

## FUNDING OPPORTUNITY

### ADMINISTRATIVE SUPPLEMENTS TO CTSA PROGRAM HUBS TO DEVELOP BEST PRACTICES FOR sIRB IMPLEMENTATION (FY17)

The Clinical and Translational Science Awards (CTSA) Program involves multi-site clinical research and may not be currently using a single Institutional Review Board (sIRB).

The National Institutes of Health Office of the Director (NIH OD) is responsible for the allocation of funds, which are appropriated annually, to support bioethics, research, training, and translation. To this end, FY2017 funds have been allocated to support approximately 10-11 administrative supplements (~300K/award) for infrastructure development at CTSA Program hub institutions expected to follow the "NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research" ([NOT-OD-16-094](#) and [NOT-OD-17-027](#)). The NIH sIRB policy will apply to applications and proposals submitted on or after September 25, 2017 and the Common Rule requirement for the use of sIRBs for cooperative research is anticipated to be effective on January 20, 2020.

NCATS is therefore soliciting requests from CTSA Program hub institutions with current NIH-funded award(s) for one year of supplemental support to cover direct costs for the development of costing models, business processes, system changes, and efficient procedures and tools needed to facilitate sIRB review for multi-site research. In addition to being within the scope of the award, administrative supplement requests will need to describe plans to:

- Continue the proposed activities after the period of supplemental support, and
- Share any information, methods, resources, or products developed using these funds widely and without charge to other institutions, via publications, presentations, and workshops.

Awardees that submit requests that, in combination, cover multiple recognized sIRB infrastructural needs with supplemental requests from other institutions may be considered more favorably in funding decisions. All requests must include a detailed description of the proposed activities. The following is a list of examples of activities that could be proposed to assist institutions in implementing sIRB review:

- Development and/or testing of infrastructure/technologies for computer tracking of human subjects protocols, secure records retention, electronic protocol submission, adverse events across multiple research sites for sIRB use.
- Development of methods for confidential and secure data storage and sharing systems for all stages of research across multiple research sites for sIRB review and use.
- Strategies to coordinate sIRB approval of consent forms and other activities used at relying sites in multi-site clinical research.
- Optimization of systems for coordinating across research sites conducting multi-site clinical research for sIRB review.
- Development of tools for strengthening continuing sIRB reviews for multi-site research.

A meeting of grantees who receive supplemental funding will be held in the Washington D.C. area approximately one year after receiving an award, at which time recipients will share successful strategies, modalities, and processes for sIRB review. Funds should be

budgeted for travel by PI(s) and/or other relevant individual(s) with significant day-to-day involvement in the activities performed under the administrative supplement request. Institutions should use their expanded authorities to extend the funds in order to charge meeting travel costs. At the conclusion of the meeting, participants will develop a final report to be posted on the NIH website, which describes promising and widely applicable approaches for modifying and enhancing institutional IRB infrastructure to allow for efficient and effective sIRB review of multi-site studies.

Budgets should not exceed \$300,000, but need to reflect the actual needs of the proposed project. As stated above, **F&A costs will not be covered**. All program-related expenses must be justified as specifically required by the proposed activities and must not duplicate items generally available from other sources at the applicant or collaborating institutions.

**Submission information:** Requests must be submitted on or before COB local time **June 2, 2017**. Applicants are instructed to cite [PA-16-287 Administrative Supplements to Existing NIH Grants and Contracts](#) when submitting their proposal. It is recommended for applicants to discuss proposed projects with their NCATS/DCI Program Director prior to submission.

Questions? Contact via email [Philip J. Brooks, Ph.D.](#) or by phone (301) 443-0513.