Amendment #1 to RFP-NIH-NIAID-DAIDS-04-23

"Master Contract for Preclinical Development"

Amendment to Solicitation No.: **RFP-NIH-NIAID-DAIDS-04-23**

Amendment No.: **1**

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Name and Address of Offeror: **To All Offerors**

THIS AMENDMENT AMENDS THE STATEMENT OF WORK, ADDS ADDITIONAL CLAUSES AND PROVIDES QUESTIONS SUBMITTED BY OFFERORS AND THE RESPONSES PROVIDED BY THE NIAID PROJECT OFFICER. ANY FURTHER QUESTIONS AND THEIR RELATED RESPONSES WILL BE ADDED TO THIS AMENDMENT UPON RECEIPT. ALL OFFERORS SHOULD REFER BACK TO THIS AMENDMENT #1 FOR ADDITIONAL QUESTIONS AND RESPONSES.

1.) **Statement of Work, V. Information Technology and Data Management is amended to add the following:**

H. The Contractor shall establish reliable electronic communication links with DAIDS that permit sending email and sharing word processing, data files, and product timelines in a format that is compatible with the software used by DAIDS. The Contractor will be responsible for maintaining the compatibility with the software packages used by DAIDS. Web sites for data communication should be implemented with appropriate secured access. Procedures must be employed to ensure that access to all data is given only to staff members who have been

determined by DAIDS and the Contractor to view the data. The system must allow for access at different security levels.

2.) Statement of Work, VI. Option is added as follows:

<u>Statement of Work - Option</u>

Independently and not as an agent of the government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the work described below.

Expand original statement of work capabilities to allow for production of up to four (4) DNA vaccines and six (6) microbicides per year during the course of the contract.

3.) Part II – Contract Clauses, Article I.3. Additional Contract Clauses is amended to add the following:

FAR 52.239-1, Privacy or Security Safeguards (AUGUST 1996)
FAR 52.204-2, Security Requirements (AUGUST 1996)
FAR 52.217-8, Option to Extend Services (NOVEMBER 1999).

"...The Contracting Officer may exercise the option by written notice to the Contractor provided that the Government gives the Contractor a preliminary written notice of its intent to exercise the option at least 90 days before the contract expires. The preliminary notice does not commit the Government to an extension.

4.) Section L – Instructions, Conditions and Notices to Offerors Instructions to Offerors, 2. Instructions to Offeror, paragraphs (9) through (14) are deleted in their entirety.

5.) Section L.2., (29) is added as follows:

(29) Electronic and Information Technology Accessibility

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

6.) Section L.2., Technical Proposal Instructions Paragraph (5) Information Technology Systems Security is superseded by the following:

(5) Information Technology Systems Security

a) The Statement of Work (SOW) requires the successful offeror to access a Federal Automated Information System (AIS). Based upon the security guidelines contained in the *Department of Health and Human Services (DHHS) Automated Information Systems Security Program (AISSP) Handbook*, the Government has determined that the following apply:

(1) Category of Safeguarded Information

The safeguarded agency information that the successful offeror will access from an AIS is categorized as **High Sensitivity**.

(2) Security Level Designations

Level 3 – High Sensitivity applies to the sensitivity of the data contained in the AIS and **Level 2 – Moderate Criticality** applies to the operational criticality of the data processing capabilities of the AIS. The overall security level designation is **Level 3 – High sensitivity.**

(3) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each contractor employee that the successful offeror proposes to work under the contract. For proposal preparation purposes, the following minimum designations apply:
Level 6C: Sensitive – High Risk (Suitability Determination with a BI)

Contractor employees assigned to a Level 6C (High Risk) position are subject to a Background Investigation (BI).

The following table summarizes investigation requirements by position risk level.

Required Investigation by Position Risk Level		
Level	**Description**	**Required Investigation**
6C	Public Trust (High Risk)	BI
5C	Public Trust (Moderate Risk)	NACIC (or LBI)
4C/3C	Special Access/Top Secret	SSBI
2C	Secret/Confidential Access	LBI
1C	Non-sensitive (Low Risk)	NACI

Contractor employees who have previously met investigative requirements within the past five years may only need to be subject to an updated or upgraded investigation.

b) The offeror's proposal must include:

(1) A detailed outline (commensurate with the size and complexity of the requirements of the SOW) of its present and proposed Information Technology systems security program and demonstrate that it complies with the AISSP security requirements of the SOW, the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS AISSP Handbook. At a minimum, the offeror's proposed information technology systems security program must address the minimum requirements of a **Security Level Designation Level 3 – High sensitivity** identified in the DHHS AISSP Handbook, Exhibit III-A, Matrix of Minimum Security Safeguards.

