

I. CHARGING INVESTIGATOR(S) WORK FOR CLINICAL RESEARCH/CLINICAL TRIALS

PURPOSE / BACKGROUND

The University of Louisville conducts numerous clinical research projects and clinical trials. Sponsors and governmental (e.g. FDA) regulations assign specific responsibilities and duties to investigator(s) who conduct this clinical research in addition to those typically expected of investigator(s) at the University. Clinical coordinators and other staff routinely provide services for particular clinical research projects or clinical trials. An accurate accounting of personnel is essential to provide a correct balance of the expenses associated with a given trial or clinical research project and will aid the effort to improve time and effort reporting.

POLICY

The University of Louisville requires that each clinical research/clinical trial project have an accounting of the expenses associated with the respective project. This will include an accounting of the work done by the investigator(s) leading the project and those other support personnel working on the respective project. Each department (or division at the department head's discretion) conducting clinical research/clinical trials will designate one individual to function as the "Clinical Financial Manager" for clinical research within their respective department (or division as applicable.) The Clinical Financial Manager will coordinate the budgetary and financial aspects for the department (or division) for clinical research and will serve as the primary financial contact with Research Administration and the Controller's Office. An estimate of the planned work for individual investigator(s) and supporting staff members will be provided on the appropriate transmittal documents approved by Research Administration and the Controller's Office (1) annually in conjunction with the annual clinical work plan if pooling will be used and (2) when the project is proposed or initiated based on the anticipated required effort of the investigator(s) and other support personnel. The actual expenses of each respective project will be posted to the respective clinical research/trial project expense budget (PeopleSoft Chartfield) as the project progresses with the expense charges reflecting work done by the investigator(s) and other personnel using a mechanism for accounting for the expenses approved by Research Administration and the Controller's Office.

ORGANIZATIONAL RESPONSIBILITIES

Deans, Directors and Department Heads

Communicate to their respective units about this policy.

Department Heads, Division Heads (if applicable) of departments conducting clinical research

Make a determination if divisions will have clinical financial managers (CFMs)

Designate the clinical financial manager for department (and division clinical financial manager(s) if applicable.) These CFM(s) will coordinate the financial aspects of budgeting and posting expenses associated with clinical research among the investigator(s), clinical coordinators and the primary Unit Business Administrator for the department (or division). This CFM will be the primary interface with

the Clinical Research Services (CRS) division of the Office of Industry Contracts and the Controller's Office regarding budgets and expenses associated with clinical research project.

Establish a clinical work plan budget for each investigator conducting clinical research in their department (either via the departmental/division budget or a separate PeopleSoft chartfield for clinical research) based on the proposed work plan.

Periodically (at least annually) assess and correct inconsistencies arising from significant deviations from the proposed work plan.

Via the Clinical Financial Manager, verify the amount of "pooled" work assigned on any individual protocol and provide approval for the individual clinical trial budget.

Via the Clinical Financial Manager, approve subsequent changes in an individual clinical trial budget/allocation.

Via the Clinical Financial Manager, verify that all outstanding expenses have been posted and sign off on the closure of an individual clinical trial chartfield.

Research Administration (Primarily Clinical Research Services (CRS) division of the Office of Industry Contracts)

Review transmittal documents (e.g. MIRA/annual work plan) for estimated costs/expenses.

Review proposed budget of a particular clinical research/clinical trial project for reasonableness vis a vis estimated effort and scope of study.

Recommend best practices processes and techniques for budgeting and expense reporting for clinical research (e.g. encouraging sharing among departments).

Provide periodic education and training to the identified Clinical Financial Managers (CFMs).

Communicate to, and provide training as needed, for investigator(s) and clinical coordinators regarding this policy and the procedures/mechanisms approved for budgeting and tracking clinical research expenses.

Provide an optional service (fee for service) for estimating, budgeting, posting and billing clinical research expenses for those departments wishing for CRS to do such on their behalf.

Establish budgets only with spending authority that has been appropriately approved by the department (e.g. via CFM) and that reasonably reflects the expenses required to complete the project as approved by the Sponsor.

Controller's Office

Review of "close-out" requests to ensure investigator(s) and other personnel time have been posted.

Obtain from the Clinical Financial Manager, names of all personnel who were assigned to perform work on the study. Confirm that the expenses for the work done have been charged via an approved mechanism and that the expenses reasonably reflects the work committed to the study for the period(s) under review.

Investigators

Develop, in conjunction with their department/division of annual clinical work plan to estimate percentage of effort anticipated to be spent on clinical research per fiscal year.

Provide and/or review reporting to respective Clinical Financial Manager of their work done on a particular clinical project.

Clinical Financial Managers (CFMs)

Work with the appropriate individuals in the department/division to coordinate the development of and/or estimate and develop the clinical annual work plan for investigators and estimates of support personnel needed to conduct clinical research within that department/division annually.

Prepare and submit the appropriate transmittal documents for any planned pooling of investigator and support personnel expenses.

Review and coordinate department/division approvals of budgets at time of project initiation/proposal and/or award/contract signing.

