

# Industry-Sponsored Clinical Trials Standards

## Department of Pediatrics

### Patient Oriented Research Unit (PORU)

**Effective 5/1/2012**

This policy relates to industry-sponsored clinical trials or studies within the Department of Pediatrics. Industry-sponsored clinical trials may be considered industry-initiated or investigator-initiated, but are always funded by a for-profit industry business, such as a pharmaceutical company. The guidelines are slightly different for industry-initiated versus investigator-initiated clinical trials.

***NOTE: Projects funded by NIH or other government agencies and by non-profit foundations or associations are not governed by this policy.***

#### ***Definitions:***

**Industry-initiated** projects are those which are designed, directed, and funded by proprietary organizations and are performed primarily at their request and/or for their benefit. All costs related to this type of trial, including all personnel and faculty oversight time and effort, must be covered by the sponsor.

**Investigator-initiated**, but industry-sponsored, clinical trials are those which are initiated, designed, and directed by an individual investigator or investigators, but may be partially supported by a proprietary organization through a grant of unrestricted funds or by a donation of

drugs or devices for use in the study. For investigator-initiated, industry-sponsored trials, the investigator must document:

1. that the initial idea for the project was that of the investigator(s);
2. that the design, implementation and reporting of the project are under the sole direction of the investigator(s) with no restrictions placed by the sponsor; and
3. that the sponsor is unwilling to support the project in its entirety, other than providing limited funds, devices or drugs for the study.

### **New Study Notification:**

In addition to Principal Investigators being contacted directly by Industry, The Center for Clinical Studies (CCS) marketing personnel will notify the Clinical Trials Coordinator when potential industry sponsored studies are identified.

## **INDUSTRY SPONSORED STUDIES**

### **Budgets**

All industry-sponsored clinical trials, whether industry-initiated or investigator-initiated, will be submitted through the Patient Oriented Research Unit (PORU).

The Clinical Trials Coordinator will work directly with the PI and/or Coordinator to develop a detailed budget. This budget will include ALL costs, regardless of the amount industry is proposing. For investigator-initiated studies in which there are no (or little) industry funds provided, costs may be considered as chargeable to division funds, or other available funds, at

the discretion of the Division Director. This information must be made available to the PORU Manager, Financial Operations prior to the research commencing.

For industry-initiated studies, all costs must be covered by the sponsor. Costs include time spent on preparatory work for IRB, PCRU and IRU applications, close out, and contract negotiations, etc. During budget preparation, the PI and Research Coordinator will determine and establish which visits and measures are considered standard of care, and which are considered research. This must be predetermined during the budget development phase of the project. The budget will be negotiated between the Clinical Trials Coordinator and the sponsor, with involvement and input from the PI.

If a Research Coordinator is required, but the PI does not have one identified, the PI can consult with the PORU Senior Clinical Research Administrator to determine if there is an existing coordinator who may have the needed hours available. Alternatively, utilization of a CCS coordinator is available for a fee. In either case, the cost of the coordinator should be included in the budget. CCS also offers many other services (such as blood draws, lab testing, etc.) for a fee. The current application can be found at [www.ccs.wustl.edu](http://www.ccs.wustl.edu).

Actual estimated costs, entered on the internal budget questionnaire, to carry out the study will be compared to the amount the sponsor proposes. All studies will be expected to cover all costs, including personnel effort related to the project. If the costs exceed the negotiated amount, the PI needs to determine if there is merit in performing the study despite its failure to cover costs. If this is the case, the PI will need to justify the reason to his/her Division Director. This information must also be provided to the PORU Manager, Financial Operations. In the case of investigator-initiated studies, the Division Director may decide to cover costs from funds

within the Division. These arrangements must be communicated to the Senior Financial Analyst for the division, and the PORU Manager, Financial Operations.

In addition to the Medical School's overhead (26%), the Department will assess an additional 10% on industry-provided funds to every study. Waiver or reduction of the Departmental overhead is at the discretion of the Chairman. Waiver or reduction of the Medical School overhead is at the discretion of the Dean. The principal investigator will work with the Clinical Trials Coordinator to process the paperwork necessary for an overhead waiver.

Investigators are encouraged to arrange for start-up funds to pay for any administrative work, as well as HRPO review fees. These expenses are incurred for work completed and are not contingent upon execution of the contract, or enrollment of participants.

### **Proposal Review**

All proposals will be reviewed by the Division Director for scientific merit and budgetary feasibility. The Division Directors may seek outside advice as they feel appropriate to make an informed decision. The PORU Unit Leaders are also available for advice. Budgets will be reviewed, and must be approved by the Division Director and the Manager, Financial Operations or Senior Clinical Research Administrator for financial accuracy and feasibility to carry out the project.

