

Office of Research

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October 3, 2008

Research Colleagues,

The National Center for Research Resources (NCRR) prohibits the use of federal funds to subsidize industry-sponsored research activities. The University of Pittsburgh Clinical and Translational Science Institute (CTSI) is supportive of the conduct of industry-sponsored research in its Clinical and Translational Research Centers (CTRCs). To provide a mechanism that allows the conduct of industry-sponsored research and meets the compliance requirements of NCRR and federal accounting standards, the CTSI is establishing a service center cost model.

The University defines a service center as a self supporting ancillary business enterprise that charges other University departments and sponsored awards. The service center will allow the CTRCs to recover costs incurred in the execution of research protocols and to ensure that federal funds are not subsidizing industry sponsored research. The service center cost model will provide accurate accounting and permit reporting essential for providing these services in a cost-compliant manner. The service center agreements provided to investigators will include all CTRC expenses and will be used to request appropriate budgets from sponsors. A formal announcement about the service center can be expected in the next few weeks and will be sent to the University community upon final approval of the cost model. In the interim, budget preparation assistance can be obtained from the individual unit administrators. Links to the individual unit websites and the appropriate administrative contacts can be found at http://www.ctsi.pitt.edu/content.asp?id=1446.

The creation of the service center cost model for the CTRCs will result in a change in the responsible contracting party for industry designed and sponsored protocols. With the establishment of the UPMC Clinical Trials Office (CTO) four years ago, the University and UPMC agreed that clinical trial contracts for industry initiated protocols utilizing the services of a federally supported CTRC would be handled through the University. Since the creation of the service center removes the federal subsidiary, under terms of the agreement between the University and UPMC, the contracting and oversight associated with industry initiated protocols utilizing the CTRC service center cost model will be handled through the UPMC CTO.

Effective November 1, 2008, the Office of Research ("OoR") will only accept clinical research agreements for *industry designed and sponsored protocols* that:

1) include evaluation of an experimental intervention that emits ionizing radiation,

2) include evaluation of an experimental gene transfer intervention or xenotransplantation, or 3) are conducted exclusively within University facilities other than the CTRC.

For further information about OoR purview for industry designed and sponsored trials, contact the OoR at 412-624-7419.

The UPMC Clinical Trials Office ("CTO") will handle all other clinical trial agreements for industry-initiated projects under UPMC CTO policies. Investigators should contact the UPMC CTO at 412-647-4461, or visit the UPMC CTO website at <u>http://www.irb.pitt.edu/CTO/cto.htm</u> for further information about the UPMC CTO.

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