RFP-NIH-NIAID-DMID-08-03

Amendment 3

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

Amendment Issue Date:	11/9/2006
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

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Offerors must acknowledge receipt 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.

A CUTOFF DATE FOR QUESTIONS HAS BEEN SET AT 11/27/06.

PURPOSE: This Amendment revises:

- **Section M, Evaluation Factors for Award,**
- **Attachment 6, Additional Technical Proposal Instructions, and**
- **Attachment 7 – Additional Business Proposal Instructions and Uniform Cost Assumptions.**

Section M – Evaluation Factors for Award is hereby revised as follows to add the wording noted in bold/underline to Criteria A only under the Technical Evaluation Criteria. In addition, the subcriteria for Criteria A have been **reordered** to reflect the order of importance. ALL OTHER EVALUATION CRITERIA AND THEIR WEIGHTS REMAIN UNCHANGED.

CRITERIA A – TECHNICAL PLAN/APPROACH WEIGHT = 35 (UNCHANGED)

The offeror's overall understanding of the objectives and requirements of the RFP, ability to identify problems and suggest solutions, and the ability to enhance the achievement of the scientific goals of the overall program will be evaluated for the following elements.

The following subcriteria are listed in descending order of importance.

1. Study Populations and Enrollment Requirements:

    a. General Population:

        1) Adequacy of documentation with respect to access to the number and type of populations required to serve as study participants, and ability to recruit and retain study participants from the general population;

        2) Ability to identify anticipated recruitment and retention problems and difficulties that may arise and adequacy of proposed approaches to overcome or minimize anticipated problems and difficulties.

    b. Additional Populations:

        1) Adequacy of documentation with respect to access to the scope of additional populations to serve as study participants, including women of child-bearing age, pregnant women, immunocompromised populations, non-U.S. populations, and populations with underlying medical conditions;
        2) Ability to recruit and retain additional study populations; and;
        3) Ability to identify anticipated recruitment and retention problems and difficulties that may arise and adequacy of proposed approaches to overcome or minimize anticipated problems and difficulties.

    c. Demonstrated ability to adhere to Good Clinical Practices (GCP).

2. Clinical Trials, Clinical Studies and Other Evaluations and Analyses:

        1) Ability to design and conduct clinical trials and clinical studies, as well as other evaluations and analyses, as evidenced by the soundness, appropriateness, adequacy and feasibility of the scientific, technical and operational plans for the three case studies:

3. Case Studies

    a. Case Study 1: Phase 1 Clinical Trial of West Nile Virus Vaccine
    b. Case Study 2: Phase 3 Clinical Trial of an Inactivated Influenza Vaccine
    c. Case Study 3: Phase 1 Clinical Trial of a Meningitis Vaccine

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Attachment 6 – Additional Technical Proposal Instructions is hereby revised to change the suggested number of pages for the case studies from 20 single-sided pages each to 10-15 single sided pages each.

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Attachment 7 - Additional Business Proposal Instructions and Uniform Cost Assumptions is hereby revised to delete the following (that was added in Amendment 2) in Section 1.a. Clinical Trials and Study Participants and replace it with the following:

"Assume that one (1) inpatient trial will be conducted under the contract every two (2) years (Year 2, 4, and 6). In addition, assume that each inpatient trial will have fifty (50) subjects and will last for ten (10) days."

This does not change the originally listed five protocols per year, but rather is 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.