

**Date:** August 4, 2004  
**To:** Mary Adams, Research Subjects Review Board  
David Forster, Western Institutional Review Board  
**From:** Gary L. Chadwick, PharmD, MPH, CIP  
**Through:** Charles Phelps, Provost  
**RE:** Placebo controlled studies

*Gary Chadwick*  
*Charles Phelps*

---

Placebo controlled clinical trials are permitted by the University of Rochester only if they are both scientifically and ethically justified. This memo is to formalize a long-standing practice of the University's institutional review boards (IRBs), which is supported by the literature in research ethics, guidance from federal regulatory agencies and common practice.

Historically, the University IRBs have not permitted placebo use in studies of immediately life-threatening diseases, or those that pose potential permanent harm from delay or withholding known active treatment. University policy supports the practice not to allow such studies where placebo is given in lieu of known active treatment. If an investigational drug and its placebo control is added to standard of care, the IRB may determine that placebo use is justified, as long as the use would not jeopardize clinical care.

This policy guidance is consistent with current IRB operations and it is intended to support accepted procedures and practices.

**cc:** Thomas Pearson, MD, PhD  
Spencer Studwell, Esq.  
Gunta Lidars