

Office of the President

TO MEMBERS OF THE NATIONAL LABORATORIES COMMITTEE:

ACTION ITEM

For Meeting of January 18, 2023

APPROVAL TO SUBMIT BID FOR THE CONTRACT TO MANAGE FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH

EXECUTIVE SUMMARY

The University has a strong interest in managing the Frederick National Laboratory for Cancer Research to further its mission of education, research, and public service. The current management contract expires in 2024. The final Request for Proposal (RFP) for the follow-on contract was released on June 23, 2022 and requires proposals to be submitted by February 20, 2023. This action item would delegate to the President the authority to submit a bid on behalf of the University's team in response to the final RFP. Submission of a bid would commit the University's team to enter into the contract if selected.

RECOMMENDATION

The President of the University recommends that the National Laboratories Committee recommend to the Regents that the President or his delegate be authorized to execute all necessary and appropriate documents to effect submission of a bid on behalf the University's team for the contract to manage Frederick National Laboratory for Cancer Research.

BACKGROUND

The University has a long history of managing the country's National Laboratories. The University has participated in the management of Berkeley Lab, Los Alamos National Laboratory (LANL), and Lawrence Livermore National Laboratory (LLNL) since their respective foundings in 1931, 1943, and 1952. Each of these institutions is a Federally Funded Research and Development Center (FFRDC).

FFRDCs differ from other performers of federal research and development in that they are designed to meet a "special long-term research or development need that cannot be met as effectively by existing in-house or contractor resources" and that they have "access, beyond that which is common to the normal contractual relationship, to government and supplier data, including sensitive and proprietary data, and to employees and installations equipment and real property." FFRDCs are government-owned, contractor-operated research facilities that are

owned or leased by the U.S. Government and managed by third-party contractors who operate the facilities and function in accordance with strict statutory and regulatory requirements.

There are currently 42 FFRDCs sponsored by 12 different federal agencies. These FFRDCs provide a wide variety of capabilities to various federal agency sponsors, including the Department of Energy (DOE) and the Department of Health and Human Services (HHS).

The Frederick National Laboratory for Cancer Research (FNLCR) is one of two HHS-sponsored FFRDCs and is the only FFRDC dedicated exclusively to biomedical research to discover, innovate, and improve human health. The FNLCR is overseen by the National Cancer Institute (NCI), one of the 11 HHS National Institutes of Health (NIH). The FNLCR originated in 1971 with the enactment of the National Cancer Act. In 1972, the National Cancer Institute (NCI)-Frederick Cancer Research Center was established by a presidential directive to convert the federal Biological Defense Research Laboratories at Fort Detrick in Frederick, Maryland, into a contractor-operated “leading center for cancer research.” In 1975, the FCRC was formerly designated as an FFRDC. In 2012, the Center was designated as a National Laboratory and renamed the FNLCR, elevating its broader national mission.

As a national resource, the FNLCR provides cancer researchers a bridge between basic, translational, preclinical, and clinical practice, bringing together public and private partners, including intramural investigators from NCI and other NIH intramural laboratories, extramural NCI-supported laboratories, biotechnical and pharmaceutical companies, and contract research groups. Because of its status as a FFRDC, FNLCR affords NCI and other NIH Institutes a unique national resource and capabilities (flexibility, rapid response, and increased efficiency) to accelerate the development and delivery of effective preventive, diagnostic, and therapeutic agents for rare and recalcitrant cancers, and rapid response to emerging infectious disease (e.g., Ebola, Zika, Influenza.) challenges. The breadth of FNLCR activities is extensive and designed specifically to support the research goals and mission of the NIH, including investigator-initiated, hypothesis-driven research; drug discovery and development; biomarker identification and validation; translational genomics; next-generation preclinical assay development; oncology-focused computational science; production of clinical-grade biopharmaceuticals for first-in-human studies; acceleration of nanotechnology applications for treatments and diagnostics; preclinical model development, validation, and testing; Center for Cancer Research clinical operations in support of NCI, the National Institute of Allergy and Infectious Diseases (NIAID), and other NIH Institute-sponsored clinical trials; and management and operation of biopharmaceutical development and manufacturing programs under two current Good Manufacturing Practice facilities.