### **Billing**

All office visits and measures determined to be standard of care will be billed to insurance at the rate designated by University policy. For visits involving standard of care, the co-pay and any

balance due by the participant will be expected to be paid by the participant. This must be made clear on the written informed consent form. Co-pays for participants not seen in the suites (i.e. PCRU, IRU) will be collected.

All research visits and measures not considered standard of care will be billed to the study. Likewise, any research components or procedures performed at the same time as standard of care will also be billed to the study. When completing the charge ticket, "research" and the name and HRPO number of the study should be indicated. All research-only visits will need to be entered into IDX (name and account number will also need to be entered into IDX). These charge tickets will need to be taken to the suites (even if patients are seen in locations other than the suites, such as the PCRU and IRU). The billing office will generate a monthly statement of charges and will put an interdepartmental invoice (ID) online. This statement with the ID number will be sent to the Clinical Trials Coordinator for payment.

Participants new to the system will require completion of a standard registration form, which will be sent to the Billing Supervisor for entry.

### **CCS Billing Matrix**

In addition to the billing procedures for study visits, the Dean of the School of Medicine has mandated that all studies be entered into the Billing Matrix. The Billing Matrix was developed as a communication tool to help the billing departments at the University and the affiliated hospitals recognize patients who are in clinical trials so that the correct qualifiers can be appended to the items or services when a claim is submitted to Medicare in compliance with its regulations. It

also determines which procedures within those trials are standard of care and billed to the patient's third-party payer, or if the procedures are research-only and should be billed to the study sponsor. All clinical trials, regardless of funding source, must be entered into the Billing Matrix system, including NIH-funded, industry-sponsored and PI-initiated clinical trials.

In an effort to ease the burden on research coordinators and investigators, Kelly Granda, of the Center for Clinical Studies, has been appointed as the Billing Matrix Administrator and her staff will enter the clinical trial profile (e.g., type of study, protocol numbers, and departmental contact information) and a list of trial-related procedures into the billing matrix system. Most of this information will be extracted from the written informed consent and protocol that the PI sends in the initial submission packet to the University's Human Research Protection Office.

When a participant is enrolled in a clinical trial, his/her name and information **MUST** be entered into the Billing Matrix. There is no further requirement for entry work beyond this step. research coordinators will need to be trained on the system, and obtain an ID and password from Kelly Granda (362-4127). Principal Investigators and Coordinators must complete online training to obtain access the Billing Matrix. ([ccsbillingmatrix@wusm.wustl.edu](mailto:ccsbillingmatrix@wusm.wustl.edu) or go to [http://train2web.wustl.edu/billing\\_matrix](http://train2web.wustl.edu/billing_matrix)).

### **Post Award**

On a monthly basis, investigators will receive a financial status report from the Senior Financial Analyst, which will contain accounting for all research studies, including NIH, foundation and industry-sponsored studies for which he/she is the PI.

If a Research Coordinator assists a PI with various aspects of a study (i.e. IRB work, recruitment strategies, etc.), but they are not the coordinator on that study, any time spent can be charged to that study.

The Principal Investigator is encouraged to be sourced to the study at  $\geq 1\%$  effort to provide oversight for the scientific aims and management of research staff.

### **Residual Funds**

Once a study is complete and all payments have been received/invoices paid, the Clinical Trials Coordinator will transfer 25% of residual industry-provided funds to a Central Administration account, which will be held to cover any future audit, storage, and other unanticipated expenses. The remaining 75% will be transferred to the PI's closed drug study account (typically Div-93199X). He/She may spend those funds according to departmental and university guidelines (see below). This applies to studies that start on or after the effective date of the original Clinical Trials Standards Policy (**11/1/05**). Any capitation agreements sponsored by the NIH are exempt from this rule and 100% of the residual balance will be moved to the PI's closed drug study account. However, all funds in the PI closed drug study fund must adhere to the department and university guidelines below.

All current accounts holding residual funds will remain as is, but will be held to the same spending guidelines.

- Funds may be used to support the Investigator's research (such as pilot projects, travel, education, lapses in extramural funding, computer equipment, etc.).
- Funds can be used to pay research staff effort

- Funds are not to be used for social expenses
- Funds are not to be used as a source of non-academic benefit to any individual

### **Cancelled Negotiations**

Occasionally a sponsor or PI will decide to break off negotiations and/or cancel a study before a contract is in place. Often they will allow invoicing for expenses related to the study up to that point. In the event that this takes place, any money received from the sponsor is subject to the department and university overhead rules, and will be deposited into the PI's closed drug study fund. Any internal or external expenses incurred on the study will be paid out of those funds, i.e. salaries for effort, IRB charges etc. Any residual money remaining may then be spent at the investigator's discretion, subject to the same restrictions and guidelines listed above for other closed drug study money.