

Draft_FFRDC Statement of Work

1.0 Introduction / Mission

The Frederick National Laboratory for Cancer Research (FNLCR) is a Federally Funded Research and Development Center (FFRDC), sponsored by the National Institutes of Health (NIH), and established in accordance with Federal Acquisition Regulation (FAR) 35.017. The purpose of the FNLCR is to provide a unique biomedical resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis, and treatment of cancer, HIV/AIDS, and other diseases.

As an FFRDC, the FNLCR has access to the National Cancer Institute (NCI), including access to Governmental and Non-Governmental sensitive and proprietary information, well beyond that which is encountered within the boundaries of a normal contractual relationship. This access facilitates the NCI in the planning, executing, assessing, and redirecting the policies, programs, and projects as necessary to meet the nation's needs. Accordingly, the Contractor must ensure that the public's interest is always placed above any corporate interest, and potential or actual organizational conflicts of interest are promptly identified and mitigated. The Contractor must ensure objectivity and independence in all technology, research, policy, and market matters.

The Contractor shall provide the intellectual leadership, management expertise, and scientific capability to accomplish the research and operational objectives assigned by the NCI to the FNLCR. Specific research and research support activities are executed through several mechanisms, including, but not limited to, strategic planning, program coordination, Government-Contractor cooperation and collaboration, and through a work request system utilized by NCI and NIH components. In the Contractor's planning, execution, and completion of work, work systems, work processes, and work execution must be communicated, coordinated and integrated with the NCI, NIH, and Department of Health and Human Services (DHHS) as appropriate and as required by the Government. As part of the Contractor's stewardship of the laboratory, it is expected that the Contractor maintain relationships with the broader research community to enhance the intellectual vitality and research relevance of the laboratory, and to bring the best possible capabilities forward as it pertains to the FNLCR mission needs through partnerships.

Inasmuch as the assigned objectives and activities of the FNLCR are dynamic and subject to continuing evolution, this Statement of Work is not intended to be all-inclusive or restrictive. It is intended to provide a broad framework and general scope of the work to be performed at the FNLCR during the contract term.

Any references to specific programs or objectives in this Statement of Work do not reflect commitments, obligations, or implications, for funding those programs or objectives. All projects or programs are authorized by the NCI in accordance with the terms and conditions of the contract.

2.0 Performance Goals, Objectives, and Outcomes

This contract is set forth such that the Contractor is responsible and accountable for the planning, execution, completion, assessment, and delivery of all work. The Contractor is responsible for furnishing corporate leadership, and FNLCR scientific, management, analytical, technical, and support personnel with the requisite experience and expertise to conduct all FNLCR activities and operations with distinction. Moreover, the Contractor will assure compliance with all Standards, Policies, Regulations, Licenses, Certifications and Accreditations as required by the Government.

The Contractor is provided the freedom to exercise innovation and creativity to achieve the mission and operational results expected of the FNLCR in exchange for full accountability for the FNLCR's performance within the parameters of the contract. It is the responsibility of the Contractor to develop and implement innovative approaches and adopt practices which foster continuous improvement in accomplishing the FNLCR mission. This includes an emphasis on the utilization and application of robust project management processes, including post-implementation reviews.

To that end, the Contractor shall implement appropriate program and project management systems to track progress and pursue cost-effectiveness in work activities. This includes but is not limited to: the development of integrated plans and schedules to achieve program objectives, seeking input from stakeholders, maintaining sufficient technical expertise to accomplish the work and manage activities/projects throughout the project/program lifecycle, maintain FNLCR infrastructure and facilities, and utilize appropriate technology and management systems to improve cost efficiency, performance, and which accommodate urgent and shifting priorities.

3.0 Statement of Work (SOW)

The Contractor shall conduct Government initiated collaborative research and research support, Government initiated Contractor executed projects, and Contractor initiated and executed projects. Additionally, the Contractor shall provide research and research support for NIH entities and other federal agencies as authorized. All sponsored work shall be within the purpose of the FNLCR.

This research and research support shall encompass a wide range of scientific disciplines that may include for example, but shall not be limited to: (i) analytical and biomolecular chemistry; (ii) biochemistry; (iii) immunology, including clinical immunology and patient monitoring; (iv) molecular biology and related molecular technologies, including genotyping, gene sequencing, gene expression and protein production; (v) genetics, including epidemiological studies; (vi) virology, including virus production and diagnostics; (vii) structural biology; (viii) biophysics; (ix) cell biology; (x) microscopy; (xi) laboratory animal medicine, including diagnostic microbiology, animal health diagnostics, characterization of the immune response repertoire in animal models (including NHPs), toxicology, challenge studies, pathology, and targeted genome

