DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

MEMORANDUM

Date: April 15, 2017

To: Network Leadership Group
Operations and CORE Leadership
Data Management Center Leadership

From: Carol Worrell, MD
Director, Office for Policy in Clinical Research Operations

Jui Shah, PhD, Health Scientist Administrator
Contracting Officer's Technical Representative: DAIDS Regulatory Support Center Contract
Office for Policy in Clinical Research Operations

Subject: New DAIDS Regulatory Support Center Contract

On behalf of DAIDS and the Office for Policy in Clinical Research Operations (OPCRO), we are pleased to announce the award of the new DAIDS Regulatory Support Center (RSC) Contract to Technical Resources International, Inc. (TRI) of Bethesda, Maryland. The period of performance (POP) under this contract is one year, starting on April 15, 2017, with options for six additional one-year options granted at the Government's discretion, for a total possible POP of seven years. TRI is the contractor for the current DAIDS RSC Contract for which the POP ends on April 14, 2017. This cost-plus-award-fee, level-of-effort (term) type contract is a performance-based contract and will provide regulatory expertise and support to operate and manage the Division of AIDS (DAIDS) Regulatory Support Center (RSC) to provide a wide range of clinical research activities and programs.

The scope of activities to be supported by this new contract includes the following continuing major task areas:

- IND and other Regulatory Support including the electronic submissions to the FDA;
- Safety and Pharmacovigilance support and safety reporting/distributions;
- Various protocol registration activities;
- Maintain clinical study and study-related information;
- Support clinical trial agreements (CTAs) and other research agreements;
- Technical, regulatory and administrative review of clinical documents (such as protocols and sample informed consents) for scientific review committees;
- Conduct human subjects protection reviews; and
- Assist NIAID with developing SOPs, quality assurance/quality control (QA/QC) plans, training, meetings with Health Authorities and other stakeholders, and other related, general tasks.

A new task area for the RSC is to provide support for meeting ClinicalTrials.gov requirements.

We are very excited about this mission-critical contract. We would like to take this opportunity to thank you and your sites in advance for your cooperation as we begin to execute this new contract.

Should you have any general questions about the Regulatory Support Center Contract, please do not hesitate to contact Jui Shah at 240-669-5608 or by e-mail at jui.shah@nih.gov.