

RFP-NIH-NIAID-DMID-08-03

Amendment 2

“Vaccine and Treatment Evaluation Units (VTEUs): Evaluation of Control Measures Against Diseases Other than AIDS”

Amendment Issue Date:	07/10/2006
Proposal Due Date/Time: (UNCHANGED)	12/15/2006 at 3:00 P.M., EST
Issued By/Point of Contact: (UNCHANGED)	Teresa A. Baughman Contracting Officer OA/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 3214, Bethesda, Maryland 20892-7612 tb14j@nih.gov

Offerors must acknowledge receipt of this Amendment 2, 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.

PURPOSE: This Amendment corrects website links that did not work in the original RFP and amends Attachment 7 – Additional Business Proposal Instructions and Uniform Cost Assumptions.

1. Part I – The Schedule, Section H, Article H.11. Information Security, item i.12, NIH Systems Security Plan Outline (outline only) – The website link is deleted and replaced with Attachment 14 included in this Amendment.
2. Section L.2.b., Item (18) Information Technology Systems Security, (g)(4), NIH Systems Security Plan Outline (outline only) – The website link is deleted and replaced with Attachment 14 included in this Amendment.
3. Section J – List of Attachments – is revised to add Attachment 14, NIH Systems Security Plan Outline (outline only).
4. Section J – List of Attachments – For the titles listed below, the website listed is deleted and replaced with the following website:

<http://rcb.cancer.gov/rcb-internet/forms/forms.htm>

Small Business Subcontracting Plan (Business Proposal Attachments)
Inclusion Enrollment Report (Informational Attachments)
Employee Separation Checklist (Informational Attachments)

5. Section L.2.b., Item (10) Research Involving Prisoners as Subjects, paragraph a. – the website listed is deleted and replaced with:

<http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.htm>

6. Section L.2.b., Item (10) Research Involving Prisoners as Subjects, paragraph b. – the website listed is deleted and replaced with:

<http://www.hhs.gov/ohrp/special/prisoners/>

7. Section L.2.b., Item (12) Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research) is revised to delete the website for “The NIH Guidelines for Research Involving Recombinant DNA Molecules” and replace it with:

<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

8. Section L.2.b., Item (17) Obtaining and Disseminating Biomedical Research Resources, item (b) is revised to delete the website for Simple Letter Agreement (SLA) and replace it with:

http://www.ott.nih.gov/forms_model_agreements/forms_model_agreements.html#MTACTA

9. Attachment 4, Statement of Work, section 4. Protocol Implementation, item f.7), the two (2) links for the annual report are deleted and replaced with the following websites:

http://a257.g.akamaitech.net/7/257/2422/01apr20051500/edocket.access.gpo.gov/cfr_2005/aprqr/21cfr312.23.htm

http://a257.g.akamaitech.net/7/257/2422/01apr20051500/edocket.access.gpo.gov/cfr_2005/aprqr/21cfr312.64.htm

10. Attachment 7 – Additional Business Proposal Instructions and Uniform Cost Assumptions is hereby revised to include the following in Section 1.a. Clinical Trials and Study Participants:

“Assume that there may be one (1) protocol involving neonates per contract in the entire 7 year contract period of performance.

“Assume that one (1) inpatient trial will be conducted under the contract every two (2) years (Year 2, 4, and 6)”.

These two new assumptions do not change the originally listed five protocols per year, but rather are included in them.

Offerors shall use these uniform cost assumptions, in addition to the cost assumptions already included in Attachment 7, in preparation of their cost proposal.

Security Plan (SP) Outline (from NIH SP Template)

Executive Summary

- 1 APPLICATION/SYSTEM IDENTIFICATION
 - 1.1 Application/System Category (MA or GSS)
 - 1.2 Application/System Name/Title
 - 1.3 Responsible Organization
 - 1.4 Information Contact(s)
 - 1.5 Assignment of Security Responsibility
 - 1.6 Application/System Operational Status
 - 1.7 General Description/Purpose
 - 1.8 Application/System Environment
 - 1.9 Application/System Interconnection/Information Sharing
 - 1.10 Applicable Laws or Regulations Affecting the Application/System
 - 1.11 Information Sensitivity and Criticality Assessment
 - 1.12 Privacy Impact Assessment
- 2 MANAGEMENT CONTROLS
 - 2.1 Risk Assessment and Management
 - 2.2 Review of Security Controls
 - 2.3 Rules of Behavior
 - 2.4 Planning for Security in the Life Cycle
 - 2.5 Certification and Accreditation
- 3 OPERATIONAL CONTROLS
 - 3.1 Personnel Security
 - 3.2 Physical and Environmental Protection
 - 3.3 Production, Input/Output Controls
 - 3.4 Contingency Planning and Disaster Recovery
 - 3.5 Application/System Configuration Management Controls
 - 3.6 Data Integrity/Validation Controls
 - 3.7 Documentation
 - 3.8 Security Awareness and Training
 - 3.9 Incident Response Capability
- 4 TECHNICAL CONTROLS
 - 4.1 Identification and Authentication
 - 4.2 Logical Access Controls
 - 4.3 Public Access Controls
 - 4.4 Audit Trails

Appendices

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| Appendix A | Acronyms |
| Appendix B | Definitions |
| Appendix C | References |
| Appendix D | Rules of Behavior (optional as an Appendix, required as part of the C&A package) |
| Appendix E | System Interconnection Agreement/Memorandum of Agreement (optional as an Appendix, required as part of the C&A package) |
| Appendix F | Contingency Plan/Disaster Recovery (optional as an Appendix, required as part of the C&A package) |
| Appendix G | Configuration Management Plan (optional as an Appendix, required as part of the C&A package) |
| Appendix H | Privacy Impact Assessment (optional as an Appendix, required as part of the C&A package) |
| Appendix J | Document History |