RFP-NIH-NIAID-DAIDS-07-45
Amendment #02

"NIAID Specimen Repository"

Amendment Issue Date: November 1, 2006

Proposal Due Date/Time: November 27, 2006, at 3:00 P.M., EST

Issued By:
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Offerors must acknowledge receipt of this Amendment #02, for each posting, on each copy of the proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your proposal.

The hour and date specified for receipt of proposals HAS NOT been extended.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS, Paragraph 1, General Information, is hereby modified to add the following paragraph:

(m) Technical Questions
Offerors should submit all questions concerning this solicitation in writing to the Contract Specialist/Contracting Officer indicated on the cover page of the RFP under Points of Contact. NIAID should receive all questions no later than **5 p.m., local time, Monday, November 10, 2006.** NIAID will answer questions which may affect offers in an amendment to the solicitation. NIAID will not reference the source of the questions.

The following questions have arisen in regard to this solicitation. Responses are provided below:

Questions in reference to the specimens stored at -70◦C:

1. What are the different tube sizes in the current NSR and approximately how many each?

Answer: Primarily 1 ml cryovials; approximately 4.5 million is the number of both mechanical freezer stored and LN2 stored vials, however, this is constantly changing.

2. What are the sizes and quantities of each storage box utilized in the freezers?

   Answer: Two inch boxes holding 81 vials.

3. Do all the freezers have metal racking systems and if so, what are the array formats (ex. 3x3, 2x4, etc.) and the quantity of each array format?

   Answer: Primarily a format of 13 shelves holding 2 inch boxes.

4. As samples are continually being sent out from the NSR, this creates empty storage positions at the vial and/or storage box level. What percentage of empty positions at the vial level is currently in the NSR? What percentage of empty positions at the storage box level is currently in the NSR (i.e. number of empty box positions in a given rack)?

   Answer: 2-10% for both questions.

5. In the current solicitation (RFP-NIH-NIAID-DAIDS-07-45) there is mention of 140 freezers to be relocated, however on the list in Attachment 11/Appendix F, only 119 are listed. This is the same listing as was in the first solicitation for this work (RFP-NIH-NIAID-DAIDS-06-07) posted on November 29, 2005. It is assumed that additional equipment such as freezers have been obtained since that time, how many freezers currently exist and is there an updated list of equipment?

   Answer: 147 mechanical freezers currently exist. We do not currently have an updated listing of equipment.

6. As this award is scheduled to start September 15, 2007, what is the anticipated number of -70° C freezers that will be added from now until that time period? What is the expected number of -70° C freezers to be replaced from now until the start of the award?

   Answer: It is estimated that 27 will be added between now and September 2007. However, it is unknown how many will replace old freezers versus new ones.

7. Appendix F, list the -70° Celsius freezers as either Harris or So-Low freezers with the majority and most recently purchased as So-Low. Is So-Low the preferred vendor for DAIDS or can another vendor with GSA pricing be utilized?

   Answer: Another vendor may be used.

8. The freezers listed on Appendix F are all chest freezers, does DAIDS require the use of only chest freezers or can uprights be substituted?

   Answer: Uprights may be substituted.

Questions in reference to the specimens stored in the Liquid nitrogen (LN_2):

9. What are the different tube sizes in the current NSR and approximately how many of each?

Answer: Primarily 1 ml cryovials; approximately 4.5 million is the number of both mechanical freezer stored and LN2 stored vials, however, this is constantly changing.

10. What are the sizes and quantities of each storage box utilized in the freezers?

Answer: Two inch boxes holding 81 vials.

11. Do all the freezers have metal racking systems and if so, what are the array formats (ex. 3x3, 2x4, etc.) and the quantity of each array format?

Answer: Primarily a format of 13 shelves holding 2 inch boxes.

12. As samples are continually being sent out from the NSR, this creates empty storage positions at the vial and/or storage box level. What percentage of empty positions at the vial level is currently in the NSR? What percentage of empty positions at the storage box level is currently in the NSR (i.e. number of empty box positions in a given rack)?

