

SOP: 502E
TREATMENT USE OF INVESTIGATIONAL NEW DRUGS/DEVICES

1. POLICY

The IRB shall review applications for the treatment use of investigational new drugs/devices. The investigator must meet FDA requirements under 21 CFR 312.34 and 21 CFR 312.35 prior to IRB approval. The investigator must obtain written informed consent from the participant prior to treatment use of the drug/device.

Treatment use is defined as use of a drug/device that is not approved for marketing but is under clinical investigation for a serious or immediately life-threatening disease condition in patients for whom no comparable or satisfactory alternative drug/device or other therapy is available. During a clinical investigation of the drug/device, it may be appropriate to use the drug/device in the treatment of patients who do not qualify for that particular clinical investigation, in accordance with a treatment protocol or treatment IND/IDE.

Specific Policies

1.1 Treatment IND/IDE

A treatment IND/IDE is a mechanism established by the FDA for providing eligible participants with investigational drugs/devices for the treatment of serious and life-threatening illnesses for which there are no satisfactory alternative treatments. The IRB may grant a treatment IND/IDE after the investigator has demonstrated that sufficient data have been collected to show that the drug/device "may be effective" and does not have unreasonable risks. Because data related to safety and side effects are collected during a treatment IND investigation, treatment IND/IDEs also expand the body of knowledge about the drug/device.

There are four FDA requirements that must be demonstrated before the IRB can issue a treatment IND/IDE:

- 1) the drug/device is intended to treat a serious or immediately life-threatening disease;
- 2) there is no satisfactory alternative treatment available;
- 3) the drug/device is already under investigation, or trials have been completed; and
- 4) the trial sponsor is actively pursuing marketing approval.

Treatment IND/IDE studies require prospective IRB review and approval and informed consent from the participants.

1.2 Consent of the Participant

The IRB requires that the research team obtain legally effective informed consent prior to conducting any study-related procedure or intervention from each research participant or from his/her legally authorized representative.

Test articles given to human subjects under a treatment IND/IDE require prior IRB approval, with two exceptions. If a life-threatening emergency exists, as defined by 21 CFR 56.102(d), the procedures described in 56.104(c) ("Exemptions from IRB Requirement") may be followed. In addition, the FDA may grant the sponsor or sponsor/investigator a waiver of the IRB requirement in accord with 21 CFR 56.105. The IRB may still choose to review a study even if the FDA has granted a waiver.

The Investigator shall obtain informed consent from the participant or the participant's legally authorized representative, as applicable. If obtaining such consent is not possible, both the investigator and a physician who is not otherwise participating in the investigation (or care of the participant) shall certify in writing all of the following:

- A. The participant is confronted by a life-threatening situation necessitating the use of the test article;
- B. Informed consent cannot be obtained because of an inability to communicate with or obtain legally effective consent from the participant;
- C. Time is not sufficient to obtain consent from the participant's legally authorized representative; and
- D. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the life of the participant.

If, in the investigator's opinion, immediate use of the test article is required to preserve the participant's life and time is not sufficient to obtain an independent physician's determination that the above four conditions apply, the investigator shall make the determination and after the use of the test article, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation or participant's care. The investigator shall submit to the IRB a copy of the independent physician's evaluation within five working days of use of the test article.

2. SCOPE

This policy and these procedures apply to all prospective treatment use research protocols submitted to the IRB.

3. RESPONSIBILITY

The IRB administrative staff is responsible to facilitate the review of the treatment use.

The IRB Administrator is responsible for posting the protocol to the next available IRB meeting and providing appropriate review sheets to the IRB Chair/Reviewers.

The HRPP Director is responsible for maintaining up-to-date review tools for review of treatment use of investigational new drugs/devices.

IRB Chair or designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one primary and one secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or designee cannot select primary and secondary reviewers with the relevant expertise, the IRB Chair or designee defers the review to another IRB with primary and secondary reviewers with the relevant expertise or obtains consultation for that expertise.

The IRB Reviewer is responsible for conducting appropriate review of research planned for this category in consultation with appropriate experts and resources.

The IRB is responsible for conducting a thorough discussion of this type of protocol to verify that all regulations have been followed.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.23, 50.24, 50.25

FDA Information Sheets, Guidance for IRBs and Clinical Investigators, Frequently Asked Questions, 1998 Update.

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301, Research Submission Requirements

SOP 403, Initial Review

SOP 502G, Emergency Use of FDA Regulated Products.

6. ATTACHMENTS

203-A New Study Reviewer Checklist – Full Board

203-E Reviewer Checklist for Research Involving Pregnant Women, Fetuses & Neonates

203-F Reviewer Checklist for Research Involving Prisoners

203-G Reviewer Checklist for Research Involving Children

7. PROCESS OVERVIEW

7.1 Upon receipt of the documents, the IRB Administrator forwards the submission to the IRB Chair or designee for a preliminary assessment to confirm that the submission is a Treatment Use request. If the Chair determines the

submission is actually an emergency request, SOP 502G, Emergency Use of FDA Regulated Products applies.

- 7.2 If the Chair or designee determines that the submission does not qualify as emergency use, the IRB Staff ensures all documents are reviewed for submission per SOP 301, Research Submission Requirements, including documentation from sponsor of FDA approval of IND for this particular use. The submission is processed as an initial new study submission, following SOP 403, Initial Review.
- 7.3 The IRB Reviewers review the Treatment Use submission to verify that it falls within the criteria stated in the regulations.
- 7.4 Modifications may be required before final approval. Once the modifications are received by the IRB, the IRB Administrator confirms all changes are made before placing the changes in the file and presenting the file to the IRB Chair for review/approval.
- 7.5 Final IRB approval is not granted until all required institutional committees have completed their review and the contract is signed, when applicable. Evidence of these reviews and ORA release are placed in the file.
- 7.6 Once the IRB review is completed, the IRB Administrator generates the appropriate letter to notify the Investigator of the results of the review.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012