

BU'S BIOTERRORISM LABORATORY IS BEING FUNDED UNDER THIS RFP

Excerpts from the NIAID Request for Proposals and Applications for Regional Biocontainment Laboratories (RBLs) and National Biocontainment Laboratories (NBLs)

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Part B -- National Biocontainment Laboratories (NBLs)

The overall objective of the NBL construction program is to provide funding to design, construct, renovate (if needed) and commission and install and certify fixed equipment into comprehensive, state-of-the-art BSL-4 biocontainment laboratories and the necessary associated BSL-3 labs, BSL-2 labs, animal facilities, insectary facilities, clinical facilities and research support space. NBLs will serve as a national resource for efforts in conducting clinical and laboratory (*in vitro* and *in vivo*) research and testing on hazardous biological agents in support of the NIAID's Biodefense Agenda. NBLs must preferentially support the research activities of NIAID Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCE), as well as other NIAID funded biodefense research. NBLs will be part of the NIAID RCE BiodefenseNetwork and will serve as a national resource. In addition, NBLs must be available and prepared to assist national, state, and local public health efforts in the event of a bioterrorism emergency.

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The following requirements/assurances apply to both Parts A and B and must be met and agreed to by the offeror/applicant in order to be considered eligible for an award under this BAA:

1. Only domestic (U.S.), non-Federal, public or private non-profit organizations that support biomedical research are eligible to apply.
2. A description of the anticipated sources of the non-Federal funding for the project (both matching funds and funds needed to complete the total project) must be provided with the application/proposal. A letter from an appropriate institutional official authorized to commit funds at the institution describing and committing the matching funds and assuring that they are in-hand must be provided prior to an award. The minimum match requirement will be \$1 (awardee) to \$3 (federal). Only applications proposing a federal share of \$1.5 to 40 million for Part A and up to \$150 million for Part B will be accepted. Organizations may contribute more than the required matching funds to allow for larger projects. It is anticipated that award sizes will vary. Smaller renovations and alterations may be funded through other initiatives.
<http://www.niaid.nih.gov/ncn/newsletters/nl092602/nl092602.htm#n04>
3. The Offeror/Applicant must be associated with or have planned linkages to one or more institutions or consortia that are applying for NIAID Regional Centers of Excellence (RCE) Biodefense and Emerging Infectious Diseases Research grant awards. In addition to any such proposed arrangements, awardees may be required to link to one or more RCEs or other research institutions as determined by NIAID staff who are managing the program and network. A consortium of institutions, with one applicant institution, may apply for awards under this BAA.
4. Biocontainment facilities must be used for research and research training, with the specific goal of supporting the NIAID Biodefense Research Agenda and research identified by the NIAID as important to program goals. Proposals should document a research base of currently funded and/or planned biodefense research that will make use of the proposed biocontainment facilities.
5. RBLs and NBLs must be ready and available to provide facilities and scientific support to first-line responders and be available and prepared to support public health efforts in the event of a national biodefense emergency.
6. The facility must be utilized for biomedical research purposes as determined by NIAID program needs for at least 20 years beginning 90 days following completion of the construction project. Any lease agreement must cover a time period sufficient for the usage requirement and be a minimum of 20 years in length from the completion of the facility. Federal interest in the facility must be acknowledged as a condition of this award. An annual progress report is required for 20 years and must include a list of publications originating from the use of this project facility. This list should be limited to those scientific

papers acknowledging NIAID support including grant and/or contract numbers. Failure to comply with the 20-year utilization requirement will result in recovery of the Federal share of the value of the facility in accordance with Federal Regulations at 45 CFR 74.32.

