

Statement of Work (SOW)

Agency/Institute: National Institutes of Health (NIH)/ National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Background

In response to the COVID-19 pandemic, the NIBIB created the Rapid Acceleration of Diagnostics (RADx-Tech) initiative, an innovation funnel aimed at increasing the speed of development, commercialization, and implementation of technologies for COVID-19 testing. The RADx-Tech innovation funnel was designed to compress the customary technology development timeline from years down to just months. This was accomplished by employing, in parallel, expert teams of contracted consultants to assist technology developers in addressing technical, regulatory, clinical, and commercialization requirements. Additionally, milestone-based award management was employed to drive projects effectively through development while mitigating risks. It is envisioned that further acceleration of healthcare innovations will enable greater preparedness for future pandemics, as well as provide significant advances to the current healthcare paradigm across a broad range of clinical indications. To support rapid technology development, funding mechanisms must be efficient, agile, and scalable. The review and management of funding awards remains a critical component of the initiative and requires expertise in project management, subcontracting, and financial management. Infrastructure for the funding of milestone-driven, research and development efforts across various biomedical technology areas is required.

Objective

The objective of this requirement is to award subcontracts or agreements for validation and risk review projects and challenges utilizing the RADx Innovation Funnel which supports technology development through various NIH translational activities.

Scope

This requirement is for a single vendor to negotiate, award, and administer subcontracts or agreements resulting from the RADx Innovation Funnel. These subcontracts or agreements will cover validation and risk review as directed by the Government. Responsibilities will cover negotiations, award execution, post-award management and payments, and ongoing IT and legal resource support. Expertise in reviewing and negotiating of milestones, budgets, and timelines for biomedical research and development awards is required, along with establishing terms & conditions, and execution of awards. Resources for ongoing oversight and support for milestone-based award contracts are required, including financial management capabilities to process invoices and payments.

TASK 1: STANDARD OPERATING PROCEDURES

The contractor shall generate a set of Standard Operating Procedures specific to the requirements of each Task Order (TO). This includes tasks supported across the innovation

funnel network, covering interactions and workflows among the Coordination Center, Commercialization Center, and Validation Center. The Standard Operating Procedures will be reviewed annually for efficiency and updated as needed.

TASK 2: AWARD MANAGEMENT

The Contractor shall be responsible for the award of subcontracts or agreements for validation and risk review projects and challenges utilizing the RADx Innovation Funnel. Responsibilities will cover negotiations, award execution, post-award management and payments, and ongoing IT and legal resource support. Resources for ongoing oversight and support for milestone-based award contracts are required, including financial management capabilities to process invoices and payments.