

October 16, 2006

MEMORANDUM

TO: All Medical Center Faculty

FROM: Harry Jacobson, M.D.



RE: Liability for cost of medical treatment necessitated by adverse events caused by participation in commercially sponsored clinical trials

The Medical Center's policy on financial responsibility for subject injuries caused by participation in clinical research at Vanderbilt has changed since my memorandum of September 5, 2000. This policy has been re-visited in light of recent regulatory guidance and the fact that health insurance companies are making patients responsible for increasing percentages of cost sharing (co-payments and deductibles).

The new policy is that Vanderbilt does not hold the patient/research subject responsible for the cost of treating illness or injury caused by participation in research at Vanderbilt. Accordingly, Vanderbilt does not, nor may the sponsor require that Vanderbilt, bill the patient/research subject, or his or her insurance plan, for these costs.

As part of any contract negotiation, Vanderbilt's position is that the sponsor of commercially sponsored studies will agree to take responsibility for the cost of treating research injuries caused by that sponsor's investigational drug, device, or protocol. In the event that a commercial sponsor does not agree to accept this risk, VUMC has a process for assessing the risk that significant subject injuries may occur and determining whether or not VUMC will assume this risk and proceed with the research.

We believe that this new policy will simplify and expedite contracting for clinical trials with industry sponsors. Additional materials regarding research policies and required language for consent forms and clinical trial agreements can be found on the IRB website at: <http://www.mc.vanderbilt.edu/irb/templates.htm>, on the Finance website at: <http://finweb.mc.vanderbilt.edu>, and on the Grants and Contracts Management website at: <http://www.vanderbilt.edu/oor/gcm>.