

Pre-solicitation Non-competitive (Notice of Intent) Synopsis

Type: Pre-Solicitation

Notice Number: 75N92019R001 - NOI

Title: National Ferret Resource and Research Center Requirement

Classification Code: 88 – Live Animals

NAICS Code: 112990

Is this a Recovery and Reinvestment Act Action: No

Response Date: May 03, 2019

Primary Point of Contact: Cornelius Moore

INTRODUCTION

THIS IS A PRE-SOLICITATION NON-COMPETITIVE (NOTICE OF INTENT) SYNOPSIS TO AWARD A CONTRACT WITHOUT PROVIDING FOR FULL OR OPEN COMPETITION (INCLUDING BRAND-NAME).

This acquisition is conducted under the authority of 41 U.S.C. 253(c) under provisions of the statutory authority of FAR subpart 6.302-1.

The National Heart, Lung, and Blood Institute (NHLBI) intends to negotiate and award a contract without providing for full and open competition (including brand-name) to University of Iowa for the National Ferret Resource and Research Center on Lung Disease. It is anticipated that one award will be made around September 2019 for a period of five (5) years. THIS IS A SYNOPSIS. THIS IS NOT A SOLICITAION.

BACKGROUND AND PROGRAM OBJECTIVES

Due to various similarities with the human pulmonary system, including the ability to cough, ferrets have been used for many years as a model for respiratory infections. Using somatic cell nuclear transfer techniques, the ferret system was converted from solely an infectious disease model into a genetic model through generation of the first ferret cystic fibrosis knockout. Since then, the ferret has been used in many lung disease studies, and multiple genetically modified animals have been generated that will enable lung disease research. The advent of CRISPR/Cas9 technology is enabling more specific knockout and transgenic lines. This resource has partnered with over sixty academic researchers, as well as at least eight companies, many of which are interested in drug development, and has distributed over 1,000 ferret samples. It has popularized the ferret model as a model of choice for cystic fibrosis and there is a great deal of growing interest in ferrets as a possible model system for other lung diseases such as alpha-1-antitrypsin deficiency. Work for the National Ferret Resource and Research Center on Lung Disease is currently performed under a NHLBI grant.

The purpose of this resource is to generate and distribute ferret animal models of genetically based lung diseases, in particular, but not limited to, various genotypes that are associated with cystic fibrosis. There are three parts to this resource: 1) distribution of existing cystic fibrosis ferret resources and facilitation of their usage, 2) creation of additional CFTR-mutant and other genetic ferret models relevant to the NHLBI mission, as requested by the external community, and 3) creation of a centralized repository for reagents and information needed for a ferret resource.

It is anticipated that one contract award will be made. The award will comprise of a twelve (12) month base with four (4) consecutive twelve (12) month options.

Options	Anticipated Dates
Base Period	September 20, 2019 – September 19, 2020
Option Period 1	September 20, 2020 – September 19, 2021
Option Period 2	September 20, 2021 – September 19, 2022
Option Period 3	September 20, 2022 – September 19, 2023
Option Period 4	September 20, 2023 – September 19, 2024

PROJECT REQUIREMENTS

Throughout the period of performance, the Contractor shall work cooperatively with the NHLBI Contracting Officer's Representative (COR) in all relevant aspects of study development and execution. The Contractor shall designate key personnel, including a principal investigator, to lead and manage the study. The investigators shall have the following experience: (1) training and experience in generating genetically modified ferrets and/or cystic fibrosis; (2) developing various operating procedures and further animal modifications to ensure the survival and breeding of animals; and (3) determining whether the animal properly models disease, use the animal to study the pathobiological mechanisms of the disease, and use the animals to test potentially therapeutic drugs.

The Contractor shall:

Task Area A - Core Resource Maintenance Task

1. The contractor shall accomplish a smooth, efficient, and orderly transition for the contract work at the start of the contract.
2. The contractor shall provide administrative support through dedicated staff who manage scientific, fiscal, and regulatory aspects of maintaining the animals and other aspects of the resource.
3. The contractor shall adhere to the treatment of animals in accordance with IACUC (Institutional Animal Care and Use Committee) guidelines, as well as all local, state, and Federal guidelines.

4. The contractor shall provide colony maintenance services including dedicated personnel to perform daily health checks and weekly examination of research and donor/normal animals.
 - a. Maintenance services shall include provision of general preventative health and well-being services to all animals.
5. The contractor shall assist the COR in identifying and establishing collaborations with non-NHLBI scientific groups throughout the contract period to increase the visibility of the ferret resource. The contractor shall disseminate information to raise awareness of the resource to the lung disease research community.
 - a. The dissemination plan shall include participation of the contractor at national and international scientific meetings on lung diseases and cystic fibrosis.
6. The contractor shall create, and regularly maintain for the life of the contract, a Manual of Procedures (MOP) describing processes and methodologies to be employed for animal care, investigator and NHLBI staff communications, protocol development, execution and management.
7. The contractor shall develop and maintain a public-facing website to communicate information about the ferret resource including but not limited to the mission and features of the program and the process for applying for services.
8. The contractor shall develop a private electronic application receipt and review process, for requests of animals, tissues, or biospecimens, that is accessed through the public-facing website, as well as a system for monitoring the workflow and status of the application process. The code for the website shall be open source, Section 508 compliant, compliant with all NIH/HHS/Federal security policies, and made available at the discretion of the COR.
9. The contractor shall develop a private electronic application receipt process, for requests of new genetically modified animals, that is accessed through the public-facing website, as well as a system for monitoring the workflow and status of the application process. The code for the website shall be open source, Section 508 compliant, compliant with all NIH/HHS/Federal security policies, and made available at the discretion of the COR.
10. The contractor shall establish and maintain an External Advisory Committee (EAC) that will review applications for new genetically modified ferrets. The EAC will meet regularly on a scheduled agreed on by the contractor and COR and transmit review results to the contractor.
11. Taking into account feedback from the EAC, the contractor shall work with the COR to choose new genetically modified ferrets to generate.
12. The contractor will maintain breeding ferrets of previously generated ferret models.
13. The contractor shall provide ferrets, ferret tissues or biospecimens, and ferret scientific reagents for NHLBI approved projects.

