

Proposal for the Establishment of a Center or Institute

Proposed name of Center or Institute:

Center of Predictive Medicine for Bio-Defense and Emerging Infectious Diseases

Name(s) and title(s) of individual(s) submitting this proposal:

**Dr. Manuel Martinez Maldonado, Executive Vice President for Research and
Dr. Larry Cook, Executive Vice President for Health Affairs**

Anticipated Date of Initiation of this Center or Institute:

October 11, 2007

Existing Center or Institute the proposed Center or Institute is intended to replace:

None

Please respond to the following set of instructions, following the numbering scheme indicated. The entire proposal document should not exceed six pages (excluding appended materials).

1. Describe the purpose of the proposed Center or Institute. Indicate why a separate organizational structure is needed to fulfill this purpose. Include reference to the relationship of the Center or Institute to the mission of the university, the Strategy for Excellence, and to the mission of each college, school, unit, department or program of which the Center or Institute will be a part. Include references to specific unit 'scorecard' indicators to which the Center or Institute will contribute.

The proposed Center of Predictive Medicine for Bio-Defense and Emerging Infectious Diseases (CPMBEID) has arisen from the successful attraction of a NIAID funded grant for a Regional Bio-Safety Laboratory (RBL). The RBL is a facility whereas CPMBEID is the academic/research effort needed to strengthen and expand the faculty with research interests in Immunology and Microbial Pathogenesis. In addition, the Center will become a vehicle for interdisciplinary and translational research and serve as a means for the exchange of ideas and generation of intellectual ferment for faculty using the new facility. A strong academic center in these disciplines will, in turn, assure that the RBL physical facility is an efficiently used asset.

Faculty will be drawn from the Health Science Center, the College of Arts and Sciences, and the Speed School of Engineering enhancing the possibility of interdisciplinary projects. The Director of the Center will work with current faculty members as well as assist in the recruitment of at least five additional faculty to build collaborative teams for extramural grant competitions and provide training opportunities for students and post doctoral fellows. Members of the faculty will develop new diagnostic procedures, therapeutic drugs, and

countermeasures to biowarfare and emerging infectious agents. This comprehensive Center will be at the forefront of the new discipline of predictive medicine – a discipline that should allow the United States to stay ahead in the knowledge of bio-warfare and emerging infectious disease, so that it can curtail, control or preempt threats to the National Security and well-being by emerging infections of either natural or manmade origin.

This center is consistent with the University and Research Strategic Plans, with the strategic focus of preparedness on the Shelby Campus, and with the biosciences and health strategic areas of the Commonwealth. The center will contribute to “scorecard” indicators of publications, grant and contract funding, training of postdoctoral fellows and other health professionals, inventions and community partnerships.

2. Indicate who will direct the proposed Center or Institute and what other members of the administration and faculty will be involved in it. Indicate also the level of each individual's involvement on an annual FTE basis for the first three years of the Center's or Institute's operation. Attach brief *curriculum vitae* for the person who will direct the Center or Institute and for the key faculty members who will be involved in it. Indicate how any current members of the faculty or administration that will be involved in the Center or Institute will be replaced in their present activities. Provide a statement from each key faculty member (5% time commitment or greater) indicating that his or her approved work plan includes time spent on Center or Institute activity.

The CPMBEID will be housed in the Office of the Executive Vice President for Research and will report to the Executive Vice President for Research, Dr. Manuel Martinez, and to the Executive Vice President for Health Affairs, Dr. Larry Cook. Central administration has dedicated three (3) new faculty positions to the Center in FY07-08, two (2) additional positions in FY08-09 and one (1) in FY09-10. One of the first three positions will be used to recruit a Scientific Director (SD) for CPMBEID, who will hold a faculty appointment in the School of Medicine. The SD will be funded by the state allocation and will report to the EVPR, Dr. Manuel Martinez and to the EVPHA, Dr. Larry Cook. The SD will be an individual who has an ongoing research program in an animal model of an infectious disease, who is adept at translational research, and at collaborating with fellow faculty members and with outside researchers from academia and industry. The Scientific Director of the Center will work with presently active faculty members to formalize current informal programs that have brought them (see attached list) together in activities such as the November 6, 2006 Bio-safety Workshop and the January 12, 2007 Regional Bio-safety Meeting, both held in the Baxter Auditorium. A one-day symposium was held in April, 2007 (see attached program). The SD will work with research and other faculty members to build collaborative teams for extramural grant and contract competitions, to identify and bring to campus outside speakers, and to provide

