AMENDMENT FIVE (5)

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PURPOSE OF SOLICITATION AMENDMENT

The purpose of this amendment is to:
- Respond to Questions received regarding the solicitation.

The hour and date specified for receipt of Offers remains unchanged.
Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full effect.

Questions: Section 12 Component Instructions and Technical Topic Descriptions

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)
NIAID TOPIC 124 - Development of Next-Generation Devices and Materials-Based Platforms for the Administration of HIV-1 Broadly Neutralizing Antibodies

Question 1: **Are offerors required to use bnAbs that have been or are planned for in NIAID-sponsored trials?**
Answer 1: No, offerors may use any anti-HIV Env antibody and are not restricted to those NIAID has or plans to test in clinical trials. NIAID-sponsored trials in clinicaltrials.gov will indicate which bnAbs are currently in use.

Question 2: **Can offerors propose using a model antigen or other protein?**
Answer 2: Use of a model antigen (e.g. Ova) or other protein alone is not responsive. Offerors must propose use of an anti-HIV antibody.

Question 3: **How can offerors obtain anti-HIV bnAbs for proposed work?**

Answer 3: The HIV Reagent Program, a NIAID-supported resource, has small quantities of antibodies available without charge, and may have antibody-encoding plasmids and hybridomas as well.

https://www.hivreagentprogram.org/

Antibody-encoding plasmids and hybridomas are available from commercial vendors as well.

Offerors proposing use of antibodies from non-commercial sources should include a letter of support from the supplier.

Question 4: **Does NIAID have a preferred or recommended animal model?**

Answer 4: No, any animal model that is well-justified is acceptable. Use of animal models is not required for this topic.

Question 5: **What is the budget for this solicitation?**

Answer 5: For Phase I proposals, the budget is limited to $300,000 total costs for 1 year. For Phase II proposals (Fast-track only), the budget is limited to $2 million total costs, for an award duration of 3 years.

Question 6: **Are there quantitative targets for improving sustained release, bioavailability, or protective durability?**

Answer 6: No, offerors propose targets and must propose improving sustained release, bioavailability, OR protective durability relative to bolus intravenous or subcutaneous administration. Offerors may propose further refining these parameters during or after the contract performance period.

Question 7: **Can NIAID recommend technical parameters (e.g. particle size)?**

Answer 7: No, offerors determine and propose technical parameters, including parameters to optimize during contract performance.

Question 8: **Are proposals for administration of multiple/cocktail antibodies responsive?**

Answer 8: Yes, offerors may propose devices or materials for administration of single or multiple antibodies.

Question 9: **Are offerors expected to work with the HIV virus?**

Answer 9: No, offerors are not expected to work with the HIV virus itself.