Subject: Institutional Review Board Review Responsibilities

Procedure:
This procedure outlines the review responsibilities of the Institutional Review Board (IRB).

I. IRB Committee Member Responsibilities.
   A. Evaluation of each research study, including scientific review, will be relative to the complexity of the study. Outside review of the research (e.g., NIH review, Cooperative Group review) will be acknowledged as contributing to the review, but will not be considered as the only scientific/scholarly review. It is the IRB’s responsibility to determine that risks are minimized through sound research design and reasonable in relation to anticipated benefits. The IRB will seek the expertise of consultants or ad hoc reviewers if the IRB Committee Members lack the scientific expertise to make these determinations without such consultation.
   B. Evaluation of the research will comply with DHHS and FDA regulations as described in the Code of Federal Regulations on Institutional Review Boards. Evaluation will require the completion of the Reviewer’s Comment Form by the Primary and Secondary Reviewer. Literature searches are available upon request by the clinical librarian at the Eskind Biomedical Library for additional information to aid in the evaluation of the research.
   C. If a member has identified a conflict of interest, the member will excuse themselves from the discussion and vote. If during the discussion, input from the excused member would provide benefit to the review process, the excused member may return for questions, then excuse themselves for further discussion and vote.
   D. Members are expected to keep in strict confidence all information discussed whether during or after the meeting.
   E. Committee members may contact an RCA or a member of the Process Improvement Team if they require guidance or additional information in order to conduct an adequate study evaluation. The Committee member is also encouraged to contact Investigators directly in order to obtain the necessary information for Committee review and determination, especially if clarification is needed.

II. Consultants and Ad Hoc Reviewer Responsibilities.
   A. Consultants and ad hoc reviewers will evaluate the research proposal for scientific, scholarly merit, and other issues as requested by the IRB. This includes consideration of research design, statistical power, equitable subject selection process, risk/benefit ratio, etc.
   B. The consultant or ad hoc reviewer will not agree to review research in which he/she has or may be perceived as having a conflict of interest.
   C. The consultant or ad hoc reviewer will sign a confidentiality agreement each time he/she is asked to provide a review.
   D. The consultant or ad hoc reviewer will provide a written report to the IRB. They may be requested to attend the Committee meeting for questions and clarification of issues.
III. Investigational Drug Service (IDS) Reviewer Responsibilities.

A. The IDS representative will complete the Pharmacy Reviewer Comment Form as documentation of the representative’s completed evaluation of all research proposals involving drugs, agents, and biologics for compliance with FDA regulations for the storage, dispensing, handling, and disposal of investigational and FDA-approved drugs, agents, and biologics.

B. The IDS representative will evaluate the consent documents of all research activities involving drugs, agents, or biologics to assure that the associated risks are adequately disclosed and described in the consent documents. The IDS representative will maintain all versions of each Investigator’s Brochure provided to them as a part of their IRB review packet.

C. The IDS may independently audit sites that are not dispensing investigational drugs, agents, or biologics through the IDS. Potential compliance issues discovered during an independent audit will be submitted in writing to the applicable IRB Chair or his/her designee. The report should include actions taken by the IDS and the Investigator to resolve potential compliance issues and any additional recommendations or determinations made by the IDS.

D. For research proposals that involve drugs, agents, or biologics, the IDS representative will evaluate and assess all adverse events that are reviewed at full Committee and make recommendations.