editing; (xii) *in vivo* and *in vitro* cancer and viral therapeutics; (xiii) advanced scientific computing and bioinformatics; (xiv) molecular targets and assay development; (xv) advanced and emerging technologies including but not limited to nanotechnology and advanced scientific computing; (xvi) small animal imaging; (xvii) clinical studies support including but not limited to regulatory management, monitoring and oversight, site selection, study implementation, and data management/analysis, clinical trials monitoring, management and regulatory affairs for clinical research efforts; (xviii) cGMP production, cGMP manufacture of clinical materials, including product/process development and support activities, technology transfer and research, development and IND enabling preclinical/GLP toxicology support; (xix) repositories, (xx) protein/hormone detection and quantification; (xxi) molecular profiling/-omics technologies; (xxii) nucleic acid extraction; (xxiii) human pathology; (xxiv) histotechnology services; and (xxv) histology imaging.

3.1. Research and Research Support Programs, Projects, and Activities

3.1.1. Satellite Research Centers and Special Projects

The Contractor shall provide support to domestic and/or international research/research support centers and support to domestic and/or international special projects as required by the government.

3.1.2. Clinical Research and Research Support

The Contractor shall provide research and research support for laboratory and clinical investigations to the NCI, other NIH Institutes and Centers (ICs) and other government agencies in the areas including but not limited to cancer, HIV/AIDS and other diseases. For example, this will include, but not be limited to, planning, conducting and supporting clinical studies including staffing, site selection, regulatory support of clinical research, monitoring via laboratory tests and other assays, including but not limited to: flow cytometry, histotechnology, and imaging. Staffing includes and involves, but is not limited to: patient care coordination, provision of patient care through physicians, physician extenders and nurses. In addition, activities may include cGMP process development, process transfer, and pilot production of experimental therapeutics and vaccines, manufactured under cGMP requirements.

All work shall follow all regulations, policies, Federal Drug Administration requirements, and international regulatory requirements. Support may be provided as a shared service to multiple groups or as a dedicated service to a specific group.

3.1.3. Basic and Translational Research and Research Support

The Contractor shall provide basic and translational research and research support to the NCI, other NIH ICs and other government agencies. Areas of research and research support may include cancer, HIV/AIDS and other diseases. Examples of support

activities may include research, technical support, laboratory management, administrative support, and project management.

3.1.4. Animal Research and Research Support

The Contractor shall provide animal research and research support. This includes activities in support of animal care and use, such as animal safety oversight and animal use protocol establishment and management. In addition, the Contractor shall provide personnel and expertise for laboratory animal medicine, including acquisition and holding, technical and health diagnostic support to the NCI/NIH principal investigators and programs at NCI-designated locations.

The Contractor shall provide scientific and technical expertise for animal modeling experimentation. Examples of expertise may include but are not limited to: generation of genetically engineered animals, cryopreservation, histology, pathology, and small animal imaging.

3.1.5. Advanced Technologies

The Contractor shall research, evaluate, recommend, develop, implement, and apply advanced technologies, in support of government research initiatives, projects and programs as required. Areas of support may include, but are not limited to, nanotechnology, genomics, high performance computing research informatics, antibodyomics, proteomics, metabolomics, and development and application of advanced imaging technologies. Specific genomic approaches may include: gene expression, methylation, and miRNA.

3.1.6. Repository Operation

The Contractor shall provide technical expertise in the operation and cost control of repositories at various locations and will provide facilities as needed. Oversight of repository operations will be provided by the Repository Quality Board (or equivalent oversight committee) comprised of both Government and Contractor personnel.

3.1.7. Information Systems, Information Technologies, and Data Science

The contractor shall research, evaluate, recommend, develop, implement and manage information systems and services in support of government research initiatives, projects, and programs. These systems and services shall include, but not be limited to, data science (bioinformatics, biostatistics); computer services (desktop computer and user support); web development; software training; systems development, implementation, and support (including enterprise wide solutions supporting science and business operations); data warehousing; data center operations (server system support, storage support, batch operations, data center consolidation support; data center security);

database administration; network management and operations support; telecommunications; and information / computer security. The contractor shall provide project management resources and use project management best practices (PMI, HHS EPLC, ITIL, and Agile) to deliver full project management life-cycle solutions on all IT projects.

3.1.8. Technology Transfer Program

The Contractor shall establish, as appropriate, research and development partnerships with industry that capitalize on the Contractor's expertise and facilities in support of the FFRDC. Cooperation with industry partners may include long term strategic partnerships aimed at the commercialization of FNLCR inventions. The Contractor is encouraged to develop and capitalize on productive relationships with regional and local organizations, including companies and educational institutions, and through forums such as conferences, workshops and presentations.

