September 2004 (revised) **Department of Medicine Policy**
Clinical Trials Budgets

I. Purpose:

Clinical trials are valuable to the Department and faculty for reasons including: trials allow faculty members early involvement with an experimental drug, device, or procedure and early access to these for their patient populations; trials allow them to have a more interesting career; clinical trials are a means to enhance research experience; trials support effort to reduce clinical assignments; and trials provide financial resources to the faculty.

Goals for those performing clinical trials include being on the team that originally designs the trial, participating in the trial, and then being an author on the final paper. In the majority of commercially sponsored trials, IU investigators are not participating in the design of the trial and are not authors on the paper; therefore, in those instances financial considerations are paramount.

The financial reward of doing clinical trials may be the most important aspect for many faculty. The residual funds generated from these studies can be used to pay for meetings, seed money for investigator-initiated research, and bridge funding between grants. For the most part, these studies should not be accepted if they do not generate income or at least cover their costs. To ensure the financial success of trials, they must be properly budgeted and accounts properly reconciled.

II. Policy

1. The following will be an expectation of new recruits intending to do clinical trials. It will be inserted into offer letters.

   > The development of clinical trials programs is a high priority for the Department of Medicine. As this area of medicine is highly regulated, success in this endeavor requires time, training, and dedication. You will be provided x% time for x years *(this will usually be 1 or 2 years)* for development of a clinical trials portfolio. You are required to attend the following clinical trials training seminars: (1) "SOS for the SSS" - understanding the summary safeguard statement and the IRB approval process; (2) "Budgets and Contracts"; (3) "Intro to Clinical Research" (4) "HIPAA and Medicare update"; (5) Consent and recruitment"; (6) " Adverse Event Reporting"; and (7) "The FDA is Coming". An attachment with the dates of the seminars is appended. You will report on your progress in obtaining contracts and enrolling patients at 6-month intervals to the Division Chief and Vice-chair for research. Inadequate progress or inability to attend the educational sessions may result in adjustment of effort. After this period of support, you will be expected to defer the costs of clinical trials onto *grants, contracts (commercial)* sources, or accumulated residual funds."

2. All current faculty who intend to become involved as a PI or sub-investigator and have not been the principal investigator (PI) on a commercially sponsored clinical trial in the past 2 years will be expected to attend the same series of seminars.

3. Divisions should provide for legitimate administrative costs in their budgets with commercial sponsors This may be accomplished as a flat administrative fee or by making sure that personnel time spent on administrative tasks (e.g. completing start up documents, analyzing budgets, responding to sponsor queries, etc) is adequately reflected in the study budget for personnel time and effort (the latter being a generally

more palatable method to industry). In addition, certain expendable costs such as express mailing, dry ice, long-distance calls, frequent invoicing, etc should be evaluated and charged for on a protocol by protocol basis. The cost of long terms storage of study records needs to be included in the budget. The storage cost will be charged to the Pi's reserve account after the study closes.

4. Similarly, faculty and coordinator effort should be charged to each trial as appropriate. This may be accomplished by percent effort (where effort is available to be allocated) and/or as compensation for actual study procedures performed, e.g. history and physicals, interpretation of test results, case report form review, adverse event review, etc. Thus, it is critical that individuals who are familiar with the protocol and with the actual time required to perform specific tasks be involved in the budget development process.

5. No budgets will be processed without the inclusion of reasonable personnel costs (based upon a careful analysis of the actual time requirements of the project). At a minimum this will include PI and coordinator time. (This may be accomplished by percentage of salary and/or charge per actual study procedure performed. See # 3 and #4 above).

6. Each division will establish a research budget "expert" (e.g., research manager) who understands clinical research study protocols, study procedures, operational factors required to implement clinical research projects, and financial affairs. This individual will be responsible for reviewing the adequacy of all study budgets, comparing actual costs to proposed budgets, and making revisions and/or recommendations, as necessary. This person will also assist the PI to prospectively prepare budget documents in such a way as to be compliant with Medicare requirements if "standard of care services" are to be billed to insurance. (If such a person does not currently exist, divisions are expected to designate a qualified individual who can obtain training by contacting the Clinical Trials Program - CTP.)

7. The "expert designee" identified above must also review the proposed contract and verify the adequacy of the cash flow / payment schedule described in the contract. In addition, the designee shall be responsible for reviewing contract documents on behalf of the investigator, prior to routing to R&SP, for the inclusion of language that is favorable to the researcher, e.g. non-refundable start-up charges, payment for screen failures, and special invoicing. This individual will assist the PI to communicate any issues that need negotiation, to the R&SP contracts office.

8. No commercially funded clinical research project will be conducted that does not make a profit or break even, unless reviewed and approved by the Division Chief and Vice-Chair for Research. Upon granting an exception, the Division Chief must identify an account number to which the additional costs may be charged.

9. All commercial accounts will be reviewed on a quarterly basis by the division business manager, PI, and lead coordinator (or research manager) for <u>each</u> project to verify enrollment, compare receipts to contract payment milestones, and to invoice company, as appropriate.

10. Division managers should continue to use 45 accounts to pay for all costs associated with the study and refrain from prematurely closing them into 22 accounts before making sure that all payments have been received and all costs associated with a study have been properly paid. *Note: Many studies have contractual arrangements that allow commercial sponsors to withhold as much as 20% of their final payment for long periods of time after study accrual has ended; therefore, 45 accounts should not be rolled into 22 accounts until all payments have been received and all costs paid.*

11. If a financial loss is sustained from the trial, the faculty member will be expected to cover the loss from his/her 22 account. If the faculty has no 22 account funds at the time of the loss, future 22 accounts will be charged the loss unless the Division Chief identifies and approves an alternate appropriate source of divisional support.

12. All departmental personnel who participate in or assist with commercially sponsored research studies must receive training in the issues related to budget and contract development. This includes investigators, coordinators, and business managers. (Such training currently offered by CTP.)

Approved by:

David Cowan — 9.7.04

Chairman, Department of Medicine — Date