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B. ADDITIONAL REQUIREMENTS AND GOALS THAT MUST BE MET

(applies to Part B . NBLs only):

1. Facilities must be suitable for work on dangerous or exotic agents that pose a high or yet to be determined risk of life threatening disease and that are capable of aerosol transmission. The facility must be suitable for: safely and securely transporting, receiving, working with, and storing or housing all NIAID Category A, B and C priority pathogens and other emerging infectious agents as well as animals and humans exposed to and/or infected with such agents; and performing research directed at the prevention, detection, diagnosis and treatment of diseases these agents cause.
2. The most stringent interpretation of the BSL-4 biosafety requirements found in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, most current Edition, (<http://bmbi.od.nih.gov/>) are to be the basis for design and construction.
3. BSL-4 laboratories that consist of both Cabinet Laboratory space where all handling of the agent is performed in a Class III Biological Safety Cabinet, and Suit Laboratory space where personnel wear a protective suit are required. BSL-4 facilities should be comprehensive and have the ability to support animal work and isolation chambers/wards for clinical research.
4. At a minimum, the facility shall contain 121,450 gross square feet (GSF), with at least 58,800 net square feet (NSF). The specific allocation of square footage for proposed functions is at the discretion of the contractor; however, the following minimum square footage requirements must be met:

Required Function NSF GSF

BSL-4 Laboratories	4,000	12,000
BSL-4 Animal laboratories	5,000	15,000
BSL-3/4 Clinical space	3000	6000
BSL-3 Animal laboratories	4,000	12,000
BSL-3 Laboratories	9,000	18,000
BSL-2 Laboratories	12,000	24000
Animal support space	12,000	20,000
Building Entry	2,000	3,000
Offices & Office Support	4,000	6000
Lunch Room	500	750
Conference Room (2)	800	1200
Storage	1500	2,000
Building Support and Loading	1,000	1,500

Total 58,800 121,450

5. At a minimum the facilities must provide/support the following functions:
 - a. High-level biocontainment laboratory facilities including BSL-4, BSL-3 and BSL-2 laboratory space for conducting a variety of *in vitro* research activities (microbiology, biochemistry, cell biology, molecular biology, etc.).
 - b. High-level biocontainment animal facilities including BSL-4, BSL-3, and BSL-2 space for conducting research in multiple species of animals, including non-human primates. Procedures rooms for work with both infected and uninfected animals, surgical suites and pathology laboratory space are required, as are housing areas for many types of animals ranging from rodents to non-human primates. Suitable animal space to allow for work on vector borne diseases shall be included.
 - c. High-level biocontainment insectary facilities including BSL-4, BSL-3, BSL-2 space for housing and conducting research with arthropod vectors.
 - d. High-level containment clinical facilities consisting of BSL-3/4 isolation units for evaluation and treatment of infected individuals, and for conducting small-scale, Phase I/II human clinical trials. BAA-NIH-NIAID-NCRR-DMID-03-36 11
 - e. Systems for monitoring and controlling all facilities including safety and security systems that are redundant and highly secure; integral computer systems; integral decontamination systems; environmental

controls; space for scientific, technical, safety and maintenance support personnel who will provide core services for the facilities.

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NOTE #6. FACILITY USE -- The facility must be utilized for biomedical research purposes as specified by NIAID program needs for at least 20 years beginning 90 days following completion of the construction project. Any lease agreement must cover a time period sufficient for the usage requirement and be a minimum of 20 years in length from the completion of the facility. Federal interest in the facility must be acknowledged as a condition of this award and must include a list of publications originating from the use of this project facility. An annual progress report is required for 20 years. This list should be limited to those scientific papers acknowledging NIAID support including grant and/or contract numbers. Failure to comply with the 20-year utilization requirement will result in recovery of the Federal share of the value of the facility in accordance with Federal Regulations at 45 CFR 74.32.

Excerpts from amendment 1 of the RFP and A
(the amendment is in question and answer format)

Question 1 It is my understanding from reading the RFP that the parties that are awarded the contracts will own 100% of the building; however, NIH would control 100% of the activity in the building for 20 years. If a contractor contributes 25% of the cost of the building should the contractor be able to control 25% of the work done in that building?

No. See page 7, item 6 of the BAA. Additionally, the priorities for usage of the facilities are described on page 5, first paragraph of Parts A and B.

Question 3 Can the contractor stipulate in the proposal that it is contingent upon being awarded the operating contract?

We have significant concerns about building a facility and then having another contractor be awarded the contract to operate a facility on our campus. If we are responsible for security, safety and the overall operations then another company operating a facility we own is an issue.

