

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE J	PAGE OF PAGES 1 56
2. AMENDMENT/MODIFICATION NO. 0002	3. EFFECTIVE DATE 15-Apr-2009	4. REQUISITION/PURCHASE REQ. NO. W74MYF8337N213		5. PROJECT NO.(If applicable)
6. ISSUED BY USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	CODE W81XWH	7. ADMINISTERED BY (If other than item 6) USA MED RESEARCH ACQ ACTIVITY ATTN:BLOSSOM WIDDER 301-619-7143 BLOSSOM.WIDDER@AMEDD.ARMY.MIL FORT DETRICK MD 21702		CODE W81XWH
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		X	9A. AMENDMENT OF SOLICITATION NO. W81XWH-09-R-0012	
		X	9B. DATED (SEE ITEM 11) 19-Mar-2009	
			10A. MOD. OF CONTRACT/ORDER NO.	
			10B. DATED (SEE ITEM 13)	
CODE	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input checked="" type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input checked="" type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning <u>1</u> copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) This amendment is to provide answers to questions submitted on the solicitation (See attached). No additional questions will be accepted. The closing date remains 5 May 2009, at 1:00 pm ET.				
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)		
		TEL:	EMAIL:	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA		16C. DATE SIGNED
_____ (Signature of person authorized to sign)		BY _____ (Signature of Contracting Officer)		15-Apr-2009

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

QUESTIONS AND ANSWERS

W81XWH-09-R-0012 Questions and Answers

1. Page 9 - What additional OCONUS operations will this contract support? What percentage of effort is dedicated to supporting these operations? How is this program related to the PEPFAR (President's Emergency Plan for Aids Relief)?

OCONUS OPERATIONS WILL INCLUDE SUPPORT FOR EFFORTS IN KENYA, TANZANIA, UGANDA, NIGERIA, THAILAND AT A MINIMUM. ABOUT 20% OF EFFORT MAY BE DESIGNATED TO SUPPORT THESE EFFORTS. THE PROGRAM IS NOT RELATED TO PEPFAR.

2. Page 9 - How many current contract staff, if any, is supporting COE research efforts now? What companies are supporting these efforts? Will these companies be allowed to bid on this Performance Work Statement?

THERE ARE NO CONTRACT STAFF SUPPORTING THE COE AT THIS TIME.

3. Page 10 - What is the existing IT and communications support?

IT SUPPORT IS CURRENTLY SUPPLIED BY THE DIVISION OF BIOMETRICS AT WRAIR.

4. Page 11- What type of clinical trial support is required? Is the contractor expected to conduct or manage clinical trials at CONUS and OCONUS locations? Or is the contractor expected to provide administration support? Will the contractor sponsor the IND? CLINICAL TRIAL SUPPORT MIGHT INCLUDE THE STAFFING OF CLINICAL SITES (MEDICAL, TECHNICAL AND ADMINISTRATIVE), THE SUPPORT OF CLINIC FACILITIES TO INCLUDE INFRASTRUCTURE AND IT SUPPORT. THE CONTRACTOR WOULD BE EXPECTED TO SUPPORT BOTH CONUS AND OCONUS CLINICAL SITES. IND ASSIGNMENTS ARE MADE ON A CASE BY CASE BASIS.

5. Page 13 - What type of samples and how many are anticipated to be stored each year? UP TO 2000 SAMPLES PER YEAR COULD BE EXPECTED IN SUPPORT OF THE JBR. A SUBSET OF THESE WOULD NEED TO BE ARCHIVED.

6. Page 15 - Are these QA audits? If so, how many audits are anticipated per year? NO. THESE ARE NOT QA AUDITS.

7. Page 16 Is the contractor expected to have GMP manufacturing capabilities? NO. THIS COULD BE SUBCONTRACTED OR DONE AT THE WRAIR FACILITY.

8. Page 18 - Is the contractor expected to work with WRAIR COE staff to secure outside funding to support this effort?

NO. COE INVESTIGATORS WOULD SEEK FUNDING.

9. Task #1

a. What is the total number of FTE required to carry out the specific tasks outlined in this PWS?
GOVERNMENT ESTIMATES FTE NOT TO EXCEED 12.

b. How will these FTEs be divided between the CONUS and OCONUS locations?
TASK ONE WILL SUPPORT CONUS OPERATIONS ONLY.

c. How many administrative support personnel will be required to carry out: a) managerial operations, b) clinical support (for presentations, briefings, reports, etc)?
GOVERNMENT ESTIMATES 3-5 FTES FOR MANAGERIAL OPERATIONS, 3-5 FOR SCIENTIFIC OR TECHNICAL OPERATIONS.

d. How many FTE are estimated for the support of IT and communications?
GOVERNMENT ESTIMATES 4 FTES FOR IT SUPPORT.

e. How many FTE are estimated for purchasing and receiving supplies?
GOVERNMENT ESTIMATES 1 FTE FOR PROCUREMENT.

f. What is the current level of travel for non-government personnel; and what is the estimated FTE to support this effort?
NON-GOVERNMENTAL TRAVEL WOULD BE PRIMARILY FOR THE CONTRACTOR STAFF.
GOVERNMENT ESTIMATES 1 OR LESS FTE WOULD BE NEEDED.

g. How many FTE will be utilized for marketing and public relations?
GOVERNMENT ESTIMATES 1 FTE FOR MARKETING AND PAO.

h. How many FTE are estimated for facility maintenance and security?
GOVERNMENT ESTIMATES NO FTES FOR FACILITY MAINTENANCE AND SECURITY.

i. How many FTEs are estimated for training and instructional support?
GOVERNMENT ESTIMATES NO FTES FOR TRAINING OR INSTRUCTIONAL SUPPORT.

10. Task #2

a. How many FTE are currently in Antimalarial Drug Development Division?
THE TOTAL NUMBER OF FTES IN ANTIMALARIAL DRUG DEVELOPMENT IS NOT RELEVANT. THERE WOULD BE UP TO 3 SENIOR GOVERNMENT PERSONNEL INTERACTING WITH CONTRACTOR STAFF.

b. How many FTE are expected to be added to this division?
GOVERNMENT ESTIMATES 8 -12 FTES FOR THIS TASK.

c. How many FTE will be required for each of the "specific task elements"? For example, how many technicians and scientists will be needed for base year and successive years to specifically: a) identify and validate new drug targets; b) identify and optimize lead compounds; c) conduct preclinical tests in preparation for IND filings; and d) training and fellowship support?
GOVERNMENT ESTIMATES APPROXIMATELY 3 FTES PER SUBTASK.

d. What is the desired educational background for the technical staff supporting Antimalarial Drug Development?

FOR TECHNICAL STAFF AN UNDERGRADUATE DEGREE FROM AN ACCREDITED INSTITUTION IN THE RESPECTIVE FIELD IS DESIRED. PROFESSIONAL RESEARCH SCIENTISTS, IT IS DESIREABLE TO HAVE A PH.D. OR MD WITH SOME POSTDOCTORAL TRAINING.

e. Will the contractor be expected to provide direct laboratory research support on-site; and/or oversee and manage milestones of subcontractors at off-site locations?

ALL WORK SHOULD BE EXECUTED AT THE WRAIR.

11. Task #3

a. How many FTE are currently in the Wound Infection Research Division?

THE TOTAL NUMBER OF FTES IN WOUND INFECTION IS NOT RELEVANT. THERE WOULD BE UP TO 3 SENIOR GOVERNMENT PERSONNEL INTERACTING WITH THE CONTRACTOR.

b. How many FTE are expected to be added to this division?

GOVERNMENT ESTIMATES 5-10 FTES FOR THIS TASK.

c. How many FTE will be required for each of the "specific task elements"? For example, how many technicians and scientists will be needed for base year and successive years to: characterize the molecular epidemiology of MRSA or VRE; develop quantitative measures of wound infection, etc.?

GOVERNMENT ESTIMATES 5-10 FTES FROM THE BASE YEAR FORWARD FOR THESE SUBTASKS.

d. What is the desired educational background for the technical staff supporting these task elements?

FOR TECHNICAL STAFF, AN UNDERGRADUATE DEGREE FROM AN ACCREDITED INSTITUTION IN THE RESPECTIVE FIELD IS DESIRED. FOR PROFESSIONAL RESEARCH SCIENTISTS, IT IS DESIREABLE TO HAVE A PH.D. OR MD WITH SOME POSTDOCTORAL TRAINING.

12. Task #4

a. How many FTE are currently in the Viral Diseases Research Division?

THE TOTAL NUMBER OF FTES IN VIRUS DISEASES DIVISION IS NOT RELEVANT. THERE WOULD BE UP TO 3 SENIOR GOVERNMENT PERSONNEL INTERACTING WITH THE CONTRACTOR.

b. How many FTE are expected to be added to this division?

GOVERNMENT ESTIMATES 4-8 FTES FOR THIS TASK.

c. How many FTE will be required for each of the "specific task elements"? For example, how many technicians and scientists will be needed for base year and successive years to: characterize the determinants of virulence; investigate host factors in pathogenesis; etc.?

GOVERNMENT ESTIMATES 4-8 FTES FROM THE BASE YEAR FORWARD.

d. What is the desired educational background for the technical staff supporting these task elements?

FOR TECHNICAL STAFF, AN UNDERGRADUATE DEGREE FROM AN ACCREDITED INSTITUTION IN THE RESPECTIVE FIELD IS DESIRED. FOR PROFESSIONAL RESEARCH SCIENTISTS, IT IS DESIREABLE TO HAVE A PH.D. OR MD WITH SOME POSTDOCTORAL TRAINING.

13. Task #5

a. How many FTE are currently in the Malaria Vaccine Development Division?

THE TOTAL NUMBER OF FTES IN MALARIA VACCINE DEVELOPMENT IS NOT RELEVANT. THERE WOULD BE UP TO 3 SENIOR GOVERNMENT PERSONNEL INTERACTING WITH THE CONTRACTOR.

b. How many FTE are expected to be added to this division?

GOVERNMENT ESTIMATES 5-10 FTES FOR THIS TASK.

c. How many FTE will be required for each of the "specific task elements"? For example, how many technicians and scientists will be needed for base year and successive years to: characterize antigenic targets against malaria; characterize protective immune mechanisms; etc.?

GOVERNMENT ESTIMATES 5-10 FTES.

d. What is the desired educational background for the technical staff supporting these task elements?

FOR TECHNICAL STAFF, AN UNDERGRADUATE DEGREE FROM AN ACCREDITED INSTITUTION IN THE RESPECTIVE FIELD IS DESIRED. FOR PROFESSIONAL RESEARCH SCIENTISTS WOULD BE EXPECTED TO HAVE A PH.D. OR MD WITH SOME POSTDOCTORAL TRAINING.

14. Task #6

a. Is there currently a Host and Pathogen Genomics/Proteomics Division?

THIS IS A NEW EFFORT. THERE IS CURRENTLY NO DEFINED DIVISION ASSIGNED THIS EFFORT. ONE OR TWO GOVERNMENT SCIENTISTS WOULD INTERACT WITH THE CONTRACTOR.

b. How many FTE are expected to be added to this division?

GOVERNMENT ESTIMATES 5-10 FTES FOR THIS TASK.

c. How many FTE will be required for each of the "specific task elements"? For example, how many technicians and scientists will be needed for base year and successive years to: establish genomics/proteomics at WRAIR; establish bioinformatics/statistical competency; etc.?

GOVERNMENT ESTIMATES 5-10 FTES FOR THIS TASK.

d. What is the desired educational background for the technical staff supporting these task elements?

FOR TECHNICAL STAFF, WOULD BE EXPECTED TO HAVE AN UNDERGRADUATE DEGREE FROM AN ACCREDITED INSTITUTION IN THE RESPECTIVE FIELD IS DESIRED.

FOR PROFESSIONAL RESEARCH SCIENTISTS, IT IS DESIREABLE TO HAVE A PH.D. OR MD WITH SOME POSTDOCTORAL TRAINING.

15. Page 50, “offeror’s capability to comply with the applicable Performance Work Statement (PWS) including a full explanation of the techniques and procedures to be followed.” In many of the task elements, specific techniques are not mentioned. Would you like our response to suggest appropriate techniques that may be useful?

THE OFFEROR MAY ADDRESS APPROPRIATE APPROACHES THAT MAY BE USEFUL.

16. What is the page limitation for this proposal?

THERE IS NO PAGE LIMIT ESTABLISHED. PROPOSALS SHOULD NOT CONTAIN AN EXCESSIVE AMOUNT OF INFORMATION.

17. Attachment 2 Past Performance References: Is the contractor to fill out Attachment 2 and send directly to Ms. Widder or should those be sent out to the contractor's references for them to send in to Ms. Widder?

