INTRODUCTION

PURSUANT TO RFO SUBPART 5.101- PRESOLICITATION NOTICE, THIS IS A NOTICE OF A PROPOSED CONTRACT ACTION.

THIS IS A NOTICE OF INTENT TO AWARD MODIFICATIONS TO EXTEND THE ORDERING PERIOD BY TWO (2) YEARS UNDER THE FOLLOWING CONTRACT NOS:

HHSN271201600006i - SRI International
HHSN27120160007i - Southern Research
75N95021D00026 - IIT Research Institute (IITRI)
75N95022D00026 - University of Illinois Chicago

The National Institute on Neurological Disorders and Stroke (NINDS) intends to modify the multiple-award Indefinite Quantity Indefinite Delivery (IDIQ) contracts under the Pharmacology and Toxicology for Therapeutics Program (PTTP). These contracts serve as part of the NIH Blueprint Neurotherapeutics Network (BPN) and are also utilized for individual development projects outside of the Blueprint Network. These services are a critical component of the BPN drug development infrastructure, supporting all preclinical pharmacology and toxicology testing needed to inform lead discovery and the selection of a clinical candidate, as well as comprehensive studies needed for regulatory filings such as FDA Investigational New Drug (IND) applications to allow for clinical evaluation of the candidates. This modification will extend the ordering period as denoted in IDIQ contract clause FAR 52.216-18, Ordering (AUG 2020), to be extended September 12, 2026, to September 12, 2028.

The extension will allow the four existing IDIQ holders to continue supporting BPN and other NINDS initiatives - including pharmacokinetic (PK), non-GLP, and GLP-IND-enabling studies - while the PTTP requirement is recompeted and a new IDIQ contract is awarded.

NORTH AMERICAN INDUSTRY CLASSIFICATION SYSTEM (NAICS) CODE

The requirement is classified under NAICS code is 541715: Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology), with a size standard of 1,000 employees.

REGULATORY AUTHORITY

The resultant modification will include all the applicable provisions and clauses of the RFO initiative, in accordance with Executive Order 14275 and OMB Memorandum M-25-26.

STATUTORY AUTHORITY

This modification is conducted under the authority of 41 U.S.C. 3304(a)(1) and in accordance with RFO – FAR 6.103-1- Only one responsible source and no other supplies or services will satisfy agency requirements.

DESCRIPTION

Background

The National Institute of Neurological Disorders and Stroke (NINDS) and the NIH Blueprint Neurotherapeutics Network (BPN) have established a 'virtual pharma' network of contract service providers and consultants with extensive industry experience to enable therapeutic (e.g., small molecule, peptide, biologic) development in the NIH research community. The Network, similar NINDS and NIH programs offer researchers access to a range of industry style therapeutic development services and expertise, including medicinal chemistry, IND-enabling studies, and Phase I clinical trial infrastructure, with the goal of supporting efforts to advance compounds successfully through Phase I clinical testing. Projects may utilize some or all of the BPN infrastructure. The PTTP contract will support all preclinical pharmacology and toxicology testing needed to inform lead discovery, the selection of a clinical candidate, and comprehensive studies needed for regulatory filings, such as an Investigational New Drug (IND) application to the FDA, to allow for clinical evaluation of the candidates. This contract will serve as part of the NIH Blueprint Neurotherapeutics Network and will also be utilized for individual development projects outside of the Blueprint Network.

Scope and Objectives

The goal of the PTTP is to assess the pharmacokinetics, toxicology and safety of promising candidates to support their eventual use as therapeutics. It is anticipated that NIH-approved samples will be submitted from a variety of sources including NIH-funded research programs, pharmaceutical companies, biotechnology companies, or other sources. Pharmacology, toxicology and safety data generated from this program may be used by investigators in support of an Investigational New Drug (IND) application.

Studies to be performed may include, but are not limited to:

- Development and validation of the analytical methods for quantitating

drug/biologic concentrations in dosing solutions, biological fluids, and tissues, as required
• In vivo pharmacokinetic studies through various routes of administration
• Preclinical acute toxicity evaluations on lead compounds or therapeutics
• Subacute, subchronic, and/or long-term toxicity evaluations in rodents and non-rodent species
• Safety Pharmacology Studies in rodent and non-rodent species (e.g., cardiovascular, pulmonary, CNS)
• Genotoxicity assessments using a battery of appropriate assays and carcinogenicity assessments
• In vitro predictive ADMET assays, including metabolic stability studies, hepatotoxicity, permeability studies, cytochrome P450 assays, plasma protein binding, and cytotoxicity assay

Period of Performance

As a result of this modification, the ordering period of the IDIQ will be extended by two (2) years, from September 12, 2026, to September 12, 2028.

Closing Statement

This synopsis is not a request for competitive proposals and the government is not committed to award a contract pursuant to this announcement. However, interested parties may respond by identifying their interest, submitting capability statements, or submitting objections to the proposed contract modification. The government will consider responses, however, a determination by the government to proceed with the proposed contract modification is solely within the discretion of the government.

Any potential offeror must have an active registration in the System for Award Management (SAM), housed at www.sam.gov. In addition, the Unique Entity Identifier (UEI), Taxpayer Identification Number (TIN), and the certification of business size must be included in the response.

A determination by the government not to compete these requirements based upon responses to this notice is solely within the discretion of the government. The information received will normally be considered solely for the purposes for determining whether to proceed on a non-competitive basis or to conduct a competitive procurement.

Based upon market research, the government is not using RFO Part 12, Acquisition of Commercial Products and Commercial Services, to fulfill this requirement. However,

interested persons may identify to the Contracting Officer their interest and capability to satisfy the Government's requirement with a commercial item within 15 days of this notice.

All responses must be received by August 18, 2026, at 3:00 pm Eastern Time. Responses must be submitted electronically to Sneha Singh, Contacting Officer, at sneha.singh@nih.gov. Please reference notice, 75N98026R00138 in any responses or inquiries.