Answer: 2-10% for both questions.

13. In the current solicitation (RFP-NIH-NIAID-DAIDS-07-45) there is mention of 37 freezers to be relocated, however on the list in Attachment 11/Appendix F, 44 are listed. This is the same listing as was in the first solicitation for this work (RFP-NIH-NIAID-DAIDS-06-07) posted on November 29, 2005. It is assumed that additional equipment such as freezers have been obtained since that time, how many freezers currently exist and is there an updated list of equipment?

Answer: 48 liquid nitrogen freezers. We do not currently have an updated listing of equipment.

14. As this award is scheduled to start September 15, 2007, what is the anticipated number of LN_2 freezers that will be added from now until that time period? What is the expected number of LN_2 freezers to be replaced from now until the start of the award?

Answer: It is estimated that 8 will be added from now until September 2007. However, it is unknown how many will replace old freezers versus new ones.

15. In Attachment 4, Statement of Work, page 6, C.3.a., it is mentioned that the vendor must "maintain and operate controlled freezers for the following storage conditions" for – 10 to - 20° C, however there is no other mention of freezers currently being used at this temperature range. How many freezers at this temperature range currently exist? Will these freezers be transferred to a new location?

Answer: No freezers at -10 to -20 C currently exist.

16. In Appendix F, there is listed a Bulk LN_2 storage tank, is it anticipated that this would be relocated to a new facility and installed for use prior to the movement of the LN_2 tanks with samples being relocated to a new facility? If so, how would the cost of removal of the unit be estimated without

an inspection by a certified installation vendor? Or is it anticipated that the current vendor would purchase/reimburse the government for this item?

Answer: The offeror should propose a plan for providing LN_2 supply, assuming that the piping and the tank will not be transferred. The plan does not necessarily have to match the current contractor plan for handling LN_2.

17. In Appendix F, there is listed vacuum jacketed pipe. This is the pipe that more than likely is connected to the Bulk LN_2 storage tank listed in Question 13. There is no quantity on this item (i.e. total length, number of segments, etc). Is it anticipated that this would be relocated to a new facility and installed for use prior to the movement of the LN_2 tanks with samples being relocated to a new facility? If so, how would the cost of removal of the piping be estimated without an inspection by a certified installation vendor? Or is it anticipated that the current vendor would purchase/reimburse the government for this item?

    Answer: The offeror should propose a plan for providing LN_2 supply, assuming that the piping and the tank will not be transferred. The plan does not necessarily have to match the current contractor plan for handling LN_2.

18. What is the frequency and schedule (daily, weekly, monthly, semi-annual, annual, etc) of shipping from the sites within the US?

    Answer: The frequency is daily.

19. What is the frequency and schedule (daily, weekly, monthly, semi-annual, annual, etc) of shipping from the sites outside the US?

    Answer: Currently, the frequency is minimal and sporadic.

20. Do the US and/or International sites ship on a set schedule?

    Answer: No

21. When will a potential new vendor know if they are selected as the contractor for this solicitation? Is there an expected timeline for review, discussion and award?

    Answer: The only date we can give you with any certainty is the date of award which is scheduled for September 15, 2007. The apparent successful offeror would be notified no sooner than 1week to 10 days prior to that date.

22. In the Attachment 4, Statement of Work, B.2.d, there is a requirement to "perform a 100% documented inspection and verification of all incoming shipments at the vial level. Received shipments not containing any discrepancies shall be inventoried and committed within 5 business days." In B.2.i, there is a requirement that "after permanent storage commitment, perform, at a minimum, a 5% location quality control check on vial location for each specimen shipment." Could this be further clarified?

Answer: Inventory and commitment refer to incoming specimens, location check refers to outgoing vials.

23. Specimens that are sent out from NSR but are not fully expended and returned to the NSR, is it required that these be placed back in the original storage location in freezer (-70° Celsius or LN_2). If blinded will these need to be unblinded?

Answer: Specimens not fully expended after shipping are not returned to the repository.