Litton Bionetics, Inc. was the first NCI contractor, starting in 1972. In 1995, a contract competition was conducted and SAIC-Frederick was selected as the successor contractor. In 2013, the SAIC-Frederick contractor changed its name to Leidos Biomedical Research, Inc., which remains the current contractor at FNLCR.

In addition to the primary facility in Frederick, there are FNLCR facilities in Gaithersburg and Bethesda, Maryland. FNLCR also conducts international operations in South America, Africa,

and Asia. There are approximately 2,300 contractor employees and 750 federal employees working at FNLCR.

UC's Interests in Managing the FNLCR

UC's interests in managing and operating the FNLCR are manifold. First and foremost, UC's objective in pursuing the FNLCR contract is to translate the University's mission of public service, research excellence and integrity, and commitment to education in pursuit of:

- Advancing biomedical research;
- Enhancing and supporting both intramural and extramural programs; and
- Partnering with NCI in the fight against cancer.

This opportunity squarely aligns with and furthers UC's public service mission by leveraging UC's world-class cancer centers in particular and health system generally to assist the federal government in driving profound advances in cancer and infectious disease research.

It would strengthen UC's position at the forefront of emerging scientific discoveries and innovative technologies and provide UC researchers with more exposure to NCI, NIH, FNLCR and other academic and medical institutions. UC would be able to enhance existing, and develop new, student-oriented programs, potentially including in-residence research and post-doctoral fellowship programs. Finally, UC would earn modest fee income from managing FNLCR that could be used to support educational and research programs within UC.

FNLCR Procurement Status

In September 2020, NCI announced that it would begin the process of competing the FNLCR management contract. Thereafter, NCI convened an Industry Day in April 2021 and issued multiple Requests for Information to engage with potential bidders. Two draft RFPs were released in July 2021 and February 2022 to solicit feedback from interested parties. UC has engaged with NCI throughout the process, attending Industry Day and providing feedback to each Request.

NCI released the final RFP on June 23, 2022, with responses initially required by November 21. NCI later extended the response deadline to February 20, 2023. On the basis of this proposed schedule, the President sought and received Regents' approval on an interim basis to form a team of partners, which together would jointly prepare a bid. Regents' approval was also granted to establish a special purpose entity (SPE)—such as a corporation or limited liability company—to bid on and ultimately hold the FNLCR management contract. The Regents further approved the appointment of three UC executives as voting members of the SPE's governing board: Vice President for National Laboratories Craig Leasure, Chief Clinical Officer Anne Foster, and Senior Advisor Gary Falle.

Summary of Important RFP Terms

The following is a summary of the important terms contained in the final RFP, which will be

incorporated into the FNLCR contract.

Contract Type and Duration

The contract type at FNLCR differs from the management and operating (M&O) contract used at UC's three DOE National Laboratories. The FNLCR solicitation indicates that NCI will continue to utilize an Indefinite Delivery–Indefinite Quantity (IDIQ) type contract. IDIQ contracts are a very common type of government contract that provide greater agency flexibility and direction of program activities as compared with M&O contracts.

The solicitation contemplates the award of a single “parent” or “master” IDIQ contract with a maximum 25-year ordering period: a base ordering period of ten years and three options to extend the ordering period for an additional five-years per option. Under this parent contract, the agency will award task orders for particular activities to supporting the operations and research at the Lab. There are approximately 114 task orders currently at FNLCR, with 56 science-based task orders, 32 medical-based task orders, and 26 facilities-based task orders.

Contract Value

The task orders and any associated fee income are negotiated individually. Task orders come in varying types, including firm-fixed-price, cost reimbursement, cost-plus-fixed-fee, and cost-plus-award-fee. Because any fixed or award fees are negotiated individually on each applicable task order, it is difficult to estimate the total amount of fee income the University stands to earn if awarded the FNLCR parent contract. Annual gross fee would be estimated to be \$8 million to \$15 million.

