



Small Business Sources Sought Notice ASPR/BARDA Contract Research Organizations for Nonclinical Studies (BIO)

Sources Sought Notice No.: SS-BARDA-2015-BIO-Nonclinical_Development_Network-001A

I. INTRODUCTION

The purpose of this Small Business Sources Sought Notice (SBSSN) is to seek declarations of technical capabilities, data, and materials from qualified small business concerns [including Small Disadvantaged Businesses (SDB), Woman-owned Small Businesses (WOSB), Historically Underutilized Business Zone (HUBZone), Small Businesses, Veteran-Owned Small Businesses (VOSB), Economically Disadvantaged Woman-Owned Small Business (EDWOSB) and Service-Disabled Veteran-owned Small Businesses (SDVOSB)]. The Office of the Assistant Secretary for Preparedness and Response (ASPR) intends to provide maximum practicable opportunities in its acquisitions to all types and categories of small businesses. The proposed NAICS (North American Industry Classification System) for this proposed requirement is 541711.

Please note that an Other Than Small Business Sources Sought Notice (OTSBSSN) will also be posted regarding this possible requirement, and is intended solely for prospective offeror's that are considered to be Other Than Small Business. Prospective offeror's should respond to the appropriate SSN relative to their business size standard.

II. AUTHORITY

The Office of Acquisitions Management, Contracts and Grants (AMCG) issues this Small Business Sources Sought Notice (SBSSN) on behalf of the Biomedical Advanced Research and Development Authority (BARDA) pursuant to FAR paragraphs 5.205(c), 15.201(e) and FAR parts 10, 19.

III. ACRONYMS

“AMCG” means Acquisition Management, Contracts, and Grants
“ASPR” means Assistant Secretary for Preparedness and Response
“BARDA” means Biomedical Advanced Research and Development Authority
“BIO” means Biological
“CBRN” means Chemical, Biological, Radiological, and Nuclear
“CRO” means Contract Research Organization
“FAR” means Federal Acquisition Regulation
“FDA” means the U.S. Food and Drug Administration
“GLP” means Good Laboratory Practices
“HHS” means the U.S. Department of Health and Human Services
“NAICS” means North American Industry Classification System
“Notice” means this Sources Sought Notice and Request for Information
“OTSBSSN” means Other Than Small Business Sources Sought Notice
“PHEMCE” means the Public Health Emergency Medical Countermeasures Enterprise
“SBSSN” means Small Business Sources Sought Notice
“USG” means United States Government

IV. PURPOSE

This notice seeks declarations of technical capabilities, data and materials from the public on current Good Laboratory Practice-compliant research organizations that are capable of managing nonclinical animal model development studies in Biological (BIO) medical countermeasures. The Office of the Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), intends to use responses to this Notice for planning potential future acquisitions. BARDA will not award any contracts under this Notice, but rather availabilities, capabilities, and other pertinent marketplace data to strengthen BARDA's understanding of the current and future marketplace, enhance its ability to obtain quality services economically, efficiently and lawfully and establish potential vendor source files and listings.

V. BACKGROUND

The Office of the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS) intends to use responses to this Small Business Sources Sought Notice (SBSSN) for planning purposes towards the possible procurement of services from Contract Research Organizations (CROs).

The Department of Health and Human Services through the Biomedical Advanced Research and Development Authority (BARDA) requires the development of animal models for the development of medical countermeasures for Chemical, Biological, Radiological, Nuclear (CBRN); Influenza; and Emerging Infectious Diseases. The mission and priorities of the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) are articulated in the PHEMCE Implementation Plan <https://www.medicalcountermeasures.gov/media/9035/2012-phemce-strategy.pdf>

The Pandemic and All-Hazards Preparedness Act, signed into law on December 19, 2006 and reauthorized in March 2013, codifies HHS as the lead of Federal public health and medical response to public health emergencies and National Response Plan incidents and specified that one of the duties of the HHS Assistant Secretary for Preparedness and Response is to oversee advanced research, development, and procurement of qualified countermeasures and qualified pandemic or epidemic products. Section 319L (a)(6): Advanced Research and Development subsection (b) "activities includes": ii) Design and development of tests or models, including animal models, for such testing.

The development of animal models is a key element in the successful development of medical countermeasures for CBRN, influenza, and emerging infectious agents, particularly since efficacy of products against most of these threats could never be evaluated in clinical studies. In 2002, the FDA amended its regulations for drugs and biologics to permit approval or licensure of medical countermeasures based on substantial evidence of effectiveness in animals when adequate and well-controlled efficacy studies in humans cannot be conducted because it would be unethical to expose healthy human volunteers to lethal or disabling agents, and relevant field efficacy trials in humans are not feasible. This change in the regulations (21 CFR 314.600 for drugs and 21 CFR 601.90 for biologics), commonly referred to as the "Animal Efficacy Rule," (updated by FDA May 2014) made the design and conduct of adequate efficacy studies in appropriate animal models of paramount regulatory importance, since the inference of efficacy in humans is based on efficacy data derived in animals.