24. Is this a review of every submitting institution's protocol and all collected informed consents or is this a review of a typical informed consent utilized for the Study Group's protocol?

Answer: This is a review of informed consent from the study groups.

25. Is the vendor's IRB responsible for monitoring that the vendor releases specimens/samples per a directive from the Study Group who is actually responsible for verifying and consenting the patient for storage and use of samples?

Answer: The Principal Investigators of the study groups institution's IRB are responsible for verifying and consenting the patient for storage and use of samples.

26. Is it a requirement of the vendor to track informed consent at the specimen level and that various informed consent options and have the vendors IRB responsible for the review of the Study Group's collected informed consent documents for the request prior to release of all requisitions? Or, will the tracking of informed consent at the specimen level be maintained by the Study Group's statistical and database management group and the vendor will be directed to release specimens/samples?

Answer: We don't require the offeror to track consent of the specimen samples. This is the responsibility of the study group. The offeror will be directed to release specimens/samples.

27. Attachment 4, item 2.b. indicates that all shipments from international sites must be received within 72 hours. Where Appendix D indicates the countries to expect shipments from, it does not indicate the region within these countries. Should we assume for planning and budgeting purposes that shipments from these countries would be from major cities/ providences?

Answer: Yes

28. Attachment 4, item C states that we should receive 4 million specimens over the 7 year term of the contract. Should we normalize this number over the 7 year period or should we expect a scale up between year 1 and year 7?

Answer: Normalize the number over the 7 year period.

29. Attachment 4, item 2 that describes the requirements for incoming samples does not indicate the number of shipments and the average number of specimens per shipment expected per year. Can you provide this information?

Answer: We don't know this information so we cannot provide it.

30. Attachment 4, item 3 that describes the requirements for outgoing specimen shipments does not indicate the number of shipments and the average number of specimens per shipment expected per year. Can you provide this information?

Answer: We don't know this information so we cannot provide it.

31. If the same database that is currently being used for this contract is the one that is being proposed, will the security plan cited on Page 48 still have to be submitted?

Answer: Yes.

32. Please explain attachment 4, item F.1.D. What are these codes to be used for?

Answer: Security Access.

33. Attachment 4, item F.2 cites F.1.f for examples of relevant information for the web site. However, that reference is to database back ups. Is the reference incorrect?

Answer: Attachment 4, Item F.2 should be citing F.1.g. and not F.1.f. for examples of relevant information for the web site.

34. The reference to interfacing with the DAIDS Enterprise System is vague. Is there an anticipated level of effort in this area?

Answer: We cannot provide additional information regarding the DAIDS Enterprise System with regard to the system itself or to the anticipated level of effort. The DAIDS Enterprise System is still in the developmental phase.

35. Attachment 4, item F.6.a. cites "OTIS standards", however the standards are not defined. Could a copy of the standards be provided?

Answer: Please refer to Item F.5. where the OTIS website is provided.

36. Attachment 4, item F.6.c. states that computer systems will remain the property of NIAID. Are enhancements added to the BSI system, to which NIAID owns a license but not the code, excluded from this clause?

Answer: No.

37. For planning purposes, will incoming specimen vials be labeled with typed identifiers that must also be verified during inventory, or will electronic scanning of vial barcodes be sufficient for inventory verification purposes?

Answer: All typed identifiers must also be verified during inventory, but it is anticipated that the barcode will be sufficient for inventory verification.

38. My work involves stabilizing macromolecules (DNA, protein, membranes) during freezing and drying. Of course, this could be applied to repository samples that are currently stored frozen, but could be stored much cheaper in the dried state. But, studies need to be conducted to optimize storage conditions (e.g., residual water content in the samples, quantities of stabilizing additives). My proposal would focus on storage stability of dry DNA….would that be of interest?

Answer: Work involved in stabilizing repository specimens and validating such a procedure could be a relatively minor part of a proposal. Any proposal must be responsive to all aspects of the Statement of Work to be considered competitive.