Principal mechanisms for facilitating these partnerships include: contractor cooperative research and development agreement (cCRADA) pursuant to 15 U.S.C. 3710(a), material transfer agreement (MTA), beta-testing agreement, collaboration agreement, and technical service agreement (TSA). Under cCRADAs, the Contractor, as appropriate, is responsible for collecting and managing cCRADA funds from research partners, as well as, managing patents, licenses, and royalties resulting from inventions developed under cCRADAs.

The Contractor may also provide scientific support under government technology transfer agreements in direct support of the specific government initiatives and activities within the scope of the FNLCR.

3.1.9. Other Laboratory Support

The Contractor shall provide additional laboratory support including but not limited to: (i) glassware services and associated special processing services for glassware; and (ii) laundry services for reusable laboratory apparel.

3.2. Facility Operations

3.2.1. Environment, Health and Safety

The Contractor is responsible for the safety and health of workers and the public, and for the provision of a safe and healthful environment.

The Contractor is responsible for establishing and maintaining effective management systems to identify deficiencies, resolve them in a timely manner, ensure corrective

actions are implemented (addressing the extent of conditions, root causes, and measures to prevent recurrence), and prioritize and track commitments and actions.

Elements of the program may include, but are not limited to: (i) accident reports and trend analysis; (ii) emergency response management/preparedness; (iii) OSHA compliant exposure monitoring/control; (iv) Institutional Animal Care and Use Committee (IACUC) liaison; (v) inspection program; (vi) respiratory protection and air quality evaluation program; (vii) risk assessment program (industrial, chemical, and biological); (viii) monitoring of select agents; (ix) biological control program and a radiation safety program compliant with the site specific radioactive material use licenses; and (x) OSHA training program; (xi) facilitate AAALAC accreditation; (xii) perform ES, EIS as applicable; (xiii) provide institutional biosafety and biosafety officers.

3.2.2. Occupational Health Services

The Contractor shall be responsible for the health and safety of workers. Activities include for example, but are not limited to: (i) emergency treatment; (ii) emergency care training; (iii) treatment of work related injuries and illnesses; (iv) preventative health care programs; (v) fitness for duty evaluations and work termination physical examinations; (vi) clinical and hematological screening tests; and (vii) the preparation and maintenance of any health records, OHS program manuals, and the operation of the Employee Assistance Program; (viii) provide medical surveillance program.

3.2.3. Facilities' Maintenance and Engineering

Maintenance plans shall be compatible with elements of the current Interagency Agreement including any revisions thereto, between the U.S. Army Garrison (USAG), Fort Detrick, and the NCI at Frederick with the Contractor performing those functions designated as being the responsibility of the NCI at Frederick. Examples of services to be provided include, but are not limited to: (i) start up, maintenance, repair, and operation of all buildings and their utilities systems, including the animal research facility (vivarium); (ii) modifying or rearranging laboratory or administrative spaces to make them functional as the NCI or occupants require to meet all applicable local, national codes and the BMBL, DRM (as instructed by the Government); (iii) modification, repair, calibration, and installation of special research equipment; (iv) general housekeeping; (v) general groundskeeping for NCI at Frederick property and any Contractor-leased facilities, to include, but not limited to, landscaping, preventative surface treatments (i.e. salting), and snow removal and other appropriate surface treatments ; (vi) maintenance of roads and surfaces for NCI at Frederick property; and (vii) A/V telecommunication installation and repairs. The Contractor shall be responsible for daily maintenance services requests including emergency services after normal working hours, weekends, and holidays.

3.2.4. Security Program

The Contractor shall be responsible for the establishment and maintenance of a security program at the FNLCR, which encompasses the assurance of safety and security for infrastructure, personnel, animals, equipment, materials, and other vital components, as well as crime prevention services, employee safety education programs, and other emergency programs/plans as appropriate. The Contractor shall perform risk assessment as required by the ISC Guideline, where applicable.

3.2.5. Emergency Management/Preparedness

The Contractor shall maintain an emergency management program that encompasses laboratory activities and infrastructure, to include emergency planning, preparedness, response, and readiness assurance procedures, elements of which inform the Continuity of Operations Program (COOP). Additionally, the program shall contain an occurrence notification and reporting system.

3.2.6. Transportation and Logistics Services

The Contractor shall provide shuttle services and personnel transportation on a scheduled basis. The Contractor shall also provide transportation as requested to support the transportation of personnel, animals, biological specimens, select agents, and other materials as required.

The Contractor will also be responsible for fleet management, providing maintenance and management services for NCI at Frederick Government vehicles. The Contractor shall be responsible for the establishment, operation, and maintenance, of a mail and courier service center, including incoming and outgoing mail and shipments, as well as courier services from internal personnel and external organizations.

