Amendment #1
To RFP-NIH-NIAID-DIR-01-01

"Operation of a Facility for the Study of Infectious Agents, Vaccines and Antimicrobials in Adult and Pediatric Human Subjects"

Amendment to Solicitation No.:	**NIH-NIAID-DIR-01-01**
Amendment No.:	**One (1)**
Amendment Date:	**August 29, 2000**
RFP Issue Date:	**August 17, 2000**
Issued by:	**Rosemary Hamill** **Senior Contracting Officer** **NIH/NIAID** **Contract Management Branch** **6700-B Rockledge Drive** **Room 2230, MSC 7612** **Bethesda, Md., 20892-7612**
Point of Contact:	**Brenda Velez (bv4y@nih.gov)**
Name and Address of Offeror:	**To All Offerors**

1. **TECHNICAL EVALUATION FACTORS FOR AWARD, Section 2 is changed to read as follows:**

The Offeror shall demonstrate that their facility is located within the Washington/Baltimore Metropolitan area to facilitate the need for NIAID scientists to travel to the contractor's facility several times a week to examine volunteers and to receive labile clinical specimens obtained from volunteers including samples for virus isolation as well as mosquitoes fed on infected volunteers.

2. **TECHNICAL EVALUATION FACTORS FOR AWARD, Section 3. E. is modified to delete the requirement for past performance information. Criterion E. now reads as follows:**

E.1. Provide documentation of your organization's success in managing and administering Phase I and II clinical trials.

3. **Section L.2.a.(23) is hereby deleted in its entirety.**

4. **Task 4. of the SOW is changed to add the number 4 in front of the task starting with "Contractor shall perform studies in subjects of all ages".**

5. **Task 4. (A) is changed to read as follows: (A) Perform intensive studies of infants and children of less than 21 years of age in a daycare or other setting that is conducive to the growth and development of the child**. It is estimated that such studies would involve up to 20 children at a time. Observe the children for symptoms of illness due to the agent or vaccine under study or due to viral and bacterial adventitious pathogens. The signs and symptoms of each child shall be carefully recorded (for example, temperature, number of coughs per hour, etc.) and compared to a control group that is studied simultaneously. Collect the appropriate specimens and make the indicated observations required by each specific research protocol. Evaluate the transmissibility of attenuated vaccine viruses in this setting. It is estimated that 150 infants and young children will be studied each year in these intensive studies.

6. **FAR Clause 52.237-3 is hereby incorporated by reference to this Solicitation and will be added to any resultant contract.**

7. **In accordance with the requirements of OMB Circular A-130, Appendix III, a Systems Security Plan must be submitted with the Business Proposal. Information concerning this requirements can be found in http://www.whitehouse.gov/OMB/circulars/a130/a130.html**

8. **This Amendment 1 incorporates the following Article in full text under Section L.1.o.**

Data and Safety Monitoring in Clinical Trials

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data safety and monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data safety and monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, FDA and NIH. The frequency of reporting of the conclusions of the monitoring activities should also be described in the plan. The overall elements of each plan may vary depending on the size and complexity of the trial. Examples of monitoring activities to be considered are described in the NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

CONTRACT LANGUAGE:

SECTION H. . DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the

following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The contractor must comply with the NIH Policy cited in these NIH Announcements and any other data safety and monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data Safety and Monitoring [BOARD and PLAN] shall be established and approved prior to beginning the conduct of the clinical trial.

******** **(Select and/or delete the appropriate wording from the bracketed information. Note: Phase III Clinical Trials generally require both a DSMB and a Plan. Phase I and Phase II Clinical Trials generally require only a Plan.) ******

9. The following Article is incorporated in full text under Section L.1.p.

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal a description of education in the protection of human subjects that has been completed (or will be completed at the time of contract award) by the principal investigator and any other individuals working under the contract who are responsible for the design and conduct of the research. This requirement extends to investigators and all individuals responsible for the design and conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://helix.nih.gov:8001/ohsr/newcbt/. This site may be downloaded at no cost and modified for use by the offeror, if desired. In addition, the

University of Rochester has made available its training program for individual investigators, and completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution has already developed educational programs on the protection of research participants, completion of these programs will also satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and conduct of the research under the contract, the contractor shall provide information in writing to the contracting officer describing the education in the protection of human subjects that has been completed by the replacement.

******(The Article below will be incorporated in any resultant contract.) Note: It is anticipated that the NIH Policy will be superceded by the DHHS-ORI's institutional assurance once this requirement has been incorporated)******

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:

The contractor shall maintain a description of education in the protection of human subjects that the Principal Investigator and any other individuals working under the contract, who are responsible for the design and conduct of the research, have completed. In addition, the requirement extends to investigators and all individuals responsible for the design and conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and conduct of the research under the contract, the contractor shall provide information in writing to the Contracting Officer describing the education in the protection of human subjects that has been completed by successor personnel.