REFERENCE SECTION L.3., PARAGRAPH 4.B. THE OFFEROR IS TO COMPLETE ATTACHMENT 2 FOR 3-5 REFERENCES AND INCLUDE WITH THE PROPOSAL. THE OFFEROR IS TO ENSURE THAT THE 3 TO 5 REFERENCES COMPLETE ATTACHMENT 3 AND RETURN TO THE CONTRACTING OFFICER PRIOR TO THE CLOSING TIME OF THE SOLICITATION.

18. Will the Government provide the necessary space for the professional and administrative personnel required under this contract?

YES. CONTRACT STAFF WOULD WORK IN BLDG 503 ON THE FOREST GLENN CAMPUS OF THE MAIN WALTER REED ARMY INSTITUTE OF RESEARCH FACILITY.

19. Can the Government define the magnitude of the supplies and equipment which might need to be purchased?

THE SUPPLIES AND EQUIPMENT PURCHASES COULD CONSTITUTE ABOUT 40-45% OF THE TOTAL EFFORT ON THIS CONTRACT.

20. Intentionally blank.

21. The current NAICS applied to this solicitation is 541990 All Other Professional, Scientific, and Technical Services. Given the heavy focus placed on Biological research stated in the Performance Work Statement (PWS), will the Government consider changing the NAICS to 541711 Research and Development in Biotechnology and making this a small business set-aside?

NO. THIS IS A FULL AND OPEN COMPETITION. SMALL BUSINESS CONCERNS MAY PARTICIPATE IN THE COMPETITION.

22. Given the size, scope and complexity of this solicitation, would the Government consider making multiple awards?

NO

23. The estimated cost of this contract is given at 84 million dollars. Is this cost per year or over the life of the contract?

\$84M IS THE ESTIMATED COST for the Base year and 4 option years.

24. The scope of this solicitation appears to overlap with several current ongoing efforts/contracts at WRAIR. Is it the Government's intention to cancel, phase out, transition, and or replace the work on existing contracts with the COE contract?

NO

25. Will the winner be involved in planning activities that afford visibility to other company's contracts and sensitive/proprietary information (i.e. staffing levels/plans, labor categories, rates, management plans, etc.)?

NO

26. Does the Government intend on issuing Task Orders for performance of the work once the contract is awarded, such that all Task Orders will be priced individually, or will all work be collectively priced within each year's CLIN (i.e., 0001, 1001, 2001, etc.)? If the work is to be awarded based on individual Task Orders, will the Government provide a description of the proposed Task Orders.

NO INDIVIDUAL TASK ORDERS WILL BE ISSUED AFTER THE CONTRACT IS AWARDED.

27. Section L of the solicitation states that this is for "Performance Based Service", however the Performance Requirements Summary Table (in Attachment 1) seems to be centered around the provision of personnel services and support. Can the Government confirm whether this contract will be a personnel services and support services contract or a non-personal services performance based contract?

THE REQUIREMENT IS A PERFORMANCE BASED ACQUISITION. THE SERVICES ARE NON-PERSONAL.

28. Is the Government asking bidders to provide cost estimates to accomplish each specific task and sub element listed in the PWS? The current descriptions state the type of service to be performed but does not quantify nor define sufficient level of detail for prospective bidders to quantify the level of effort (LOE) needed to support each task in the SOW. If yes, please provide a sufficient level of detail to allow contractors to cost and price each task.

THE PROPOSAL IS TO PROVIDE THE ESTIMATED COST OF EACH CLIN FOR THE WORK THAT IS PROPOSED AND A BREAKDOWN OF THOSE COSTS IN THE COST PROPOSAL.

29. The Solicitation includes FAR Clause 52.219-9 Small Business Subcontracting Plan. Does the Government require offerors to include a small business subcontracting plan in its submission? If not, does the Government intend to require submission of a plan after award?

SEE SECTION L.3, PARAGRAPH 1.D.

30. In Section L.1 on page 47, the Government estimates travel costs as \$267,000 per year. Does the Government intend offerors use this figure as the estimated direct travel cost for each year of the proposal?

THE GOVERNMENT'S AVERAGE ESTIMATED TRAVEL COST PER YEAR IS \$267,000. THE OFFEROR'S ESTIMATED COST PER YEAR MAY BE DIFFERENT.

31. This contract calls for centralizing services, other than communications, IT, marketing, administrative support, travel, and purchasing, what other areas does the Government intend to centralize?

SERVICES LISTED IN THE PWS ARE TO SUPPORT THE COE.

32. Section 1.0 of the Solicitation requires facility and security support by the contractor. The security support is not defined elsewhere in the Solicitation. Can the Government provide additional detail defining the scope of this required support?

THE CONTRACTOR WILL NEED TO PROVIDE SECURITY CLEARANCE FOR PERSONNEL IN KEEPING WITH DOD REGULATIONS FOR ACCESS TO GOVERNMENT FACILITIES.

33. Does the Government intend for the contractor to provide security and facility support to both the WRAIR and its overseas locations? If the scope of these specific services includes overseas locations, can the Government provide a list of the locations?

NO

34. Will the Government provide a current organization chart for the COE and the department within WRAIR and its overseas that will be affected by this contract?

NO.

35. Does the Government expect the contractor to pay for utilities, communications, or facilities leases?

WORK IS ANTICIPATED TO TAKE PLACE IN GOVERNMENT FACILITIES.

36. Are any currently contracted positions to be included to support this specific contract? Does the Government's overall target budget figure for this effort include costs attributable to current contract personnel positions, or is it expected to cover only additional positions or services under this contract?

NO. THIS CONTRACT IS FOR NEW WORK.

37. Is this RFP funded with new money or does it represent a reorganization of existing activities within WRAIR and its overseas locations?

THE CONTRACT WILL BE INCREMENTALLY FUNDED AND IS NOT A REORGANIZATION OF EXISTING ACTIVITIES.

38. Will the Government provide a comparison of the levels of support required between WRAIR and its overseas locations?

SUPPORT FOR OVERSEAS SITES IS ANTICIPATED TO BE ABOUT 20% OF THE OVERALL EFFORT.

39. Does the Government anticipate that the majority of the work on this contract will take place overseas?

NO

40. Can the Government define what it means in the Performance Requirement Summary Table when it states "no more than 2 interruptions in OCONUS laboratory operations per year"?

SHUT DOWN OF OCONUS LAB OPERATIONS DUE TO LACK OF SUPPORT OR FAILURE TO MAINTAIN ACCREDITATION (IF APPLICABLE).

41. Can the Government define what it means in the Performance Requirement Summary Table when it states "no more than 5, 15, 1 problematic actions per year" for Procurement Support (Equipment, Expendables, Contract)?

THESE ARE ACCEPTABLE QUALITY LEVELS OF PERFORMANCE.

42. Would an award to a single contractor mean that current activities with other contractor(s) be moved to the awardee? If so, please delineate the current activities that will be moved to the awardee.

NO

43. In the Performance Requirement Summary Table, the Government states that all Security Personnel must have a USAMRIID photo ID badge. Does the Government mean that all Security Personnel must have a WRAIR badge?

YES. THIS IS A MISPRINT. THE CONTRACT SHOULD READ WRAIR ID.

44. In the Performance Requirement Summary Table it states that "there is to be no equipment malfunction due to contractor failure 95% of the time". Can the Government give a description of the repairs and preventative maintenance that it requires for this large mechanical equipment?

EQUIPMENT UTILIZED ON THE CONTRACT BY THE CONTRACTOR MUST BE REPAIRED AND MAINTAINED TO ASSURE CONTINUOUS FUNCTIONING OF THE EQUIPMENT.

45. How will the contract be operationalized between WRAIR and the contractor? Will there be an identified POC for each task with whom the contractor will work with?

THE TECHNICAL POC FOR THE CONTRACT WILL BE THE CONTRACTING OFFICER'S REPRESENTATIVE.

46. Will the Government WRAIR staff identify specific areas for support and request the contractor to fill those positions, or will the contractor play any role in the initial processes in terms of defining the positions to be filled and identification of new drug targets, classes, and compounds?

THE OFFEROR IS TO PROVIDE A TECHNICAL AND COST PROPOSAL DESCRIBING HOW THEY PROPOSE TO ACCOMPLISH THE PWS.

47. Will the contractor be required to undertake scientific, clinical, educational, or other professional supervisory activities?

YES. THE CONTRACTOR WILL SUPERVISE CONTRACTOR EMPLOYEES.

48. Will the contractor be required to undertake specific research or support objectives within its own organization on behalf of WRAIR? For example, will the contractor be required to develop a compound, or target, using their own facilities?

NO

49. Will the contractor be responsible for providing support personnel to WRAIR who will have the responsibility of delivering a compound, product or vaccine target?

YES

50. How will the contractor be judged on its performance, and how will that be linked to payment?

SURVEILLANCE OF PERFORMANCE WILL BE BY PERIODIC INSPECTION AND CUSTOMER COMPLAINTS. DISCREPANCIES WILL REQUIRE CORRECTIVE ACTION. PAYMENT WILL NOT BE MADE FOR NON-PERFORMANCE.

51. Will all the tasks presented in the Solicitation be administered by a central authority within the COE including budgeting, or will the COE component entities (Divisions etc.) operate independently with the contractor?

A COR WILL OVERSEE AND FACILITATE THE CONTRACT.

52. Will the contractor be required to provide any animal, manufacturing, or clinical trials facilities for this work?

NO

53. For grants coming through the COE, will there be a duplicate charge for overhead (one for WRAIR and one for the contractor)?

THIS SENARIO IS NOT A CONTRACTUAL ISSUE.

54. In Section L.1 on page 48, paragraph 4, the instructions require offerors to "Provide the procedures that will be used to develop and maintain oversight of funding, expenditures, budget plans, allocations, commitments, and obligation." Would the Government provide additional detail on any requirements regarding these procedures?

PROCEDURES OF HOW THE CONTRACTOR CONDUCTS COST ACCOUNTING ARE PART OF COST-TYPE AWARD ACCOUNTING.

55. Does the Government want the contractor to retain Intellectual Property Rights for products developed under this contract?

NO

56. Task 1, Sub task 1

a. Can the Government provide an estimated level of FTEs to perform this task?

3-5 FTES

b. Does the Government intend for the professional administrative support personnel to the Commander, WRAIR to be located at the Government's WRAIR facility?

YES

c. Does the Government intend for any of the professional administrative support personnel to be located overseas? If yes, can the Government provide the overseas locations where these support personnel will be expected to provide services?

NO ADMINISTRATIVE STAFF IN SUPPORT OF TASK ONE ARE EXPECTED TO WORK AT OCONUS SITES.

d. Does the Government expect the overseas professional administrative support personnel to be located at a Government facility, or at the contractor's facility?

N/A

e. If the Government is requiring the contract staff to work on a Government site, is the Government going to provide office space, computers, and phones for the personnel?

THE CONTRACTOR WILL PROVIDE COMPUTERS. OFFICE SPACE AND PHONES ARE PROVIDED BY THE GOVERNMENT.

f. Does the Government intend to award such work on a Task Basis after award of the main contract? If the work is to be performed on a Task Basis, can the Government provide

additional detail defining the number of potential Tasks and scope of support required to meet the objectives of each specific Task?"

NO

57. Task 1, Subtask 2

a. For proposal purposes, how many presentations does the Government anticipate the contractor providing per contract year?

30-40

b. Does the Government want the contractor's clinical support personnel to represent the WRAIR COE and present findings and accomplishments to others?

NO

c. Can the Government provide a description of what a standard presentation encompasses (i.e., does the Government want the contractor to create power-points presentations with hand-outs in color?)

POWERPOINT PRESENTATIONS AND PRINTED MATERIALS ARE STANDARD.

d. Can the Government provide a description of what it means by the term "briefing"?

PRESENTATION/SEMINAR

e. How many briefings does the Government anticipate the contractor providing per contract year?

SEE a. ABOVE.

f. Does the Government want the contractor personnel to provide briefings regarding the COE?

THE CONTRACTOR WILL PREPARE MATERIALS PROVIDED BY THE GOVERNMENT.

g. Can the Government provide the number and type of reports they anticipate the contractor to provide per year?

NUMBER WILL VARY. ESTIMATE NO MORE THAN 1 FTE TO SUPPORT.

h. Can the Government provide a description of a standard report (i.e., how many pages, are graphics required, how many copies of the reports does the Government anticipate?)

SEE g. ABOVE.

i. Does the Government want the contractor to use the on-site MAVS services, or the contractor's own facilities to produce the printed, visual, and electronic media for the dissemination of COE findings and accomplishments?

ON SITE FACILITIES CAN BE USE OR THE CONTRACTORS FACILITIES CAN BE USED.

j. Does the Government want the contractor to use Government equipment for printing, copying, and electronically distributing this media?

