AMENDMENT TO NIAID SOLICITATION
"CLINICAL TRIAL FOR COMMUNITY-ACQUIRED METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (CA-MRSA) INFECTIONS"

Solicitation Number:	RFP NIH-NIAID-DMID-07-12
Amendment Number:	1
Amendment Issue Date:	July 19, 2006
Proposal Intent Response Sheet Due Date: **Proposal Due Date:**	July 31, 2006 CHANGED September 15, 2006, 4:00PM, Local Time CHANGED
Issued By:	Ross Kelley Contracting Officer NIAID, NIH, DHHS Office of Acquisitions, DEA 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, Maryland 20892-7612
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This amendment is issued to all potential Offerors.	

The above numbered solicitation is amended as set forth below. The hour and date specified for receipt of proposals **HAS** been extended. Offerors must acknowledge receipt of this amendment by identifying this amendment number and date on each copy of the offer submitted. Failure to receive your acknowledgement may result in the rejection of your offer.

If by virtue of this amendment you desire to change an offer already submitted, such change may be made by fax, letter or e-mail, provided each fax, letter or e-mail makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

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

PURPOSE OF AMENDMENT:

1) **TO CHANGE SECTION M, ITEM 9. TECHNICAL EVALUATION CRITERIA, CRITERION 1, TECHNICAL PLAN / APPROACH, PARAGRAPH 2. CLINICAL TRIAL TIMELINES, ACCESS TO AND ABILITY TO RECRUIT AND RETAIN PROPOSED STUDY POPULATIONS (PAGE 74). LANGUAGE THAT HAS BEEN CHANGED BY THIS AMENDMENT IS HIGHLIGHTED.**

2) **TO CHANGE THE STATEMENT OF WORK (ATTACHMENT 4) ITEM 1 B. CLINICAL TRIAL SITE REQUIREMENTS (PAGE 3 OF 8). LANGUAGE THAT HAS BEEN CHANGED BY THIS AMENDMENT IS HIGHLIGHTED.**

3) TO CHANGE APPENDIX A (ATTACHMENT 6), SECTION 3 - TECHNICAL APPROACH, ITEM 1. CLINICAL TRIAL DESIGN, AND ITEM 2. CLINICAL TRIAL TIMELINES, ACCESS TO AND ABILITY TO RECRUIT AND RETAIN PROPOSED STUDY POPULATIONS. LANGUAGE THAT HAS BEEN CHANGED BY THIS AMENDMENT IS HIGHLIGHTED.

4) TO CHANGE APPENDIX B (ATTACHMENT 7, PAGE 1 OF 2), SECTION 3 - UNIFORM COST ASSUMPTIONS ITEM 1, TECHNICAL COST ASUMPTIONS. THE ASSUMPTION FOR HUMAN SUBJECTS HAS BEEN DELETED.

1) SECTION M, ITEM 3. TECHNICAL EVALUATION CRITERIA, CRITERION 1, TECHNICAL PLAN /APPROACH, PARAGRAPH 2. CLINICAL TRIAL TIMELINES, ACCESS TO AND ABILITY TO RECRUIT AND RETAIN PROPOSED STUDY POPULATIONS, IS DELETED IN ENTIRETY AND REPLACED WITH THE FOLLOWING:

2. Clinical Trial Timelines, Access to and Ability to Recruit and Retain Proposed Study Population(s)

a. Proposed timelines for all steps involved, including protocol development, initiation, completion of enrollment, and analysis and publication of final study results, including past experience in meeting timelines for projects of similar size and complexity, obstacles and problems encountered during the conduct of these projects, and how they were resolved.

b. Documented evidence of access to adequate numbers of study participants, based on the proposed clinical trial design.

c. Plan for the recruitment and retention of the study participants, a description of potential problems and obstacles to achieving the required enrollment targets, as well as proposed solutions to overcome identified problems/obstacles.

d. Organizational experience with a track record in the screening, recruitment and retention of study participants within the scope of the proposed clinical trial.

2) STATEMENT OF WORK (ATTACHMENT 4), ITEM 1 B. CLINICAL TRIAL SITE REQUIREMENTS (PAGE 3 OF 8), IS DELETED IN ENTIRETY AND REPLACED WITH THE FOLLOWING:

b. Clinical Trial Site Requirements

The clinical trial shall include a minimum of two (2) and a maximum of five (5) clinical trial sites. Each clinical trial site, including the Contractor, shall:

1) Operate in compliance with all Federal regulations and NIH policies applying to the conduct of all research involving human subjects including Title 21 CFR 50, 56 and 312, and Title 45 CFR 46.

2) Have access to adequate numbers of subjects with skin and soft tissue infection to ensure enrollment of approximately forty (40) subjects every three (3) months. Clinical sites must be located in areas of high prevalence for CA-MRSA.

3) Provide clinical research staff with experience in the design and conduct of clinical trials in infectious diseases and training in Good Clinical Practice (GCP) necessary to conduct the clinical trial, including the Principal Investigator and all clinical investigators at participating trial sites who shall be medical doctors licensed to practice in the U.S and shall ensure that active licensure is maintained for the entire period of contract performance, and a Study Coordinator with a RN license or equivalent medical credentials.

