1. **POLICY**

The IRB shall review human research project submissions 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 legally effective informed consent from the participant prior to treatment use of the investigational new 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 to participants. 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 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 research project-related procedure or intervention from each research participant or from his/her legally authorized representative.

Test articles given to human participants 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 research project, even if the FDA has granted a waiver. SOP 502G: Emergency Use of FDA Regulated Products describes the process for obtaining informed consent and the documentation requirements for situations requiring exceptions.

2. SCOPE

This SOP applies to all prospective treatment use research projects submitted to the IRB.

3. RESPONSIBILITY

3.1 The IRB administrative staff is responsible to facilitate the review of the treatment use of investigational new drugs/devices.

3.2 The IRB Administrator is responsible for posting the research project to the next available IRB meeting agenda and providing appropriate review sheets to the IRB Chair and IRB Reviewers.

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

3.4 IRB Chair or IRB 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 IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with Primary and Secondary reviewers with the relevant expertise or obtains consultation for that expertise.

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

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

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.23, 50.24, 50.25

5. REFERENCES TO OTHER APPLICABLE SOPS
   SOP 301: Research Submission Requirements
   SOP 403: Initial Review
   SOP 502G: Emergency Use of FDA Regulated Product

6. ATTACHMENTS
   203-A HSC Reviewer Checklist

7. PROCESS OVERVIEW
   7.1 The Investigator or Investigator staff submits a new study application and
       uploads all applicable documents into the IRB electronic information system.

   7.2 The submission is received in the IRB Office and processed (see SOP 301:
       Research Submission Requirements and SOP 403: Initial Review – Criteria for
       IRB Approval). The submission with all applicable documents is made available
       to all IRB members.

   7.2 The IRB Administrator conducts a pre-review of the submission and verifies all
       necessary documents are received as required, including documentation from
       the FDA approving the treatment use, Investigator’s Brochure or drug package
       insert or device information. The IRB Administrator also verifies if additional
       University committee review or information is required. The IRB Administrator
       communicates with the investigator and/or research staff to obtain any addition
       information and/or reviews.

   7.3 The IRB Administrator assigns the submission to an appropriate Board agenda,
       and follows the process as detailed in SOP #403: Initial Review – Criteria for
       IRB Approval.

   7.4 Following review of the submission, the IRB Administrator updates the outcome
       of the IRB review and communicates the outcome and any stipulations to the
       Investigator.

   7.5 Treatment use of the drug or device may not commence until all required
       University committees have completed their review and the research contract is
       signed, if applicable.

APPROVED BY ________________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016