Request modifications to the clinical work plan and associated budget allocations when a significant deviation (more than 5%) is anticipated (e.g. involvement in more than planned clinical research, deviations in actual enrollment from what was anticipated.)

Provide guidance to investigator(s) and other personnel spending time on clinical research on the appropriate reimbursement for a particular clinical research project (e.g. based on anticipated enrollment and the nature of the activities planned for the particular clinical research.)

Ensure that the posting of expenses for a particular clinical research project budget (PeopleSoft chartfield) based on the actual work done by the investigators is done on a timely basis and see that any pooled chartfields (departmental budget or separate PeopleSoft chartfield) are reimbursed for the expenses.

Ensure that the department/division is using the invoicing and receivables process established by the Controller's Office.

See that expenses posted for work done against income projected and received from sponsor are reconciled regularly ensuring tracking revenues earned to cash received.

Maintain documentation of personnel assigned to a particular study and expenses charged for the purpose of verifying that appropriate wages and fringe benefits were charged to the study in a timely manner.

Initiated the closeout process with the Controller's Office when the clinical research/clinical trial has ended/concluded.

Audit Services

Conduct periodic audits to verify that work done is being posted to the respective clinical research budget (PeopleSoft Chartfield).

Review departmental processes for estimating and tracking work done on particular research projects (e.g. periodic validation that the "CPT-like" mechanism is an accurate reflection of actual average expenditures if that mechanism were was chosen to track expenses)

VIOLATIONS OF THIS POLICY

Violations of this policy will be addressed as outlined in the [Administrative Sanctions for Violations of University of Louisville Research Policies](#).

II. PROCEDURE FOR POLICY

This policy will be implemented in phases. The initial phase will entail each department/division designating their respective Clinical Financial Manager during the first quarter of fiscal year 2006-07. Clinical Research Services (CRS) will provide education and training and provide a budgeting spreadsheet tool for those departments/divisions wishing to utilize it to better estimate clinical trial expenses. Discussions regarding the "CPT-like" mechanism for posting expenses will begin in phase one. The second phase will entail the piloting of the department/division "pooling" chartfield and review and approval of mechanisms for allocating and posting expenses for each respective clinical trial chartfield. The second phase is planned to begin during the 2nd quarter and continue in the 3rd quarter of fiscal year 2006-07. The third and final phase, prior to full implementation, is planned to occur during 4th quarter of fiscal year 2006-07. The third phase will entail the establishment (or use of a department chartfield) of a department/division pooling chartfield, development of the annual investigator work plan (for FY 2007-08) and development of the estimates for other support personnel in the pooled chartfield(s).

During phase 1 each department/division will designate their respective CFM(s) to CRS. CRS will maintain the list of CFMs. Any subsequent changes are to be sent to CRS by the department. CRS will review, with the CFMs (collectively or in small groups as appropriate), the planned phased implementation and the budgeting spreadsheet. By the end of phase 1, selected departments/divisions will be identified to serve as pilots for pooling and/or expense posting mechanisms.

During phase 1 and 2 the discussion of mechanisms for tracking and posting work done by investigators and other support personnel will occur. One mechanism to be discussed and further developed is based on using an applicable internal "CPT-like" code for the activities performed by the individuals working on the project. A "CPT-like" code would use an "average" cost per procedure based upon the typical or average resources consumed by performing that procedure which is anticipated to be more practical and efficient for the departments to use rather than tracking small

amounts of time for each individual involved. For example, a blood draw might include x charge for a nurse or a routine patient visit might include y charge for the investigator.

By the end of the 3rd quarter, at least one mechanism for pooling and one method for charging work done by investigator(s) and other clinical support personnel will have been approved for implementation in FY 2007-08. It is possible that multiple mechanisms could be approved to meet the requirements of particular studies or the unique needs of a particular department.

During 4th quarter FY 2006-07, each investigator and other personnel participating in clinical research projects will develop a planned clinical work plan estimating the approximate effort to be dedicated for a particular fiscal year. (For clinical coordinators, 100% of their time and effort might be budgeted to clinical research projects; however, for a particular faculty member a lesser amount of their total University effort would be planned for clinical research.)

By July 1, 2007 for fiscal year 2007-08, the salaries of those engaged in clinical research will be assigned an appropriate percentage based on their planned clinical work plan in a pooled chartfield (either in the departmental chartfield or in a separate departmental clinical research chartfield.)

As a particular clinical research project progresses (either monthly or when an invoice is issued to sponsor but no less frequently than quarterly) based on actual work done, charge the salary and fringe benefits expenses for the respective individuals to the particular clinical research project budget and reimburse the departmental clinical research pooled chartfield accordingly.

If the actual aggregate work done per individual deviates by more than 5% from what was estimated in the original proposed clinical work plan, revise the departmental clinical research pooled chartfield and, as needed, revise the respective time and effort percentage reports accordingly.

The percent effort/calendar months mechanism currently in use for tracking personnel time and effort for those federally funded clinical research projects will continue. The pooling approach outlined in this procedure is not intended to change that mechanism.

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