Answers to Applicant Questions: N62645-PA-19-2

(Please note that italicized text is from the Program Announcement or Application Instructions).

Q1. Can existing foreign scientific collaborators participate in research that is part of the cooperative agreement and/or receive funding through the organization receiving the cooperative agreement to support international collaborations for vaccines, diagnostics, therapeutic and other product development that is a priority noted in the program announcement?

A1. All participants (awardee/subawardee) are eligible to apply and collaborate to complete the research project as long as conflict of interest or duplicate efforts are not involved. This agreement is a re-compete of the existing project that will be ending.

Q2. The program announcement states that a substantial amount of the laboratory research work that will be conducted in IDD laboratory facilities. The information available on IDD related websites is very helpful. However, more detailed facilities description may help in providing detailed project activities that depend on knowledge of equipment and skill sets of personnel in the laboratories.

A2. The NMRC-IDD laboratories consist of a total of 3,000 square feet of BL-2 laboratory space and 1,145 square feet of office space. The laboratories are equipped with routine equipment for microbiology and molecular biology including biosafety cabinets, high capacity autoclaves, ultracentrifuges, fluorescence microscopy equipment, incubators, water baths, real time and digital PCR instruments, light microscopes, NGS sequencing equipment, fluorescence activated cell sorters, ELISA plate reader with software (SpectraMax M5 plate reader), ELISPOT reader, Guava PCA System, FACSARRAY bioanalyzer, FACScan, and microarray readers.

WRAIR/NMRC maintains Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation. The animal facility for large animals has 61,159 square feet of animal holding and support space, while the animal facility for small animals, including a barrier facility for housing immunocompromised animals, consists of 94,249 square feet of animal holding and support space. The animal facilities can house approximately 60 swine and 400 non-human primates (NHPs) and maintains full-time animal care professionals providing health and husbandry care.

Q3. Can the IDD provide a description of laboratory facilities and equipment that are available for collaborative research project related experiments and trials?

A3. Refer to Answer 2 above.

Q4. If IDD laboratories do not have special equipment, resources, or supplies to conduct some research activities, can university or private company laboratories or facilities be utilized for the research under the cooperative agreement?

A4. Yes, if the IDD laboratories do not have the capabilities to conduct some activities, university or private company laboratories can be used.

Q5. Can the cooperative agreement include description of research/project activities that take place at overseas Naval research laboratories or among deployed troops in Asia, Africa and Latin America to facilitate evaluation of countermeasures?

A5. Although there are currently no known research/project activities taking place at overseas Naval research laboratories or among deployed troops, some activities could be conducted overseas. As stated in the Program Announcement, research activities under this cooperative agreement will take place primarily within IDD-NMRC laboratories.

Q6. Based on information we have available, the scientific/ethical clearance process with Navy research is similar to that in the civilian sector. For this PA, are there any special scientific/ethical clearance issues that you would like applicants to be aware of beyond that which is noted already in the PA and application?

A6. No, the scientific/ethical clearance process is outlined in the PA.

Q7. Can the proposal contain products that are developed or co-developed in overseas laboratories and potentially then brought to US Navy or US laboratories for further study?

A7. The proposal can contain products that are developed or co-developed in overseas laboratories and potentially then brought to US Navy or US laboratories for further study, but as stated in the Program Announcement, research activities under this cooperative agreement will take place primarily within IDD-NMRC laboratories.

Q8. Can the proposal contain activities for development of products in which some of the product development (e.g., pilot lots or scale-up for larger scale trials) occurs in laboratories outside the United States? If this is allowed, is work with Canadian partners permissible? Is work with other development partners in South Korea or India permissible?

A8. Yes, proposals can contain activities for development of products in which some of the product development occurs in laboratories outside the United States; however, as stated in the Program Announcement, research activities under this cooperative agreement will take place primarily within IDD-NMRC laboratories. Yes, work with Canadian partners and other development partners in South Korea or India is permissible, as long as all regulatory requirements are met.

Q9. From the announcement, it was not immediately clear to me whether your are seeking applications for a large center that will simultaneously address all of the needs or whether you are seeking more targeted applications. For the former, are there institutions already involved in applying that are seeking partners with content expertise?

A9. Any institution/organization that has the ability to meet and complete the research can submit an application and will be reviewed and rated in accordance with the review process outlined in the application package.

Q10. On page 2 of the program announcement, the award description explains that the intent of this award including the partnership with IDD-NMRC. We understand that IDD-NMRC laboratories will support the research activities to minimize the need for the awardee to purchase specialized equipment or acquire additional laboratory space to conduct the research. Our first question is if we (the team) have and have access to all the specialized equipment and lab space to conduct the research at our institution XXXREDACTEDXXX, can the proposed research be primarily conducted at XXXREDACTEDXXX?

A10. No, per Section B. Award Description of the Program Announcement, "Research activities under this cooperative agreement will take place primarily within IDD-NMRC laboratories…."