NO

k. Does the Government anticipate needing printed, visual, and electronic media outside of those already mentioned (presentations, briefings, reports)? If yes, can the Government provide a description of the amount of media required?

NO

l. Does the Government intend to award such work on Task Basis after award of the main contract? If the work is to be performed on a Task Basis, can the Government provide additional detail defining the number of potential Tasks and scope of support required to meet the objectives of each specific Task?".

NO

m. The Government states that the contractor should provide "clinical support" for this task. Is the Government referring to medical and/or scientific support for technical writing and editing purposes?

YES

58. Task 1, Subtask 3

a. What are the specific worldwide locations where the Government needs IT and communications support?

EAST, WEST AFRICA, AND THE FAR EAST.

b. Will the contractor be required to purchase and establish these state of the art IT and communications systems?

YES

c. Does the Government intend for the contractor to provide highly specialized person and logistical support to WRAIR for the installations of these systems?

YES

d. What are the Government's current IT and communications systems including hardware and software for WRAIR and its overseas locations?

IT SUPPORT WILL ONLY PROVIDE FOR THE NEW EFFORTS.

e. Will current communication systems including hardware and software for WRAIR be used, or will the contractor be responsible for providing a new system to include hardware and software?

CONTRACTOR WILL PROVIDE NEW WHERE NEEDED.

f. Does the Government want the contractor to host any of these IT or communications systems/applications at their own facilities or will Government space be provided?

HOSTED ON GOVERNMENT FACILITIES.

g. Does the Government want the contractor to augment the current military and/or Government civilian IT and communications support personnel within WRAIR or its overseas locations? If yes, how many FTEs does the Government expect the contractor to provide?

YES. 1-2 FTES.

h. Does the Government want the contractor to provide a 24 hour IT support desk?

NO

i. If the Government wants the contractor to provide a 24 hour IT support desk, does the Government want this help desk to be located within WRAIR or on the contractor's facilities?

N/A

j. Does the Government anticipate the contractor providing overseas IT support?
YES

k. If the Government anticipates the contractor providing overseas IT support, does the Government want the contractor to provide IT personnel that are stationed overseas? If yes, in which overseas areas does the Government want IT personnel located?
NO

l. Does the Government anticipate the contractor using the Government IT system? If yes, please provide background information on the hardware and software programs currently in use by the Government that would pertain to this contract.
THE CONTRACTOR MAY USE BOTH THE GOVERNEMENT SYSTEM AND A SYSTEM AUGMENTED BY THE CONTRACTOR.

m. Does the Government anticipate that the contractor should provide overseas telephone and communication systems for WRAIR?
NO

n. Will the contractor be required to provide their own telephone and communication systems for WRAIR or any of WRAIR's overseas organizations?
NO

o. The Government asks for highly specialized personnel – can the Government give a definition of what it considers highly specialized personnel for IT and communications?
THE CONTRACTOR IS TO PROVIDE SUBJECT MATTER EXPERTS SUFFICIENT TO CARRY OUT THE TASKS.

p. Does the Government want the contractor to provide global visual, real-time, and audio communications for this task?
NO

q. Does the Government intend to award such work on Task Basis after award of the main contract? If the work is to be performed on a Task Basis, can the Government provide additional detail defining the number of potential Tasks and scope of support required to meet the objectives of each specific Task?"
NO

59. Task 1, Subtask 4

a. How many professional workshops does the Government anticipate per contract year?
UP TO 10

b. What is the Government's anticipated duration of the professional workshops per contract year?
FROM ONE DAY TO MULTIPLE DAYS

c. How many individuals does the Government anticipate attending the professional workshops per contract year?
100 OR MORE

d. Does the Government want the contractor to provide food, travel, and lodging for the professional workshops?

YES

e. Does the Government want the contractor to provide expert speakers for the professional workshops? If yes, how many expert speakers does the Government anticipate the contractor to provide per workshop?

NO

f. Does the Government want the contractor to provide audio/visual services for each professional workshop?

IF NECESSARY.

g. Will the professional workshops be provided on site at WRAIR or should the contractor include the price of "off site" facilities to conduct these workshops in their proposal?

BOTH ON SITE AND OFFSITE VENUES MAY BE NEEDED.

h. Will any of these professional workshops take place at overseas locations? If so, please specify the anticipated number and location.

POSSIBLE LOCATIONS FOR AN OCONUS MEETING COULD BE NAIROBI , KENYA, OR BANGKOK THAILAND FOR 30-40 PERSONS, ONCE A YEAR.

i. How many technical workshops does the Government anticipate per contract year?

2-3

j. What is the Government's anticipated duration of the technical workshops per contract year?

FROM 1 DAY TO MULTIPLE DAYS.

k. How many individuals does the Government anticipate attending the technical workshops per contract year?

100 OR MORE.

l. Does the Government want the contractor to provide food, travel and lodging for the technical workshops?

YES

m. Does the Government want the contractor to provide expert speakers for the technical workshops? If yes, how many expert speakers does the Government anticipate the contractor to provide per technical workshop?

EXPERT SPEAKERS WILL BE INVITED BY THE GOVERNMENT.

n. Does the Government want the contractor to provide audio/visual services for each technical workshop?

IF NECESSARY.

o. Will the technical workshops be provided on site at WRAIR or should the contractor include the price of "off site" facilities to conduct these workshops in their proposal?

BOTH ONSITE AND OFFSITE VENUES MAY BE NEEDED.

p. Will any of these technical workshops take place at overseas locations? If so, please specify the anticipated number and location.

POSSIBLE LOCATIONS FOR AN OCONUS MEETING COULD BE NAIROBI , KENYA, OR BANGKOK THAILAND FOR 30-40 PERSONS, ONCE A YEAR.

q. How many seminar series does the Government anticipate per contract year?
20

r. What is the Government's anticipated duration of the seminar series per contract year?
A SEMINAR IS A SINGLE DAY EVENT.

s. How many individuals does the Government anticipate attending the seminar series per contract year?
100 OR MORE.

t. Does the Government want the contractor to provide food, travel, and lodging for the seminar series?
YES

u. Does the Government want the contractor to provide expert speakers for the seminar series? If yes, how many expert speakers does the Government anticipate the contractor to provide per seminar series?
YES, 5-6 PER YEAR.

v. Does the Government want the contractor to provide audio/visual services for each seminar series?
IF NECESSARY.

w. Does the Government intend for the seminar series to be attended by the general public?
NO

x. Will these seminar series be provided on site at WRAIR or should the contractor include the price of "off site" facilities to conduct these in their proposal?
BOTH ONSITE AND OFFSITE VENUES MAY BE NEEDED.

y. Will any of these seminar series take place at overseas locations? If so, please specify the anticipated number and location.
POSSIBLE LOCATIONS FOR AN OCONUS MEETING COULD BE NAIROBI , KENYA, OR BANGKOK THAILAND FOR 30-40 PERSONS, ONCE A YEAR.

z. Are the on and off site meetings different than the professional and technical workshops or seminar series? If yes:
NO

aa. How many on site meetings does the Government anticipate per contract year?
2-3

ab. What is the Government's anticipated duration of the on site meetings per contract year?
ONE TO SEVERAL DAYS.

- ac. How many individuals does the Government anticipate attending the on site meetings per contract year?
100 OR MORE.
- ad. Does the Government want the contractor to provide food, travel and lodging for individuals participating in the on site meetings?
YES
- ae. Does the Government want the contractor to provide audio/visual services for each on-site meeting?
IF NECESSARY.
- af. How many off site meetings does the Government anticipate per contract year?
2-3
- ag. What is the Government's anticipated duration of the off site meetings per contract year?
2-3 DAYS
- ah. How many individuals does the Government anticipate attending the off site meetings per contract year?
2-3 PER YEAR
- ai. Does the Government want the contractor to provide food, travel and lodging for individuals participating in the off site meetings?
YES
- aj. Does the Government want the contractor to provide audio/visual services for each off site meeting?
IF NECESSARY.

60. Task 1, Subtask 5

- a. Does the Government want the contractor to provide new research support platforms that will replace the current research platforms at WRAIR?
NO EXISITNG PLATFORMS WILL BE SUPPLANTED.
- b. Does the Government want the contractor to provide new research platforms that will augment those already in place at WRAIR?
YES
- c. Does the Government intend to approve the new research platforms?
YES
- d. Many research platforms exist within institution in which WRAIR researchers already collaborate, and use cooperatively with others (i.e., NIH and universities). Does the Government want the contractor to replicate these existing research platforms within WRAIR?
NO
- e. Many of these research platforms are expensive - Does the Government intend for the contractor to secure funding for these platforms?

NO

f. How many research platforms does the Government anticipate the contractor providing per contract year?

N/A

g. Can the Government provide a definition of the type of research platform it would like?

LOGISTIC, PERSONNEL AND MATERIEL SUPPORT.

h. When the Government asks for a research platform, does it mean a physical infrastructure and system, or a management system?

ALL COMPONENTS ARE RELEVANT.

61. Task 1, Subtask 6

a. How many supplies and pieces of equipment does the Government anticipate the contractor ordering per contract year?

THE AMOUNT REQUIRED TO EXECUTE THE MISSION.

b. In order to assist the Government in reviewing proposals, will the Government provide a monetary figure for all contractors to use to price this task?

NO

c. Does the Government want the contractor to approve and purchase supplies and equipment in support of the COE under \$3,000.00?

NEEDED SUPPLIES AND EQUIPMENT UNDER \$3000 IN SUPPORT OF THE COE DO NOT REQUIRE COR APPROVAL.

d. In order to assist the Government in reviewing proposals, will the Government provide a monetary figure for all contractors to use to price this task?

NO

62. Task 1, Subtask 7

a. How many travel arrangements in the United States does the Government anticipate the contractor to make per contract year?

25-50

b. How many travel arrangements outside of the United States does the Government anticipate the contractor to make per contract year?

20-50

c. In order to assist the Government in reviewing proposals, will the Government provide a monetary figure for all contractors to use to price this task

NO

63. Task 1, Subtask 8

a. Does the Government want the contractor to provide a marketing and public relations group on site at WRAIR?

THE REQUIREMENT IS TO PROVIDE SUPPORT FOR SUCH A GROUP.

b. Does the Government want the contractor to provide a marketing and public relations group on site in the Government's overseas locations? If yes, please provide the overseas locations.
NO

c. If the Government wants the contractor to provide marketing and public relations personnel on site at WRAIR or its overseas locations, will the Government be providing desks, computers, and telephones for the personnel?
THE GOVERNMENT WILL PROVIDE DESKS AND PHONE. THE CONTRACTOR WILL PROVIDE COMPUTERS.

d. How many FTEs does the Government anticipate the contractor providing for marketing and public relations efforts?
GOVERNMENT ESTIMATES 1-2.

e. How many public relations events does the Government anticipate the contractor hosting or attending?
2 PER YEAR

f. Does the Government want the contractor to provide press releases for the COE?
NO

g. Does the Government want the contractor to create a newsletter for the COE?
NO

h. Does the Government want the contractor to provide business development opportunities for the COE?
NO

i. Does the Government want the contractor to develop a new web site for the COE?
NO

j. Will the Government provide a proposed outline of the number of FTEs it anticipates needing to provide support for marketing and public relations efforts to foster the reputation of the COE?
GOVERNMENT ESTIMATES 1-2.

64. Task 2, Subtask 1

a. How many new drug targets does the Government anticipate the contractor will identify and validate per contract year?
THIS INFORMATION CANNOT BE PROVIDED.

b. How many new drug classes does the Government anticipate the contractor will identify and validate per contract year?
THIS INFORMATION CANNOT BE PROVIDED.

c. How many new compounds does the Government anticipate the contractor will identify and validate per contract year?
THIS INFORMATION CANNOT BE PROVIDED.

d. The solicitation mentions that this program performs medicinal chemistry and pharmacological testing of drugs. Does the Government intend for this solicitation to replace WRAIR's current Antimalarial Drug Development work?

NO

e. In the background to this Task, the Government states that "a Government senior scientist and/or clinician with significant drug development experience coordinates each Task Area." Does the Government intend for the contractor to replace these senior scientists or to work with them for drug development?

NO

f. Will the research support personnel services required under this task work closely with the current Government WRAIR researchers in this Department?

YES

g. Does the Government want the contractor to provide these research support services at the WRAIR using WRAIR laboratories?

YES

h. If the Government wants the contractor to provide research support services using the WRAIR laboratories, will the contractor need to work side by side with other contractors or Government personnel?

YES

i. Does the Government anticipate that any of this work will take place in the WRAIR overseas locations? If yes, please provide the specific locations.

NO

j. Will WRAIR provide laboratory space, desks, computers, and phones for research support personnel working on a Government site?

