

## Notice of Intent to Sole Source - DUNCAN E TEBOW

The Food and Drug Administration (FDA) intends to award a Sole Source firm-fixed price purchase order to Duncan E. Tebow, 9811 CAPITOL VIEW AVE, SILVER SPRING MD 20910-1031, in accordance with the authority under FAR Part 13.501(a). This procurement is being conducted under simplified acquisition procedures in accordance with FAR Parts 12 and 13, including subpart 13.5. The NAICS code is 238990 - All Other Specialty Trade Contractors.

The White Oak Animal Program (WOAP) is responsible for ensuring that the animal facility in Building 10 on the U.S. Federal Drug Administration's (FDA) White Oak (WO) campus functions in conformance with applicable laws, policies and guidelines that govern the humane care and use of animals used in biomedical research. The facility is registered with the United States Department of Agriculture (USDA), has a current assurance on file with the National Institutes of Health's (NIH) Office of Laboratory Animal Welfare, and is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

The Institutional Official (IO) of the WOC IACUC and the WOC AP is required by law to ensure a nonaffiliated member is appointed to its IACUC. The Center for Biologics Evaluation & Research (CBER) Director is the IO and appoints the nonaffiliated member. The nonaffiliated member is an individual who represents general community interests in the proper care and use of animals, is not a laboratory animal user, and is not affiliated, nor has an immediate family member who is affiliated with FDA, CBER, and the WOAP. The Guide for the Care and Use of Laboratory Animals is a reference utilized by AAALAC when it assesses animal facilities for accreditation. The guide advises that the non-affiliated member (referred to as contractor from this point forward) may receive a modest stipend for ancillary expenses, and the WOAP chooses to adopt this practice.

This notice is not a request for competitive quotes. However, any party that believes it is capable of meeting the requirements as stated herein may submit a written response, i.e. capability statement, which clearly supports and demonstrates its ability to perform the requirements. Any response shall be received by the response date and time of this notice. Any response shall undergo review to determine if it can meet the requirements. A determination by the Government not to compete this proposed requirement based upon a response to this notice is solely within the discretion of the Government.

Response Date: 10:30 a.m. ET on December 11, 2021. Responses must be emailed to Bonnie M. Amond at [bonnie.amond@fda.hhs.gov](mailto:bonnie.amond@fda.hhs.gov) with a cc to James G. Whitt at [james.whitt@fda.hhs.gov](mailto:james.whitt@fda.hhs.gov).

**Statement of Work  
Nonaffiliated Member of the White Oak (WO)  
Institutional Animal Care and Use Committee (IACUC)**

**Background**

The White Oak Animal Program (WOAP) is responsible for ensuring that the animal facility in Building 10 on the U.S. Federal Drug Administration's (FDA) White Oak (WO) campus functions in conformance with applicable laws, policies and guidelines that govern the humane care and use of animals used in biomedical research. The facility is registered with the United States Department of Agriculture (USDA), has a current assurance on file with the National Institutes of Health's (NIH) Office of Laboratory Animal Welfare, and is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

The Institutional Official (IO) of the WOC IACUC and the WOC AP is required by law<sup>1</sup> to ensure a nonaffiliated member is appointed to its IACUC. The Center for Biologics Evaluation & Research (CBER) Director is the IO and appoints the nonaffiliated member. The nonaffiliated member is an individual who represents general community interests in the proper care and use of animals, is not a laboratory animal user, and is not affiliated, nor has an immediate family member who is affiliated with FDA, CBER, and the WOAP. The Guide for the Care and Use of Laboratory Animals<sup>2</sup> is a reference utilized by AAALAC when it assesses animal facilities for accreditation. The guide advises that the non-affiliated member (referred to as contractor from this point forward) may receive a modest stipend for ancillary expenses, and the WOAP chooses to adopt this practice.

**Objectives/Scope**

The objective of this purchase order is to provide reimbursement for the contractor's ancillary expenses as a stipend in order to provide services and attend monthly IACUC meetings and site visits, program reviews and/or facility inspections. This is not for reimbursement of time and/or salary, as that would make the contractors affiliated with the Institution, which would not be in compliance with the USDA Animal Welfare Act laws and regulations, or this acquisition.

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<sup>1</sup> 9 CFR (Animal Welfare Act) Ch.1 Section 2.31.b.3.ii; Public Health Policy (PHS) IV.a.3.b.4; USDA/Animal Public Health Inspection Service (APHIS) Animal care Policy #15.

<sup>2</sup> Eighth edition, National Research Council, Institute for Laboratory Animal Research, 2011 pp. 24-25.

## **Tasks and Delivery**

Under this statement of work, the contractor shall:

- Attend at least 80% of the monthly meetings;
- Review protocols, policies and other documents that pertain to the animal care and use program, and provide comments and engage in discussions during the monthly meeting on materials reviewed;
- Participate in semiannual program reviews/facility inspections;
- Complete all required training, primarily on-line but occasionally on-site maybe required (registration fees to be paid by the government/WOC AP);
- Attend and participate in the triennial AAALAC International accreditation site visit.

The FDA shall provide the contractor with electronic copies of protocols, policies, and other documents that pertain to the animal care and use program. The contractor will be provided draft copies of these materials for review and comment.

## **Security**

The IACUC meetings are held at the FDA's WO campus or virtually, and the contractor shall attend each meeting in person, whenever possible and safe to do so, based on current FDA and IACUC guidance. When attending in person, the contractor shall check in at a security check point, register as a visitor, and follow the visitor security screening process. The contractor will be escorted to and from the meeting location by an IACUC member or IACUC Administrator and will be accompanied at all times by an IACUC member or IACUC Administrator when participating in facility inspections.

## **Confidentiality**

The Contractor shall treat as confidential all business and proprietary information of the FDA in connection with the Services provided in the Statement of Work or becoming known to Contractor as a result of entering into this Agreement or performing the Services requested hereunder, including without limitation, information relating to FDA. Contractor shall not use or duplicate any material containing Confidential Information, except in the direct performance of the Services. Contractor shall return all materials that FDA provides under this Agreement upon request or upon termination of this Agreement.

## **Place of Performance**

At the contractor's site/home; and at 10903 New Hampshire Avenue, Building 10, 32, 52/72, 71, or 75, Silver Spring, MD 20993, where WOAP IACUC meetings are held and when the non-affiliated member participates in facility inspections.

**Period of Performance**

The period of performance of this purchase order will consist of one (1) 12-month base year and two (2) 12-month option years.

12/10/2021 – 12/09/2022 Base Year

12/10/2022 – 12/09/2023 Option Year 1

12/10/2023 – 12/09/2024 Option Year 2

**Type of Contract**

This purchase order is firm-fixed price (FFP).