AMENDMENT TWO (2)

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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.

General Solicitation Questions

Question 1: The solicitation provides no instruction for references cited. In a typical SBIR Grant proposal those are uploaded as a separate doc. In the absence of any guidance from the above-referenced solicitation should references be attached to the content of the technical element?

Answer 1: Yes, References should be included.

Question 2: While the solicitation does state that the Technical Proposals Shall not exceed 50 pages, it does not specify any page-limitations for individual components such as

1. **Technical Objectives.**
2. **Detailed Approach and Methodology.**
3. **Identification and Significance of the Problem or Opportunity.**
4. **Related Research or R&D**

5. **Relationship with Future R&D.**
6. **Innovation**
7. **Potential Commercial Applications**
8. **Senior/Key Personnel and Bibliography of Directly Related Work**
9. **Subcontractors/Consultants**
10. **Multiple PI/PD Leadership Plan *(NIH Only)*. N/A**
11. **Facilities and Equipment.**
12. **Resource Sharing Plan(s). and;**

13. Draft Statement of Work (Appendix E), page limitation and what is its difference from above?

1- **TITLE**
2- **Background Information**
3- **Scope**
4- **Objectives**
5- **Services to be Performed.**

We understand that page limitations are critical and can often be grounds for disqualification. For this reason we would greatly appreciate your guidance on these matters.

Answer 2: The page limit pertains to the overall proposal length, not the individual elements.

Question 3: Is the $10 million CDC SBIR budget just for Phase I or Phase II?

Answer 3: $10 million was the CDC SBIR budget for FY2024. All SBIR Phase I and Phase II awards were funded from this $10 million set-aside.

Question 4: I recently saw an SBIR solicitation # PHS 2025-1 due on Oct 18th. That has a section for CDC/NCEZID. I was wondering do any of the sections have an option for our new diagnostic assays for H5N1?

Answer 4: H5N1 is not solicited as an SBIR Contract topic in FY25.

Questions: Section 12 Component Instructions and Technical Topic Descriptions

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
NATIONAL CENTER FOR EMERGING ZOONOTIC AND INFECTIOUS DISEASES (NCEZID)

NCEZID Topic 032: Canine Vaccines to Prevent Tick Bites

Question 1: If awarded, would extensions be granted past the 6-month budget period?

Answer 1: No. Far 52.217-8 will not be included in awards under this solicitation. Extensions will not be granted.

Question 2: Could some work toward the project be completed prior to the award start date with deliverables arriving within the 6-month budget period?

Answer 2: No. Contracts resulting from this solicitation will be not used to fund work that was completed prior to award. SBIR Phase I contracts may build upon previously completed work, however.

Question 3: My question is whether or not this topic was restricted strictly toward vaccine development or if other approaches that meet the project goal of reducing tick bites, reducing Rickettsia transmission, and reducing ticks in the region might be considered as well. This alternative approach would consist of a long lasting engineered topical skin probiotics with a protein cargo deterrent for both ticks and Rickettsia.

Answer 3: CDC would consider a project that develops a novel topical skin product. The interest in it would depend on what it means by "long-lasting." CDC expects something that lasts for at least 1-year between applications.

NCEZID Topic 033: Rapid, Portable, Point-of-Care Carbapenem Resistant Acinetobacter Colonization Screening Diagnostic

Question 1: Is this solicitation a grant and not a contract?

Answer 1: This is a solicitation for SBIR contracts.

Question 2: In reviewing the expected deliverables, I wanted to confirm that acceptable specimen types include urine? I know that current commercial CRAB screening tests are commonly performed from swabs, but we would be interested in proposing a screening test from a primary urine sample. Would this be in scope of the solicitation?

Answer 2: No. It is not recommended that proposals focus on urine samples for colonization screening purposes.

Question 3: Will molecular diagnostic assays be acceptable?

Answer 3 Yes, if the instrumentation required for such an assay could be performed in a CLIA waived environment.

Question 4: Is 30-minute time (sample to answer) acceptable as "rapid"?

Answer 4: Yes

Question 5: Do we need an academic partner or will all required controls be provided by CDC?

Answer 5: CDC could provide control strains/isolates, but would not be able to provide specimens for proof-of-concept testing.

NCEZID Topic 034: Improved Diagnostic Assays for Foodborne and Waterborne Bacterial Pathogens

Question 1: In the topic description, it heavily mentions rt-PCR; however, at times it also uses the language of "but not limited to". Would rapid diagnostic assays such

as those utilizing enzymes or other reporters linked to highly specific binding proteins leading to a colorimetric/fluorescent signal be considered? In line with the topic, these assays would still be highly, stable, deployable, and require little specialized equipment. Or is this topic exclusively for the development of rt-PCR approaches?

Answer 1: Yes – additional rapid diagnostic assays using enzymes may be included in this proposal. There are currently several rapid diagnostic assays (using antigen-based dipstick tests) currently on the market, and it would be great value added to have the development of molecular-based approaches, such as LAMP or rt-PCR assays.

