

CONCEPT CLEARANCE

FY 2016 RESEARCH INITIATIVE – NCATS

TITLE: Translational Research Informatics and Operations Support

OBJECTIVE: The purpose of this contract requirement is to provide coordinated and comprehensive scientific and technical support for NCATS translational and clinical research operations and management in order to harmonize and centralize activities across NCATS. Activities are wide-ranging and will include translational research and clinical research operations support, information management, safety oversight and administrative support.

DESCRIPTION: As part of its overall research mission, NCATS has an extensive clinical research portfolio that covers a broad range of clinical efforts. Currently most of the clinical and data coordination efforts are accomplished through a decentralized approach, with unique arrangements being made for each study. Coordination across these various entities, as well as centralized operations support and oversight, does not currently exist.

This new contract requirement will provide centralized administrative and clinical operational support to NCATS-supported studies. The contractor will provide resources to ensure sound and efficient clinical study coordination and tracking for NCATS. Tasks will include overall information management and analysis, including centralized tracking of NCATS clinical studies; safety monitoring and oversight; clinical site monitoring and quality management; development of tools, templates and processes to support improved study design and implementation; regulatory support and coordination with the Food and Drug Administration; general logistical and administrative support for effective administration and coordination of NCATS translational and clinical programs; and special operational support such as product/study agent distribution and pre-clinical product testing, if needed. Tasks performed will vary on an as-needed basis and be provided depending upon availability of resources.

IMPORTANCE: This contract will provide clinical, operational and administrative support for the Clinical and Translational Science Awards (CTSA) Program to achieve its goals to catalyze clinical and translational science. The contractor will assist NCATS staff in managing the clinical and operational activities and provide information management of NCATS' clinical activities. A centralized information system will allow NCATS to quantify and describe characteristics of individual clinical studies to analyze the overall clinical program. Additionally, the awardee will provide support for ensuring human subject safety and quality monitoring of NCATS clinical studies.

HISTORY: A past contract provided some integration of research and clinical activities within the CTSA Program. A current grant award provides some assistance with enabling collaboration and enhancing communication and outreach.

PROJECT/PROGRAM OFFICER:

Michelle A. Culp, B.S.N., M.P.H.
Phone: (301) 594-4830
e-mail: michelle.culp@nih.gov