

**Amendment #1
to RFP-NIH-NIAID-DMID-01-11**

"The Bacteriology and Mycology Study Group (BAMSG)"

Amendment to Solicitation No.:	<u>NIH-NIAID-DMID-01-11</u>
Amendment No.:	1
Amendment Date:	May 22, 2000
RFP Issue Date:	April 28, 2000
Issued By:	Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Brenda Brooks, Contract Specialist
Name and Address of Offeror:	To All Offerors

The purpose of this amendment is to provide answers to questions posed on the subject solicitation. Each question and answer is listed below:

Question #1

Please clarify the "estimate of effort" found in Section L. The RFP states that it will be 47,840 total labor hours for the five year period. Is this the intent of the RFP?

Answer #1

Yes.

Question #2

If we engage in subcontracts for the four patient risk group committee chair positions, would these subcontracts utilize estimated FTEs or are the estimated FTEs intended specifically for the BAMSG central unit only? We would request that the subcontract "effort" not be included in the estimate of effort. Furthermore, we anticipate having site subcontracts for the performance of studies, so use of subcontract personnel as part of the BAMSG estimated effort would significantly diminish the FTEs for the Central Unit.

Answer #2

The subcontract effort involving Steering Committee Members is included in the total full-time equivalent (FTE) calculation.

Question #3

We are confused regarding the BAMSG statement of work (1.a., Note C to Offerer, and Statement of Work item #2) dealing with "orphan studies". Note C indicates there will be 12 clinical trials over the life of the contract, three per risk group. Do these 12 trials include any trials done as orphan studies? OR, are the orphan studies trials an add-on to the 12 mandated BAMSG clinical trials?

Answer #3

Yes. The Orphan Studies are included in the 12 trials.

Question #4

The RFP (Section 2.0 Orphan Studies) indicates that BAMSG will negotiate and secure funds for BAMBU. What are the expected responsibilities of BAMSG to negotiate on behalf of the BAMBU contractor? Will any additional funds from industry go to BAMBU through BAMSG as a subcontract?

Answer #4

Expenses for an Orphan Study could exceed the capacity of the Reserve Funds. Such excess expenses could include costs for data management or site monitoring that exceed the capacity of the BAMBU budget. If this occurs, BAMSG will be encouraged to seek outside support for that study which could come from industry, a foundation, or other Government agencies. Any necessary funding for BAMBU would be provided directly to BAMBU from the source of the outside support.

Question #5

- a) For funds available from industry for clinical sites (e.g., when NIAID holds the IND), would the funds come to BAMSG and be distributed to the sites via subcontracts?
- b) Would the funds go through BAMBU after BAMSG completes the negotiations? Please clarify.

Answer #5

- a) Yes, unless the industrial sponsor insists on contracting directly with sites.
- b) No

Question #6

- a) When funds are available for sites from the orphan study reserves, how will these funds flow?
- b) Will they come to BAMSG and be distributed to the sites via subcontracts between the site and the BAMSG contractor? Please clarify.

Answer #6

- a) See b)
- b) Yes

Question #7

In BAMSG Statement of Work 4.c., and BAMBU Statement of Work D.2., each group is asked to provide support associated with IND applications. This is confusing. Which group has the primary responsibility?

Answer #7

BAMBU. BAMSG may need to provide information necessary for IND filing and applications from its investigators to BAMBU.

Question #8

There are multiple overlapping areas in which BAMSG and BAMBU are preparing documents (LORs, study documents) in collaboration. Will there be travel funds for BAMSG and BAMBU to have face to face working meetings?

Answer #8

No, unless face-to-face meetings would be needed to address extraordinarily difficult issues. It is expected that this work could be accomplished by e-mail, telephone conversations and/or teleconferences. Use of travel funds to attend such meetings would require the prior approval of the Project Officer.

Question #9

Please clarify the intended role of BAMBU in organizing and interacting with the BAMSG Steering Committee. Statement of Work (BAMSG) 3.c. states that BAMSG will be organizing and supporting the functions of the Steering Committee but in 4.j., Statement of Work, has BAMSG and BAMBU collaborating in this effort. This is confusing.

Answer #9

BAMSG will provide all the operational support for the BAMSG Steering Committee. BAMBU will collaborate in the development of policies and procedures for the committee.

Question #10

Statement of Work 4.k states that BAMSG will assist BAMBU in obtaining necessary regulatory documents from the BAMSG sites. There appears to be significant overlap in the BAMBU and BAMSG statements of work relating to interactions with sites. Please clarify which group will be interacting with sites to collect and verify regulatory documents.

Answer #10

BAMBU will have the lead for obtaining the necessary documentation from the BAMSG sites. BAMSG will be expected to engender the cooperation of the BAMSG sites in responding appropriately to these requests and requirements.

Question #11

Statement of Work - 6.a. indicates that BAMSG will establish collaborations with other groups (NCI-CALGB, DAIDS-ACTG). Will travel funds be available for attendance at such group annual meetings by the BAMSG coordinator and/or a BAMSG PI?

Answer #11

Yes; however, it is expected that whenever possible, BAMSG will travel representatives of the collaborating group to the BAMSG meetings and that collaborating groups will reciprocally travel BAMSG representatives to their meetings.

Question #12

Statement of Work - 7. This item discusses the policy for publications with an attached suggested SOP; however, this SOP does not include two NIH-required statements ("acknowledgement of support" and "disclaimer") that the current MSG has in its SOP. Those typical statements are:

"This project has been funded in part with Federal Funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health under Contract Number:XXXXX"

"The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. government."

Has the policy at NIH changed to no longer require these statements in contract associated publications?

Answer #12

The citation of the contract number remains and is addressed in the Statement of Work and in Attachment A.2 at item #7. The second (disclaimer) statement does not apply to contracts unless a U.S. Government employee is among the authors. If any NIAID employee is included as an author of a MSG publication, the disclaimer should be present on those manuscripts.

Question #13

We don't consider the site investigators to be "key personnel" for the BAMSG; but just wanted verification that we are correct in our interpretation that CVs were not required for the RFP submission for the individual site investigators.

Answer #13

Yes, you are correct.

Except as provided herein, all terms and conditions of the RFP document NIH-NIAID-DMID-01-11 remain unchanged and in full force and effect.

The hour and date specified for receipt of offers is **NOT** extended.

Offerors must acknowledge receipt of this Amendment #1, by the following method:

- By acknowledging receipt of the amendment on each copy of the offer submitted.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.