Clinical Trial Financial Policy for Sponsored Studies

Facilities and Administrative Costs on Clinical Trials:
In September 1992, August 1994, and February 2006 the Provost and Vice President for Research, respectively, issued memoranda regarding the University’s policy for recovery of facilities and administrative (F&A) costs (formerly known as indirect costs) on clinical trials involving human subjects. The purpose of this section of the policy to restate the policy to more precisely define the basis for determining which clinical studies are subject to the twenty percent (20%) F&A assessment by the Provost’s Office/Grant Administration. The distribution of 20% F&A assessment is 10% to Provost’s Office, 5% for the support of Translational Research, and 5% to the central F&A assessment pool.

Twenty percent (20%) of all revenue received from clinical trial studies is recovered by the Provost’s Office/Grant Administration if the clinical study meets all of the following requirements:

1. The study is sponsored by an industrial company, i.e. pharmaceutical, device companies, etc.;
2. The study is clinical, i.e., involves living human subjects, animals, etc.;
3. The study involves a drug or device;
4. Payment by the sponsor may be based upon number of patients enrolled, delivery of patient case report forms, a fixed fee lump sum, etc.;
5. The sponsor imposes no fiscal audit requirements on the University.

Any required college, department or section F&A charges are in addition to the 20% F&A costs recovered by the Provost’s Office/Grant Administration. All appropriate F&A costs (the Provost’s Office/Grant Administration’s 20% plus college, department or section charges) must be negotiated with the company by the investigator and included in the budget either 1) as a separate line item (administrative fees, F&A costs, etc.), or 2) added to the cost of each direct cost line item.

Cost Accounting and Allocation of Expenses
This policy is established to ensure compliance with federal cost principles and consistency in accounting and costing practices on all clinical trials (defined here as studies involving humans and sponsored by external agencies). As with all sponsored studies, investigators and staff are required to allocate and charge their actual percent effort to all clinical study accounts, as well as all other costs directly benefiting the clinical study.

Industry-sponsored clinical trials will budget the 20% F&A rate. F&A recovery for industry-sponsored clinical trials is accessed on all expenditures and related cost transfers of funds out of the account. Basic, pre-clinical (nonclinical) research projects and other human studies not involving living human subjects are subject to the University’s current negotiated F&A costs, as are clinical trials sponsored by federal, state, and non-profit agencies.

Residual Funds
Clinical trial accounts shall be properly closed at the completion of the trial. The department is
responsible for all overruns on the clinical trial. If residual funds remain in an account at the end of the
trial and the clinical trial agreement or award requires unspent funds to be returned to the sponsor, Grants
and Contracts Accounting will return the funds in accordance with the award. Residual funds that do not
have to be returned to the sponsor will be not be transferred to the Principal Investigator and may not be
transferred to another institution should the Principal Investigator leave OUHSC. Residual funds that do
not have to be returned to the sponsor will be transferred as follows:

50% to the Department Chairperson, to be used at their discretion
25% to the Dean of the College, to be used at their discretion
25% for the support of Translational Research

Additional policies, guidelines, procedures, and forms are available at the Grants and Contracts
Accounting office and web site:

http://www.ouhsc.edu/financialservices/GC/Grants.asp