Question 2: Will the qPCR assays developed under this effort be used for environmental testing, clinical diagnostic testing, or both?

Answer 2: The qPCR assays should primarily be used for clinical sample testing under surveillance and not intended to be used as a diagnostic.

Question 3: If the assays are to be developed for diagnostic clinical testing, should the FDA clearance process be addressed in Phase I of the effort?

Answer 3: At this time, the tests would primarily be designed for surveillance to support outbreak detection (not intended for diagnostics) and therefore Phase I proposals do not need to directly address the FDA clearance process. This should not preclude manufacturers from developing FDA-approved IVDs, however.

Question 4: The solicitation indicates a project goal of initial prototype development (Project Goal 2). Is envisioned that this effort will result in the development of a new field-able qPCR device or, leverage existing technology?

Answer 4: The goal would be to leverage existing technologies.

Question 5: Specifically for qPCR assays primers and probes developed for Vibrio bacteria, is the interest in broadly targeted assays (groups or genus wide) or specific groups, species, sub-species, etc., or both?

Answer 5: For Vibrio targets, the primary goal would be for Cholera diarrhea diagnostics, which is represented by a specific subtype of Vibrio cholerae (belongings to the Vibrio cholerae species, characterized primarily by the cholera toxin gene, O1 serogroup, and other toxin and virulence markers).

Question 6: The solicitation Commercialization Potential section mentions advanced technology that is more accessible and customizable. What customization features is intended by this statement?

Answer 6: The customizable feature could include an extended panel that looks at multiple diarrheal targets of public health importance (e.g., Shiga toxin producing E. coli, toxigenic Vibrio cholerae, and Campylobacter).

NCEZID Topic 035: Improved Diagnostic Assays for Parasitic Diseases

Question 1: **For the CDC NCEZID 035 topic, is it within the scope of a Phase I contract to scale up and commercially validate an assay in animals with Phase II plans of development in human subjects?**

Answer 1: This solicitation is for Phase I contracts. CDC does not fund Phase II contracts directly (i.e., Direct to Phase II). A Phase I contract could be used to scale up and commercially validate an assay in animals IF 1) your proposal could do this during the Phase I period of performance of 6-12 months and 2) the work could be done with a Phase I budget of ~$243,500 or less.

Question 2: **Our client has developed and tested a point-of-contact diagnostic assay for Trypanosoma cruzi in companion animals (dogs and cats). This assay has shown high specificity and accuracy for detecting the parasite. Their intent is to scale-up and manufacture the assay for commercial validation of test kits in companion animals with the intent to develop the assay for human subjects in Phase II. Would this be within the scope for (1) the CDC/NCEZID 035 topic and (2) a Phase I contract?**

Answer 2: The project fits within the scope of Topic 035. This solicitation is for Phase I SBIR Contract.

NCEZID Topic 037: Enhancing the CDC Autocidal Gravid Ovitrap to Control Dengue Vectors

Question 1: **The solicitation has several literature references, but no list of citations. Would you be able to provide a list of references for the solicitation?**

Answer 1: See below:

- Barrera R, Amador M, Acevedo V. 2020. Factors modulating captures of gravid females of *Aedes aegypti* (Diptera: Culicidae) in the field. J. Am. Mosq. Control. Assoc. 36:66-73. https://doi.org/10.2987/20-6931.1.
- Sharp TM, Lorenzi O, Torres-Vela´squez B, Acevedo V, Pe´rez-Padilla J, Rivera A, et al. (2019). Autocidal gravid ovitraps protect humans from chikungunya virus infection by reducing Aedes aegypti mosquito populations. PLoS Negl Trop Dis 13(7): e0007538. https://doi.org/10.1371/journal.
- Barrera R, Harris A, Hemme RR, Felix G, Nazario N, Muñoz-Jordan JL, Rodriguez D, Miranda J, Soto E, Martinez S, Ryff K, Perez C, Acevedo V, Amador M, Waterman S. 2019. Citywide control of Aedes aegypti during the 2016 Zika epidemic by integrating community awareness, education, source reduction, larvicides, and mass mosquito trapping. Journal of Medical Entomology 20: 1-14.
- Barrera R, Amador M, Acevedo V, Beltran M, Muñoz JL. 2019. A comparison of mosquito densities, weather and infection rates of *Aedes aegypti* during the first epidemics of Chikungunya (2014) and Zika (2016) in areas with and without vector control in Puerto Rico. Medical and Veterinary Entomology. doi: 10.1111/mve.12338.
- Barrera R, Amador M, Muñoz J, Acevedo V. 2018. Integrated vector control of Aedes aegypti mosquitoes around target houses. Parasites and Vectors 11:88. DOI 10.1186/s13071-017-2596-4.