THE CONTRACTOR WOULD PROVIDE COMPUTERS.

k. Does the Government want the contractor to develop liver stage screening assays? If yes, how many liver stage screening assays does the Government anticipate the contractor working on per contract year?

NO

l. Does the Government want the contractor to work on drug targets, classes, compounds and liver stage screening assays that are different from those that are currently being researched at WRAIR now?

THIS INFORMATION CANNOT BE PROVIDED.

m. Does the Government want the contractor to determine which drug targets, classes, compounds and liver stage screening assays will be worked on? If yes, does the Government want to approve the proposed targets and methods for research chosen by the contractor?

NO

n. In the Task background, the Government states, "Under this task the program performs medicinal chemistry and pharmacological testing of drugs, such as drug synthesis, toxicity

testing, pharmacokinetics, and other critical path activities required for drug selection and development.” Does the Government want the contractor to replace the current medicinal chemistry and pharmacological testing being done at WRAIR? If not, does the Government intend for the contractor to work alongside the current medicinal and pharmacological laboratory researchers within WRAIR or its overseas laboratories?

NO. YES.

o. Does the Government want the contractor to store chemicals and maintain a database of their activities resulting from screening and testing activities of the program? If yes, does the Government want the contractor to provide these services on-site at WRAIR or its overseas laboratories?

YES. YES.

p. Can the Government provide the names of the overseas laboratories where it wants the contractor to provide chemical storage and maintenance of database activities?

N/A

q. If the Government wants the contractor to store chemicals and maintain a database of their activities on-site at WRAIR, does the Government intend for the contractor to use the already established Government chemical storage and database or does the Government want the contractor to provide new storage space and database?

BOTH

r. Does the Government want the contractor to take the scientific lead for all of Task 2 or to support the current Government lead within WRAIR?

SUPPORT THE GOVERNMENT LEAD.

s. How many acceptable lead compounds with potent antimalarial activity does the Government anticipate the contractor providing per contract year?

THIS INFORMATION CANNOT BE PROVIDED.

t. How many alternative delivery systems does the Government anticipate the contractor developing per contract year?

THIS INFORMATION CANNOT BE PROVIDED.

u. The Government states in subtask #2 that a requirement of this contract is to identify and optimize acceptable lead compounds with potent antimalarial activity. Research efforts within WRAIR's Medicinal Chemistry Group currently include similar objectives under a separate contract. Does the Government intend to have two contractors working on the same objectives or will these activities be separate from those already contracted?

THE GOVERNMENT WILL USE ALL RESOURCES AT ITS DISPOSAL TO EXECUTE THE MISSION: ACTIVE DUTY, GS CIVILIANS, CONTRACTORS AND COOPERATIVE AGREEMENT PARTNERS.

v. Does the Government intend for the contractor to provide these services within WRAIR or its overseas laboratories? If yes, which overseas laboratories?

WRAIR FACILITIES WILL BE USED.

w. Does the Government intend for the contractor to work alongside the current Government/contract staff in the Medicinal Chemistry group for this effort?

THE GOVERNMENT WILL USE ALL RESOURCES AT ITS DISPOSAL TO EXECUTE THE MISSION: ACTIVE DUTY, GS CIVILIANS, CONTRACTORS AND COOPERATIVE AGREEMENT PARTNERS.

x. Does the Government intend for this contract to replace or augment the Medicinal Chemistry work that is currently on-going within WRAIR?
TO AUGMENT.

y. If the Government intends for this task to be provided within WRAIR, will the Government provide laboratory space, desks, computers, and phones for the research support personnel?
COMPUTERS WILL BE PROVIDED BY THE CONTRACTOR.

z. Does the Government intend for this contract to replace or add to the scientific leadership in the Experimental Therapeutics group?
NO

aa. Does the Government want the contractor to determine which lead compounds to research and which alternative delivery systems to develop? If yes, does the Government want to approve the proposed targets and methods for research chosen by the contractor?
NO

ab. How many new drugs come from optimization studies per contract year?
THIS INFORMATION CANNOT BE PROVIDED.

ac. Does the Government intend for the preclinical testing to be conducted in the WRAIR facility?
YES

ad. Will WRAIR provide laboratory space, desks, computers, and phones for research support personnel conducting these preclinical tests?
THE CONTRACTOR MAY NEED TO SUPPLY COMPUTERS.

ae. If the Government intends for the preclinical testing to be conducted in the WRAIR facility, will the contractor be working alongside other contractors or in a separate laboratory?
THE GOVERNMENT WILL USE ALL RESOURCES AT ITS DISPOSAL TO EXECUTE THE MISSION: ACTIVE DUTY, GS CIVILIANS, CONTRACTORS AND COOPERATIVE AGREEMENT PARTNERS AND DO SO IN ITS WRAIR OR OCONUS FACILITIES.

af. Does the Government expect the contractor to provide preclinical testing in WRAIR's overseas locations? If yes, please identify which locations.
NO

ag. Does the Government intend for this preclinical work to replace the current preclinical work that the WRAIR is currently conducting?
NO

ah. How many Phase I trials does the Government anticipate the contractor conducting per contract year?
NO MORE THAN 3

ai. How many Phase II trials does the Government anticipate the contractor conducting per contract year?

NO MORE THAN 3

aj. How many Phase III trials does the Government anticipate the contractor conducting per contract year?

NO MORE THAN 3

ak. How many Phase IV trials does the Government anticipate the contractor conducting per contract year?

N/A

al. Does the Government want the contractor to provide pricing for these clinical trials in the proposal? If yes, should the pricing include costs for the management and coordination for the trials being conducted?

YES. YES.

am. Does the Government want the contractor to test Phase I, II or III products in the WRAIR Clinical Trials Center?

YES, WITH ADDITIONAL SITES POSSIBLE.

an. If the Government wants the contractor to test these Phase I, II, or III products in the WRAIR Clinical Trials Center, how will this impact the current contractors that work in the WRAIR Clinical Trials Center? Is it the Government's intent that these contractors would be transferred onto this new contract?

THIS CONTRACT WILL SUPPORT NEW ACTIVITIES. IT WILL NOT REPLACE EXTANT ACTIVITIES. NO.

ao. Does the Government want the contractor to provide a facility to conduct Phase I, II or III trials outside of WRAIR?

NO

ap. If the Government wants the contractor to conduct clinical trials outside of WRAIR, will the contractor still need to submit a protocol through WRAIR's Internal Review Board and scientific review process?

N/A

aq. Does the Government want the contractor to conduct Phase I trials overseas?

THE CONTRACTOR WILL SUPPORT SUCH TRIALS.

ar. Does the Government want the contractor to conduct Phase II trials overseas?

THE CONTRACTOR WILL SUPPORT SUCH TRIALS.

as. Does the Government want the contractor to conduct Phase III trials overseas?

THE CONTRACTOR WILL SUPPORT SUCH TRIALS.

at. Does the Government expect the contractor to provide all the resources necessary to conduct clinical trials including statistical analysis, quality assurance, data management, clinical monitoring, and safety oversight?

THE CONTRACTOR WILL AUGMENT EXTANT RESOURCES.

au. Does the Government expect the contractor to provide safety oversight in terms of Safety Monitoring Committees and DSMBs or are there already committed procedures in place that will be applied to the COE?

NO

av. Will the Government provide indemnification for participants for the Phase I through III clinical trials or will this be the responsibility of the contractor?

GOVERNMENT WILL PROVIDE.

aw. Does the Government have Standard Operating Procedures already in place for clinical trials or should the contractor develop these?

GOVERNMENT WILL PROVIDE.

ax. What kind of indemnification will the Government provide for the contractor for clinical trials?

N/A. THE GOVERNMENT RETAINS INDEMNIFICATION.

ay. Does the Government currently have a document management system in place or should the contractor anticipate including this in the scope of their responsibilities to provide this system?

NO AND NO.

az. Will the preclinical testing and clinical trials conducted in the scope of this contract be funded by outside sources? If yes, does the Government want the contractor to receive funding from these outside sources?

THIS INFORMATION CANNOT BE PROVIDED.

ba. Does the Government need a data management system for the Phase I – III clinical trials or is there a current data management system that will be used?

YES AND NO.

bb. If the Government requires the contractor to work with a Government established electronic data management system, please provide the name of that system and whether or not that system is a 21 CFR Part 11 validated and compliant system.

NO

bc. Does the Government want the contractor to maintain each clinical trial database? If yes, will access to data by WRAIR be inclusive in this contract? If yes, please provide the access requirements.

THIS INFORMATION CANNOT BE PROVIDED.

bd. What drugs/biologics does the Government currently have in the pipeline for Phase I – III testing that would fall under this contract?

THIS INFORMATION CANNOT BE PROVIDED.

be. The Solicitation is not consistent in terms of the scope of clinical trials. In one section the Government calls for the contractor to conduct Phase I – IV clinical trials and in another it calls for Phase I – III clinical trials. Can the Government confirm whether this contract will include Phase IV clinical trials?

THE CONTRACTOR WILL NOT SUPPORT PHASE IV TRIALS.

bf. If the Government wants the contractor to conduct Phase IV clinical trials, is it reasonable to assume that products will advance through Phase IV trials during the scope of this contract?

N/A

bg. Should the contractor include the provision of contractor Principal Investigators for INDs and clinical trials in this contract?

NO

bh. Can the Government describe the specific support required from the contractors for the training and fellowship support program?

THE CONTRACTOR WOULD PROVIDE ADMINISTRATIVE SUPPORT.

bi. Is it the Government's intent to replace the current training and fellowship support program with the contractors program?

NO

bj. Is it the Government's intent to have the contractor offer an additional training and fellowship program to WRAIR?

NO

bk. The contract requirements call for forums for fellowship programs. Are fellowship programs in the scope of the WRAIR COE and what potential impact with this have on the resources intended to be dedicated toward product development? Specifically, will FTEs provided be participating in the fellowship program and therefore reducing the percentage effort committed towards COE activities?

YES, RESOURCES WILL NEED TO BE AUGMENTED TO ADDRESS. NO.

65. Task 3, Subtask 1

a. There are a number of clinically important Gram-negative bacteria. Will the research emphasize all of these pathogens, or will there be a greater emphasis placed on some pathogens over others?

THIS INFORMATION CANNOT BE PROVIDED.

b. Will the task element be designed to differentiate between bacteria that colonize wounds or to those that specifically cause infection?

NO

c. Are there plans to design and test appropriate animal models to investigate cause and affect relationships?

NO

d. What methodology is to be used in determining resistance mechanisms in these organisms?

THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACHES.

e. Are specific research platforms to be used for this research?

NO

f. If yes, are they currently available at WRAIR?

N/A

g. If the current research platforms are not available at WRAIR, will the contractor be required to purchase these? If yes, does the Government want the contractor to provide this as part of this proposal?

YES

h. What platforms are of interest to the Government?

THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACHES.

i. Research in this area is currently underway at WRAIR. Will this subtask be in addition to current activities?

THE CONTRACT WILL SUPPORT NEW ACTIVITIES.

j. Will this subtask replace current work at WRAIR?

NO

k. Will overseas sites be involved in this research? If yes, which locations?

NO

l. How many cause and effect relationships does the Government anticipate the contractor characterizing per contract year?

THIS INFORMATION CANNOT BE PROVIDED.

66. Task 3, Subtask 2.

a. Are there plans to liaise with civilian medical facilities to gain access to a wider strain collection and database?

NO

b. Are there plans to investigate antibiotic resistance patterns between different isolates in addition to epidemiological studies?

YES

c. Why is this an either/or subtask? Both MRSA and VRE are important resistant organisms. PLEASE RESPOND TO THE STRUCTURE OF THE PWS AS STATED AND FOR BOTH CONTINGENCIES.

d. Will PFGE typing of MRSA be performed?

YES

e. What testing is contemplated for VRE?

THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACHES.

f. Where will testing of isolates occur?

WRAIR

g. Will testing be performed outside of the United States?

NO

h. If testing will be performed outside of the United States, can the Government specify the location(s)?

N/A

i. Will contractor be required to certify these labs? If Yes, does the Government want the contractor to include this as part of their proposal?

NO

j. Where outside of WRAIR will epidemiologic studies be performed?

THIS INFORMATION CANNOT BE PROVIDED.

67. Task 3, Subtask 3

a. How many techniques does the Government anticipate the contractor developing per contract year?

THIS INFORMATION CANNOT BE PROVIDED.

b. A number of non-military agencies possess state-of-the-art technologies to screen polymicrobial samples to assess quantity and type of bacteria present. Will these agencies be approached to provide assistance in launching this program?

NO

c. Are there current cooperative research sites being used by WRAIR researchers for such studies of quantization of wound infections?

NO

d. Will this subtask duplicate current studies at WRAIR?

NO

e. If yes, how will the studies be coordinated?

N/A

f. If not, please show where the current studies differ from the proposed studies.