(2) An acknowledgement of its understanding of the security requirements in the SOW.

(3) Similar information for any proposed subcontractor having access to an AIS.

c) Note that the following documents are electronically accessible:

(1) OMB A-130, Appendix III:
http://csrc.ncsl.nist.gov/secplcy/a130app3.txt

(2) DHHS AISSP Handbook:
http://irm.cit.nih.gov/policy/aissp.html

(3) DHHS Personnel Security/Suitability Handbook
http://www.hhs.gov/ohr/manual/pssh.pdf

(4) NIH Applications/Systems Security Template:
http://irm.cit.nih.gov/security/secplantemp.html

(5) NIH CIT – Policies, Guidelines and Regulations
Table 1 – Categories of Safeguarded Agency Information; Table 2 – Security Level Designations for Agency Information and *Table 3 – Positions Sensitivity Designations for Individuals Accessing Agency Information*
http://www.cit.nih.gov/security-policies.html

7.) Section M, Evaluation Factors for Award, 2. Human Subject Evaluation is deleted in it's entirety.

7.) Questions and Answers follow:

Question 1: Under Part V Information Technology, paragraphs E and F – The RFP specifies that electronic transmission of information must be secure. Please specify the level of security that would be required under the Master Contract. For example, would password secured files suffice or is there a need for cryptographic equipment to be developed to ensure secure transmission of digital data (i.e./KG84A's) on outgoing and incoming telecommunication lines.

Answer 1: Please refer to 5.) above of this amendment**.**

Question 2: If the new system must incorporate older data, will these data be available (i.e., data fields, etc.) prior to development of the new system?

Answer 2: Yes.

Question 3: Under Part III, first paragraph, which also references NOTE #III-2 to Offeror, the RFP states, in reference to testing activities as required by the FDA or requested by the Project Officer prior to IND or Master File submissions, that "all studies shall be performed in accordance with Good Laboratory Practice (GLP) regulations". While it is clear that IND-enabling studies such as safety, toxicity, stability, potency, etc must be conducted under GLP, some preclinical studies evaluating immune response or inhibitory potency in an appropriate animal model, that would support, and could be included in, an IND application, may not be conducted under strict GLP regulations. Please clarify whether all studies related to immunogenicity and antiviral testing as stated in the RFP must be performed under GLP or if some preclinical studies used to support an IND may be performed under, rigorously controlled experimental protocols.

Answer 3: Some preclinical studies used to support an IND may be performed under, rigorously, controlled experimental protocols.

Question 4: Is there an estimate available of the approximate number of Master Files and INDs that would be filed on an annual basis?

Answer 4: For budget purposes, assume 2 master files, 2 INDs and 2 Investigator Brochures (IBs) annually and include plans for expansion to 10 master files, 10 INDs and 10 IBs.

Question 5: Is there an estimate available of the approximate number of IBs to be developed or updated on an annual basis.

Answer 5: For budget purposes, assume 2 per year and include plans for expansion to 10 per year.

Question 6: The RFP states that for the technical proposal there is a page limitation of 150 pages including all appendices, attachments, letters of intent, etc. It would seem that the extensive amount of information and supporting documentation required for this proposal could easily exceed the page limitation. Will the NIAID consider excluding attachments, appendices from the 150-page limitation?

Answer 6: The page limitation remains at 150 pages, including all attachments and appendices.

Question 7: It is our interpretation that the Master Contract Holder is expected to develop the preclinical work plan leading to an IND and will not be responsible for designing the clinical trial protocol or conduct the clinical trial and hold the IND. Thus, the need to address Human Subjects provisions included in the "Instructions to Offerors, Section L, 2, (9) through (14)" and as an "evaluation factor in Section M" is unclear. Please clarify.

Answer 7: Correct. The Master Contract Holder is expected to develop the preclinical work plan leading to an IND and will not be responsible for designing the clinical trial protocol or conduct the clinical trial and hold the IND. The requirement for Human Subjects has been deleted from this RFP.

Question 8: It appears that Section 508 of the Rehabilitation Act applies to this project due to the technical requirements in Section V of the Statement of Work. Will the Government either provide the applicable Section 508 performance standards or state that a waiver has been granted for this project.

