Procedure

This procedure outlines the process for review and approval for use of a Humanitarian Use Device (HUD).

I. Investigator Responsibilities.
   A. The Investigator will provide all applicable information regarding the use of a HUD in the "Human Subject Research Application".
   B. A HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market. The Investigator will provide the IRB with a copy the FDA HDE application which contains the following supplemental information:
      1. The generic and trade name of the device;
      2. The FDA HDE number;
      3. The date the HDE was granted;
      4. The indications for use of the device;
      5. A description of the device;
      6. Contraindications, warnings, and precautions for use of the device;
      7. Adverse effects of the device on health;
      8. Alternative practices and procedures;
      9. The HUD brochure;
      10. Marketing history; and
      11. A summary of studies using the device.
   C. An informed consent document will be written, using the IRB consent template, and submitted, when applicable.
   D. The HUD brochure prepared by the manufacturer is to be provided and reviewed with the patient prior to use.
   E. The Investigator will fulfill continuing review requirements at the designated IRB intervals. In addition, at each continuing review, a summary of any individual use of the HUD for the previous six (6) months at other sites should be available from the sponsor and will include the following:
      1. The clinical indications for the use of the HUD in each patient;
      2. Adverse events or unanticipated problems to participants or others that are possibly related to the use of the HUD; and
      3. Clinical outcomes of each participant, if known.
   F. Amendments, serious adverse events or unanticipated problems to participants or others, and continuing reviews are to be reported according to HRPP policies and procedures. In addition, these occurrences are to be reported to the FDA and/or manufacturer as outlined in 21 CFR 803.30.
G. When the use of a HUD is for diagnosis or treatment, and not associated with research or data collection, HIPAA regulations for research are not applicable. However, HIPAA regulations for hospital medical records per Institutional policy are applicable.

II. IRB Committee Responsibilities.
A. The initial review of a HUD is completed by the full IRB Committee. The full IRB Committee may make the determination at initial review that subsequent continuing reviews can be reviewed by expedited review procedures if it is minimal risk or if it meets one of the expedited review categories.
B. The assigned reviewers of the HUD will verify that the provided documents for use of the HUD are congruent with the manufacturing labeling and the approved use under the HDE. The labeling for a HUD must state that the device is a humanitarian use device and that, although the device is authorized by federal law, the effectiveness of the device for the specific indication has not been demonstrated.
C. Based on the information above, the Committee will determine if the HUD request meets the FDA criteria.
D. The Committee may request a literature review from the clinical librarian at the Eskind Biomedical Library.
E. Submission of amendments, serious adverse events or unanticipated problems to participants or others, and continuing review will be reviewed at the level for which criteria is met.

III. Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will pre-review and request any necessary revisions for submitted documents for the use of the HUD as outlined for new study submissions.
B. The RCA will verify that any supplemental information regarding the HUD supplied by the manufacturer have been submitted with the initial application as required.
C. Once the pre-review revisions are received from the Investigator, the RCA will place the new study on the next available Committee agenda, assign reviewers, and assure appropriate materials are available. Reviewers are electronically notified once assigned.
D. The RCA will assist reviewers in obtaining additional information that may be requested regarding the HUD from the Investigator.
E. The RCA will notify the PI in writing of the IRB Committee’s determinations. This letter requires a signature of the Chairperson or his/her designee.
F. The RCA will process all requests for amendments, serious adverse events or unanticipated problems to participants or others, and continuing reviews per corresponding HRPP policies and procedures.
G. Appropriate HRPP database entries are completed.