

Agenda Item No. 5

AGENDA ITEM BRIEFING

Submitted by: Billy Hamilton, Executive Vice Chancellor and Chief Financial Officer
The Texas A&M University System

Subject: Approval of the Project Scope and Budget, Appropriation for Pre-Construction and Construction Services, and Approval for Construction for the Live Virus Vaccine Facility, The Texas A&M University System, College Station, Texas (Project No. 1-3138)

Background and Prior Actions:

This project was included on the FY 2014-FY 2018 System Capital Plan as an approved project, approved by the Board at the August 2013 meeting.

Proposed Board Action:

- (1) Approve the project scope and budget.
- (2) Appropriate \$2,983,817 for pre-construction and construction services and related project costs. \$631,082 of funding has been previously appropriated to this project.
- (3) Approve construction of the Live Virus Vaccine Facility (LVVF) for The Texas A&M University System (A&M System) subject to the stipulations set forth in the project Minute Order included in this agenda item.

Funding/Budget Amount:

<u>Funding Source</u>	<u>Budget Amount</u>	Average <u>Estimated Annual Debt Service</u>	<u>Debt Service Source</u>
Federal Grant	\$34,990,119	N/A	N/A
Private Partner	<u>\$18,840,832</u>	N/A	N/A
Total Project Funds	<u>\$53,830,951</u>		

Project Justification:

On June 15, 2012, the U.S. Department of Health and Human Services, Biomedical Advanced Research and Development Authority, awarded the A&M System a \$286 million contract (Prime Contract) to develop and implement the Texas A&M Center for Innovation in Advanced Development and Manufacturing (CIADM). As part of its base period of performance, the A&M System will construct the Live Virus Vaccine Facility (LVVF) and provide the cost-sharing funding required under the Prime Contract through the private partner to fulfill the requirements for the CIADM mission. The construction of the LVVF will add additional capabilities and allow the production of live virus-based vaccines and therapeutics which will be a key component of the national capability to rapidly develop and manufacture a variety of

Agenda Item No. 5
Agenda Item Briefing

vaccines and therapeutic products critical for biosecurity. To minimize the risk of cross contamination of live virus and other products, the U.S. government has contracted for the LVVF according to designs and specifications negotiated with the Department of Health and Human Services. The LVVF will also be available to support research and development for both academic and commercial clients when not utilized under the CIADM contract. The LVVF, in addition to its biosecurity mission, will add a critical state capability to support live virus vaccines for other diseases, such as cancer. These vaccines also require a specialized and isolated facility such as the LVVF.

Scope:

This project will be located in the designated bio-corridor area of Bryan/College Station south of the Texas A&M Health Science Center campus and Health Science Center Parkway and will adjoin and be just west of the proposed Pandemic Influenza Facility (under construction) as shown on the map with this agenda item.

The project will construct a 75,078 SF Live Virus Vaccine Facility (LVVF) to include:

- + Quality Assurance/Quality Control (QA/QC) labs and support
- + QA/QC and manufacturing personnel office spaces
- + Clean room spaces for upstream and downstream full Live Virus manufacturing operations
- + Shared utility plant
- + Gowning/locker rooms
- + Flexible space to accommodate additional process specialized operations that may be required such as egg incubators

The project will also provide all bioprocess equipment required for the LVVF to meet US Department of Health and Human Services requirements under the recently awarded CIADM contract. The LVVF will be designed and constructed to assure compliance with all Food & Drug Administration (FDA) Good Manufacturing Practices (GMP) regulations. Additional Commissioning, Quality Assurance and Validation (CQV) work will be conducted as part of the project to verify that compliance.

The current schedule calls for substantial completion of the Live Virus Vaccine Facility Project in June 2015. The total project budget is \$53,830,951.

Other Major Fiscal Impacts:

None.

THE TEXAS A&M UNIVERSITY SYSTEM
FACILITIES PLANNING AND CONSTRUCTION
Office of the Executive Vice Chancellor and Chief Financial Officer
September 20, 2013

Members, Board of Regents
The Texas A&M University System

Subject: Approval of the Project Scope and Budget, Appropriation for Pre-Construction and Construction Services, and Approval for Construction for the Live Virus Vaccine Facility, The Texas A&M University System, College Station, Texas (Project No. 1-3138)

I recommend adoption of the following minute order:

“The project scope along with a project budget of \$53,830,951 for the Live Virus Vaccine Facility Project is approved.

The amount of \$1,939,481 is appropriated from Account No. 01-048600, BARDA-CIADM-Program Management, and the amount of \$1,044,336 is appropriated from Account No. 01-048570, CIADM-Kalon LVV Cost Share, for pre-construction and construction services and related project costs.

The Live Virus Vaccine Facility Project, The Texas A&M University System, College Station, Texas, is approved for construction. However, an initial phase of construction is authorized and limited to work that can be performed in an amount not to exceed the appropriated funds referred to above. Additional construction following the initial phase is approved but is contingent upon the certification by the Chancellor that additional cost-share funding for the project has been secured by the private partner. Authority is hereby granted to appropriate additional project funds as they become available.”

