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Lakeland Regional Health

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Owner	Trudy Wittenberg: 4388 Institutional Review Board Administrator
Department	HRPP/Research

Research: Expanded Access, Emergency Use of Devices for Individual Patients- AD.0200

PURPOSE

The purpose of this policy is to outline the treating physician's responsibilities, IRB submission requirements and review process for emergency use of devices for individual patients. Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

APPLICABILITY

This policy applies to Lakeland Regional Health's **Workforce** and Research Personnel engaged in research. This policy applies to use of **investigational devices**, diagnostics, or other interventions that are regulated by the FDA. This policy does not regulate or interfere with the clinical practice of medicine.

POLICY

I. **Expanded Access**: Emergency Use Exemption Requirements for the Use of Devices

A. **Emergency use** is the use of an investigational device (i.e., **test articles**) with a human subject in an **immediately life-threatening (or severely debilitating) situation** in which no standard acceptable treatment is available and in which there is not sufficient time to obtain prospective IRB approval. At Lakeland Regional Health, the IRB requires seven (7)

calendar days to convene a quorum. If the device must be used in less than seven (7) days from the time of the treating physician's determination, then the emergency exemption requirements are automatically invoked. This exemption from prior IRB review and approval is limited to a single use. FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval. The FDA acknowledges, however, that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue.

B. The FDA has not objected if a physician chooses to use an unapproved device in an emergency, provided that the physician later justifies that an emergency actually existed. Each of the following conditions must exist to justify emergency use of an investigational device:
    1. The patient is in a life-threatening condition that requires immediate treatment (within seven (7) calendar days); and;
    2. No generally acceptable alternative for treating the patient is available; and
    3. Because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use. Under very limited circumstances, the requirements for informed consent may be waived in an emergency situation.

C. The IRB requires notification prior to the emergency use of a device. In this situation, notification to the IRB is subject to the requirements outlined below. Notification does not substitute for approval and is used only to initiate tracking to ensure the treating physician files a report within five (5) days of the emergency use. The five (5) day notification window is not to be confused with the seven (7) day window of indications for emergency use. Expedited approval is not permissible for emergency use; full board approval is required unless the device must be used on the patient within seven (7) calendar days.

II. Emergency Exemption from Prospective IRB Review

Immediate life-threatening situations typically occur with short notice, although occasionally the planned use can be foreseen three (3) or four (4) weeks in advance. When there is sufficient time (eight (8) or more calendar days), the IRB must review the proposed single patient use (see Expanded Access: Compassionate Use (Devices)). When there is insufficient time for IRB review (seven (7) or less calendar days), the treating physician may exercise the emergency exemption from prior IRB review and administer the investigational device.

III. Limitations of Emergency Use without Prior IRB Approval

A treating physician may exercise the emergency exemption from prior IRB approval to use an investigational device once without prospective IRB review, provided that the use qualifies as emergency use. Any subsequent use of the investigational device at LRH is subject to IRB review (21 CFR § 56.104), unless requiring prospective review would inappropriately deny emergency treatment to a second individual.

PROCEDURE

I. Treating Physician Responsibilities for Emergency Use of an Unapproved Device

A. Confirm that the patient has a life-threatening condition that needs immediate (within seven (7) days or less) treatment (the criteria of "life-threatening condition" include **serious diseases or conditions** such as sight-threatening and limb-threatening conditions as well as other situations involving risk of irreversible morbidity); and

B. No generally acceptable alternative treatment for the condition exists; and because of the immediate (within seven (7) days or less) need to use the device, there is no time to use existing procedures to get FDA approval for the use.

C. The treating physician must document the above conclusion(s) in the patient's medical record.

II. Before Emergency Use

A. The FDA expects that the treating physician will follow as many patient protection procedures as possible. These protection procedures include:

1. Obtain informed consent from the patient or a legal representative;
2. Notify and obtain the approval of the IRB Chair or Vice Chair;
3. Clearance from the institution as specified by their policies (at LRH, this requirement is met by notification of the IRB Chair or Vice Chair);
4. An independent assessment by an uninvolved physician; and
5. Authorization from the **IDE** holder, if an approved IDE for the device exists.

B. If any of the requirements listed in II.A cannot be met due to the urgency of the clinical situation, the treating physician must document in writing their reasons for proceeding and include it in their submission to the IRB.

C. If the informed consent of the subject cannot be obtained prior to use of the device, the treating physician must certify that all of the following have been documented in writing in the subject's medical record:

1. The subject is confronted by a life-threatening situation necessitating the use of the test article (device);
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 legally authorized 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.