The Contractor shall be responsible for the establishment, operation, and maintenance of a warehouse and distribution center.

3.2.7. Cafeteria Services

The Contractor shall be responsible for the operation and maintenance of the on-site cafeteria. The Contractor shall meet business and industry standards of quality and nutrition, and comply with and support the 1990 and all subsequent revisions of U.S. Dietary Guidelines. Licenses and permits shall be obtained as required by State and local authorities, and all applicable building, health, sanitary, and other regulations and laws shall be observed. The contractor shall secure and maintain insurance, and maintain records as appropriate.

3.2.8. Library Services

The Contractor shall provide library support services to the Scientific Library including but not limited to: access services, digitization and digital library support, scientific research and instructional outreach, cataloging and collection management, purchasing

and maintenance of hard copy and digital subscriptions, maintain an interlibrary loan program, and provide specific scientific research and research support as requested.

3.2.9. Other Administrative/Support Services

The Contractor shall provide additional administrative and support services to include: (i) publications, graphic arts, photography, and illustration services and resources; and (ii) conference/meeting/seminar services and associated facility management services.

3.3. Business Operations and Management

The Contractor shall manage and administer a system of internal controls for all business and administrative operations. Management of the FNLCCR business and administrative operations including, but not limited to, establishing internal controls across the FNLCCR, as necessary, and implementing business processes which are risk-based, cross-functional, cost effective, optimize and streamline operations, increase efficiency, and enhance productivity.

In support of the FNLCCR, the Contractor shall maintain electronic business/information systems for organizational operations and for activities involving general purpose data collection, data processing, and report generation. The Contractor also shall maintain a comprehensive records management program.

3.3.1. Human Resources Management

The Contractor shall establish and maintain electronic human resource systems which attract and retain outstanding employees and promote workforce diversity. The Contractor shall conduct comprehensive pre-employment screening as part of its strategic human capital management system.

3.3.2. Financial Management

The Contractor shall maintain and operate an electronic financial management system responsive to the obligations of sound financial stewardship and public accountability. The overall system shall include an integrated accounting system suitable to capture, record, and report financial activities in a timely manner; a budgeting system which includes the short and long term forecasting of all resource requirements needed to accomplish projected missions; an internal control system for all financial and other business management processes, including the tracking and expenditure of funds obligated under the contract; and a disbursements system for both employee payroll and other supplier payments. The establishment of an internal audit program is also required as referenced herein Section 3.3.8.

3.3.3. Purchasing System

The Contractor shall have an approved electronic purchasing system to provide purchasing support and subcontract administration, including subcontract pre-award and post-award reviews.

3.3.4. Acquisition Services/Purchasing Management

The Contractor, in accordance with approval requirements set forth in the contract, may enter into subcontracts for the performance of any part of the work under this Contract. The Contractor will be responsible for the establishment, execution, and administration of: subcontracts, leases, consultant agreements, purchase orders, maintenance service agreements, and other agreements as required or identified as appropriate.

Additionally, the Contractor shall strive to promote diversity in all of the FNLCR's subcontracting efforts with emphasis on the use of the types of businesses identified in the Small Business Subcontracting Plan, incorporated into this Contract.

3.3.5. Property Management

The Contractor shall maintain an approved electronic property management system, which provides assurance that Government owned, Contractor held property is accounted for, safeguarded, and disposed of. The Contractor's system must account for the control, use, preservation, protection, repair, and maintenance of all Government property in its possession.

The Contractor shall be responsible for space portfolio management. Physical space shall be documented, maintained, and inventoried using the NCI standard computer aided facility management software (CAFM), space shall be calculated using national Building Owners and Managers Association (BOMA) standards.

3.3.6. Project and Strategy Management

The Contractor shall maintain an electronic project management system to establish appropriate monitoring of project scope to ensure projects are completed within cost, schedule, and performance expectations, and supports the utilization of standard project management practices. The system shall include an earned value management system.

The Contractor shall maintain a formal method for strategic planning and management which includes phases of analysis, assessment, formulation, execution, and evaluation/sustainment, as it pertains to the FNLCR and to Contractor-initiated and Contractor-executed projects and initiatives, as appropriate. The Government maintains responsibility for the strategic planning of Government initiatives.

3.3.7. Legal Resources

The Contractor shall maintain legal support/resources for all contract activities including, but not limited to, those related to patents, licenses, and other intellectual property rights;

subcontracts; technology transfer; environmental compliance and protection, labor relations; and litigation and claims.

3.3.8. Audits and Assessments

The Contractor shall establish, maintain, and routinely execute an audit program which provides capabilities for internal and subcontractor audits, supporting external audits, reviews, and appraisals.

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