Answer 8: Section 508 does apply to this procurement and the applicable standards follow:

The Electronic and Information Technology Accessibility Standards, which pertain to this procurement, can be found at 36 CFR Part 1194, Subpart B – Technical Standards Section 1194.21 Software Applications and Operating Systems. These standards can be accessed in full text at http://www.access-board.gov/

Also, Attachment 1 to this amendment is a 508 Compliance Requirements Checklist for the actual web-based interfaces into the databases being developed.

Question 9: In the Notes To Offerors, Note #II-2 TO OFFEROR, second paragraph states "For purposes of budget preparation, the Offeror shall assume that one (1) DNA-based vaccine and one (1) chemical-agent simple synthesis microbicide will be assigned during the first year." Then it states "The Offeror shall also submit a plan for expanding their capabilities to allow for the production of up to four (4) DNA vaccines and six (6) microbicides/year during the course of the contract."

In Section L - Instructions, Conditions, and Notices To Offerors, part e. ESTIMATE OF EFFORT it states that "To assist you in the preparation of your proposal, the Government considers the effort to be approximately 171,600 labor hours 5/YEARS. THIS ESTIMATE IS BASED ON 4 DNA VACCINES AND 6 MICROBICIDES EACH YEAR."

Does the NIAID estimated labor of 171,600 hours refer to just the Project Management to support the two representative products? OR does it include Project Management, Production & Development, Testing, and Regulatory Documentation for the two representative products and the IT & DM to support the effort? OR is it some other combination? Please clarify and define.

Answer 9: The estimated effort should read a total of 32,823 labor hours per year for 5 years. This is broken down into 19,680 hours per year for Management and 13,143 hours per year for Production. This estimate is based on 1 DNA Vaccine and 1 Microbicide per year.

Option - The estimated effort for expansion plans to 4 DNA Vaccines and 6 Microbicides per year is 104,320 labor hours per year for 5 years. This is broken down into 34,320 hours per year for Management and 70,000 hours per year for Production.

Question 10: What does the slash mean in the "5/YEARS"? i.e. 171,600 labor hours per year for 5 years OR 171, 600 labor hours over a five-year period.

Answer 10: See answer 9 above.

Question 11: Please describe in detail the current NIAID systems and environment that we will need to interface with. In addition, please describe any custom or COTS products used in automating the current efforts. If there is an existing database design, please provide the schema and/or data dictionary.

Answer 11: NIAID/DAIDS use Windows Operating Systems and Microsoft SQL server for databases. The existing database is a Relational Database based on Oracle I (versions 8.6 and 8.7); it is a small to medium size database (MB-GB in size). The schema and/or data dictionary cannot be given at this time.

- **Except as provided herein, all terms and conditions of this RFP remain unchanged and in full force and effect.**

- **The hour and date specified for receipt of offers REMAINS: August 5, 2003, 4:00 PM, EST**

- **Offerors must acknowledge receipt of this Amendment #1 on each copy of the proposal submitted.**

    Failure to receive your acknowledgement of this Amendment may result in the rejection of your offer.

ATTACHMENT 1

508 Compliance Requirements

This paper is meant to be a brief overview of methods used to make HTML-based web pages compliant with the Section 508 requirements. The items below are the minimum requirements – more information can be found at the Section 508 website (http://www.section508.gov) or the W3 Web Accessibility Initiative (WAI) site (http://www.w3.org/WAI/).

1. An "alt" tag for all graphical elements must be provided.

   Image: `<IMG SRC="duck.gif" `**`ALT="Image of Duck"`**`>`

   Image map area: `<area shape="rect" coords="327,280,478,301" href=duck.htm" `**`alt="Link: Ducks"`**`>`

2. An "alt" tag AND a "longdesc" tag for graphical elements that convey detailed information must be provided.

   ```
   <IMG SRC="duck.gif" ALT="Image of Duck"
   longdesc="Image of Duck describing location of the
   legs, bill, and feathers">
   ```

3. Web pages must be designed so that all information conveyed with color is also available without color, for example from context or markup.

4. Documents must be organized so they are readable without requiring an associated style sheet.

5. Client-side image maps must be provided instead of server-side image maps except where the regions cannot be defined with an available geometric shape.

