



Office of Research Services

MEMORANDUM

To: Deans
Senior Business Officers

From: Neal Nathanson, M.D.
Vice Provost for Research



Andrew B. Rudczynski, Ph.D.
Associate Vice President Finance
Executive Director, Research Services

Handwritten signature of Andrew B. Rudczynski.

Date: April 2, 2003

Subject: Industry-Sponsored Clinical Trials – Change in Facilities and
Administrative (F&A) Cost Recovery Rate and Updated Definition

Effective July 1, 2003, the University's Facilities and Administrative (F&A) cost recovery rate for industry-sponsored clinical trials will be increased to 26% of total direct costs of the project, from the current rate of 23.6%. The 26% rate, which is the University's negotiated off-campus F&A cost recovery rate, will provide the University and the Schools with F&A cost reimbursements that more closely approximate the University's actual costs. The decision to increase the rate was made in consultation with senior officials of the University schools that conduct clinical trials, and with members of the Human Research Advisory Committee.

Also, effective immediately, the University will adopt the NIH's definition of a "clinical trial," for the purpose of assigning the F&A cost recovery rate to industry-sponsored clinical trial proposals. The NIH definition is: "a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious and effective. Clinical trials of experimental drug, treatment device or behavioral intervention may proceed through four phases....." The definition goes on to define the four phases of clinical trials that proceed through epidemiological studies. The full definition is available at http://grants.nih.gov/grants/peer/tree_glossary.pdf.

We ask that you communicate this F&A cost rate change and the updated definition to all faculty and business administrators in departments that conduct industry-sponsored clinical trials. The new rate will apply to industry-sponsored clinical trials for which proposals are submitted on or after July 1, 2003.

It is very important that faculty understand that, in developing the budgets for clinical trials, all appropriate costs, including minimal expected faculty effort and corresponding salary, and F&A costs, must be included in the total costs proposed to sponsors. We recognize that the sponsors of clinical trials frequently approach an investigator with a pre-determined budget amount. Faculty should be cautioned that an internal budget that accounts for all institutional costs must be developed, in order to determine if it is financially feasible to participate in the clinical trial.

The Human Research Advisory Committee will monitor the effects that this change may have on the ability of schools to recover more of their costs associated with the conduct of clinical trials.

Thank you for your cooperation in communicating this information to faculty and staff for whom it is relevant.