**LETTER OF UNDERSTANDING**

Transferring Institution: Enter institution name

Receiving Institution: Enter institution name

This letter reflects the understanding between Enter transferring institution name (hereinafter referred to as “transferring institution”) and Enter receiving institution name (hereinafter referred to as the “receiving institution”) regarding the circumstances under which the transferring institution agrees to provide the Investigational Drug or Device to the receiving institution for the following research study, Study title, IRB# (hereinafter referred to as "STUDY").

The receiving institution Pharmacy will serve as the liaison between the transferring institution and the receiving institution investigator and will act as the central control and distribution center for donated drugs or devices for the STUDY. The Research Pharmacy will provide guidance and information regarding Investigational Drugs or Devices as well as serving as a conduit for communications between the transferring institution and the Food and Drug Administration (FDA) or any other regulatory body when appropriate.

The transferring institution will provide Enter drug name per protocol (hereinafter referred to as "Investigational Drug or Device") for the STUDY in accordance with the following provisions.

The receiving institution and the transferring institution have agreed upon the following operating procedures in connection with the STUDY and this Letter of Understanding:

**1. Conduct of the STUDY.** The receiving institution will conduct the STUDY in accordance with the terms of Protocol and within receiving institution guidelines with the participation of the transferring institution.

1. **Drug or Device Supply, Distribution, and Accountability.** The transferring institution will supply the Investigational Drug or Device for the duration of the STUDY, free of charge, and will include in planning allowances for wastage that may unavoidably occur during dispensing. The transferring institution will provide shipment of the Investigational Drug or Device directly to the receiving institution’s Research Pharmacy in accordance with the schedule agreed to by both parties. The transferring institution will be responsible for procuring, preparing and dispensing of the Investigational Drug or Device in accordance with the Food, Drug and Cosmetic Act and maintaining Drug or Device accountability records. The Research Pharmacy will receive and provide to nursing or the study subject the Investigational Drug or Device and keep all records of Drug or Device disposition. The Research Pharmacy warrants that in its processes the Investigational Drug or Device shall not be adulterated or misbranded, in accordance with the Food, Drug and Cosmetic Act. The Research Pharmacy agrees to use the Investigational Drug or Device supplied by the transferring institution only for the investigational purposes authorized under the Protocol; no other use of the Drug or Device will be permitted by the Research Pharmacy. In the event that the Research Pharmacy has any unused Investigational Drugs or Devices at the time the STUDY is completed or terminated, the Research Pharmacy will dispose of the Investigational Drug or Device in accordance with operating procedures outlined by the transferring institution.
2. **Safety Information Reporting.** The local investigator is responsible for reporting adverse events with respect to the Investigational Drug or Device to the IRB at UTHSCSA and/or FDA in conformance with all

applicable laws, rules, and regulations in effect. It is understood and agreed that these adverse events reporting requirement provisions are based upon the IRB at UTHSCSA's respective policies and procedures and regulatory reporting requirements. Accordingly, in the event of changes to the IRB at UTHSCSA's policies and procedures for adverse events reporting, the local investigator agrees to comply with such revised notification requirements as reasonably requested in writing by the IRB at UTHSCSA. This is provided that the scope and extent of activity and undertakings are not materially increased.

1. **Early Study Termination.** The STUDY may be terminated at any time by the Investigational Review Board or the receiving institution for safety or efficacy reasons if it is thought to be in the best interests of the patients. Either the receiving or the transferring institution may withdraw support from the STUDY with 90 days written notice only if this agreement has been violated.
2. **Patient Confidentiality.** Patient confidentiality will be maintained at all times in accordance with applicable law and the receiving institution’s policy. Reports issued for public distribution will contain only aggregate data with all patient identifiers removed.
3. **Selection of Participants.** The principle investigator will be responsible for all decisions concerning the selection and/or discontinuation of participants in the STUDY.
4. **Record Retention.** The receiving institution shall retain all records related to the STUDY for a minimum period of 3 years from the date of the last patient follow-up. At that point the STUDY records will be evaluated for archiving.
5. **Term of Agreement.** This agreement shall be effective as of the date last signed below and shall expire upon completion of all activities related to the STUDY as defined by the submission of the final STUDY report to the transferring institution and the primary publication of the STUDY results.
6. **Modification to Agreement.** This agreement can only be modified in writing and would require signatures by the receiving institution and transferring institution’s representatives.
7. **Approval.** The following signatures indicate approval of the terms of this letter of understanding.

STUDY PI Date

Transferring Institution Representative Date

Receiving Institution Representative Date