

TRANSLATIONAL RESEARCH INITIATIVE
(formerly Translational Research Fund)
February 2004

**LOI reviewed at
weekly CTEP/IDB
meeting...**

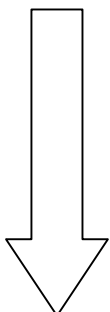
**If Correlative Study
Support is ultimately
APPROVED...**



**SAIC-Frederick, Inc
Solicitation is Sent to
Institution's Business
Office**



Contract Awarded



**Work Performed
and Invoices Paid**

- **TRI support must be requested at LOI stage only; LOI must include preliminary budget and justification, using the cost estimate worksheet.**
- **CTEP reviews the LOI and provides two Priority Scores**
 - **LOI Review Criteria**
Strong scientific hypothesis; not duplicative; supporting preliminary data and/or a strong rationale; adequate patient accrual; innovative correlative studies; agent availability; industry sponsor concurs; ability to meet regulatory requirements
 - **Correlative Studies for TRI Support Review Criteria**
Importance of proposed correlative hypothesis for further development of agent; biologic rationale for studying the target effect; relevant preclinical data behind hypothesis; rationale for selection of assay; technical performance characteristics of assay; investigator experience with the assay; comparability of results with other published data; impact on future studies; statistics for data analysis - prevalence of target, study power for chosen endpoint
- **If Correlative Studies score warrants TRI support:**
 - The LOI approval letter provides details of discussion, and the plans for the SAIC-Frederick, Inc. contract to support the correlative studies; a draft budget must be included in the LOI or will be requested at this time. Justification should be provided:
 - **Personnel effort appropriate and reasonable (PI support very limited)**
 - **Supplies**
 - **Shared Resource Costs**
 - **No Equipment or Travel costs**
 - **Equipment maintenance/service costs if appropriately justified**
 - **No costs associated with the development of new assays/technologies**
 - **No Record keeping or IRB filing costs**
 - **No indirect costs may be applied to patient care costs**
 - The LOI approval letter requests that the **protocol be submitted to PIO**, and indicates that SAIC-Frederick, Inc. will be forwarding a **Solicitation, following receipt of the protocol at the PIO.**
 - At this point in the process, the **PI should alert the institution's business office** that a solicitation from SAIC-Frederick, Inc. will be coming.
- **The SAIC-Frederick, Inc. technical project officer contacts the correlative studies PI** to obtain information regarding current trial status, accurate contact information for the contract PI and for the institution's business office, and may **discuss** additional information regarding the level of CTEP.
- **The SAIC-Frederick, Inc. solicitation is forwarded to the institution's business office.** The solicitation will include the Statement of Work to be reviewed, and will request a detailed cost estimate/budget and justification.
- **The institution submits the proposal to the SAIC-Frederick, Inc. contracting officer who then negotiates the "cost reimbursement" contract.** Final approval is granted by CTEP.
- **Correlative studies are completed by the awarded institution.** Once costs are incurred, either per sample (lab assays) or per patient (imaging study), an invoice is submitted to SAIC-Frederick, Inc. with all accompanying documentation, as outlined in the solicitation. Payment is made after invoices are submitted and after deliverables are confirmed. Additional details are included in the solicitation.
- **Deliverables include CDUS data entry and monthly/annual data reports.** Before payment can be made, the SAIC-Frederick, Inc. technical project officer checks the CDUS database to confirm that documentation exists for the completion of the correlative studies being billed for – this is the primary "deliverable" of the contract. The second deliverable is reporting to CTEP and SAIC-Frederick, Inc. the progress reports/annual reports for the studies. Details are provided in the solicitation.