VI. DISCUSSION

This Notice seeks information from other than small businesses with regard to their qualifications, experience and capability to conduct and manage studies related to the development of animal models in support of chemical, radiological and nuclear medical countermeasure development within BARDA's portfolio.

The United States Government (USG) seeks appropriate Good Laboratory Practices (GLP) facilities that are adequate and available to develop new or existing animal tests, models and/or critical reagents for the development of BIO MCMs. In these models, the challenge dose generally should be the same as that which produces the human disease or condition and the pathophysiological mechanism of its toxicity should be reasonably well-understood and mimic the human disease/condition as closely as possible.

When these models are used to test the efficacy of potential MCMs for BIO agents, the mechanism of action of the countermeasure will need to establish the utility of the animal model as a surrogate for humans.

The USG seeks safe facilities that have current approved Federal, State and/or local licenses/certifications for animal work and where applicable, ensure that the select agent regulations through CDC and/or USDA are followed (42 CFR Part 73, 7 CFR Part 331, and/or 9 CFR Part 121). The USG seeks to conduct work in accordance with all applicable Federal, state and local laws, codes, ordinances and regulations (or if foreign, equivalent regulatory oversight).

The USG seeks laboratories that have established protocols for routine care and health surveillance for laboratory animals, including on-call veterinary coverage 24 hours per day.

The USG seeks laboratories that can conduct pilot efficacy studies for candidate MCMs using new or existing animal models or tests (see C.1.1.) to establish the pathophysiology/natural history of threat agents in appropriate animal species.

The USG seeks laboratories that can perform efficacy evaluations in various species on candidate compounds (e.g., drugs and biologics) as specified in the Task Order Statement of Work, to permit further product development including, but not limited to, the assessment and optimization of the formulation, route of administration, effective dose level, dose schedule, therapeutic index (i.e. the ratio of the drug/biologic's adverse event plasma concentration over the plasma concentration sufficient for efficacy), and timing of administration (pre-exposure, post-exposure, delayed administration).

The USG seeks laboratories that can develop and/or provide acceptance criteria for the use of challenge material in animal model studies.

The USG seeks laboratories that can provide analytical support to monitor the progression of disease in animal models and demonstrate prospective correlates of protection (e.g., clinical laboratory capabilities and adoption of novel biomarker testing).

The USG seeks laboratories that have adequate statistical and pharmacokinetics support to analyze and predict experimental hypotheses for models, including pharmacokinetic modeling (both individual animal and population approaches using compartmental and non-compartmental methods).

In all cases described above, the USG seeks laboratories with the capability to perform these procedures and studies in animal models of human at-risk and special populations (e.g., pediatric, geriatric, pregnancy, etc).

*Please note that potential offerors are not expected to be proficient in all areas mentioned above.

VII. INFORMATION SUBMISSION INSTRUCTIONS

Respondents are asked to provide only the most pertinent information, data, and materials necessary to adequately convey a declaration of capability in line with this notice. Respondents must make a separate Business and Technical Representation, the Business Representation shall not exceed 10 pages, and the Technical Representation shall not exceed 10 pages. Content contained in excess of the stated limit per

section will not be reviewed. Respondents are asked to state in their capability statement, whether they are responding to the Small Business Sources Sought Notice or the Other Than Small Business Sources Sought Notice.

1. Business Representations

Respondents must make business representations to ASPR/BARDA in the following order:

a) Business Information

Provide potential respondent name, principal place of business, DUNS number, taxpayer identification number, number of employees, annual revenue of company, point of contact, and email address.

b) NAICS Codes

Provide your applicable NAICS Code.

c) Compliance Statement

Provide a statement assuring compliance with all applicable laws and this Notice.

d) Capability Statement

Provide relevant business information on capability, prior experience, and business interests to provide the goods and services specified under Section V, above.

2. Technical Representations

Respondents shall make the technical representations to ASPR/BARDA in the order listed below as separate sections. (Note: sections not relevant to the respondent may be left without information by marking it 'NA/Reserved,' to maintain the section numbering).

a) Response Specification

Specify the intent of the response to this Notice (i.e., identify the relevant product or service types as specified in Section VI).

b) Technical Outline I. Overview:

The narrative (including figures, schematics, diagrams, photographs, etc.) should describe the proposed final products/services and is also an opportunity to demonstrate knowledge of the "animal rule" in the development of animal models to support BARDA.