The BAA is silent regarding an operations contract for the NBL except for pg 6 where it states that the awardee may "compete" for an operations contract. Previous information from NIAID had indicated the intent to award an operations contract simultaneously with the construction contract. Is this still the intent? If not, is it contemplated that the operations contract might be awarded to an institution that did not build the facility? When will the solicitation be released?

NBL awardees will be eligible to submit a separate proposal for support activities related to the operation and maintenance of the NBL.

Question 4 Can the government provide any assurance as to the level of contracts/grants placed in the RBL/NBL over the next 20 years?

No

Question 9 We have significant concerns about the impact on insurance rates from the standpoint of increased risk related to doing BSL-4 work and also the possibility of conducting human clinical trials. If the contractor is unable to get reasonable insurance, is NIH willing to

provide it? If the contractor is able to get insurance but at a much higher rate, can the premium associated to the new facility be charged to the projects conducted in that facility?

Insurance for the operation of the facility is outside of the scope of this announcement. The core costs of operating the facility will be included in a separate Operation and Maintenance contract. Insurance may be included as one of the core costs.

Question 11 What would be the anticipated scale of any clinical isolation capability? Again, from the briefing, I understood that this space should support 5 to 10 people, either for index case observation or in the event of accidental exposure within the rest of the RBL. Would one be able to justify considerably more clinical isolation space (10x)?

The Notice of Intent (NOT-AI-02-038) dated July 19, 2002, and the discussions that took place at the August 8, 2002, meeting no longer accurately represent our plans. Please refer to the BAA for current information. Clinical facilities are not required for the RBLs. For the NBLs, clinical space is required that will support small-scale clinical trials, and a patient containment ward for accidentally exposed users. See page 10 of the BAA for square footage requirements. The NBLs should not include clinical space that would only be used in the event of a bioterrorism emergency.

Question 14 The BAA refers to a cost share of 25% for the awardee (pg 7, para. 2). Does this provision apply to the construction cost of the NBL? The operation of the NBL?

Yes, for construction costs. The details of the separate operations and management contract have not been determined and are not within the scope of this BAA.

Question 16 The BAA states that "The facility must be utilized for biomedical research projects as determined by NIAID program needs" (pg. 7, para. 6). Our Institution has biodefense contracts from several Federal agencies. Can this work or similar work be performed in the NBL? Or only work funded/approved by NIAID? What specific restrictions on the use of the facility are contemplated?

The facility must give priority to Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs), followed by other NIAID funded biodefense research, and finally to biodefense work funded by other agencies and entities. See page 5, paragraphs 2 and 3 of the BAA.

Question 25 What will be the "ownership" arrangement of the NBL facility?

The applicant institution, not the NIH, will be the owner of the building.

Question 35 The applicable security standards and setbacks required greatly affect both setting and cost issues. What security standards will apply to the NBLs?

All local, state, and federal codes shall apply. It is encouraged that offerors perform a risk assessment and threat analysis to aide in the development of facility security program requirements.

Question 41 RFP Number BAA-NIH-NIAID-NCRR-DMID-03-36, Regional Biocontainment Laboratories (RBL) and National Biocontainment Laboratories (NBL), states "a suitable community relations plan and assurance of acceptance of the intended research activities .

must be addressed in the proposal" and "documentation of community acceptance. before award/construction." (page 26, paragraph 7).

What are the acceptable means of documenting community acceptance?

It is the offerors responsibility to develop and implement a proactive community relations plan that will demonstrate effective means of acquiring and subsequently maintaining community acceptance of the RBL/NBL project. The offerors proposal shall include documentation about the steps that have been taken as well as evidence of community opinion regarding the proposed siting of the subject RBL/NBL facility.

More information:

If you would like the full Request for Proposals and Applications, see the links below. The first link will get you to the RFP. The second link will get you to a page from which you can download the amendments to the RFP, ID # 03-36.

<http://www.niaid.nih.gov/contract/archive/RFP0336-0.pdf>

<http://www.niaid.nih.gov/contract/archive2003.htm>