Q11. Our research project would fall in item (f) in the summary of responsibilities on page 5 of program announcement document. One question is about item (f)Development of Countermeasures Against Multidrug Resistant Wound Infections. This is the area of our proposed project. There are three bullet points listed below. Does the proposed project have to include all the three bullet points? Or can it focus on only two bullet points and still be considered for funding?

A11. See Section IV. Evaluation Information of Program Announcement. All applications will undergo a review and selection process to determine the application that best suits the research project's needs. Failure of an application to document support of all areas outlined in the Program Announcement may (at the discretion of the Grants Officer) cause an application to not be forwarded for the peer and programmatic reviews and therefore, not be eligible to be funded.

Q12. We understand research activities utilizing human subjects and biological substances are a core requirement of this agreement. We have two questions. Do you want us to work with IDD-NMRC in the activities utilizing human subjects and biological substances? Or, do we need someone in our team, whose has the expertise in the specific activities proposed? We have the same questions for the research activities utilized animal species. Second, do you have any preference of animal models? Small, intermedia or large animals?

A12. The intent is for a collaborative effort on research activities. Thus, the partner should both work with IDD-NMRC and have expertise for the proposed activities. We have no preference of animal models. The animal model proposed should be appropriate for the proposed activities.

Q13. Application Instructions, pg. 1 – **Technical Volume Format.** Would the government consider allowing the font in tables and graphics to be Times New Roman 10 point?

A13. The font has been set at a standard of 12pt for clarity of review and standard. Please submit the Technical Volume in the Font 12 point as detailed within the Application Instructions.

Q14. Application Instructions, pg. 4 – **Current and Pending Project and Application Submissions.** Would the Government consider allowing Offerors to submit the list of Current and Pending support as an attachment that does not count toward the page limit?

A14. Please note that under section 2. Content and Format of Applications, Section A. Technical Volume Format that the Current and Pending Project and Application Submissions does count toward the 30 page limit for the Technical Proposal.

Q15. Application Instructions, pg. 4 – Page Limits. Do references fall under the same category as Resumes and therefore do not count toward the page limit? Would the government consider allowing Offerors to submit references as an attachment that does not count toward the page limit?

A15. References fall under the same category as Resumes or Curriculum Vitae (CVs) and do not count toward the page limit.

Q16. Period of Performance Application Instructions, pg. 4 –

B. Research & Related Budget Instructions: An estimate of the total proposed research project cost, with a breakdown of all cost categories for the 60-month period of performance (divided into five 12-month budgets), must accompany each application. The award will include a single 60-month period of performance. The budget is broken into five 12-month periods for ease of cost proposal evaluation. Include a sufficiently detailed budget and budget justification so that the Government can determine the proposed costs to be allowable, allocable, and reasonable for the proposed research. The budget justification for the entire period of performance must be uploaded to the Research & Related Budget form after completion of the budget.

Assume that performance will start no later than 25 days after the date the application is submitted. The Government reserves the right to request a revised budget and budget justification and/or additional information.

Is a September 23, 2019 through Aug. 24, 2024 period-of-performance acceptable?

A16. A 23 September 2019 start date is unrealistic for estimated budget submission, a proposed 15 October 2019 – 14 October 2024 is a more realistic for budgeting and negotiating purposes.

Q17. Program Announcement, pg. 15 – **Organizational Conflicts of Interest.** Would the Government consider allowing Offerors to submit their Organizational Conflicts of Interest disclosure as an attachment that does not count toward the page limit?

A17. Yes, Organizational Conflicts of Interest disclosures can be sent as an attachment that will not be counted toward the page limit.

Q18. Application Instruction, pg. 3 – **Required Assurances for Human Subject Research Federalwide Assurance (FWA) -** The applicant shall hold an active (i.e., not expired) FWA appropriate for research to be supported under the award. The FWA shall remain active for the duration of the award. The FWA is issued by the Department of Health and Human Services. The applicant shall provide a copy of the approved FWA in its application response.

Proposed Subawards - The application requirements identified herein also apply separately to any proposed subaward that may perform human subject research. Failure to address the application requirements for a proposed subaward will make the applicant's submission unacceptable and it will not be eligible for award.

Will a screenshot from the Department of Health and Human Services website, showing the subrecipient is active, fulfill this requirement?

Would the Government consider allowing Offerors to submit the Federalwide Assurance (FWA) as an attachment that does not count toward the page limit?

A18. In accordance with Section 2.A. of the Application Instructions, “the page limit for the Technical Volume is 30 pages (**excluding** Resumes or Curriculum Vitae (CVs), Cover Page, Table of Contents (TOC) and **Federalwide Assurance (FWA)**).” A screenshot will be deemed acceptable as long as the following information appears on the FWA visibly and legibly: Entity Name, full FWA number, and the FWA expiration date for the offeror or any proposed subcontractor that may perform human subject research.