Respectfully submitted,

[ORIGINAL SIGNED BY]

Billy Hamilton
Executive Vice Chancellor and
Chief Financial Officer

Approval Recommended:

[ORIGINAL SIGNED BY]

John Sharp
Chancellor

[ORIGINAL SIGNED BY]

Phillip Ray
Chief Business Development Officer

Approved for Legal Sufficiency:

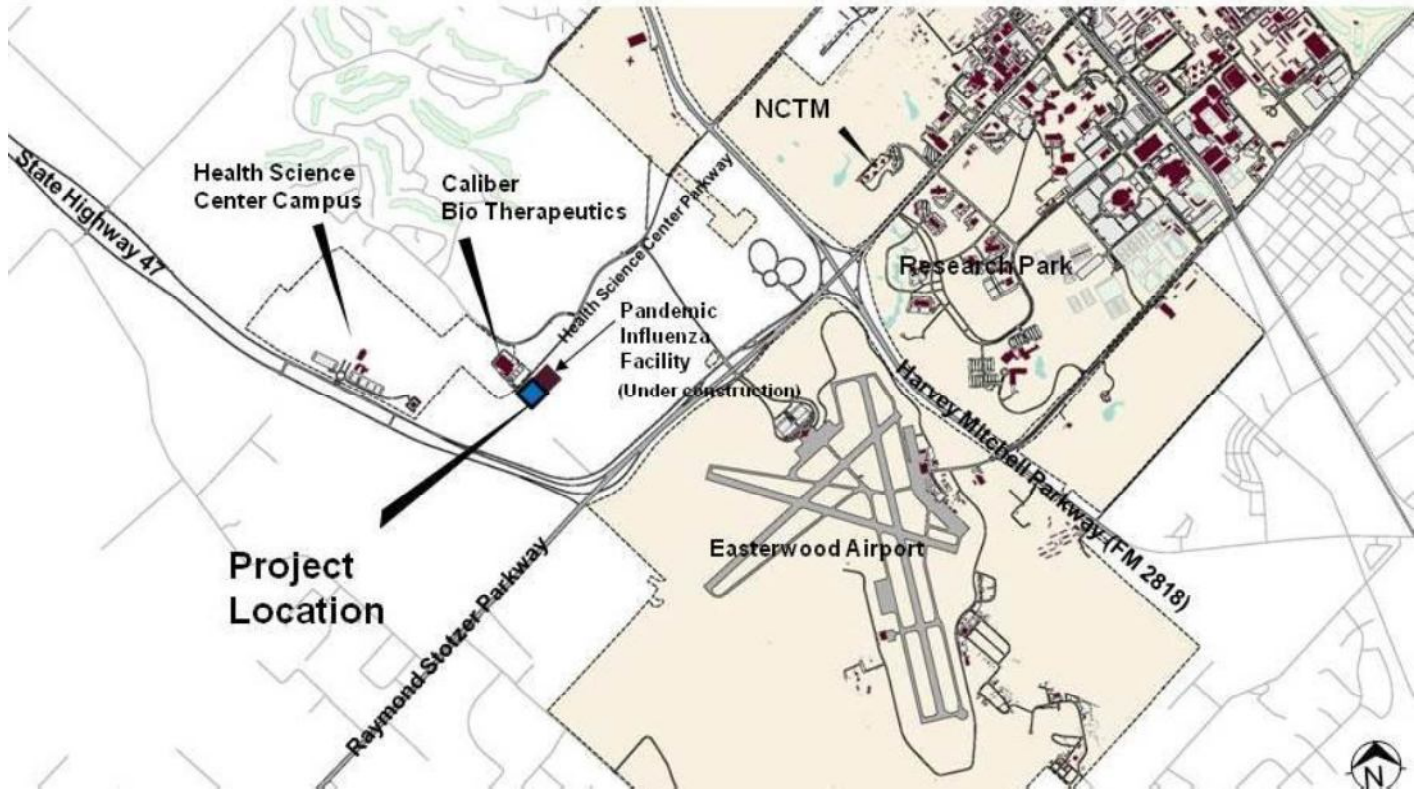
[ORIGINAL SIGNED BY]

Ray Bonilla
General Counsel

LIVE VIRUS VACCINE FACILITY THE TEXAS A&M UNIVERSITY SYSTEM PROJECT NO. 1-3138	PROJECT BUDGET
---	-----------------------

1.	Amount Available for Design-Build Construction Contract	\$34,310,073
2.	Owner Project Management Reserve.....	4,617,821
3.	Equipment by Owner	10,027,276
4.	Commissioning, Quality, Validation	<u>4,875,781</u>
5.	TOTAL ESTIMATED COST OF PROJECT.....	<u>\$53,830,951</u>

1. Coordinating Board ApprovalAugust 12, 2012
2. Execute Design Build Contract October 10, 2012
3. Complete Program VerificationJune 21, 2013
4. Complete Basis of DesignSeptember 30, 2013
5. Complete Schematic Design October 30, 2013
6. Board of Regents Approval for Construction October 31, 2013
7. Issue NTP for Construction November 24, 2013
8. Complete Design DevelopmentFebruary 9, 2014
9. GMP Submission by DBMarch 10, 2014
10. Complete Construction DrawingsApril 10, 2014
11. Substantial Completion.....June 2015
12. User Occupancy..... July 2015



Live Virus Vaccine Facility

Texas A&M University System

Project No. 01- 3138