- Barrera R, Amador M, Muñoz J, Acevedo V. 2018. Integrated vector control of Aedes aegypti mosquitoes around target houses. Parasites and Vectors 11:88. DOI 10.1186/s13071-017-2596-4.
- Barrera R, Amador M, Muñoz J, Acevedo V. 2018. Integrated vector control of Aedes aegypti mosquitoes around target houses. Parasites and Vectors 11:88. DOI 10.1186/s13071-017-2596-4.
- Barrera R, Amador M, Muñoz J, Acevedo V. 2018. Integrated vector control of Aedes aegypti mosquitoes around target houses. Parasites and Vectors 11:88. DOI 10.1186/s13071-017-2596-4

Question 2: Technology License terms: would multiple organizations be awarded a license to use the CDC IP referenced in this topic? If so, what license fee structure is being considered?

Answer 2: The CDC IP is available for licensing on a non-exclusive basis. A model non-exclusive license agreement may be found at: https://www.techtransfer.nih.gov/partnerships/forms-model-agreements#MLA.

Question 3: Intellectual property: are there any other US or international patents, in addition to US10219505B2 and US9237741B2 referenced in the topic? Is there any internal knowhow that is available to the licensee?

Answer 3: The IP associated with the Autocidal Gravid Ovitrap consists of the following patents: AU 2012217569, BR 1120130075112, IN 355773, MX 345017, MX 364909, US 9237741, US 10,219,505.

Question 4: What are the priorities in having an alternative attractant to the hay infusion? For example, should the new attractant last longer; should it be effective on a wider range of mosquitoes; etc.

Answer 4: The alternative attractant is to avoid using hay because it is difficult to obtain in some countries and there is a variety of hay species, making it difficult to standardize results. The target is Aedes aegypti.

Question 5: What is the motivation for having a different sticky glue? For example, is the goal a more reliable supply or a second manufacturer? Or is the goal to provide a glue with enhanced properties vs. what is currently used, for example improved durability, lower cost, other reasons?

Answer 5: There is only one provider of the most effective glue. The idea is to diversify the source since only one company produces it. Developing an effective glue is highly desirable but the attractant and disposable trap chamber are priorities.

Question 6: What is the current source of the sticky glue? Would we be able to purchase a small quantity of the current glue?

Answer 6: The supplier is Catchmaster (AP &G, Inc.). Those who sell CDC AGO traps should sell the sticky boards that contain the glue.

Question 7: **The solicitation specifies a "disposable capture chamber". Does this mean that the capture chamber with glue and mosquitoes that were caught could be removed and discarded (landfilled) and replaced with a new capture chamber, while the original reservoir and attractant continue to be used?**

Answer 7: Correct. The capture chamber is currently made of plastic. It carries the glue board and screens on the top and bottom of the chamber. The top screen is to prevent leaves and other objects falling within the chamber. The bottom screen prevents mosquitoes from reaching the infusion below. The idea is to have a disposable trap chamber that can be removed, discarded, and replaced with a new one.

Question 8: **Who produces the "official" CDC AGO trap? There are several companies that have AGO traps that are very similar to the CDC trap.**

Answer 8: The CDC has non-exclusively licensed its patent rights to AP &G, Inc.

Question 9: **We were a prior Phase I and Phase II awardee to develop the AGO trap under previous SBIR grants, thus we have completed the Phase I step and are qualified to conduct a Phase II project.**

But it is not clear that this topic will accept a Phase II application[. . .] Please Advise.

Answer 9: This solicitation is for Phase I contracts. CDC does not fund Phase II contracts directly (i.e., Direct to Phase II). A Phase I contract could be used to scale up and commercially validate an assay in animals IF 1) your proposal could do this during the Phase I period of performance of 6-12 months and 2) the work could be done with a Phase I budget of ~$243,500 or less.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)
NIAID Topic NIH/NIAID 139– Rapid Diagnostic Assays for Self-Monitoring of Acute or Rebound HIV-1 Infection

Question 1: **Regarding the stated requirement for an assay with a detection sensitivity equal to / less than 1000 copies of viral RNA / ml of blood or the viral protein antigen equivalent, is this an absolute for a HIV protein antigen-based assay or would it be acceptable if the sensitivity of the protein antigen-based prototype is equivalent to or exceeds that of current commercially available predicate HIV rapid tests, FDA-approved for use in point-of- care settings?**

Answer 1: This is not an absolute requirement; it is stated that the assay should have the potential to achieve sensitivity of <1,000 RNA copies per mL or protein equivalent for antigen detection.

Question 2: **Would archived serum / whole blood specimens, procured from commercial repositories, be acceptable for preliminary validation of the prototype developed in the Phase I component?**

Answer 2: Yes, this would be acceptable.

Question 3. **Can you indicate whether development of a prototype based on a HIV-1 "shed" protein antigen alone (i.e., not combined with an anti-HIV antibody) for self-monitoring of acute HIV 1 infection would be responsive?**

Answer 3: Yes, this would be responsive.