Subject: Procedure for Investigator and Key Study Personnel Disclosures of Conflicts of Interest

Procedure:
This procedure outlines the process for reporting and disclosing any conflicts of interest in human subjects research.

I. Investigator Responsibilities.
   A. Investigators must disclose to the IRB and the Medical Center Conflict of Interest Committee (MCCOIC) or University Conflicts Committee (UCC) all conflicts of interest in association with the human subjects research project under review. This includes assuring that all Key Study Personnel conflicts are disclosed and reported appropriately.
   B. Disclosures must be performed:
      1. With the initial IRB application using the application form;
      2. At each continuing review of the project using the continuing review form and;
      3. Within 10 days of becoming aware of any previously undisclosed significant financial interest via an amendment to the project.
   C. The Investigator must comply with all recommendations of the MCCOIC and/or UCC to minimize the conflict.

II. IRB Committee Responsibilities.
   A. The IRB forwards disclosures of significant financial interest to the MCCOIC or UCC as appropriate.
   B. The IRB may approve the research pending review and approval of the MCCOIC/UCC.
   C. The final recommendations of the MCCOIC/UCC are sent to the reviewing IRB Committee Chair of designated Committee Member for review. If the MCCOIC/UCC has not imposed any additional criteria that would impact the previously determined risk-potential benefit profile of the study, the Chair or designated Committee Member may conduct an expedited review of the MCCOIC/UCC final recommendation. Otherwise, the research and the recommendations of the MCCOIC/UCC are reviewed by the convened IRB.
   D. The IRB may choose to accept or not accept the recommendations of the MCCOIC/UCC. If the IRB does not accept the recommendations of the MCCOIC/UCC it will include in its decision the reasons for non-acceptance in a letter to the MCCOIC/UCC and the Investigator.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA forwards any disclosures of significant financial interests to the MCCOIC or UCC as applicable for review. In the event more information is needed, the RCA contacts the Investigator for more information or clarification prior to forwarding.
   B. The RCA makes appropriate database entries assuring documentation of the conflicts of interest and the nature of the conflict in the notes section of the database.
   C. The RCA assures that final recommendations from the MCCOIC/UCC are reviewed and accepted by the IRB prior to releasing a signed approval.

IV. Institutional Responsibilities.
   A. The MCCOIC reviews all conflicts of interest deemed significant in
accordance with Vanderbilt University Medical Center's policies and federal regulations.

B. The UCC reviews all conflicts of interest deemed significant according to Vanderbilt University policies and federal regulations.

C. The IRB and the Investigator are informed in writing of the outcome of the review from either the MCOIC or the UCC.