

Clinical Investigator Team Leadership Award

Purpose: Enhance recognition & career development for individuals who make substantive contributions to clinical trials efforts

- 34 awards over 3 years (FY9-11)
 - \$50,000/year for 2 years
 - 30-40 applications/year from NCI Cancer Centers
- New announcement available in January 2012
- Developing a process to evaluate the program

Clinical Investigator Team Leadership Award Recipients - 2011

- Dr. Julie Bauman, University of New Mexico Cancer Center
- Dr. Tanios Bekaii-Saab, Ohio State University Comprehensive Cancer Center
- Dr. Anthony El-Khoueiry, University of Southern California Norris Comprehensive Cancer Center
- Dr. David Gerber, Harold C. Simmons Cancer Center, University of Texas Southwestern Medical Center
- Dr. Andrew Ko, UCSF Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco

Clinical Investigator Team Leadership Award Recipients - 2011

- Dr. Antonio Omuro, Memorial Sloan-Kettering Cancer Center
- Dr. Chong-xian Pan, UC Davis Cancer Center, University of California, Davis
- Dr. John Sarantopoulos, Cancer Therapy & Research Center, UT Health Science Center at San Antonio
- Dr. Scott Schuetze, University of Michigan Comprehensive Cancer Center
- Dr. Tait Shanafelt, Mayo Clinic
- Dr. Brenda Weigel, Masonic Cancer Center, University of Minnesota



CTSU Support for Collaborative Multi-Center Phase 2 Trials

Purpose:

Encourage collaborations and “hand-offs” (bench to bedside and back) between Cooperative Group, Cancer Center, and SPORE investigators through Steering Committee (SC) discussions on clinical trial concepts

Funding Opportunity (ccct.nci.nih.gov):

- SPORE, NCI Designated Cancer Center Investigators bring ideas for clinical trials or components (e.g., biomarkers) to SCs for input and collaborations → **merits “review credit”** under new SPORE and Center guidelines
- Support for CTSU services for Phase II treatment trials reviewed & approved by SC, CTROC

CTSU Support

Multi-Center Coordination Services Available from CTSU under Current announcement:

- Regulatory support
- Website document hosting
- Protocol coordination
- Patient registration
- Study coordination
- Clinical database development
- Data management
- Data processing
- Information technology
- Capitation

Investigational New Drug (IND) application and statistical support, data safety monitoring, and auditing services are not available through the CTSU.

FY 2011 Activity

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- 4 submissions
 - 1 – Gastrointestinal Steering committee
 - 2 – Head & Neck Task Force
 - 1 – Lymphoma Steering Committee
- 1 funded
- Identified need for additional flexibility for consideration of uncommon (rare) tumors

FY12 Eligibility Criteria

- Phase 2 randomized multi-center treatment trial (at least four accrual sites) with ≥ 100 and < 200 total patients led by a SPORE, NCI Designated Cancer Center or CCR investigator.
- Under special circumstances when there is a unique opportunity for important improvement to clinical outcomes, concepts of less than 100 patients and/or single arm or non-randomized concepts may be considered.
- Requires collaboration with either another SPORE or NCI Designated Cancer Center, Cooperative Group or CCR.