THIS INFORMATION CANNOT BE PROVIDED.

g. What platforms are currently being used by researchers in this area at WRAIR?

THIS INFORMATION CANNOT BE PROVIDED.

h. Are other research platforms contemplated?

NEW STATE OF THE ART APPROACHES ARE ANTICIPATED.

i. Are these platforms available at facilities outside of WRAIR?

NO

j. Will studies be performed outside the U.S.?

NO

k. If studies will be performed outside the U.S., can the Government define the location(s)?

N/A

68. Task 3, Subtask 4

a. Will the full spectrum of Gram-positive and Gram-negative clinically-important bacteria be earmarked for investigation?

YES

b. What technologies/platforms (e.g. microarray, qRT-PCR, Comprehensive Genomic Hybridization) are most sought after to achieve these aims?

ALL OF THE CITED AND/OR ADDITIONAL APPROACHES MAY BE PROPOSED.

c. Will funding be devoted to the discovery of new virulence factors in these bacteria, or will there be a greater emphasis on existing virulence mechanisms?

NO

d. What collaborations are currently used by WRAIR researchers to research virulence factors and genomic elements?

THIS INFORMATION CANNOT BE PROVIDED.

e. Will other collaborations be sought?

NO

f. Where will these collaborations occur? Inside the U.S.? Outside the U.S.? If outside the U.S. please provide the locations.

N/A

69. Task 3, Subtask 5.

a. Will these activities occur only at WRAIR?

YES

b. If these activities will occur outside of WRAIR, where else will the activities occur?

N/A

c. Is it the intent of this RFP to develop clinical surveillance activities at the battlefield level?

THIS INFORMATION CANNOT BE PROVIDED.

d. Will the laboratory/molecular based epidemiology and surveillance be a separate effort or will it be a part of the tri-service registry?

THE LAB EFFORT WILL BE SEPARATE AND LOCATED AT THE WRAIR.

e. Are there not current, well established guidelines for clinical surveillance of infections as required by Joint Commission and other bodies?

THIS INFORMATION CANNOT BE PROVIDED.

f. In what way is this sub-task going to contribute to clinical care considering infection control measures already exist?

THIS INFORMATION CANNOT BE PROVIDED.

g. Since most issues related to breaches of infection control relate to behavior of health care providers, does this subtask address behavior modification of health care personnel.

YES

h. If so, how will these behavioral modification methods be researched and monitored, especially in combat situations?

THIS INFORMATION CANNOT BE PROVIDED.

i. Are there any special platforms contemplated for the molecular-based epidemiologic studies?

THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACHES.

j. If there are special platforms contemplated for the molecular-based epidemiologic studies, can the Government define these?

THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACHES.

70. Task 3, Subtask 6

a. Given the cost associated with developing novel drugs, will research be confined to the initial stages of drug discovery, or will there be a more comprehensive approach?

THE PWS IS FOR BASIC R & D NOT ADVANCED DEVELOPMENT.

b. Will novel in vitro and in vivo models be developed from first principles, or will there be an emphasis on using established protocols?

BOTH

c. Are there plans to enlist pharmaceutical companies to assist in this effort? If yes, does the Government want the contractor to initiate these discussions?

NO

d. Is the WRAIR aware of any current activities and efforts at NIH that address these specific questions?

NO

e. Will WRAIR address all phases of animal testing and clinical "first in humans" studies?

YES

f. If the intent is for WRAIR to address all phases of animal testing and clinical "first in human" studies, how will this be approached?

THIS INFORMATION CANNOT BE PROVIDED.

g. Does the Government anticipate conducting the Phase 1 studies at the WRAIR Clinical Trials Center or the contractors facilities?

AT THE WRAIR FACILITY

h. Will pK/pD studies be performed at WRAIR or by collaborating investigators?

AT THE WRAIR

i. Does the Government want the contractor to provide Principal Investigators for the human clinical studies?

NO

j. Will Phase 3 studies be performed under this subtask?

NO

k. If Phase 3 studies will be performed under this subtask, can the Government specify who will perform them?

N/A

71. Task 3, Subtask 7

a. Will human use protocols be required to meet these targets?

YES

b. Given the large number of potential responses to therapy, will specific areas (e.g. immune response) be given priority for research?

NO

c. What platforms are currently available for use in these studies?

THIS INFORMATION CANNOT BE PROVIDED.

d. Are platforms contemplated for the future?

YES

e. If there are platforms contemplated for the future, please specify which ones?

THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACHES.

f. Will these studies parallel existing studies at WRAIR?

NO

g. If these studies do not parallel existing studies at WRAIR, how do they differ?

THIS INFORMATION CANNOT BE PROVIDED.

72. Task 3, Subtask 8.

a. Please specify the scope of this outcomes based research?

THEY ARE SPECIFIED AS DIAGNOSTICS, CLINICAL CARE AND ETC.

b. What specific areas/conditions are of concern to the military?

AS STATED IN THE PWS.

c. Will diagnostic and laboratory support be available in the battlefield situation?

THIS INFORMATION CANNOT BE PROVIDED.

d. Will specific clinical platforms be used in this subtask?

NO

e. Are these platforms available at WRAIR?

N/A

f. If these platforms are not available at WRAIR, which ones are contemplated?

N/A

g. Are they available outside of WRAIR?

N/A

73. Task 3, Subtask 9

a. Will therapies and/or recommendations be restricted to the military, or will they be shared with civilian organizations?

MILITARY

b. Since “standards of care” are already available for most situations, can current standards be adapted to combat situations?

THIS INFORMATION CANNOT BE PROVIDED.

c. If not, how will the research necessary be carried out in combat situations and be standardized?

THIS INFORMATION CANNOT BE PROVIDED.

74. Task 3, Subtask 10

a. Will the bacterial registry be confined to clinically important bacteria only, or will other pathogens be included?

CONFINED TO CLINICAL EMPHASIS

b. Are there plans to include bacterial strains isolated by Allied forces serving alongside the US military?

NO

c. Is it anticipated that data pertaining to antibiotic resistance profiles, molecular epidemiological profiles and other molecular characteristics of the bacteria will be included in the database?

YES

d. Are there reporting mechanisms already in place?

YES

e. Will reports and samples come directly to the registry, similar to current mechanisms seen for reporting to state health departments by private healthcare entities or will reports go to a service branch (Army, Navy, Air Force) coordinators first before forwarding to the Registry?

WILL ROUTE VIA A JOINT SERVICE DATA BASE.

f. What specimens will be stored?

THIS INFORMATION CANNOT BE PROVIDED.

g. How many total specimens will be stored per year?

1000-2000

h. How long will these specimens be stored?

10 YEARS OR MORE

i. In what way does the Registry not duplicate or at least mimic work already done by CDC, WHO, and other national and international registries?

THIS INFORMATION CANNOT BE PROVIDED.

j. What are the efficiencies to be gained by duplicating such efforts?

N/A

k. Cannot the registry concept simply be transferred to CDC where systems already exist to provide surveillance for infectious diseases?

THIS INFORMATION CANNOT BE PROVIDED.

l. In such an effort, would National Guardsman and Reservists be included in the registry if wounded in combat?

YES

m. How long after the wound would active cultures be submitted to the registry?

HOURS OR DAYS

n. Would secondary or nosocomial acquired organisms be included, or only primary infections?

SECONDARY AND NOSOCOMIAL WILL BE INCLUDED.

o. How would different agents from the same individual with the same wound be tracked?

THIS INFORMATION CANNOT BE PROVIDED.

p. Will agents from the same person with different wounds be tracked?

YES

q. Where would this Registry be located?

WRAIR

r. How much space would be required?

SUFFICIENT SPACE HAS BEEN IDENTIFIED.

s. Will the contractor be required to provide or construct storage space?

NO

75. Task 4, Subtask 1

a. What are the current viruses being investigated (targeted pathogens) for determination of virulence factors related to disease and pathogenicity?

THIS INFORMATION CANNOT BE PROVIDED.

b. How many viral determinants does the Government anticipate the contractor investigating per contract year?

NOT LIMITED

c. What specific platforms are being used by researchers for this sub-task?

IMMUNOLOGIC AND MOLECULAR

d. Does the Government want additional platforms to perform tasks in this section of the RFP?
If yes, what platforms?

THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACHES.

e. Will the contractor be required to purchase new platforms?

YES

f. Are there other viruses (target pathogens) currently envisioned to be added to this list?

THIS INFORMATION CANNOT BE PROVIDED.

g. Will all the research on virulence factors for target pathogens be performed at WRAIR?

YES

h. If all the research on virulence factors for target pathogens will be performed at WRAIR are facilities already available for this research on target pathogens?

YES

i. Is the Contractor required to provide facilities and equipment for this research into target pathogens?

NO

j. If the contractor is required to provide facilities and equipment for this research into target pathogens, what will be the basic needs of this facility?

N/A

k. If not to be performed at WRAIR or if the research will also occur elsewhere, where will the research be performed?

N/A

l. If the research is to occur outside of WRAIR facilities, are facilities available in these non-WRAIR sites?

N/A

m. If the research is to occur outside of WRAIR facilities, and facilities are not available in these non-WRAIR sites, will the Contractor be required to provide these facilities?

N/A

n. If the contractor is required to provide facilities at non-WRAIR sites, what will the basic requirements for these sites be?

N/A

o. Will the contractor be required to monitor research activities at any site other than WRAIR?
If so, where?

N/A

p. Since antigenic and phylogenetic relatedness studies differ or can differ from virulence factor research, are there viruses of interest to WRAIR for antigenic and phylogenetic relatedness studies that are not included investigations of virulence?

THIS INFORMATION CANNOT BE PROVIDED.

q. If there are viruses of interest to WRAIR for antigenic and phylogenetic relatedness studies that are not included investigations of virulence, please define which ones?

THIS INFORMATION CANNOT BE PROVIDED.

r. Will antigenic and phylogenetic studies upon target pathogens be performed only at WRAIR or elsewhere?

THESE STUDIES WILL BE PERFORMED AT THE WRAIR.

s. If antigenic and phylogenetic studies upon target pathogens will be performed outside of WRAIR, can the Government define the specific locations?

N/A

t. Are facilities available at all research sites to be involved in antigenic and phylogenetic research upon target pathogens?

N/A

u. If facilities are not available at all research sites to be involved in antigenic and phylogenetic research upon target pathogens, will the contractor be required to provide these facilities?

N/A

v. If the contractor is required to provide facilities for all research sites to be involved in antigenic and phylogenetic research upon target pathogens, what will the basic requirements for these sites be?

N/A

w. Will research support personnel related to this RFP work closely with current WRAIR researchers in this department?

YES

x. Does the Government intend for any of this task work to replace the current work that the WRAIR Virus Disease group is currently doing?

NO

76. Task 4, Sub-task 2

a. Since investigation of host factors in pathogenesis would depend on viral agents being investigated, specific routes of infection, and the specific details of the host involved, please detail these parameters as they relate to current investigations at WRAIR.

THIS INFORMATION CANNOT BE PROVIDED.

b. How many host factors does the Government anticipate the contractor investigating per contract year?

NOT LIMITED

c. Are there specific research platforms currently in use for the investigation of the indicated host factors in the current WRAIR program?

YES

d. Are there plans to increase the number and types of research platforms being used for this research at WRAIR?

YES

e. Are there plans for investigations of other viral agents involving host factors in pathogenesis not currently being researched at WRAIR?

YES

f. Is research for this sub-task being done in locations other than WRAIR?

WRAIR AND ITS ASSOCIATED LABORATORIES ONLY.

g. If research for this sub-task are being done in locations other than WRAIR, can the Government share with us the location(s)?

N/A

h. What are the responsibilities of the contractor for efforts being done at these external locations?

N/A

i. Will research on this sub-task be performed outside the United States?

NO

j. If the research on this sub-task is to be performed outside of the United States, can the Government share with us the location(s)?

N/A

k. Are research platforms and other facilities available at all external (to WRAIR) sites?

N/A

l. Can the Government provide a description of where the current areas of research into immunologic protection is being done at WRAIR?

AT THE WRAIR IN BLDG 503

m. Can the Government provide a description of any research platforms currently being used for this research?

THIS INFORMATION CANNOT BE PROVIDED.

n. Will new platforms be required in the future for this contract?

YES

o. Who will be responsible for purchase of such platforms?

TBD

p. Will sites outside of WRAIR be used for immunologic protection studies?

N/A

q. Will such sites be in foreign countries?

N/A

r. If there are sites in foreign countries to be used for immunologic protection studies, can the specific locations be provided?

N/A

s. How many pre-clinical and clinical studies will be required on a yearly basis?

4-5 PRE-CLINICAL AND 2-3 CLINICAL

t. What phases of testing in humans will these studies entail and how many at each phase?

