

RFP-NIH-NIAID-DMID-08-04

Amendment 3

“Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases”

Amendment Issue Date:	04/04/2007
Proposal Due Date/Time: (UNCHANGED)	05/14/2007 at 3:00 P.M., EST
Issued By/Point of Contact: (UNCHANGED)	Deborah A. Baca Contract Specialist OA/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 3214, Bethesda, Maryland 20892-7612 dbaca@niaid.nih.gov Please also cc: baughmat@niaid.nih.gov Terry Baughman, Contracting Officer

Offerors must acknowledge receipt of each posting of this Amendment 3, 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.

April 27, 2007, 4:00 P.M. EST WILL BE THE LAST DAY QUESTIONS REGARDING THIS RFP WILL BE ACCEPTED.

THE FOLLOWING REVISIONS (noted in bold) ARE HEREBY MADE TO THE RFP AND ITS ATTACHMENTS:

1. Section L.2.b.(5) "Information Security", subparagraph (c) Position Sensitivity

Designation Levels, is changed from **Level 1 to Level 5.**

2. Attachment 3, "Statement of Work", Technical Requirements Section 1.b. 9) b) is deleted in its entirety and replaced with the following:

b) **An Information System Security Plan (ISSP)**, which minimally shall include the Risk Analysis (RA) and the Continuity of Operations Plan (COOP -- also known as the Contingency Plan).

3. Attachment 3, "Statement of Work", Technical Requirements Section 1.b.2) is deleted in its entirety and, replaced with the following:

2) Compliance with all current Federal regulations (§21 CFR 11 and/or similar statutes), <http://www.fda.gov/cber/guidelines.htm> and meet current globally-accepted standards, including International Conference on Harmonization (ICH) E-2, Clinical Safety Data Management and ICH M-5, Data Elements and Standards for Drug Dictionaries <http://www.ich.org/cache/compo/475-272-1.html> and <http://www.ich.org/cache/compo/2196-272-1.html>, respectively. **Also, compliance with MedDRA - the Medical Dictionary for Regulatory Activities, web address: <http://www.meddramsso.com/MSSOWeb/index.htm> and the World Health Organization, Drug Dictionary, web address: http://www.who.int/medicines/services/medicines_etools/en/print.html**

4. Attachment 4, "Reporting Requirements and Other Deliverables", Section C, subparagraph 2., is deleted in its entirety and replaced with the following:

2. Within 30 calendar days after the effective date of the Contract, the Contractor shall submit an **Information System Security Plan (ISSP). Thereafter, the ISSP shall be submitted annually.**

The **ISSP** shall provide all information required by HHS Secure One Policy and shall contain information about system interconnectivity with other networks and system infrastructure.

5. Attachment 5, "Additional Technical Proposal Instructions", Section 2.B. is deleted in its entirety and replaced with the following:

B. The key features of the proposed computer-based systems for:

- Data collection;
- Storage;
- Tracking and retrieval;
- Electronic specimen tracking; and
- Quality control for monitoring the data accuracy, completeness and timeliness by study sites.

Examples of the platform/systems having the functionality to perform the tasks required in the Statement of Work include:

- **AdvantageEDC**
- **Oracle**
- **Oracle Clinical**
- **Clintrial**

6. Attachment 5, "Additional Technical Proposal Instructions", Section 3.A.11. is deleted in its entirety and replaced with the following:

11. The plans and procedures to provide security against anticipated risks. **Provide the AIS, ISSP and COOP.**

7. Attachment 5, "Additional Technical Proposal Instructions", Sections 3.B.1.a) and d) are deleted in their entirety and replaced with the following:

a) The plans and procedures for generating electronic and paper CRFs. Provide examples of CRFs produced for **clinical trials for vaccines and therapeutics.**

d) Examples of previously generated source documents, questionnaires, memory aids, subject instructions, screening and recruitment logs, order forms for clinical supplies and test articles, and test article accountability logs for **clinical trials for vaccines and therapeutics.**

8. Attachment 6, "Additional Business Proposal Instructions and Uniform Budget Assumptions", Section 3, item 1.b.3) is revised to add the following:

- **8,000 clinical trial subjects per year for entire contract period of performance**