

MEMORANDUM

To: Medical Center Deans, Chairs, Directors and Administrators

From: David S. Guzick, M.D., Ph.D., Dean of the School of Medicine and Dentistry
Thomas A. Pearson, M.D., Ph.D., Senior Associate Dean for Clinical Research

Date: January 7, 2003

Re: Tracking Research Grants

As we engage in building the research enterprise and its infrastructure, we must have in place appropriate measures to indicate the success of strengthening this important facet of the Medical Center's mission. The following steps have been put in place to assess the growth of research within the School of Medicine and Dentistry, as well as its distribution by research category.

1. The University of Rochester Proposal Sign Off Form has been modified so that investigators can indicate whether the type of research to be conducted is basic or clinical. Please begin to use the modified form immediately.
2. In determining whether a project qualifies as clinical research, the NIH definition for clinical research will be used. This definition follows:

"(a) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. This area of research includes:

Mechanism of human disease
Therapeutic interventions
Clinical Trials
Development of new technologies

(b) Epidemiological and behavioral studies

(c) Outcomes research and health services research.

Excluded from this definition are in vitro studies that utilize human tissues but do not deal directly with patients. In other words, clinical or patient-oriented research is research in which it is necessary to know the identity of the patients from whom the cells or tissues under study are derived"

3. For those projects that involve a combination of basic and clinical research, as in program projects in which one element of the proposal is an animal model and one is a human model, the "clinical" box should be checked in accordance with NIH guidelines.

4. Industry-sponsored clinical trials should continue to be classified separately, and the University of Rochester Proposal Sign-Off for Industry-Supported Clinical Trials should be used for these studies.

The Medical Center will start classifying and tracking research effective January 1, 2003. For those new applications and awards that will be received without having gone through the aforementioned identification process, the Dean's office will review the award and classify it appropriately. We may be in contact with you if there are any questions with respect to this review.

I thank you for your cooperation with this tracking process. Once we are through this initial nine (9) month period, we anticipate that it will be a relatively seamless process as currently exists for tracking the purpose of other University projects. It is important that we are able to measure our success as we move forward with our strategic plan for research.

DSG/TAP/GJL/glw