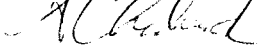



February 10, 2004

MEMORANDUM

To: University Deans, Directors, Chairs, NIH Principal Investigators and Administrators

From: Gary L. Chadwick 
Director, Office for Human Subject Protection

Gunta J. Lidars 
Director, Office of Research and Project Administration

Ref: UR POLICY: IRB APPROVAL AND NIH/FOUNDATION GRANT APPLICATIONS

Beginning with applications submitted for the January 2001 Council, NIH adopted a "just in time" policy for institutional reviews and approvals. The current NIH implementation of this policy may be found at <http://www.grants.nih.gov/grants/oer.htm>.

While NIH no longer requires IRB approval prior to NIH peer review of an application, NIH still requires IRB approval before actually awarding a grant involving human subjects. The institution may still determine that certain research should receive IRB review prior to submission of the application.

Accordingly, the University of Rochester had placed some limits on the new NIH policy to ensure that appropriate levels of institutional review occurred before submission. Upon reviewing the experience with the policy at the University over the past three years, it has been decided to remove the restrictions with the exception of studies proposed by principal investigators who are on a probationary/restricted status with the IRB. These studies will still require prior IRB review.

Because investigators will be submitting proposals without RSRB review under the "just in time" process, the RSRB will no longer issue "pending letters."

The "just in time" process adopted by NIH and other sponsors does not alleviate the responsibility of the investigator to have the scientific quality of the proposal reviewed under regular University procedures.

Should you have any questions on this policy, please contact the RSRB at 275-2398. This policy, the revised University Sign-Off Form and a quick reference to funding sponsor policies with respect to the timing of IRB review will be posted on the ORPA web site (<http://www.rochester.edu/ORPA>)

cc: Provost Phelps