D. In the event an unapproved device is used in an emergency, the sponsor must notify the FDA immediately after shipment. In addition, the physician employing the test article (device) should make every effort to protect subjects including, as applicable:

1. Obtaining an independent assessment by an uninvolved physician;
2. Obtaining informed consent from the patient or legally authorized representative (see Informed Consent- AD.0122);
3. Notifying the appropriate IRB as soon as practicable (must be completed within five (5) days of use); and
4. Obtaining authorization from the IDE holder, if an approved IDE for the device

exists.

III. After Emergency Use of an Unapproved Device

A. The treating physician must do the following:

1. Report to the IRB within five (5) days and otherwise comply with provisions of the IRB regulations (21 CFR § 56);
2. Evaluate the likelihood of a similar need for the device occurring again, and if future use is likely, immediately initiate efforts to obtain IRB approval and an approved IDE for the device's subsequent use; and
3. If an IDE for the use does exist, notify the sponsor of the emergency use, or if an IDE does not exist, 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.

B. Subsequent emergency use of the device may not occur unless the physician or another person obtains approval of an IDE for the device and its use.

C. The emergency use of the test article (device) must be reported to FDA by the IDE sponsor within five (5) working days from the time the sponsor learns of the use. The report should contain a summary of the conditions constituting the emergency, patient outcome information, and the patient protection measures that were followed.

1. If the treating physician is the IDE holder, the FDA must be notified by the treating physician and provided with a written summary of the conditions constituting the emergency, subject protection measures, and results.
2. A second use of an unapproved device may not take place until approval of an IDE for the proposed use has been issued by the FDA.

D. If the emergency exemption is exercised, the IRB Office must be notified via email and by submission of all appropriate documents in IRBNet. The IRB may also be notified prior to the use, but regardless of whether an initial notification is filed, the treating physician must complete a report to the IRB within five (5) days, so that the IRB can ascertain that the use was appropriate.

1. If it was not possible to obtain informed consent prior to the emergency use, the determination to proceed must be reviewed by a physician independent of the clinical investigation.
2. The report of the independent physician's findings must be submitted to the IRB along with the treating physician's report.

E. The information contained above should be captured in a letter to the IRB by the treating physician. The IRB also requests a copy of the Investigator's Brochure or device manual, and either the consent template that will be used or a redacted copy of the signed informed consent form.

F. After the information is submitted in IRBNet, the IRB Chairperson or Vice Chair will:

1. Confirm that the emergency use of the test article (device) meets all of the criteria outlined above;
2. Concur with the use of the test article;
3. Review reports of the emergency use (including the consent document used);

4. Review exemptions from the requirement to obtain consent; and
5. Determine if the use met FDA regulatory requirements. If the requirements were not met, the Chair or Vice Chair will work with the IRB Administrator to inform the treating physician of the appropriate processes for future uses.

G. A letter will be provided to the treating physician through IRBNet by the IRB Administrator acknowledging the review from the Chairperson/Vice Chair.

H. The emergency use of test articles (devices) will be relayed to the convened IRB at their next meeting as information.

DEFINITIONS

Emergency Use: The use of a test article on 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.

Expanded Access: Expanded access for medical devices is a potential pathway for patients with either a serious, life-threatening disease, or condition, to access an investigational medical device that has not been approved or cleared by the FDA for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

Immediately Life-Threatening Disease or Condition: A stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

Investigational Device Exemption (IDE): IDE refers to the regulations under 21 CFR § 812. An approved IDE means that the IRB (and FDA for significant risk devices) has approved the sponsor's study application and the requirements under 21 CFR § 812, as applicable, are met. An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements of the Food, Drug, and Cosmetic Act (FD&C Act) that would apply to devices in commercial distribution.

Serious Disease or Condition: A disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.

Test Article: A drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the jurisdiction of the Food and Drug Administration.

Workforce: All LRH employees, volunteers, trainees/students, contractors, and medical staff.

REFERENCES

I. eCFR :: 21 CFR 56.102 -- Definitions.
II. eCFR :: 21 CFR 312.310 -- Individual patients, including for emergency use.

III. eCFR :: 21 CFR 56.105 -- Waiver of IRB requirement.

IV. eCFR :: 21 CFR 56.108 -- IRB functions and operations.

V. Emergency Use | CHOP Institutional Review Board

VI. CHOP SOP - Emergency Use_2021-6-28

Approval Signatures

Step Description	Approver	Date
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