PHASE 1 AND 2 TRIALS (1-2 PER YEAR EACH)

u. How many product licensures are expected each year from this sub-task?

NONE

v. What will be the contractor responsibilities regarding immunologic protection studies outside of WRAIR?

N/A

w. What are the current vaccine studies being done in the Division of Viral Diseases?

THIS INFORMATION CANNOT BE PROVIDED.

x. Where are these studies currently being conducted in the Division of Viral Diseases being done?

THIS INFORMATION CANNOT BE PROVIDED.

y. Are immune modulator studies being done for viral agents currently being tested at WRAIR?

Elsewhere with collaborators?

THIS INFORMATION CANNOT BE PROVIDED.

z. How many biologics are currently in pre-clinical testing at WRAIR or elsewhere that involve WRAIR researchers?

THIS INFORMATION CANNOT BE PROVIDED.

aa. What animal models are currently being used for these preclinical tests?

THIS INFORMATION CANNOT BE PROVIDED.

ab. What emerging technologies, novel population genomic and systems biology strategies are of interest to the DVD that may require input and budgetary planning by the contractor?

THIS INFORMATION CANNOT BE PROVIDED.

77. Task 4, Sub-task 3

a. Please describe the current research platforms being used to perform sub-task 3?

THIS INFORMATION CANNOT BE PROVIDED.

b. What are the current viral agents of military interest to WRAIR?

THESE ARE LISTED IN THE PWS.

c. How many assays does the Government anticipate the contractor developing per contractor year?

2-3 PER YEAR

d. Is research currently being conducted on sub-task 3 at facilities outside of WRAIR? If yes, can the Government provide the locations?

NO

e. Is research currently being conducted on sub-task 3 at facilities outside of the U.S.? If yes, can the Government provide the locations?

NO

f. Are field sampling techniques for viral agents currently being tested at WRAIR?

THIS INFORMATION CANNOT BE PROVIDED.

g. Are such techniques being tested elsewhere with WRAIR collaborators? If yes, can the Government provide the locations?

THIS INFORMATION CANNOT BE PROVIDED.

h. Can the Government describe the specific methods currently being tested?

THIS INFORMATION CANNOT BE PROVIDED.

i. Can the Government describe the specifics of this research?

THIS INFORMATION CANNOT BE PROVIDED.

j. Can the Government reveal who will receive the data forthcoming from the global epidemiologic studies?

THIS INFORMATION CANNOT BE PROVIDED.

k. Does this epidemiologic reporting process parallel or duplicate that of CDC or WHO?

NO

l. Does the Government want the contractor to process and store the data?

NO

78. Task 4, Subtask 4

a. How many epidemiologic studies does the Government anticipate the contractor to conduct per contract year?

2-3 PER YEAR

b. Does WRAIR currently perform such epidemiologic studies of viral diseases?

THIS INFORMATION CANNOT BE PROVIDED.

c. Does the WRAIR effort in this subtask differ from efforts currently undertaken by the CDC, WHO and other U.S. or world-wide agencies? If yes, can the Government explain how these efforts are different?

THIS INFORMATION CANNOT BE PROVIDED.

d. Does the Government have current and planned future sites for studies related to this sub-task?

YES

e. Does the Government have specific epidemiologic and IT platforms that are required for this task? If yes, what are they?

NO

f. Will the contractor be required to purchase these platforms?

NO

g. How many personnel and what will be the required backgrounds for these personnel for this sub-task?

5-6

h. Will the contractor be responsible for hiring such personnel?

YES

79. Task 4, Subtask 5

a. How many animal trials does the Government anticipate the contractor conducting per contract year?

3 OR LESS

b. How many clinical trials does the Government anticipate the contractor conducting per contract year?

3-4 PHASE 1 AND 1-2 PHASE 2

c. Does the Government intend for all animal studies to be done at WRAIR?

NO

d. Does the Government intend for any animal studies to be conducted overseas? If yes, which locations?

YES, AFRIMS (WHICH IS PART OF THE WRAIR)

e. What species of animals will be used to test these agents?

THIS INFORMATION CANNOT BE PROVIDED.

f. Will cooperating organizations be used for testing?

NO

g. If cooperating organizations will be used for testing, what is the location of these organizations?

N/A

h. What is the responsibility of the contractor in the conduct of animal studies?

PROTOCOL DEVELOPMENT AND EXECUTION IN COMPLIANCE WITH ALL DOD REGULATIONS.

i. Is AAALAC accreditation required for the animal testing facility?

YES

j. Will personnel being used in such studies be veterinarians and other AALAS certified personnel?

YES

k. Who will perform the clinical trials?

GOVERNMENT PERSONNEL

l. Where will the trial be performed?

WRAIR AND ITS ASSOCIATED LABORATORIES

m. Will the contractor be responsible for certifying the clinical site?

NO

n. Will trials be performed outside of WRAIR?

TBD

o. If the clinical trials will be performed outside of WRAIR, can the location(s) be specified?

LIKELY TO BE NAIROBI, KENYA AND BANGKOK THAILAND AND OTHER WRAIR OCONUS SITES.

p. Will clinical trials be performed outside the U.S.?

TBD

q. If clinical trial will be performed outside of the U.S., can the location(s) be specified,?

TBD

r. Who will be responsible for certifying sites external to WRAIR?

WRAIR

s. What phases of trials will be performed?

PHASE 1 AND 2

t. How many agents will be tested in animal studies each year?

THIS INFORMATION CANNOT BE PROVIDED.

u. How many agents will be tested in clinical trials at each phase, each year?

THIS INFORMATION CANNOT BE PROVIDED.

v. Who will be responsible for pK/pD determinations for phase 1 studies?

WRAIR

w. Who will be responsible for human toxicity testing?

BOTH THE GOVERNMENT AND THE CONTRACTOR.

x. Who is responsible for IRB approvals for sites and investigators outside of WRAIR?

TBD

y. Who is legally liable for Adverse Events both inside and outside of WRAIR?

TBD

80. Task 4, Subtask 6

a. Where will the lab be located?

WRAIR

b. Will the contractor be responsible for providing appropriate personnel for this lab?
YES

c. Will this be a virus dedicated reference lab?
NO

d. How many specimens will be processed per year?
THIS INFORMATION CANNOT BE PROVIDED.

e. If agents other than viruses will be tested in this facility, what are those agents?
THIS INFORMATION CANNOT BE PROVIDED.

f. Specifically what level of pathogen (BSL) will be tested in this facility?
BSL2+

g. Will the contractor be responsible for providing equipment for this lab?
YES

h. Is this lab duplicating facilities already available at CDC, Johns Hopkins and other national laboratories throughout the country?
NO

81. Task 4, Subtask 7

a. Describe what agents are of interest?
THIS INFORMATION CANNOT BE PROVIDED.

b. Are there agents other than viruses of interest in this subtask?
YES

c. Research platforms for clinical vs. environmental isolation of agents will most likely differ. Describe what the particular array of novel technologies are of interest?
THIS INFORMATION CANNOT BE PROVIDED.

d. What are the current technologies of interest?
THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACHES.

e. Are these technologies and platforms currently available at WRAIR?
SOME ARE AVAILABLE.

f. If the technologies of interest and platforms are not currently available at WRAIR, will the contractor be responsible for obtaining these technologies?
YES

g. How many new personnel will be involved in this sub-task?
3-4

h. Will activities in this sub-task be performed outside of WRAIR?
NO

i. If the activities in this sub-task will be performed outside of WRAIR, can the Government define the location(s)?

N/A

j. Will activities related to this sub-task be performed outside of the U.S.?

NO

k. If the activities related to this sub-task be performed outside of the U.S.?

INCOMPLETE QUESTION. CAN'T ANSWER.

l. Will they be working alongside current DVD personnel?

YES

82. Task 4, Subtask 8

a. Describe how this subtask differs from current similar efforts of the DVD?

THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACHES.

b. How many agents will be anticipated each year?

3-4

c. How does subtask 8 differ from subtask 5 in this section?

SUFFICIENT BACKGROUND IS PROVIDED TO DISTINGUISH THESE TASKS.

d. Will current DVD personnel be working side by side with personnel on this task?

YES

e. Describe how agents are currently being developed and assessed by the DVD?

THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACHES.

f. What research platforms (if any) are currently being used for this task at WRAIR? At cooperating institutions?

THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACHES.

g. Is the contractor required to develop new procedures to develop and assess such agents and biological?

INCOMPLETE SENTENCE. CAN'T ANSWER.

h. With the information presented, how is a budget for such activities to be developed?

PROPOSAL IS TO PROVIDE COSTS FOR PROPOSED ACTIVITIES.

i. Who will own the intellectual assets of newly developed agents or biologicals developed by the contractor?

TBD

j. Will agents and biologicals be tested outside of WRAIR?

NO

k. If agents and biologicals be tested outside of WRAIR, can the Government specify the location(s)?

N/A

l. Will agents and biologicals be tested outside of the U.S.?

N/A

m. If agents and biologicals are to be tested outside of the U.S., can the Government specify the location?

N/A

83. Task 4, Subtask 9

a. Define host nation?

A NATION THAT HOSTS ONE OF WRAIR'S OCONUS OPERATIONS.

b. Who are the organizations involved in partnering in this effort, both inside the U.S. and outside the U.S.?

THIS INFORMATION CANNOT BE PROVIDED.

c. What will be the level of assessment required?

BASIC QUALITY CONTROL AND ASSEMENT PROCEDURES.

d. How often will these assessments occur?

ON AN ANNUAL BASIS.

e. What training efforts will be required?

TECHNICAL AND REGULATORY.

f. What specific areas of training are required?

TECHNICAL AND REGULATORY.

g. Where will training occur?

CONUS AND OCONUS

h. How will such training be provided?

THE CONTRACTOR IS TO PROPOSE.

i. What IT and communications platforms will be required for this training?

BASIC COMPUTER BASED PROJECTIONS AND ACCESS.

j. How many persons are expected to be provided training?

25-30

k. How many sessions of training per year will be required?

1 PER YEAR

l. Define "build capacity"?

PROVIDE INFRASTRUCTURE TO SUPPORT THE RESEARCH EFFORT.

m. Where will such capacity building occur?

AT THE OCONUS SITES.

n. Will outside of WRAIR sites be involved? If so, can the locations be provided?

YES

o. Will outside of the U.S. sites be involved? If so, can the location(s) be provided?

SITES MAY INCLUDE BUT ARE NOT LIMITED TO: KENYA, TANZANIA, UGANDA, NIGERIA, AND THAILAND.

p. What objectives are to be achieved?

TECHNICAL AND REGULATORY TRAINING

q. Who determines these objectives?

THE GOVERNMENT

r. What are the specific requirements of the contractor as related to achieving objectives?

PROVIDE TECHNICAL AND REGULATORY TRAINING FOR THE CONDUCT OF THE RESEARCH PROGRAM.

s. Will these objectives be required of contractors working in the DVD under the COE only?

NO

t. Will these objectives be required of contractors in the DVD not working for contractors under the COE?

THIS INFORMATION CANNOT BE PROVIDED.

84. Task 5

a. How many antigenic targets does the Government anticipate the contractor identifying per contract year?

NOT LIMITED

b. Does the Government intend for this task to be performed on site at WRAIR? If yes, will the Government provide laboratories, desks, computers, and phones for the research support personnel conducting this work?

YES. COMPUTERS WILL BE PROVIDED BY THE CONTRACTOR.

c. Does the Government intend for this task to be performed on site at WRAIR's overseas locations? If yes, please provide the locations.

AT THE WRAIR

d. Does the Government intend for the work under this Solicitation to take the place of the current Plasmodium research that is being done at WRAIR or its overseas laboratories?

NO

e. Will the research support personnel services required under this task work closely with the current Government WRAIR researchers in the Malaria Vaccine Department?

YES

f. How many immunological assays does the Government anticipate the contractor will develop per contract year?

NOT LIMITED

g. Does the Government intend for the contractor to replace the current personnel and services for developing immunological assays within WRAIR or its overseas laboratories?

NO

h. Does the Government intend for the immunological assays to be developed at WRAIR? If yes, will the Government provide laboratory space, desks, computers, and phones for the research support personnel?

THE CONTRACTOR WILL PROVIDE COMPUTERS IF NEEDED.

i. Does the Government intend for the immunological assays to be developed at WRAIR's overseas locations? If yes, will the Government provide the locations where it wants this service?

AT WRAIR

j. Will the Government provide laboratory space, desks, computers, and phones for the overseas research support personnel?

THE CONTRACTOR WILL PROVIDE COMPUTERS IF NEEDED.

k. Will the research support personnel services required under this task work closely with the current Government WRAIR researchers in this Department?

YES

l. How many vaccine deliver systems does the Government anticipate the contractor developing per contract year?

