Subject: Procedure for Use of Investigational Devices

Procedure:
The purpose of this procedure is to provide guidance on the use of investigational devices in human subjects research.

I. Investigator Responsibilities.
   A. The Investigator will provide all information regarding the use of investigational devices as required in the IRB “Application for Human Research”. This will include the identification of the IDE number, if applicable.
   B. When an IDE is required, the Investigator must provide a copy of the IDE letter from the FDA with the initial IRB application, or as soon as it is available if the investigator has not received an IDE letter from the FDA at the time of initial IRB application.
   C. The research will not start until the IDE letter from the FDA has been submitted to the IRB.
   D. The initial submission will also include all correspondence from the sponsor and/or FDA in regards to the determination of the device as being a non-significant (NSR) or a significant risk device (SR). If the sponsor considers that a study is NSR, the Investigator should provide the IRB an explanation of the determination and any other information that may assist the IRB in evaluating the risk of the study. The Investigator should provide the IRB with a description of the device, reports of prior investigations with the device, the proposed investigational plan, a description of patient selection criteria and monitoring procedures, as well as any other information that the IRB deems necessary to make its decision. The Investigator should inform the IRB whether other IRBs have reviewed the proposed study and what determination was made. The Investigator must also inform the IRB of the FDA’s assessment of the device’s risk if such an assessment has been made.
   E. It is the Investigator’s responsibility to notify the Sponsor of the SR decision made by the IRB Committee.
   F. The Investigator will complete the informed consent process, unless a waiver has been granted by the IRB.
   G. The Investigator will maintain all case report forms and records as required by the sponsor, Institution, and/or FDA.
   H. The Investigator is responsible for the accountability, storage, dispensing, tracking, and oversight of the FDA-regulated devices in accordance with applicable institutional, state, and federal laws and regulations.
   I. The Investigator will complete and submit continuing reviews at the established review intervals imposed by the IRB. At the time of continuing review, the Investigator will provide the following information in the form of a summary:
      1. The clinical indications for the use of the investigational device with each participant;
      2. Adverse events or unanticipated problems to research participants or others that are possibly related to the use of the investigational device;
      3. A copy of the accountability records (s); and
      4. Clinical outcomes of each participant, if known.
J. The Investigator will notify the IRB of any amendments, unanticipated device effects, serious adverse events or unanticipated problems to participants or others that may occur while conducting the research or follow-up.

K. The Investigator will assure that adverse device effects or unanticipated problems to participants or others are reported to the IRB as soon as possible, but no later than 7 calendar days after the Investigator first learns of the effect or problem (See HRPP Policy III.L).

L. The Investigator will assure the device is only used under their direct supervision and will discard or ship all unused devices back to the sponsor as specified by the sponsor.

M. The Investigator will notify the IRB of study closure or completion of the study and return all unused products per the sponsor’s instructions.

N. The Investigator will submit the final report as required within three months of termination or completion of study.

II. IRB Committee Responsibilities.

A. Device studies that are exempt from the IDE requirement may qualify for expedited review category 1. Waiver of consent may also be applicable. Based on the initial expedited review, the IRB reviewer may request the IDE exempt study be sent to an additional reviewer or to full Committee.

B. Both significant and non-significant risk device studies must go to full Committee for review and approval. The IRB Committee is responsible for reviewing and determining whether it is in agreement with the sponsor’s determination of non-significant risk. See I.C above for information to be submitted by the Investigator that may assist the IRB in evaluating the risk of the study. The IRB may also consult with the FDA for its opinion. The risk determination should be based on the proposed use of the device in an investigation, and not on the device alone. In deciding if a study poses a SR, an IRB must consider the nature of the harm that may result from the use of the device. Studies where the potential harm to subjects could be life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to body structure should be considered SR. Also, if the subject must undergo a procedure as part of the investigational study, e.g., a surgical procedure, the IRB must consider the potential harm that could be caused by the procedure in addition to the potential harm caused by the device.

C. When the sponsor and the IRB agree that the investigational device is of non-significant risk, the initial review and approval by the IRB may proceed under full IRB Committee review.

D. When the sponsor determines the investigational device to be of a non-significant risk and the IRB disagrees, the proposed research is to be deferred by the full IRB Committee. The IRB will draft a letter of deferral and request that the Investigator contact the sponsor and notify them of the Committee’s determination.
   1. The sponsor may proceed with submitting a request for an IDE approval from the FDA and when received the IRB will re-review the proposed research.
   2. The sponsor or the Investigator may withdraw the study and not submit the investigational device to the FDA for consideration of an IDE.

E. In the event that the FDA rules that the investigational device is a significant risk device after the sponsor and the IRB have determined the investigational device to be a non-significant risk device, the IRB will suspend the currently approved study detailing criteria for suspension.
   1. The study may not reopen until an IDE is granted by the FDA or alternate resolutions have been accepted and the study is reviewed by the full Committee with appropriate changes to the IRB application, protocol and/or informed consent documents.
   2. The Committee must direct the Investigator on the issue of re-consenting participants, if appropriate.
F. **Research vs. Therapy.** Throughout clinical trials, the distinction between therapy and research must be maintained. For example, a physician who participates in research by utilizing a new device to consenting patients must assure that the patients understand and remember that the device is experimental, and that its benefits for the condition under study are unproven. Furthermore, whereas the Principal Investigator’s primary allegiance is to the protocol, the physician’s allegiance is to the patient. Where an individual is both an Investigator and the participant’s treating physician, these two allegiances may conflict. The participant must recognize that the person with whom he or she is dealing may have such conflicting interests. The IRB should consider the need to inform the patient of the potential conflict.

G. Continuing review of an investigational device.
   1. Non-significant risk investigational devices and minimal risk studies may receive expedited review at continuing review.
   2. Significant risk investigational devices, regardless of the risk associated with the study, must be reviewed by the full IRB Committee at continuing review.

H. Submission of amendments, serious adverse events or unanticipated problems to participants or others, and continuing reviews will be reviewed at the level for which they qualify.

III. **Regulatory Compliance Analyst (RCA) Responsibilities.**
   A. The RCA will pre-review and request any necessary revisions for submitted documents for use of investigational devices as outlined for new study submissions.
   B. Once the pre-review changes 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.
   C. The RCA will assist reviewers in obtaining additional information that may be requested regarding the investigational device use from the Investigator.
   D. Minutes of IRB meetings must document the rationale for SR/NSR and subsequent approval or disapproval decisions for the clinical investigation.
   E. Letters requesting revisions from reviewers, and final approval letters are to be drafted using the appropriate template and forwarded to the Chairperson or his/her designee for signature.
   F. The RCA will process all requests for amendments, serious adverse events or unanticipated problems to participants or others, and continuing reviews per corresponding policies and procedures.
   G. Appropriate database entries are to be completed.