Answers to Applicant Questions: N62645-PA-20-1

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

Q1. Regarding to the subject CoAg, it states that "*The awardee shall have at least one active trial site approved and registered in Peru at the time of selection."* This approach limits competition to the very few organizations that have an active trial site approved and registered in Peru. That said, respectfully request that NMLC employ the approach that it has in the recent past for the same requirements in the same location for the same organization that allowed the prime or its subcontractors to meet this criteria. The NAMRU-6 RFP "N6264519R0057" that mirrors these requirements and offered the following criteria:

2.22 For executing tasks for Clinical Trials, the prime contractor (or a subcontractor) shall possess and demonstrate the ability to conduct clinical trials in Peru or show the ability to subcontract with a contractor that is capable of conducting clinical trials in Peru. They shall be certified by the General Office for Research and Technology Transfer (OGITT, OGIT in Spanish); this entails being registered at the Peruvian Clinical Trial Registry (REPEC) to conduct clinical trials in the field of infectious diseases. If the ability to conduct clinical trials in Peru is held by a subcontractor, and the Prime and Subcontractor end their contractual relationship, the Prime contractor shall notify the Contracting Officer within 24 hours.

This approach of allowing a subcontractor to meet the criteria eligibility will surely broaden the scope of competition and aligns with recent NMLC and NAMRU-6 approaches to securing the best possible research support services. Please advise if NMLC will consider issuing an amendment to accommodate this reasonable request of allowing the prime and/or its subcontractors to meet the criteria of having at least one active trial site approved and registered in Peru at the time of selection.

A1. No amendments will be made to the Program Announcement. NAMRU-6 is well aware of the potential of failure should a CoA partner be chosen who does not have current clinical trial experience in Peru. For the purpose of the CoA NAMRU-6 is looking for a partner with which to be able to execute FDA-regulated clinical trials. These trials may potentially involve greater than minimal risk interventional studies in humans, meaning that human volunteers would be given and experimental vaccine, therapeutic or drug. One of the critical points of these types of studies is the fact that those involved in the study (e.g. NAMRU-6 and the CoA partner) become legally and ethically bound to the execution of the study. When the FDA reviews and approves a study in which there is potential risk to human subjects, one of the criteria used to determine if the study should be approved is the potential benefit derived from the risk of testing an experimental product.

If a study were to stop prematurely due to a logistic issue, such as the failure of an Awardee or subawardee, then the original outcome that was used by FDA to determine the risk/benefit ratio is no longer valid and the human volunteers were put at risk for little or no benefit.

Q2. I am contacting you in reference to the recent funding opportunity (N62645-PA-20-1) "Conduct of Clinical Trials to Facilitate the Development and Approval of Novel Countermeasures (vaccines, devices, drugs) for Use by the Warfighter" sponsored by the Naval Medical Research Unit Six Lima (NAMRU-6). My team and I are interested in submitting a proposal and would like your opinion on whether our research aligns well with the program's goals.

XXXX redacted information XXX

It was somewhat unclear to us in reading the PA if such an application would align with your programmatic goals. We would like clarification as to whether our submitting a proposal along the lines outlined in the preceding paragraph would make sense. XXX Redacted Information XXX

A2. The Program Announcement for the Cooperative Agreement is looking for an Organization that can carry out the mission and objectives set forth within the program announcement working in collaboration with NAMRU-6 to obtain the objectives. All applicants will be reviewed according to the evaluation criteria set forth in the Program Announcement and Application Instructions for this Assistance Agreement.