1

m. Does the Government intend for the contractor to replace the current personnel and services for developing vaccine deliver systems within WRAIR or its overseas laboratories?

NO

n. Does the Government intend for the vaccine delivery systems to be developed at WRAIR? If yes, will the Government provide laboratory space, desks, computers, and phones for the research support personnel?

AT WRAIR

o. Does the Government intend for the vaccine delivery systems to be developed at WRAIR's overseas locations? If yes, will the Government provide the locations where it wants this service?

NO

p. Will the Government provide laboratory space, desks, computers, and phones for the overseas research support personnel?

THE CONTRACTOR WILL PROVIDE COMPUTERS IF NEEDED.

q. Will the research support personnel services required under this task work closely with the current Government WRAIR researchers in this Department?

YES

r. How many vaccine candidates for assessment in animal models does the Government anticipate the contractor testing per contract year?

2-4

s. Does the Government intend for this task to be performed on site at WRAIR? If yes, will the Government provide laboratories, animal cage space, desks, computers and phones for the research support personnel conducting this work?

YES. THE CONTRACTOR WILL PROVIDE COMPUTERS.

t. Does the Government intend for the work under this Solicitation to take the place of the current pre-clinical animal testing being done at WRAIR or its overseas laboratories?

NO

u. Will the research support personnel services required under this task work closely with the current Government WRAIR researchers in this Department?

YES

v. Does the Government want the contractor to provide their own animal facilities in the U.S. or overseas?

NO

w. In which overseas locations does the Government want the contractor to provide animal pre-clinical testing services?

N/A

x. Does the Government intend for the contractor to provide the animals for testing in this task?

NO

y. Will the contractor be expected to use the Government's animal labs for this task?

YES

z. How many vaccine candidates does the Government anticipate the contractor will need to manufacture in the United States per contract year?

TWO OR LESS

aa. Will the contractor only be expected to manufacture Phase I and II candidate vaccines?

YES

ab. Does the Government intend for the contractor to use the WRAIR Pilot Bio-production facility for GMP manufacturing?

YES

ac. If the Government intends for the contractor to use the WRAIR Pilot Bio-production facility, does the Government intend for this contract to replace the current WRAIR Pilot Bio-production facility contract?

NO

ad. Does the Government intend for the contractor to use outside GMP facilities for GMP production?

TBD

ae. Does the Government intend for the contractor to use outside GMP facilities in overseas locations?

NO

af. What is the scope of GMP required for immune modulators, drugs, or vaccines in an antimicrobial product is anticipated?

THIS INFORMATION CANNOT BE PROVIDED.

85. Task 6, Subtask 1

a. Regarding the various hypotheses to be developed with this task, who will be responsible for driving the various hypotheses?

A GOVERNMENT INVESTIGATOR WILL BE RESPONSIBLE FOR DEFINING THE HYPOTHESES DRIVEN WORK ON THIS TASK.

b. The SOLiD System platform is both a powerful and expensive system. Is this platform already at WRAIR?

NO

c. If the SOLiD System platform is already at WRAIR, how many such platforms are in place?

N/A

d. If the SOLiD System platform is not already at WRAIR, how many such systems are contemplated at WRAIR?

ONE

e. Is this platform available outside of WRAIR at collaborative institutions, such as NIH.

N/A

f. Will the contractor be required to purchase this system? If yes, does the Government want the contractor to include this price in the proposal?

YES AND YES.

g. The SOLiD System has a number of capabilities. Has it been decided what specific capabilities of this system will be utilized at WRAIR or are currently available?

NO

h. How many specimens will be run on the system per year.

NOT LIMITED

i. Does the Government want the SOLiD System to be located at WRAIR?

YES

j. Does the Government want the SOLiD System to be located in its overseas locations? If yes, which locations?

NO

k. RT-PCR is already available at WRAIR. Is the intent of the COE to centralize this activity?

THE INTENT IS TO PROVIDE ADDITIONAL SUPPORT FOR EXPANDED EFFORTS.

l. If so, can such a facility provide RT-PCR analyses for all the research currently or proposed at WRAIR?

RESOURCE WILL BE PRIMARILY FOR THE COE IN INFECTIOUS DISEASE RESEARCH.

m. Does the Government currently have RT-PCR capabilities overseas? If yes, which locations?

NOT RELEVANT.

n. Does the Government want the contractor to establish RT-PCR capabilities overseas? If yes, in which locations?

NO

o. Does the Government want the contractor to provide RT-PCR using non-Government facilities?

NO

p. Is the Luminex platform available at WRAIR?

YES

q. If the Luminex platform is available at WRAIR, how many are there?

THIS INFORMATION CANNOT BE PROVIDED.

r. Are new Luminex platforms expected to be added?

YES

s. If there are Luminex platforms to be added, how many should the contractor plan for?

GOVERNMENT ESTIMATES AT LEAST ONE NEW SYSTEM THE FIRST YEAR.

t. Is the Luminex platform available at local cooperating institutions within the U.S.?

NOT RELEVANT

u. Approximately how many samples will be run on the Luminex per year?

NOT LIMITED

v. Are new Luminex platforms expected to be added in WRAIR's overseas locations? If yes, which locations and how many?

NO

w. Is the Luminex platform available at local cooperating institutions outside of the U.S.?

NO

x. Approximately how many samples will be run on the Luminex per year overseas?

N/A

y. Does the Government want the contractor to purchase the Luminex platform? If yes, should the contractor include this price as part of the proposal?

IF INCLUDED IN THE PROPOSAL, THE COST SHOULD BE INCLUDED.

z. Are multiparameter flow cytometers available at WRAIR that would be available under this contract?

YES

aa. If there are multiparameter flow cytometers available at WRAIR that would be available under this contract, can the Government define the number that are available?

UP TO 7 UNITS

ab. Does the Government want the contractor to purchase additional multiparameter flow cytometers for WRAIR or its overseas locations? If yes, how many, and should the contractor include this price as part of the proposal

NO

ac. Are other types of flow cytometry contemplated?

NO

ad. If other types of flow cytometry is contemplated, please list, along with the numbers required.

N/A

ae. Is the contractor required to purchase these platforms? If yes, does the Government want the contractor to include this price in the proposal?

IF INCLUDED IN THE PROPOSAL, THE COST SHOULD BE INCLUDED.

af. How many flow cytometry runs does the Government anticipate the contractor conducting per contract year?

GOVERNMENT ESTIMATES 1 FOR THE FIRST YEAR ONLY.

ag. Are cell sorting platforms available at WRAIR or its overseas locations? If so, will they be available under this contract

YES AND NO

ah. If cell sorting platforms are not available at WRAIR or its overseas locations for use in this contract, does the Government want the contractor to purchase additional cell sorting platforms for WRAIR or its overseas locations? If yes, does the Government want the contractor to include this price in the proposal?

GOVERNMENT ESTIMATES ONE UNIT FOR THE FIRST YEAR

ai. If the Government wants the contractor to purchase additional cell sorting platforms, please specify the exact cell sorter required or the type of analyses requiring cell sorter capacity.

IF INCLUDED IN THE PROPOSAL, CONTRACTOR PROVIDES.

aj. How many samples does the Government anticipate will be run per contract year?

NOT LIMITED.

86. Task 6, Subtask 2

a. Both bioinformatics/statistical and structural biology capabilities already exist at WRAIR. Can the Government describe how this subtask differs from WRAIRs existing capabilities?

THIS REQUIREMENT IS TO SUPPORT EXPANDED OPERATIONS.

b. Does the Government want this contract to replace these existing capabilities at WRAIR?
NO

c. Can the Government describe the specific platforms that will be used for developing this task?
THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACH.

d. Will the Government or contractor be responsible for selecting the platforms?
THE CONTRACTOR.

e. Does the Government want the contractor to purchase these platforms? If yes, does the Government want the contractor to include this price in the proposal?
IF INCLUDED IN THE PROPOSAL, THE COST SHOULD BE INCLUDED.

f. Will this subtask involve institutions or organizations outside of WRAIR, including outside of the U.S.?
NO

g. If this subtask involves institutions or organizations outside of WRAIR, can the Government name the organizations and specify the location?
N/A

h. Will platforms need to be purchased for non-WRAIR institutions? If yes, does the Government want the contractor to include this price in the proposal?
N/A

i. Where will the WRAIR facility be housed?
AT THE WRAIR ON THE FOREST GLENN CAMPUS

j. Will the contractor be required to find space for this activity?
NO

87. Task 6, Subtask 3

a. Regarding the indicated technologies, does WRAIR have cooperative partnerships with the vendors indicated in subtask 1?
NO

b. If WRAIR has cooperative partnerships with the vendors indicated in subtask 1, who are they?
N/A

c. Please rank in order of most important to least important the Government priorities for technology education for WRAIR investigators.
AS LISTED IN THE PWS.

d. How many educational programs does the Government anticipate the contractor conducting provide per contract year?
ONE FOR EACH AREA AT LEAST ONCE A YEAR

e. Does the Government want the contractor to provide funding for all instructors/lecturers? If yes, does the Government want the contractor to include this price in the proposal?
IF PROPOSED, IT SHOULD BE PRICED.

f. Does the Government want the contractor to make the final decision regarding the adequacy of training and the core curriculum?
NO

g. Does the Government want the contractor to hold these programs within WRAIR or at an outside facility? If an outside facility, does the Government want the contractor to include this price in the proposal?
THE CONTRACTOR IS TO PROPOSE THEIR BEST APPROACH.

h. Does the Government want the contractor to provide educational programs in its overseas locations? If yes, which locations?
NO

i. Does the Government want the contractor to provide funding for all overseas instructors/lecturers? If yes, does the Government want the contractor to include this price in the proposal?
N/A

j. Does the Government want the contractor to provide this training to other contractors or only WRAIR Government employees?
ALL ASSOCIATED PERSONNEL , ACTIVE DUTY, GS, AND CONTRACTORS WOULD PARTICIPATE IN THE TRAINING.

88. Task 6, Subtask 4

a. Within this Solicitation, there are a number of subtasks that require workshop activities. Is this particular subtask considered a component of those other subtasks?
NO

b. Considering components 1, 2, and 3, how often does the Government anticipate the contractor conducting these workshops per contract year?
ONCE A YEAR

c. Each component (1, 2, 3), if to be presented in as complete a format as possible, may require several workshops. Who determines the priorities of workshops – the contractor or the Government?
THE GOVERNMENT

d. Does this subtask require the contractor to provide non-Government facilities, audiovisual and potentially laboratory facilities?
NO

e. Does the Government want the contractor to provide funding for all instructors/lecturers? If yes, does the Government want the contractor to include this price in the proposal?
NO

f. Is the contractor to cost this particular subtask or does this budget fall within Task 1, subtask 4?

IF PROPOSED, IT SHOULD BE PRICED.

g. How many participants does the Government anticipate to attend each workshop?
15-20

h. Does the Government want the contractor to hold these programs within WRAIR or at an outside facility? If an outside facility, does the Government want the contractor to include this price in the proposal?

AT WRAIR

i. Does the Government want the contractor to provide workshops in its overseas locations? If yes, which locations? Does the Government want the contractor to include this price in the proposal?

NO

89. Task 6, Subtask 5

a. Can the Government describe what it means by the term “leveraging”?

TO OFFER AS A RESOURCE.

b. Is the contractor tasked with finding funding sources?

NO

c. Does the Government want the contractor to submit proposals for WRAIR investigators in grants.gov?

NO

d. Is this subtask primarily marketing, in nature? If yes, does the budget for this subtask fall under Task 1: subtask 8?

NO

e. Can the Government provide a description of their scientific agenda?

THIS INFORMATION CANNOT BE PROVIDED.

f. Can the Government describe the meaning of the phrase “where appropriate overlaps accrue with global health initiatives”?

THIS WORK WILL HAVE AN INTERNATIONAL IMPACT.

g. How will the Government measure assess performance for this subtask?

BY THE INCREASED PUBLICATIONS, ABSTRACTS, MEETING PRESENTATIONS AND SO ON AS A RESULT OF THE CONTRACT EFFORT.

h. Does the Government have a guideline specifying how much outside funding is required per each contract year to sustain this subtask effort?

THIS INFORMATION CANNOT BE PROVIDED.

i. How many collaborative projects does the Government anticipate the contractor entering into per contract year?

THE GOVERNMENT WILL ENTER INTO THE COLLABORATIVE EFFORTS.

90. Does the Government currently house non-human primates at WRAIR?

YES

91. Does the Government want the contractor to provide animal housing for non-human primates in the U.S.? If yes, does the Government want the contractor to include this as part of the proposal?

NO

92. Does the Government want the contractor to provide animal housing for non-human primates overseas? If yes, which locations? Does the Government want the contractor to include this as part of the proposal?

