The pharmacist must be able to verify that the written order is correct and that no transcription errors occurred, (i.e. 1 mg vs. 1gm) before the drug can be released from pharmacy.

6. Before the use of the test article, both the Investigator and the Department Chair or his/her designee who is not otherwise participating in the clinical investigation must certify in writing that:
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 subject.

7. Obtain informed consent from the subject, or if the subject is incompetent to give informed consent, the subject's legally authorized representative (next-of-kin).
   o If the holder of the IND (i.e., sponsor or other local or distant physician) has an existing patient consent form that is made available, that form may be used. The IRB would prefer to review these forms in advance of their use, if time permits, though this may not be possible in an emergency situation. Whenever possible, written consent should be sought.
   o If there is no existing consent form available from a sponsor or other IND holder, a clinical consent form should be used. Physicians should discuss with patients, or legally authorized representatives, the investigational nature of the proposed emergency treatment, the risks and benefits, and document these discussions in the medical record, in clinical notes, and in a clinical consent form.
   o An exception to the requirement for informed consent may be waived if both the Investigator and the Department Chair or his/her designee who is not otherwise participating in the clinical investigation certify in writing all of the following:
     1. The subject is confronted by a life-threatening (or severely debilitating) situation necessitating the use of the investigational drug or biologic;
     2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject;
     3. Time is not sufficient to obtain consent from the subject's legal representative; and
     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.

8. Investigational drugs should be delivered to the Pharmacy, with the responsible receiving physician's name and contact information clearly noted on the mailing label. Alert the pharmacy about the expected arrival of the drug.

9. Submit the completed Emergency Use form within 5 working days after the use of the investigational drug or biologic.

10. FDA regulations require that any subsequent use of the investigational product at an institution have prospective IRB review and approval.

REFERENCES

http://www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm

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