6. For data tables, column headers must be identified using `<TH scope="col">`.

   ```
   <table>
            <tr>
                <th scope="col">Name</th>
                <th scope="col">Date</th>
   ```

```
            </tr>
            <tr>
                <td>John Doe</td>
                <td>5/5/2005</td>
            </tr>
            <tr>
                <td>Robert Roe</td>
                <td>6/6/2006</td>
            </tr>

            ….
```

7. Data cells and header cells for data tables that have two or more logical levels of row or column headers must be defined using the <TH id="idname">…</th> and <td headers="idname"> tags.

```
<table>
        <tr>
            <th id="Name">Name</th>
            <th id="Date">Date</th>
        </tr>
        <tr>
            <td headers="Name">John Doe</td>
            <td headers="Date">5/5/2005</td>
        </tr>
…
```

8. Frames must be titled with text that facilitates frame identification and navigation.

```
<frameset cols="10%, 90%" title="Our Library of
Documents">

    <frame src="nav.html" title="Navigation bar">

    <frame src="doc.html" title="Documents">

</frameset>
```

9. Pages must be designed to avoid causing the screen to flicker with a frequency greater than 2 Hz and lower than 55 Hz.

10. A text-only page, with equivalent information or functionality, must be provided to make a web site comply with the provisions of this part, when

compliance cannot be accomplished in any other way. The content of the text-only page must be updated whenever the primary page changes.

11. When pages utilize scripting languages to display content, or to create interface elements, the information provided by the script must be identified with functional text that can be read by assistive technology.

1. Flash Movie:

```
<object classid="clsid:D27CDB6E-AE6D-11cf-
96B8-444553540000"
codebase="http://download.macromedia.com/pub
/shockwave/cabs/flash/swflash.cab#version=6,
0,29,0" width="19" height="19">
      <param name="movie"
value="../flash/ducks.swf">
      <param name="quality" value="high">

      <embed src="../flash/ducks.swf"
quality="high"
pluginspage="http://www.macromedia.com/go/getflashplayer"
type="application/x-shockwave-flash" width="19"
height="19">
      </embed>

      <noembed>
      Flash movie of swimming ducks
      </noembed>

</object>
```

2. Object:

```
<object classid="java:Press.class"
width="500" height="500">
      As temperature increases, the molecules
in the balloon…
</object>
```

3. Applet:

```
<applet code="Press.class" width="500"
height="500" alt="Java applet: how temperature
affects pressure">
```

```
          As temperature increases, the molecules
in the balloon…
                </applet>
```

12.   When a web page requires that an applet, plug-in or other
    application be present on the client system to interpret page content, the
    page must provide a link to a plug-in or applet that complies with
    §1194.21(a) through 11.

13.   Explicitly associate form labels and form controls with the
    <label>..</label> tags and "id" attribute.

```
        <label for="firstname">Firstname:</label>

        <input type="text" id="firstname">


        <label for="comments">Comments:</label>

        <textarea id="comments"></textarea>
```

14. A method must be provided that permits users to skip repetitive navigation
    links.

15. When a timed response is required, the user must be alerted and given
    sufficient time to indicate more time is required.

16.   The primary language of a document and language changes within
    the document must be identified with ISO 639 2-character codes using the
    <html lang" "> and … tags.

```
    <HTML lang="en">
          …rest of document in English…
    </html>


    …This is in English but this is <span lang="es">En
    Espanol</span>
```

508 Compliance Checklist

Requirement	Yes	No	N/A
An "alt" tag for all graphical elements must be provided.			
An "alt" tag AND a "longdesc" tag for graphical elements that convey detailed information must be provided.			
Web pages must be designed so that all information conveyed with color is also available without color, for example from context or markup.			
Documents must be organized so they are readable without requiring an associated style sheet.			
Client-side image maps must be provided instead of server-side image maps except where the regions cannot be defined with an available geometric shape.			
For data tables, column headers must be identified using <TH scope="col">.			
Data cells and header cells for data tables that have two or more logical levels of row or column headers must be defined using <TH id="idname">…</th> and <td headers="idname">:.			
Frames must be titled with text that facilitates frame identification and navigation.			
Pages must be designed to avoid causing the screen to flicker with a frequency greater than 2 Hz and lower than 55 Hz.			
A text-only page, with equivalent information or functionality, must be provided to make a web site comply with the provisions of this part, when compliance cannot be accomplished in any other way. The content of the text-only page must be updated whenever the primary page changes.			
When pages utilize scripting languages to display content, or to create interface elements, the information provided by the script			

must be identified with functional text that can be read by assistive technology.			
When a web page requires that an applet, plug-in or other application be present on the client system to interpret page content, the page must provide a link to a plug-in or applet that complies with §1194.21(a) through 11.			
Explicitly associate form labels and form controls with the <label>..</label> tags and "id" attribute.			
A method must be provided that permits users to skip repetitive navigation links.			
When a timed response is required, the user must be alerted and given sufficient time to indicate more time is required.			
The primary language of a document and language changes within the document must be identified with ISO 639 2-character codes using the <html lang" "> and … tags.			