training opportunities for students and postdoctoral fellows. The SD will work closely with the RBL building manager and the safety officer to integrate the academic Center activities with the operational needs of the RBL and to assure efficient use of the RBL; this will be facilitated by the SD serving on the internal advisory board of the RBL.

Finally, the SD will be one of the first recruits and will participate in early and efficient subsequent recruitments. A&S is currently recruiting for two faculty members for the 07/08 academic year. They will have a 50% commitment on their AWP for Center –related research; the rest of their effort will be devoted to activities in the Department of Biology. Faculty members at the HSC who will become Center members have suggested that the non-director faculty positions assigned to the HSC be recruited jointly by the HSC and the Center. They will spend their BSL research time in the Center, but will be housed in their chosen department. This will allow the University to communicate to the external scientific community its commitment to the project and the resources it has dedicated to this strategic area. This will also help to allow us to attract candidates without limiting their home department choice, as would be the case if the recruitments were strictly departmental. This strategy speaks to the interdisciplinary, cross departmental nature that we wish to achieve by creating CPMBEID. Secondary appointments in departments or schools other than the home department will be encouraged and are hoped to represent the rule.

There are a number of current faculty members who will be involved in the Center and use the RBL facility. They have active research programs in immunology, microbial pathogenesis, virology, bioengineering diagnostics and other medical sciences. Their work plans include research activities that double-up as departmental activities and as Center activities. The faculty time spent in the Center will be part of their time and effort. If presently active faculty members need additional time for the use of the Center, this must be incorporated into their time and effort as part of their research activities. Some of their current activities will also become center activities, but the center should enable additional interdisciplinary interactions, more competitive grant applications and more coordinated programming. Those who spend their time at the Center will be responsible for managing their time and effort commitments. Letters of support for the Center from chairs and deans of current faculty are included in the appendix. A list of current faculty who are interested in participating in the Center is attached.

- 3. Indicate on an annual FTE basis the needs of the Center or Institute for P&A staff, classified staff, and other personnel in its first three years. Indicate how any current members of the university staff who will be involved in the Center or Institute will be replaced in their present activities.**

During the grant process, the university made personnel commitments necessary to operate the RBL facility. One of these commitments was a RBL administrative assistant dedicated 0.5 FTE (50%) to the building manager to be funded by the state allocation. This same administrative assistant will also serve 0.5 FTE (50%) to support the academic Center-related needs of the Scientific Director. This is one of the ways we will integrate the academic activities of Center faculty with the physical operation of the RBL. The administrative assistant salary will be paid from funds provided by state allocation (see below). The academic activities of CPMBEID will require the support of a software analyst to maintain the application software and the network communications used by the researchers. A systems engineer will support the complex hardware needed to maintain facilities. Additionally, a biosafety officer will be required to assist the research community in maintaining a safe work environment that is compliant with federal, state and community regulations.

4. Indicate the space requirements for the Center or Institute in its first three years, and how that space will be provided.

The Louisville RBL is a research facility that will serve as infrastructure for the activities of CPMBEID. In addition, there are two shared suites of “*in vitro*” BSL3 labs (one in the HSC-A tower and the other in HSC3/4) that will provide the specialized space necessary for microbial pathogenesis work of Center faculty. All faculty members will have regular wet lab space for non-containment work. This will be allocated under the appropriate unit space policies as part of the normal infrastructure U of L offers bench scientists.

