Document Type: Presolicitation Notice

Solicitation No. 75N95024R00025 (NIDA Ref. No. N01DA-24-2251)

Project Title: Clinical Coordinating Center for NIDA's Clinical Trials Network

Classification Code: AN11—Research & Development

NAICS Code: 541715 – Research and Development in Physical, Engineering and Life Sciences (except Biotechnology)

Description

The National Institute on Drug Abuse (NIDA) intends to solicit proposals from qualified organizations (NAICS Code 541715) having in-house capability to provide a wide range of clinical trial administrative and research support and related services for multi-site clinical trials conducted within the NIDA Clinical Trials Network (CTN). The awardee will not be responsible for actually conducting clinical trials to be carried out under this contract. Activities under this contract will support the trials carried out under cooperative agreements with CTN grantees located across the nation.

NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN) was established in 1999 to bridge the gap between research and practice to improve substance use disorder (SUD) treatment. Through the collaborative partnership of scientists, treatment providers, and other community stakeholders, the CTN seeks to address critical research questions with direct relevance to clinical practice and the needs of patients. Over the last two decades, the CTN's research infrastructure and agenda have evolved to reflect the changing landscape of the SUD treatment community, transformation of health care systems, and emerging scientific advancements.

The CTN conducts single and multi-site clinical research in sites located across the nation and in other countries. These are primarily studies of behavioral, pharmacological, and integrated behavioral and pharmacological treatment interventions in rigorous, clinical trials to determine efficacy, effectiveness, practicality, and feasibility across a broad range of treatment settings and diversified patient populations and to transfer research results to physicians, clinicians, providers, and patients. These studies could be Phase I, Phase II, Phase III, and/or Phase IV type trials. They may also include registry-based studies, data science-based studies, or surveys.

The Contractor shall provide NIDA with a broad and flexible range of clinical trial administrative and research support and related services for the research conducted within the CTN. The work required under this contract includes:

1) Providing support for regulatory functions and requirements – advising on IRB submissions, human subject protection assurances, and compliance with applicable federal regulations; establishing an online regulatory document repository; preparing and submitting Investigational New Drug Applications (IND); consulting on regulatory issues raised by the NIDA, study review boards, and study staff regarding safety and AE/SAE reporting; etc.

2) Reviewing and monitoring protocol implementation – administering a program of quality assurance visits to monitor study-related functions and implementation of trials; assessing adherence to and compliance with all procedures specified by the protocol; assessing the quality of research data; etc.

3) Providing training to research staff – participating in the development and conduct of study orientation and study closeout meetings; providing training on clinical research conduct (e.g. Good Clinical Practice, Adverse Event/ Serious Adverse Event reporting; protection of human subjects, etc.); tracking required training of study staff; etc.

4) Providing pharmaceutical services and clinical research support – purchasing of required study medications and study products; managing the receipt, packaging, storage and distribution of study materials; obtaining necessary regulatory approval for handling both controlled and non-controlled substances; providing other clinical support such as ECG consultation, etc.

5) Providing drug testing and analytical laboratory services – acquiring and distributing on-site testing devices; coordinating central lab services; monitoring performance and validity of lab tests and services; etc.

6) Providing support for protocol development – participating in protocol meetings and contributing to the development of protocol-related documents such as quality assurance plans, data and safety monitoring plans, DSMB reports, study operation manuals, etc.

7) Participating in CTN committee and subcommittee meetings and conference calls.

8) Providing other expert consultation and support services as needed.

Mandatory Evaluation Criteria:

Due to the nature of the compounds which will be evaluated under this contract**, it is mandatory that offerors possess at the time of submission of the technical proposal US Department of Justice Drug Enforcement Administration (DEA) Research Registration for Schedules II to V in order to handle substances under the Controlled**

Substances Act of 1970. In addition, the offeror must either possess or demonstrate the ability to obtain prior to award DEA registration for Schedule I controlled substances.

Notice:

NIDA anticipates that one (1) indefinite delivery, indefinite quantity (IDIQ), task order contract will be awarded with an ordering period of five (5) years. NIDA may award either cost reimbursement and/or fixed price task orders under this contract. These individual task orders may include options to extend the period of performance and/or options for increased quantities. If options or option quantities are utilized for an individual task order the will be clearly defined in the Task Order RFP and be determined and evaluated at the time of task order solicitation and award. NIDA anticipates that at least one or more task orders will be awarded with the contract. Future funding will be made through issuances of task orders and will be dependent on NIDA programmatic needs and availability of funds.

RFP No. 75N95024R00025 will be available electronically on or after December 26th, 2023. You will be able to access the RFP through SAM.gov. All information required for the submission of an offer will be contained in or accessible through the RFP package. Responses to the RFP will be due on or about 45 days after we release the RFP. NIDA will consider proposals submitted by any responsible offeror. This advertisement does not commit the Government to award a contract.

Based upon market research, the Government is not using the policies contained in Part 12, Acquisition of Commercial Items, in its solicitation for the described supplies or services. 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.