The annual budget for FNLCR is approximately \$800 million per year. NCI is the sponsoring agency for the FFRDC and provides the majority of the funding, approximately \$500 million per year. Another major source of funding is NIAID, FNLCR has recently experienced significantly NIAID funding growth associated with COVID-19 activities. The RFP provides that the maximum lifetime contract value over the 25 years is \$89 billion.

Scope of Work

The scope of work under the FNCLR master contract will largely be governed by the individual task orders. The Statement of Work in the RFP provides a broad overview of the work scope. Through its management and operation of FNLCR, the contractor will support the NCI mission to lead, conduct, and support cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives. FNLCR conducts research and provides research support for NCI Laboratories and Programs and other NIH Institutes and Centers, most notably the NIAID, as well as other government agencies.

The contractor's activities will further the FNLCR's three strategic program objectives, which are defined by NCI as:

- 1) Serving as a nucleus for large-scale projects that cannot easily be performed elsewhere or through other government mechanisms;
- 2) Supporting the intramural and extramural research components of NCI and NIH; and
- 3) Acting as a hub for technology development.

The contractor will provide or support a wide array of scientific operations and capabilities, including in the following areas:

- Advanced scientific computing and bioinformatics
- Animal sciences
- Assay development and execution
- Bioengineering
- Biospecimen processing
- Cell biology / Molecular Biology / Structural Biology
- Production of Biopharmaceuticals and Vaccine Clinical Materials
- Chemistry
- Drug Discovery and Development
- Imaging
- Nanotechnology
- Omics
- Pathology
- Repositories
- Virology

The contractor also will provide the standard business functions including facility operations and management, utilities operations, human resources, procurement, environmental protection, occupational health and safety, emergency management, property management, and legal.

Finally, the Statement of Work also contemplates that the contractor will perform Laboratory-Directed Exploratory Research to support seed studies proposed by FNLCR scientists. This program would be similar to the Laboratory-Directed Research and Development conducted at UC's DOE National Laboratories.

Standard FAR/HHSAR Contract Clauses – I Clauses

Section I of the RFP contains contract clauses incorporated from the federal regulations that will be incorporated into the final contract. The majority of contract clauses applicable to the FNLCR contract are provisions from the Federal Acquisition Regulations (FAR) and Department of Health and Human Services Acquisition Regulations (HHSAR). These FAR and HHSAR clauses are incorporated by reference or in full text in Section I. Additional FAR and HHSAR clauses may be added during negotiations with selected offeror.

Many of these I clauses are consistent with I clauses contained in the other National Laboratory M&O contracts, with which the University is well acquainted. These I clauses cover such topics

as cost reimbursement, property management, procurement, environmental protection, sustainability, labor standards, and contract changes and termination.

Nonstandard Contract Clauses – H Clauses

Section H of the final RFP contains proposed contract clauses that are not incorporated directly from the FAR or HHSAR. Roughly half of these 89 H clauses govern research-related topics such as human subjects, clinical trials, institutional review boards, human materials/specimens, data sharing, dual use research of concern, and animal welfare. The remaining H clauses pertain to a variety of other areas, including information technology, intellectual property, insurance, conflicts of interest, confidentiality and exchange of information, and health and safety. The research-related H clauses are viewed as fairly common in the context of NIH-sponsored research. Particular attention will be paid to negotiating and understanding the final H clauses prior to takeover of management in 2024.

Performance Guarantee

Under Clause H.74, NCI requires, as part of the bid, the submission of a performance guarantee from each parent company of the bidding special purpose entity (SPE). This requirement ensures that NCI has recourse to a viable entity in the event the SPE can no longer fulfill its contractual obligations. In essence, the SPE parent company will be liable for the SPE's obligations under the FNLCR contract. The University has executed similar guarantees in support of the M&O contracts for LANL and LLNL. The terms of the performance guarantee required to be signed by the University for FNLCR are no more onerous than the terms in the existing performance guarantees signed by the University for LANL and LLNL. The UC National Laboratories office maintains reserve funds to account for the risks associated with these performance guarantees.