4) Provide clinical research outpatient facilities for the screening and enrollment of study participants, the administration of study drug(s), the incision and drainage of wounds, and follow-up in accordance with the specific requirements of the clinical trial approved for implementation.

5) Provide clinical laboratory facilities and technical personnel to isolate, identify and perform susceptibility testing and storage at each individual site of pathogens present in the subjects at the time of enrollment.

6) Provide clinical pharmacy facilities and personnel for the receipt, storage, packaging, labeling, distribution, quality control and inventory of study drug(s) used in the clinical trial; and,

7) Work with the CTM, Data Management and Regulatory Support contractors for the provision of regulatory support, data management, site monitoring and meeting logistics.

3) APPENDIX A, SECTION 3., ITEM 1. CLINICAL TRIAL DESIGN AND ITEM 2. CLINICAL TRIAL TIMELINES, ACCESS TO AND ABILITY TO RECRUIT AND RETAIN PROPOSED STUDY POPULATIONS (PAGE 2 OF ATTACHMENT 6) - ARE DELETED IN ENTIRETY AND REPLACED WITH THE FOLLOWING:

1. Clinical Trial Design

Submit an expanded Concept Synopsis of no more than ten (10) pages addressing the following design features of the proposed clinical trial headed as the following:

a. Background. Include the rationale(s) for the choices of the study arms selected
b. Objectives.
c. Primary hypothesis.
d. Study design including inclusion/exclusion criteria. Provide a plan for the procedure for performing or providing wound care, including the subpopulation of patients on which the procedure will be performed or provided, and whether or not any modifications to wound care will be made with any of the subpopulations.
e. Study population. Provide rationale(s) for the choice of the study population including age, gender, and demographics. Describe how the population meets the definition required in the Statement of Work.
f. Study arms.
g. Primary and secondary endpoints. Provide the definition of invasive infection to be adopted in the study, such as bacteremia, endocarditis, pneumonia, osteomyelitis, or invasive soft tissue infection.
h. Follow-up time for study subjects. Provide an algorithm indicating how patients are to be followed should invasive infection occur or should patients not respond to the therapy.
i. Statistical methods and randomization. Include in an algorithm for the method in which subjects are to be enrolled and randomized. The algorithm must include how the offeror plans to deal with prior antibiotic use if there is any. Include a sample size calculation, provide a rationale for this calculation, and state the relevance to outcomes desired for the target patient population that is being studied.
j. Potential problems and obstacles in implementing the proposed clinical trial and strategies to overcome identified problems and obstacles.
k. The total subjects enrolled will be dependent upon the Offeror's study design.

NOTE: The clinical trial design, as proposed in Section 3 of the Technical Proposal, will be used in the evaluation of scientific and technical merit, appropriateness and feasibility. The final clinical trial design and clinical protocol shall be subject to review, modification and approval by the Project Officer post award.

2. **Clinical Trial Timelines, Access to and Ability to Recruit and Retain Proposed Study Populations**

Provide the following documentation and plans for the offeror and all proposed clinical trial sites:

a. Proposed timeline for all steps involved, including protocol development, initiation, completion of enrollment, completion of clinical trial, and analysis and publication of final study results. Include a discussion of past experience in meeting timelines for projects of similar size and complexity, obstacles and problems encountered during the conduct of these projects, and how they were resolved.

b. Evidence of the incidence of local CA-MRSA for the offeror and for each proposed clinical trial site through summaries of microbiology logs or other information documenting the number of patient visits due to skin and soft tissue infection.

c. Evidence of documented ability to enroll approximately forty (40) patients with CA-MRSA skin and soft tissue infection every three (3) months through submission of summaries of patient visit logs from the emergency room(s) and/or the clinic(s) for the offeror and for all proposed clinical trial sites. Clinical sites must be located in areas of high prevalence for CA-MRSA.

d. A plan for the recruitment and retention of the study participants and a description of potential problems and obstacles to achieving the required enrollment targets, as well as proposed solutions to overcome identified problems/obstacles.

e. Organizational experience with and a track record in the screening, recruitment and retention of study participants within the scope of the proposed clinical trial.

4) APPENDIX B, SECTION 3 - UNIFORM COST ASSUPTIONS (PAGE 1 OF ATTACHMENT 7) - IS DELETED IN ENTIRETY AND REPLACED WITH THE FOLLOWING:

SECTION 3 – UNIFORM COST ASSUMPTIONS

These are the uniform cost assumptions that the offeror should make to prepare the business proposal.

1) **Travel**

Offerors should include the following uniform assumptions:

Annual Meeting
1 trip to the Washington D.C. area once per year for one day, for 20 persons.

DSMB Meeting
2 trips to Washington D.C. for DSMB meetings for one day for 2 persons.

FDA IND Meeting
1 trip to Washington D.C. for FDA IND meeting for one day for 2 persons.

Scientific Meetings for presentation of study data
3 trips to Washington DC for three days for 1 person.

END OF AMENDMENT # 1 TO RFP-NIH-DMID-07-12