

July 20, 2000

MEMORANDUM

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

From: Gary L. Chadwick
Executive Director, Research Subjects Review Board

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

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

It has been the NIH grants policy that new and competing applications submitted to NIH, which include research involving human participants, are required to have IRB approval at the time of submission or within 60 days after application receipt date. Since fewer than half of all applications submitted to NIH are funded, and in order to reduce burden on applicants and IRBs, the NIH has modified this policy. The new NIH "just in time" policy and its current implementation may be found at <http://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html>.

Beginning with applications submitted for the January 2001 Council, NIH will no longer require IRB approval prior to NIH peer review of an application. While the NIH peer review group carefully considers whether the application includes the necessary safeguards to protect the rights and welfare of research participants, NIH will still require IRB approval before actually awarding a grant involving human subjects.

This change in policy is intended to provide flexibility at the institutional level. The institution may still determine that certain research should receive IRB review prior to submission of the application.

Accordingly, the University of Rochester has placed some limits on the new NIH policy to ensure that appropriate levels of institutional review have occurred before submission. **Note that the following conditions also apply to studies being submitted to foundation sponsors who adhere to a "just in time" IRB review policy.** The following categories of studies are subject to IRB review **PRIOR** to grant submissions:

1. **Gene transfer clinical research.**
 - Gene transfer is considered a special case because of its unique and potentially unknown risks.
2. **Studies proposed by principal investigators who are on a probationary/restricted status with the IRB.**
 - Principal investigators who are on probationary/restricted status have demonstrated past difficulties in complying with regulations, policies, and/or expected practices. These individuals could benefit from assistance from the RSRB before an application is submitted to external reviewers.
3. **Principal investigators who are submitting the first federal or foundation clinical grant application of their career and are conducting studies of greater than minimal risk.**
 - Principal investigators who have never applied for federal or foundation funding could also benefit from prior review. Note that even if the investigator has participated in an industry-supported study, this requirement would apply because such studies normally do not require the same degree of involvement in developing protocols or consent documents.

Investigators will be required to certify on the University Sign Off Form whether these conditions exist. If a study falls under any of the above categories, RSRB approval is required prior to grant submission.

Due to the change in NIH and University policy, the RSRB will no longer issue "pending letters". Because investigators either will be submitting proposals without RSRB review under the "just in time" process or, if one of the above categories applies, they will be required to have completed RSRB review before submission. New investigators should allow sufficient time to ensure RSRB and other required approvals and sign-offs are completed before submission deadlines.

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 RSRB web site (<http://www.urmc.rochester.edu/urmc/rsrb/rsrbhome>) and the ORPA web site (<http://www.rochester.edu/ORPA>)

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