Risk Profile of FNLCR Contract

Overall, the compliance, performance, and financial risks associated with the proposed the FNLCR contract are viewed as reasonable and manageable. There is heightened performance risk associated with taking over a new National Laboratory sponsored by a new customer agency with a new mission. However, the University is confident that, given its experience managing National Laboratories, its world class biomedical research enterprise, and proposed leadership team, it will be able successfully manage the transition and to execute the work scope in alignment with NCI's expectations. With respect to compliance risk, the contractual and regulatory requirements pertaining to research and operations are fairly standard in the context of the University's research and National Laboratory enterprise. An extended period between selection and takeover of management also gives the University ample time to understand and develop compliance strategies for the applicable requirements. With respect to financial risk, the cost allowability rules and cost reimbursement mechanisms are FAR-based and well understood. The available fee will be used in part to offset financial risks, including risks associated the performance guarantee. The mix of fixed fee and award fee elements will be spread out over dozens of task orders and thus the fee impact for any particular performance failure or noncompliance will likely be limited.

Overview of the Proposal Content and Process

Proposals responsive to the final RFP are due on February 21, 2023. The Proposal will consist of two volumes: Volume I – Technical Proposal and Volume II – Business Proposal.

Volume I contains the offeror's proposal for its technical and management approach to operating FNLCR, including the following sections:

- Technical approach section to discuss the offeror's biomedical scientific approach, organizational management approach, and facilities and operations approach;
- Key Personnel section to provide the qualifications for the proposed senior leadership team in the positions of Chief Executive Officer, Chief Medical Officer, Chief Scientific Officer, Chief Operating Officer, Director of Financial Operations, Director of Contracts and Acquisitions, Director of Human Resources, and Director of Facilities Management;
- Experience section to provide the offeror's organizational experience and facilities and operations experience;
- Transition Task Order to describe the offeror's approach to managing the transition from the current contractor to the new contractor; and
- Four Sample Task Orders to demonstrate the offeror's understanding of technical, scientific, and operational challenges posed by the hypothetical sets of requirements.

Volume I will be evaluated through a Scientific Peer Review by an expert panel convened by NCI. The peer review panel will be comprised of experts outside of NIH knowledgeable in the fields and disciplines under review, and will evaluate the proposals for technical and scientific merit in accordance with RFP's evaluation criteria.

The panel will also determine whether a proposal is technically acceptable, meaning that it demonstrates sufficient technical understanding and capabilities to perform the technical objectives set forth in the solicitation. If a proposal is not found technically acceptable by a majority of the panel members, then the proposal will not be considered further for award.

Volume II contains the offeror's business proposal. In this volume, the offeror sets forth its approach as to organizational structure, overall management, cost control, recruitment and retention, human resources management, subcontract management, and business planning. This volume also will contain the information on past performance and small business participation, as well as cost proposals for the Transition Task Order and 4 Sample Task Orders addressed in Volume I. Volume II will be evaluated by the Source Evaluation Board after completion of the Scientific Peer Review and only if Volume I is determined to be technically acceptable.

Selection of an offeror for contract award will be based on an evaluation of proposals against the following four factors in order of importance: technical, cost, small business participation, and past performance. The government intends to make an award to the offeror whose proposal provides the best overall value to the government.

It is currently anticipated that NCI will award the contract in early 2024 following a lengthy evaluation, selection, and negotiation period. The winning bidder is anticipated to take over management of FNLCR in late-2024 after a several-month transition period. Assuming all options are picked up, the contract would then run through 2049.

Key to Acronyms

| | |
|-------|---|
| DOE | Department of Energy |
| FAR | Federal Acquisition Regulations |
| FFRDC | Federally Funded Research and Development Center |
| FNLCR | Frederick National Laboratory for Cancer Research |
| HHS | Department of Health and Human Services |
| HHSAR | HHS Acquisition Regulations |
| IDIQ | Indefinite Delivery, Indefinite Quantity |
| LANL | Los Alamos National Laboratory |
| LLNL | Lawrence Livermore National Laboratory |
| M&O | Management and Operating |
| NIAID | National Institute of Allergy and Infectious Diseases |
| NIH | National Institutes of Health |
| NCI | National Cancer Institute |
| RFP | Request for Proposal |
| SPE | Special Purpose Entity |