1) The response date for proposals is changed, as follows:

From: February 19, 2015
To: March 12, 2015

2) The proposed award date is changed, as follows:

From: August 14, 2015
To: October 1, 2015

3) Attachment 7, Additional Technical Proposal Instructions, Format for Technical Proposal, and Table of Contents, add the following “SECTION 3: TECHNICAL PLAN/APPROACH FOR EACH TASK AREA”:

SECTION 3: TECHNICAL PLAN/APPROACH FOR EACH TASK AREA

A. General Task Order Requirements
   1. Describe proposed plans, procedures and capabilities to perform the GENERAL TASK ORDER REQUIREMENTS (Attachment 3, Section 3) of the Base Statement of Work.

B. Task Area A: Phase 1 Malaria Vaccine Trials
   1. Describe proposed plans, procedures and capabilities to perform ‘first in human’ vaccine trials to test the safety and immunogenicity of candidate malaria vaccines described in Task Area A (Attachment 3, Section 4. A.).
   2. Describe proposed specific plans, procedures and capabilities to perform Sample Task Order A-1: Phase 1 Malaria Vaccine Trials (Attachment 4).

C. Task Area B: Phase 1-2 Challenge Trials
   1. Describe proposed plans, procedures and capabilities to perform Phase 1-2 challenge trials intended to prevent malaria infection described in Task Area B (Attachment 3, Section 4. B.).
   2. Describe proposed specific plans, procedures and capabilities to perform Sample Task Order B-1: Phase 1-2 Challenge Trials (Attachment 5).

D. Task Area C: Experimental Infection Studies
   1. Describe proposed plans, procedures and capabilities to perform experimental human infection trials described in Task Area C (Attachment 3, Section 4. C.).
   2. Describe proposed specific plans, procedures and capabilities to perform Sample Task Order C-1: Experimental Infection Trials (Attachment 6).

4) Attachment 7 of the Solicitation, the following changes were made to the original Section numbers:

“Section 3: Scientific and Technical Personnel” is now Section 4
“Section 4: Facilities, Equipment, and Other Resources” is now Section 5
“Section 5: Other Considerations” is now Section 6
5) The Small Disadvantaged Participation Plan has been removed from the Solicitation

SMALL DISADVANTAGED PARTICIPATION PLAN REMOVAL LETTER- 12/4/2014

On October 14, 2014, the Secretary of Defense, the Administrator of General Services, and the Administrator for the National Aeronautics and Space Administration issued Federal Acquisition Circular (FAC) 2005-77.

This Circular amended the FAR to remove certain coverage involving procurements with small disadvantaged business concerns that is based on authority that has expired and been found to be unconstitutional by the Court of Appeals for the Federal Circuit. FAR 19.12 (Small Disadvantaged Business Participation Program) has been deleted, along with the corresponding reference in FAR 15.304. The Small Disadvantaged Business clauses have also been removed from the FAR (52.219-19-52.219-26).

As a result of this change, we have removed the Small Disadvantaged Business Participation Plan requirement from the solicitation so as not to call into question the constitutionality of the procurement. It remains in the Acquisition Plan, because the Acquisition Plan was signed before these changes went into effect.

QUESTIONS FROM POTENTIAL OFFEROR’S:

Question 1: It appears that Tasks A and B are requested to occur concomitantly (start date July 1 changed now to Aug. 14, 2015). Additionally, Task C is requested to occur Jan 2016 (now changed to Feb. 2016)? This would suggest that all three Tasks overlap in Year 1 which makes subsequent budgeting for Year 2-5 a challenge. Please advise.

Response 1: For the purpose of this proposal and cost estimates, each of the three Tasks should be viewed as independent studies being conducted non-concurrently.

Question 2: It appears that Task A and B study schedules are reversed.....I will adhere to the format in the Technical overview but this may cause confusion to applicants.

Response 2 Yes, Appendix A-1 and B-1 Sample Protocol Summary and Schedule are in reverse order. (Attachment 4 pages 5-7 and Attachment 5 pages 5-7 are reversed).

Question 3: None of the Tasks assign time for budgeting personnel to perform protocol development, IRB submission, study ramp-up, and finally close-out time/manuscript time. This might be part of the Cost to complete request but wanted to verify that we stick strictly to the RFP verbiage.

Response 3: Performing protocol development, IRB submission, study ramp-up, and close-out/manuscript time is required to meet the contract objectives and should be budgeted in the proposal. The majority of the draft clinical protocols will be provided by LMIV investigators. See Attachment 3, page 1 of 4, paragraph 3.

Question 4: Are there any funded sites already, and where are they are so we can communicate with the PI (we would like to find out more regarding how these studies work).
Response 4: There are none.

Question 5: Do we develop our own protocol?
Response 5: The majority of the draft clinical protocols will be provided by LMIV investigators. See Attachment 3, page 1 of 4, paragraph 3.

Question 6: What is the likelihood of our own project being funded?
Response 6: Only LMIV studies will be funded through this contract. Outcome is determined by an independent panel review of offerors’ bids. This is only to conduct LMIV studies, not a funding mechanism for Contractor developed internal protocols.

Question 7: How many sites will be funded?
Response 7: More than one (1).

Question 8: Who and how will the contract be reviewed?
Response 8: An independent Scientific Review Panel composed of subject matter experts will evaluate the proposals against the defined evaluation criteria.

Question 9: Regarding the infection via infected mosquitoes: does that require the existence of an insectary at our institution?
Response 9: The Contractor is responsible for meeting the following requirements regarding provision of infectious mosquitoes and ensuring safety of staff and trial participants.

See Attachment 3, page 1 of 4, Section 2) Scope.

“Independently, and not as an agent of the Government, on a task order basis, the contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the clinical studies and requirements described below.”

See Attachment 3, page 3 of 4, Section B.2.

... “The provision of infectious mosquitoes or other infectious materials and the provision of a site suitable for conducting the CHMI will be the responsibility of the contractor. Appropriate measures to ensure safety of the trial participants and staff conducting the challenges must be taken.”

Question 10: How do we predict costs? As each trial has a range of subjects.
Response 10: Each offeror will have to predict costs as best they can.

Question 11: Do we have to provide all the costs upfront and only get reimbursed after the money is spent via invoice?
Response 11: Yes.