QUESTIONS?

For more information on the **Translational Research Initiative**, please visit http://ctep.cancer.gov/resources/trf.html

For additional information/questions, contact:

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SAIC-Frederick, Inc.
A Subsidiary of Science Applications International Corporation

NCI's Cancer Therapy Evaluation Program

CTEP

Developing Cancer Therapies

Translational Research Initiative

(formerly Translational Research Fund)

Funding Opportunity for Clinical Investigators to Support Correlative Studies

Basic Information for the Investigator and the Business Office

What is the Translational Research Initiative?

Established by the NCI and CTEP, the TRI was established to support the costs of the correlative studies performed during the conduct of CTEP-sponsored early clinical trials using CTEP agents.

How is the funding provided?

SAIC-Frederick, Inc., a subsidiary of Science Applications International Corporation (SAIC), is under contract with NCI to provide operational and technical support to many of its programs. As such, SAIC-Frederick, Inc. is providing administrative support to the TRI program by creating and managing cost-reimbursement contracts to cover the costs of the approved correlative studies. Cost-effective proposals in laboratories already performing the correlative studies in the preclinical setting are preferred. This contract is supplemental funding.

What are the LOI review criteria?

Strong scientific hypothesis; not duplicative; supporting preliminary data and/or a strong rationale; innovative correlative studies; adequate patient accrual; agent availability; Industry sponsor concurs; ability to meet regulatory requirements.

In 2002, 1/3 of LOIs for early clinical trials with CTEP IND agents were approved (solicited and unsolicited).

The TRI Process

- **LOI is submitted to CTEP, including the request and draft budget for TRI support (using the cost estimate worksheet); Protocol approval follows standard CTEP process** (see The Investigator's Handbook, http://ctep.cancer.gov/handbook/index.html)
- **If LOI/correlative studies are approved (see review criteria), the PI is contacted by SAIC-Frederick, Inc. to initiate the contracting process**
- **SAIC-Frederick, Inc. sends the solicitation to the institution's Business Office**
- **Business Office works with investigator to confirm the Statement of Work and to finalize the cost proposal**
- **The contract is negotiated/awarded**
- **Work is performed and reported; invoices submitted**
- **Payment is made**

What are the Correlative Studies 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.

What costs may be provided by the TRI?

Allowable Costs *(must be adequately justified)*

- Personnel and Consultants
- Equipment maintenance/service
- Supplies
- Shared resource services
- Patient care costs

Disallowed Costs

- Equipment
- Travel
- Costs associated with development of new assays
- Indirect costs may not be applied to patient care costs