5. Indicate initial equipment and other infrastructure resources (including technology) that the Center or Institute will need, and explain how these will be provided. (See Form 1, Part II.5)

The academic focus of CPMBEID will not require equipment or infrastructure other than that required for individual and collaborative research programs. The faculty will have the normal constellation of computers and laboratory equipment germane to their research and training functions.

The Louisville RBL facility grant budget includes \$7M in equipment that will be dedicated to that containment facility and will be available to all members of CPMBEID and to outside users, this being a regional facility. Notable pieces of equipment are a QSTAR XL Pro Tandem Mass Spectroscopy System that performs high-throughput analysis of all proteins in a biological sample with high speed, maximal resolution and extraordinary sensitivity, a Microarray Robotic Arrayer system, a Fluorescence Activated Cell Sorter, and a Confocal Microscope for image analysis. In addition, other necessary equipment such as Real-Time PCR for validation experiments, and assorted protein chemistry and molecular biology instruments are included in the RBL plan. Moreover, the presence of a micro

PET/SPECT/CT scanner will make this facility a unique investigative center for evaluation of the metabolic consequences of infection *in vivo*. The building is designed with specialized ventilation and climate control to manage the heat-generated from 24/7 operation of computer hardware/servers.

Service contracts for the maintenance of the equipment are required and included in the NIH grant that funds the BSL3. Estimates for utilities, supplies and animal care costs are included in the budget. Travel to scientific meetings for the six faculty members plus the Scientific Director is also included.

6. Indicate the amount and source of funds that will be needed to operate the Center in its first three years. Include itemized amounts for personnel, equipment, technological support, and operating expenses.

A state allocation of \$1M of continuing funding to the central administration will support the non-grant-funded salaries of the new faculty positions and two technical positions to operate core facilities that will be located in the RBL containment facility. These funds have been exclusively dedicated to bio-safety research. In addition, we have been assigned five salary lines that will cover the scientific director, the associate director of the facility and other faculty FTE (approximately \$100,000 per year). We anticipate that faculty will be able to recover up to 50% of their research assigned workload from extramural grants. Until personnel are hired, these funds will be a source of one time funding for set up expenses. The EVPR and the EVPHA each will dedicate up to 3% of the F&A on grants brought in by center faculty to the center budget for M&O.

The specialized instrumentation includes mass spectrometers, a confocal microscope, a cell sorter and a micro PET/SPECT/CT scanner. As already mentioned, a seven million dollar allocation in RBL grant budget to fund special instrumentation exists.. For that reason, these are not included in the Center budget.

7. Provide a written statement from the Dean, University Libraries (or designee) concerning the adequacy of current resources. The statement should include a comparison of local holdings to standards/recommendations of national accrediting agencies, the holdings of benchmark institutions, and/or other recognized measures of adequacy. If additional resources are needed to support the program, the statement should include an estimate of costs and the sources of additional funding. The statement should be requested at least one month prior to submitting the final proposal to the Office of the University Provost.

The current library holdings are adequate to support the proposed center. As Dean Rader indicates in her letter of support: “The library has holding that support Ph.D. programs in numerous disciplines relevant to the Center, including Microbiology and Immunology, Pharmacology and Toxicology, Biochemistry and Molecular biology,

Anatomical Sciences and Neurobiology, Physiology and Biophysics, Biology, Chemistry and Chemical Engineering.”

8. Indicate the anticipated amount and source of revenue for the Center or Institute in its first three years on Form 2. Include a narrative that explains in detail all sources of revenue.

CPE has allocated \$2.5 million, which will be dispensed as indicated in line 1.b for budget form 2: \$500,000 in year one and \$1 million each in years two and three.