NO

93. Will the animal facilities for non-human primates at USAMRIID, Ft. Detrick be used for these studies?

NO

94. Will the animal studies in primates be performed at WRAIR?

YES

95. Will non-human primate research be performed at over-seas sites? If yes, which locations? AFRIMS IN BANGKOK AND IS PART OF THE WRAIR. NON-HUMAN PRIMATE RESEARCH MAY BE CONDUCTED AT AFRIMS.

96. Will the contractor need to transport these animals? If yes, does the Government want the contractor to include this as part of the proposal?

NO

97. If the animals will be transported, does the Government expect that the animals will be transported across state lines?

NO

98. Does the Government anticipate that these animals will be transported internationally? If yes, to which locations?

NO

99. Will the contractor be responsible for constructing or providing non-Government animal facilities? If yes, does the Government want the contractor to provide this as part of the proposal?

NO AND NO

100. If the Government wants the contractor to house animals in non-Government facilities, what animals will be housed?

N/A

101. How many non-human primates does the Government expect the contractor to provide per contract year?

N/A

102. If animal studies are performed outside of WRAIR, how will IRB approval of these studies be managed?

N/A

103. In our experience, a Center of Excellence (CoE) is defined as an exemplary program that promotes collaborative and innovative nationally-recognized research, teaching, and learning practices, along with sharing of information, data, protocols, reagents, and academic exchanges (e.g., symposia, conferences, workshops, journals, networking/Internet linkages), establishing it as a leader in the field of study. Is this what WRAIR is envisioning in establishing its CoE?

YES

104. What is the government's vision of the process of collaboration?

CONTRACTOR AND WRAIR INVESTIGATORS WILL WORK DIRECTLY TOGETHER.

105. Our scientists request clarification as to whether the government is seeking collaborators or subcontractors to fulfill the SOW's technical requirements?

CONTRACTORS ARE REQUESTED.

106. What disciplines/credentials will be represented on the proposal selection committee?

THE REVIEW PANEL WILL CONSIST OF DOCTORAL LEVEL (Ph.D. and MD) SUBJECT MATTER EXPERTS (INFECTIOUS DISEASE EXPERTS, IMMUNOLOGISTS, MOLECULAR BIOLOGISTS).

107. How will the government measure success in evaluating the scientific contributions of the offeror's scientific team members?

BY PUBLICATIONS, ABSTRACTS, PATENT SUBMISSIONS AND AN OVERALL INCREASE IN THE EFFICIENCY OF THE RESEARCH PLAN.

108. Can WRAIR estimate what percentage of the SOW technical work is represented by creation of new work vs. support of existing work?

THE CONTRACT WILL SUPPORT ALL NEW WORK.

109. What access limitations for the offerer's scientific team would be placed on information regarding research done under the CoE concept?

PENDING THE REQUIRED SECURITY CLEARANCE, NO LIMITATIONS.

110. To what extent does the government plan to share information regarding the status of applicable current research?

TO THE FULL EXTENT REQUIRED TO EXECUTE THE MISSION.

111. Recognizing the nature of the research identified for the CoE, how much time onsite at Army/government facilities does the contracting agency expect?

THE GOVERNMENT ESTIMATES THAT FULL TIME EMPLOYEES WILL BE NEEDED AT THE WRAIR OR ITS AFFILIATED SITES (CONUS AND OCONUS).

112. Does WRAIR have a vision of level of support/requirements for each of the clinical tasks identified under the CoE. If so, please provide some detail.

GOVERNMENT ESTIMATES TASK 1 MAY REQUIRE 3-5 FTES AND TASKS 2-6 MAY REQUIRE BETWEEN 8-12 FTES EACH.

113. In order to provide best cost estimates, will the government provide additional detail as to how the cost estimates for overall contractual costs were derived? Are general estimates available for the relative size of each work item, , the labor categories and full-time equivalents (FTEs) for each and the Other Direct Costs estimate?

NO

114. Will the government allow collaboration with the contractors by means of conferences, Video-Teleconferencing, Web meetings, conference calls, etc.?

YES

115. Describe the laboratory capabilities that exist in OCONUS locations. Is there intent to add to the functional capabilities in those locations?

STATE OF THE ART LABORATORIES (THREE COLLEGE OF AMERICAN PATHOLOGY LABS) EXIST IN KENYA, TANZANIA AND BANGKOK.

116. Will there be an opportunity under the CoE for Post-doctoral fellows/other graduate students to do collaborative training in Africa and other WRAIR sponsored locations?

MAYBE

117. In this solicitation, is WRAIR envisioning the offeror will provide enhanced security and collaborating scientist access to existing databases?

SECURITY STANDARDS WOULD NEED TO BE MET BY THE OFFEROR FOR DROPS LOCATED OUTSIDE THE GOVERNMENT'S FACILITIES.

118. How much latitude will individual government scientists in each clinical area identified in the Statement of Work (SOW) have to define the scope of their collaboration?

AS MUCH AS IS NEEDED.

119. Will collaborating scientists have access to live tissue samples/human subjects in all test/laboratory locations?

YES

120. Does WRAIR currently have a genome facility?

NO

121. Does WRAIR have or envision having access to second and third generation genome sequencing equipment?

YES

122. Are HIV studies included in the scope of this solicitation?

YES

123. Can you expand on the notion of the world-wide communication needs as identified in the solicitation?

MAY INCLUDE SUPPORT ASPECTS OF INTERNATIONAL IT RESOURCES (DESKTOP, SERVER AND ETC, UNITS) AND COMMUNICATIONS RESOURCES (BLACKBERRY AND PHONE).

124. Section L.2 states that proposals must be submitted to Fort Detrick.

a. Is it possible to hand-deliver proposals? YES

b. If so, what is the process for gaining access to the base? OBTAIN A VISITOR'S PASS AT THE FRONT GATE. TWO PHOTO IDS ARE REQUIRED.

125. Section L.2.a.4 states that cost information shall be provided in both Microsoft Word and Microsoft Excel 2000. Section L states the proposal should be delivered in either Microsoft Word or .pdf format, but does not state a specific edition. Should offerors assume that any Microsoft Word documents be created in Microsoft Word 2000 or compatible format?

YES

126. Does the customer require any specific personnel security requirements? As standard practice, we perform a background check, employment verification and drug screen. SEE ATTACHMENT 1 (PERSONNEL BACKGROUND INVESTIGATION SECURITY)

127. In Reference to Section L.3.1.b - Management Staff Expertise: ".....This process must also include a description of contingency or surge procedures for increasing the level of effort in response to unanticipated requirements for increased support for and/or expansion of OCONUS and CONUS missions (in conjunction with **GEIS** partners or combatant command [COCOM] staffs)."

From this statement, it appears that the evaluation criteria is specific to the firm that is managing the GEIS program and performing significant military medical research work OCONUS. Would the government consider amending the experience evaluation criteria to give a more fair opportunity to other corporations?

THE LAST SENTENCE IN SECTION L.3.1.B WAS INCLUDED IN ERROR. THE SENTENCE, "THIS PROCESS{COCOM}STAFFS)." IS REMOVED.

128. In Reference to Section 1.0 - One of the generic tasks specifies facility and security support. These tasks are not addressed in any detail in the SOW. Will the government please provide specific information?

THE REQUIREMENT IS TO ASSURE COMPLIANCE WITH GOVERNMENT SECURITY REGULATIONS.

129. In general, the SOW does not provide specific quantitative information to assist with determining the level of effort. Without a number of research projects and specific scheduled delivery dates, it is difficult to determine the number of personnel required to support the effort. Would the government provide an estimated level of effort or quantify the programs requiring support?

THE GOVERNMENT ESTIMATES FTES PER TASK AS FOLLOWS:

TASK 1 3-5 FTES

TASKS 2-6 8-12 FTES

130. How is the COE going to interface with the existing organizational structure at WRAIR?

THE COE WILL BE COMPRISED OF EXISTING DIVISIONS OF THE WRAIR THAT ADDRESS INFECTIOUS DISEASE RESEARCH.

131. In general, IT support is required but the government does not provide any information on how this support will interface with the current IT support contractor that is supporting WRAIR. Could the government provide more information?

THE REQUIREMENT IS TO SUPPLY HARDWARE AND/OR SOFTWARE TO SUPPORT THE PWS. SUCH EQUIPMENT WOULD NEED TO BE IN COMPLIANCE WITH THE WRAIR IT NETWORK.

132. The descriptions of the research projects Task 2 through Task 6 appear to be ongoing work. However, it is stated that there is no incumbent performing any of this work. It seems likely that some of this work may be related to existing contracts that are currently being executed. Are there existing contract staff working for other companies on existing task orders or delivery orders who are expecting to transition to this contract? If so, will the government please provide further information regarding which prior contracts are being replaced by this new contract in support of the COE?

THE EFFORTS IN THE PWS ARE INTENDED TO SIGNIFICANTLY AUGMENT THE RESEARCH EFFORTS DESCRIBED. THERE IS NO INTENT TO REPLACE OR SUPPLANT ANY EXISTING CONTRACT STAFF. GOVERNMENT INVESTIGATORS HAVE BEEN IDENTIFIED FOR EACH OF THE TASKS IN THE SOW.

133. In reference to Section L.3.3.a (1), the evaluation criteria related to Experience and Past Performance appears to be heavily weighted towards a corporation with overseas experience (i.e., The proposal will be evaluated on the scope and complexity of operations overseas in lesser developed, or developing nations, degree of interaction with host nation medical/public health/educational/defense organizations such as ministry of health, ministry of defense, ministry of education, national universities or non-governmental organizations (NGOs), private voluntary organizations (PVOs), or other non-governmental organizations operating overseas.

We are aware that the company currently supporting the HIV/AIDS and GEIS programs has strong experience and past performance in the above evaluation criteria. If the government is interested in developing a procurement approach that facilitates fair competition, it is suggested that projects representing strengths in ALL task areas be considered equally (i.e., submit projects that show experience in operational, acquisition, and logistics support; technical, clinical trial and scientific research support; facility and security support training and instructional support; support for exchange of scientific findings; and support of marketing and public relations projects.) Will the government consider amending the Experience and Past Performance evaluation criteria?

RELEVANT EXPERIENCE IN ALL TASK AREAS SHOULD BE PROVIDED BUT OVERSEAS AND LAB-BASED CAPABILITIES ARE IMPORTANT AREAS.

134. Will the Government please confirm that travel and ODC's , if any, will be reimbursed on a cost plus fixed fee basis?

YES

135. Will the Government please confirm that the \$247K average annual travel cost, as noted on page 47 of the solicitation, and ODC's, if any, should be incorporated into the contractors total CLIN 0001, 1001, 2001, 3001, and 4001 prices?

ANY PROPOSED TRAVEL COST AND ODCS SHOULD BE INCLUDED IN THE COST PROPOSAL.

136. Section C on page 48 of the solicitation states the “the offeror shall include the rationale for any conformance procedures used for those Service Contract Act employees proposed.” This statement seems to imply the solicitation is subject to the Service Contract Act; however, this solicitation includes the FAR clause 52.222.53 Exemption from Application of the Service Contract Act to Contracts for Certain Services—Requirements. Is this solicitation/contact subject to the service contract subject to the Service Contract Act? Please clarify.
**THESE SERVICES WILL NOT BE SUBJECT TO THE SERVICE CONTRACT ACT.
 THEREFORE, NO CONFORMANCE PROCEDURES SHOULD BE UTILIZED.**

137. Task 4.1, specific task element number 7 states that the contractor will “provide needed supplies and equipment in support of the COE only upon review and approval of the COR for purchases costing \$3,000.00 or more.” Does the Government intend for the contractor to purchase these supplies using contract funding or will the contractor purchase the supplies using another source of funding? I.E. Does the Government intend to provide funding on this contract for non-travel ODC’s/supplies? If so, will the Government please provide an annual ODC plug number to be included in the contractors total CLIN 0001, 1001, 2001, 3001, and 4001 proposal pricing?
ANY PROPOSED SUPPLIES, EQUIPMENT, AND ODC COSTS SHOULD BE INCLUDED IN THE COST PROPOSAL. SUPPLIES AND EQUIPMENT ACQUIRED BY THE CONTRACTOR WILL BE PAID THROUGH THE CONTRACT.

138. Will the Government please confirm that the place of performance for the resultant contract will be at the Walter Reed Army Institute of Research in Silver Spring, MD?
THE GOVERNMENT PROJECTS THAT THE PRIMARY PLACE OF PERFORMANCE WILL BE WRAIR IN SILVER SPRING, WITH SOME OCONUS SUPPORT FOR WRAIR’S OVERSEAS LABS IN THAILAND, KENYA, TANZANIA, NIGERIA, AND UGANDA.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The below Table of Contents has been added

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
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(End of Summary of Changes)