14. The contractor shall provide the necessary data management system(s), informatics and statistical support and staff to coordinate, process and track in an efficient manner all requests received through the website following the procedures established in conjunction with the NHLBI COR and documented in the MOP.
15. The contractor shall maintain, in a secure and confidential manner, an electronic database of all research requests received, including the name of the requesting investigator; the related NIH grant number or other means of support; the name and brief description of the project; information on quality control and quality assurance methods employed when applicable; the ferret genetic background, age, sex, and other pertinent information, when applicable; the tissues or biospecimens supplied when applicable; and the relevant number of animals or specimens supplied. These records shall be complete, accurate, legible, well-organized, and comprehensive. Submit data as defined and called for in the MOP.
16. The contractor shall maintain a repository of reagents and other resources, including molecular biology reagents and genetic information, to enable the use of ferrets in lung disease research.
17. The contractor shall offer support to investigators that will enable facilitation of usage of animals, tissues, or biospecimens. This may include sharing MOPs and protocols, offering animal care advice, and sharing other research resources maintain in the reagent repository.
18. The contractor shall participate, as necessary, in teleconference and meetings with the requesting investigator, NHLBI staff, and other federal agency staff members (e.g., staff from other NIH ICs or the FDA) as applicable.
19. Prepare and submit on a regular basis (e.g., semi-annually) status reports on all projects.
20. The contractor shall maintain a listing of publications and presentations that were supported by work performed by the ferret resource. .

Task Area B - Core Scientific Projects

The services include generation and characterization of new genetically modified ferrets. The specific activities to be performed will vary depending on the nature of the project and the services needed. The exact number of projects to be conducted will depend upon various factors including the methods of genetic manipulation used and particular requirements for the care, including veterinary care, and appropriate breeding of the modified animals for the experimental requirements.

1. With advice from the EAC and NHLBI, the contractor shall generate new genetically modified ferrets models that will provide utility for the lung disease research community.
2. The contractor shall breed sufficient new modified ferrets to fulfill the needs of the scientific community, and distribute ferrets and tissues as appropriate.

3. The contractor shall acquire and establish procedures and protocols for animal-care related or laboratory techniques, veterinary procedures or imaging studies needed to support the care, maintenance and evaluation of current and/or new ferret models.
4. The contractor shall adhere to the treatment of animals in accordance with IACUC (Institutional Animal Care and Use Committee) guidelines, as well as all local, state, and Federal guidelines.

CLOSING STATEMENT

This synopsis is not a request for competitive proposals. However, interested parties may identify their interest and capability to respond to this notice. Responses to this notice shall contain sufficient information to establish the interested parties bona-fide capabilities for fulfilling the requirement, addressing each project requirement separately. The response should also include: 1) the total number of employees; 2) the professional qualifications of scientists, medical experts, and technical personnel as it relates to the above outlined requirements; 3) a description of general and specific facilities and equipment available, including computer equipment and software, 4) an outline of previous research projects that are similar to the project requirements in which the organization and proposed personnel have participated, and 5) any other information considered relevant to this program.. All offerors must have an active registration in the System for Award Management (SAM) www.sam.gov.

A determination by the Government not to compete this proposed contract 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 of determining whether to proceed on a non-competitive basis or to conduct a competitive procurement.

All responses must be received by the closing date on this notice and must reference the solicitation number. Responses may be submitted electronically in accordance with the instructions below.

"All responsible sources may submit a capability statement, proposal, or quotation, which shall be considered by the agency."

Submission Instructions:

Interested parties shall submit capability statements via the FedConnect web portal (www.fedconnect.net) and reference the FedConnect Pre-solicitation Number 75N92019R001. The due date for receipt of statements is 3:00 p.m. Eastern Time on May 03, 2019. Vendors can register with FedConnect at <https://www.fedconnect.net/FedConnect/default.htm>.

Please note that FedConnect is used by multiple federal agencies and therefore FedConnect assistance will be provided by Compusearch Software Systems, not the NHLBI OA. More information about registration requirements can be found by downloading the FedConnect

Ready, Set, Go! Guide at

https://www.fedconnect.net/fedconnect/Marketing/Documents/FedConnect_Ready_Set_Go.pdf.

For assistance in registering or for other FedConnect technical questions please call the FedConnect Help Desk at (800)899-6665 or email at support@fedconnect.net. Please use the Contracting Officer/ Contract Specialist contact information provided, should you require a waiver not to use FedConnect for submitting.

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