In the first year, two FTE faculty members will be added, one full Professor (\$200,000, salary plus fringe S+F) , 0.5 FTE Associate Professor (\$140,000 S+F) and 0.5 FTE Assistant Professor (\$50,000 S+F) Each position, however, is subject to negotiation and there is an expectation that 50% of the research salary will be covered through extramural funding. Budget form 2 indicates that one FTE Associate Professor and two FTE Assistant Professors will be added in year 2. We anticipate that the full Professor will bring in grants totaling \$575,000 in Modified Total Direct Costs (MTDC) annually, which will result in \$276,000 in F&A annually. Each Associate Professor is expected to generate \$425,000 in MTDC annually, while Assistant Professors are expected to have \$150,000 of annual MTDC. Budget form 2 indicates that in year 1 the two FTEs will generate \$276,000 from the full Professor’s grants, \$204,000 from Associate professors FTE and \$72,000 per Assistant Professor FTE. The total F&A brought in by one Professor FTE, four Associate and 6 Assisitant Professors once all their grants are in would approximately \$1.5 million per year. We are contemplating the F&A to be \$762,000, for the first three years.

The revenue stream from 6% Center RIFs will be approximately \$91,800 per year, which will be under the direct control of the Scientific Director of the Center. Some of these funds will be used to cover seminar expenses, meeting expenses, visits by the external advisory committee etc. We note that the overall budget is not in balance and some additional revenue source(s) must be found. Federal grants to support the operation are the most likely possible source. The total F&A generated by the projected grant funding is \$1,530,000 which would be sufficient to cover the deficit should federal operating funds not be found.

9. Indicate how the work of the Center or Institute will be evaluated. Please describe the Center or Institute’s evaluation plan according to the following criteria:
 - a. the specific objectives or anticipated outcomes for the work of the Center or Institute;

The objective of this new center is to strengthen and expand the number of funded

faculty members working on Class A, B and C pathogens at the University of Louisville. The anticipated outcome is an increase in grants and contracts, including interdisciplinary grants in infectious disease research. The anticipated outcome is the robust use of the RBL by U of L faculty.

- b. the specific measures, assessment tools, and/or performance indicators that will be used to assess the fulfillment of the Center or Institute's objectives;

The performance indicators will include research contract obtained, grant funding, publications, collaborations, invention disclosures, patent application and RBL use. Other indicators will be the number of students, postdoctoral fellows and other personnel trained.

- c. the schedule for collection, analysis, and reporting of evaluation data described in b. above;

Data on performance indicators will be collected and published annually. All of the items in b, except RBL use, are scorecard metrics.

- d. the person, committee, or entity that will receive the evaluation data or reports and is responsible for developing and implementing changes and improvements.

The EVPR and EVPHA as well as the internal and external advisory boards. The internal advisory board will consist of the Center's Scientific Director and members to be selected from the faculty as recommended by the SD to the EVPR and the EVPHA, who will have input into the process. The external advisory committee will be similarly selected.

The Scientific Director must participate in the selection of the internal and external boards, so it is difficult nor do we (EVPR & EVPHA) wish to provide a more specific response at this time since this must be carefully carried out and may need consultation with NIH and other agencies (security clearance may be a requisite for membership).

External Advisory Board reports most likely will be once a year and will come to me. Dr. Cook and I will discuss and then share with the Scientific Director and other members of the Center and, eventually, with leadership. In general, Boards will address scientific issues, grants, contracts, progress of research and also quality and excellence of operations of the facility. It must be recalled that NIH will evaluate most of these things and may require quarterly or more frequent reports. This has yet to be established, but a conference at NIH, Oct 28-31 of this year that I will attend may provide information on this.

Signature(s) of Submitter(s)

Name _____ Date: _____

Name _____ Date: _____

Faculty members who have participated informally to date:

Haval Shirwan	Microbiology and Immunology
James Lillard	Microbiology and Immunology
Sven Gorr	Periodontics, Endodontics and Dental Hygiene
Andrea Gobin	Bioengineering
Kenneth Palmer*	Pharmacology
Susanna Remold*	Biology
Shin-je Ghim	Cancer Center
Awdhesh Kalia	Biology
Haribabu Bodduluri	Microbiology and Immunology
Tom Mitchell	Microbiology and Immunology
Yousef Abu Kwaik*	Microbiology and Immunology
Bob Stout	Microbiology and Immunology
George Hajishengallis	Periodontics, Endodontics and Dental Hygiene
Gavin Arteel*	Pharmacology
James Graham*	Microbiology and Immunology
Rey Carabeo*	Microbiology and Immunology
Martin Klotz	Biology
Craig McClain	Medicine
Ron Atlas	Biology
Eugenia Wang*	Biochemistry and Molecular Biology
Jill Suttles*	Microbiology and Immunology