The following outline shall be used in the response document:

- 1) Current approved Federal, State and/or local licenses/certifications for animal work and where applicable, ensure that the Select Agent regulations through CDC and/or USDA are followed (42 CFR Part 73, 7 CFR Part 331, and/or 9 CFR Part 121). The USG seeks to conduct work in accordance with all applicable Federal, state and local laws, codes, ordinances and regulations (or if foreign, equivalent regulatory oversight).
- 2) Laboratories that have established protocols for routine care and health surveillance for laboratory animals, including on-call veterinary coverage 24 hours per day.
- 3) Capability to conduct pilot efficacy studies for candidate MCMs using new or existing animal models or tests (see C.1.1.) to establish the pathophysiology/natural history of threat agents in appropriate animal species.
- 4) Capability to perform efficacy evaluations in various species on candidate compounds (e.g., drugs and biologics) as specified in the Task Order Statement of Work, to permit further product development including, but not limited to, the assessment and optimization of the formulation, route of administration, effective dose level, dose schedule, therapeutic index (i.e. the ratio of the drug/biologic's adverse event plasma concentration over the plasma

concentration sufficient for efficacy), and timing of administration (pre-exposure, post-exposure, delayed administration).

- 5) Capability to develop and/or provide acceptance criteria for the use of challenge material in animal model studies.
- 6) Capability to provide analytical support to monitor the progression of disease in animal models and demonstrate prospective correlates of protection (e.g., clinical laboratory capabilities and adoption of novel biomarker testing).
- 7) Statistical and pharmacokinetics support to analyze and predict experimental hypotheses for models, including pharmacokinetic modeling (both individual animal and population approaches using compartmental and non-compartmental methods).
- 8) Evidence to support GLP capability and experience (List of GLP studies conducted in the past three years.)
- 9) List of proposed staff (Subject matter in disease, Veterinarian, Number of Laboratory Technicians, Statistician, Pathology, QC/QA) and Organizational Chart

In all cases described above, the USG seeks laboratories with the capability to perform these procedures and studies in animal models of human at-risk and special populations (e.g., pediatric, geriatric, pregnancy, etc).

3. Other Information

ASPR/BARDA encourages respondents to submit currently available marketing or extant information, or to notify ASPR/BARDA of the publicly available location; thereof to the maximum extent consistent with this notice's requirements and limitations.

Respondents shall mark confidential, privileged, proprietary, trade-secret, copyrighted information, data, and materials with appropriate restrictive legends. ASPR/BARDA will presume that any unmarked information, data, and materials were furnished with an "unlimited rights" license, as FAR subpart 27.4 defines that term, and ASPR/BARDA assumes no liability for the disclosure, use, or reproduction of the information, data, and materials.

4. Response Format, Transmission, and Closing Date

Respondents shall provide declarations of capability and all information, data, and materials in Microsoft Office®, or Adobe® Acrobat® format, and furnish responses via email transmitted to the following addressee for receipt by 2:00 P.M. EDT on April 08, 2015. Any questions, comments, or concerns regarding this notice shall be written and transmitted via email to elizabeth.steiner@hhs.gov.

VIII. DISCLAIMER AND IMPORTANT NOTES

This notice does not obligate the Government to award a contract or otherwise pay for information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation.

IX. ATTACHMENT 1 - Capabilities Table (Table 1) & Capacity Chart (Table 2)

Table 1: Animal Model Capability Matrix

Biological Agent (Viral or Bacterial) Exposures¹

Table 1: Biological Agent (Viral or Bacterial) Exposures ¹ NIAID Category A & B Priority Pathogens	Host Species/Strains (i.e., Guinea pigs, NHP, Rabbits, etc)	Pathogen, Strain	Challenge Route	Stage of Model (either validated or not-validated)	Animal Supplier
Bacillus anthracis (anthrax)					
Clostridium botulinum toxin (botulism)					
Yersinia pestis (plague)					
Variola major (smallpox) and other related pox viruses					
Francisella tularensis (tularemia)					
Arenaviruses (provide subspecies)					
Bunyaviruses (provide subspecies)					
Flaviruses (provide subspecies)					
Filoviruses (provide subspecies)					
Burkholderia pseudomallei					
Coxiella burnetii (Q fever)					
Brucella species (brucellosis)					
Burkholderia mallei (glanders)					
Chlamydia psittaci (Psittacosis)					
Ricin toxin (from Ricinus communis)					
Epsilon toxin of Clostridium perfringens					
Staphylococcus enterotoxin B					
Rickettsia prowazekii (Typhus fever)					

¹ The agent listing should be the NIAID Category A & B priority pathogens.

Table 2: Capacity chart

Please include a second table supplying current and average animal species lab booking and maximum animal-room capacity.

Location of facility	Animal #1	Animal #2	Animal #3	Animal #4