

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
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Approved By: ORI Director	Signature	Date	Date First Effective: 07-24-06
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date:

OBJECTIVE

To describe the procedures for treatment investigational new drug (IND) or treatment protocol under existing IND

GENERAL DESCRIPTION

Definitions

A *treatment IND* is a mechanism for providing eligible subjects with investigational drugs (as early in the drug development process as possible) for the treatment of serious and life-threatening illnesses for which there are no satisfactory alternative treatments.

The Food and Drug Administration (FDA) defines an *immediately life-threatening disease* as a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

General Requirements

The FDA will permit an investigational drug to be used under a treatment IND after sufficient data have been collected to show that the drug “may be effective” and does not have unreasonable risks. Treatment IND studies require prospective Institutional Review Board (IRB) review and informed consent. A sponsor may apply for a waiver of IRB review under treatment IND if it can be shown to be in the best interest of the subject and if a satisfactory alternate mechanism for assuring the protection of human subjects is available such as review by a central IRB. Although the FDA may exempt the requirement for prior review and approval by the IRB in certain treatment cases [21CFR56.104(c)], University of Kentucky (UK) IRB policy requires prior review and approval by the IRB Chair, Vice Chair, or physician IRB member.

Four requirements that must be met before a treatment IND can be issued:

- The drug is intended to treat a serious or immediately life-threatening disease;

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- There is no satisfactory alternative treatment available;
- The drug is already under investigation or trials have been completed; and
- The trial sponsor is actively pursuing marketing approval.

The FDA identifies two special considerations when a patient is to be treated under a Treatment IND:

- Informed Consent: Informed consent is especially important in treatment use situations because the subjects are desperately ill and particularly vulnerable. They will receive medications which have not been proven either safe or effective in a clinical setting. Both the setting and their desperation may work against their ability to make an informed assessment of the risk involved. Therefore, the investigator must ensure that potential subjects are fully aware of the risks involved in the participation.
- Charging for Treatment INDs: The FDA permits charging for the drug, agent, or biologic when used in a treatment IND. Therefore, the IRB must pay particular attention to treatment INDs in which the subjects will be charged for the cost of the drugs. If subjects will be charged for use of the test article, economically disadvantaged persons may inadvertently be excluded from participation. Charging for participation may preclude economically disadvantaged persons as a class from receiving access to test articles. The IRB must balance this interest against the possibility that unless the sponsor can charge for the drug, it will not be available for treatment use until it receives full FDA approval.

RESPONSIBILITY

Execution of SOP: IRB Chair, IRB Vice Chair, IRB Members, Office of Research Integrity (ORI) Staff, Principal Investigator (PI)/Study Personnel

PROCEDURES

Treatment IND or Treatment Protocol in which the FDA has waived IRB Review

1. Although the FDA may waive the requirement for IRB review, the UK Medical IRB requires prior review and approval by the IRB Chair, Vice Chair, or physician IRB member using expedited review procedure. The PI must follow procedures described in the Emergency Use in a Single Subject SOP with three additions:
 - The PI includes the phrase "TREATMENT IND" in the title on the General Information Sheet;
 - The PI's letter of explanation must include the treatment IND number assigned by the FDA and the name of the sponsor;
 - A copy of documentation verifying that the FDA has waived the requirement for IRB review must accompany the request. (This requirement is necessary because the FDA also issues Treatment INDs in which the IRB review is not waived. (See below).

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2. The IRB Chair, Vice Chair, or physician IRB member reviews the request and responds in writing. He/she is responsible for forwarding the request and response to the ORI, which processes the application using expedited review procedures and informs the IRB at the next convened meeting that the IRB Chair or Vice Chair has reviewed the request and verified that the conditions have been met for a treatment IND approval. (See Expedited Initial Review SOP)

Treatment IND or Treatment Protocol for Which the FDA Has NOT Waived IRB Review

1. If in the approval of the treatment IND, the FDA does not grant a waiver for IRB review, the convened IRB reviews the use. This requirement applies even if the drug is to be administered to only one patient.
2. The IRB reviews the protocol as outlined in the Initial Full Review SOP and according to federal regulations.

Note: FDA policy specifies that "the provision for emergency use would rarely apply to a treatment protocol or treatment IND because these are planned uses of the test article and sufficient time is available to obtain IRB review and approval." However, in the rare cases in which emergency use does apply, the PI and the IRB follow the procedures outlined in the Emergency Use in a Single Subject SOP, and the title included on the General Information Sheet includes the phrase "EMERGENCY USE TREATMENT IND."

REFERENCES

- 21 CFR 312.34
- 21 CFR 312.35