* Have applied for internal grants

	FORM 1							
Expenditures for the Program (academic year)								
	2007-08	2008-09	2009-10					
I. Personnel								
1. Full-time Rated Faculty (FTEF)								
a. Number of FTEF	2	5	5					
b. Average Salary	128,926	112,364	115,735					
c. Fringes per average salary (21%)	27,074	23,596	23,120					
COST OF FTRF : a x (b+c)	\$312,000	\$679,800	\$694,275					
2. Program Related Faculty (PTF)								
3. OTHER:								
a. Number of technicians	2	2	3					
b. Average Salary	\$29,500	\$30,385	\$31,297					
c. Fringes per average salary	\$6,195	\$6,381	\$6,572					
COST OF FTRF : a x (b+c)	\$71,390	\$73,532	\$113,607					
Administrative Positions:								
Directors								
a. Number of Directors (Executive Director)	1	1	1					
b. Average Salary	160,000	164,800	169,744					
c. Fringes per Average Salary (21%)	33,600	34,608	35,646					
COST OF Directors a x (b+c)	\$193,600	\$199,408	\$205,390					
Administrative Assistant								
a. Number of AA	1	1	1					
b. Average Salary	38,000	39,140	40,314					
c. Fringes per Average Salary	7,980	8,219	8,466					
COST OF AA a x (b+c)	\$45,980	\$47,359	\$48,780					
Systems Engineer								
a. Number of system Engineer	1	1	1					
b. Average Salary	60,000	61,800	63,654					
c. Fringes per Average Salary	12,600	12,978	13,367					
COST OF Systems Engr a x (b+c)	\$72,600	\$74,778	\$77,021					
Biosafety Officer								
a. Number of Biosafety Off.	1	1	1					
b. Average Salary	70,000	72,100	74,263					
c. Fringes per Average Salary	14,700	15,141	15,595					
COST OF Biosafety Officer a x (b+c)	\$84,700	\$87,241	\$89,858					
Systems Software Analyst								
a. Number of Systems Softw Analyst	0	2	2					
b. Average Salary	55,000	56,650	58,350					
c. Fringes per Average Salary	11,550	11,897	12,253					
COST OF Systems Software Analyst a x (b+c)	\$66,550	\$137,094	\$141,206					
TOTAL PERSONAL COST	\$846,820	\$1,299,212	\$1,370,137					
II. Operating Cost								
1. Supplies								
1a. Equipment Maintance		25,000	30,000					
1b. Utilities			600,000					
1c. Animal Care Costs			300,000					
			60,000					
2. Travel								
	4,000	20,000	20,000					
5. Equipment								
a. Instructional								
b. Research								
*c. Computer equipment and software	3500	5000	5000					
d. Other								
TOTAL OPERATING COSTS	\$7,500	\$50,000	\$1,015,000					
TOTAL EXPENDITURES = Total Personnel and Operation Costs	\$854,320	\$1,349,212	\$2,385,137					
Total			\$4,588,669					
III. Capital Cost								
1. Facilities								
a. New Construction*	*Funded by BSL3 Grant							
b. Renovation								
c. Furnishings*	*Funded by BSL3 Grant							
Note: An Associate Director will be hired as an Associate Professor, see I.1, above)								

1 full (\$200k), 0.5 associate (\$140k/2), 0.5 assistant(\$100k/2) in 2007-8							
1 associate, 2 assistant hired in 2008-2009			3% annual increase				
funded from Research Support positions							
One Associate Professor and one Assistant Professor will each be 0.5 FTE							

