



Vaccines • Diagnostics • Countermeasures

DHS Science Program Update

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Defending America Against Foreign Animal Diseases



**Homeland
Security**

Science and Technology



What is the NBAF?

- NBAF will provide state-of-the-art, secure biosafety level (BSL) 3 and 4 facilities to safely address the accidental or intentional introduction of high-consequence large livestock diseases into the United States.
- NBAF's mission is to protect the Nation's animal agriculture, food supply and public health from natural or intentional outbreaks of foreign, emerging and zoonotic (animal to human) diseases.
- NBAF will meet these goals by:
 - Providing enhanced research capabilities to diagnose and control foreign animal, emerging and zoonotic diseases in large livestock
 - Replacing and expanding research currently done at the Plum Island Animal Disease Center (PIADC)
 - Providing expanded vaccine development capabilities for large livestock



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Need for NBAF

- Threats to U.S. Agriculture have changed dramatically since the Plum Island Animal Disease Center (PIADC) was established
- Several studies, including the Office of Science and Technology Policy (OSTP) Blue Ribbon Panel, have prioritized diseases of greatest concern, including Foot and Mouth Disease (FMD), Nipah, Hendra, and Rift Valley Fever
 - <http://www.whitehouse.gov/files/documents/ostp/NSTC%20Reports/2003%20Livestock%20Blue%20Ribbon.pdf>
- U.S. lacks a BSL-4 large-animal research facility to diagnose, investigate and develop countermeasures for high priority emerging and zoonotic diseases
- Existing Plum Island capacity limits the timely development of countermeasure development (next generation monovalent vaccines for FMD will require 10-14 *separate* vaccines)
- Lack of high-containment laboratory infrastructure for large animals places constraints on preparedness and response and put U.S. agricultural economy, food supply, and public health at risk



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Need for NBAF

- HSPD-9 calls for DHS and USDA to develop a plan to provide an integrated research, development, test, and evaluation infrastructure – a state of the art biocontainment facility – for combating agricultural and public health threats posed by foreign animal and zoonotic diseases
- No existing facility in the U.S. can meet mission needs and similar facilities in other countries do not have the capacity to address potential outbreak scenarios in a timely manner nor guarantee their availability to meet U.S. research requirements
- The Report of the Commission on the Prevention of Weapons of Mass Destruction (WMD) Proliferation and Terrorism (December 2008) notes the United States should continue to undertake a series of mutually reinforcing domestic measures to prevent bioterrorism
- Enhances preparedness and effective emergency response (QHSR Mission)



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Economic Impact

- In 2009, food and agriculture accounted for \$1.75 trillion of annual gross output, or 6.7% of the U.S. Total Gross Output among all industries in the U.S. and 4.6% of our nation's Gross Domestic Product (GDP).
 - www.bea.gov/industry/gdpbyind_data.htm
- Food and agriculture account for about 8.5 percent of all full-time jobs, or approximately 1 in 12 full-time jobs in the U.S.
- The U.S. cattle industry includes more than 94 million cattle valued at \$49 billion.
- In 2007, the U.S. exported approximately \$5.8 billion of beef and pork products.
- Introduction of a foreign animal disease into the U.S. could halt livestock production in affected areas, key export markets could be closed for months to years, and the impact on the economy could be severe.



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Economic Impact of FMD

- 2001 UK Outbreak: 6.6 million animals destroyed, Economic Impacts estimated at \$10.7 to \$11.7 billion U.S.
- 2007 UK Outbreak, The total estimated cost to Scotland lies in the region of £32m to the livestock sector itself, plus between £2.5 to £4.5m for allied industries.
- Spring 2010 FMD Outbreak in Japan and South Korea. Japan is allocating \$765 million for control measures. South Korea, as of January 2011, culled and buried 1.41M head of livestock with damage estimated at 1.4 trillion won (\$1.2 billion USD)



Justification: Case Study of Ebola Reston

- Request for assistance from Department of Agriculture, the Bureau of Animal Industry of the Philippines to USDA APHIS Foreign Animal Disease Diagnostic Laboratory (FADDL) – early-mid 2008
- Diagnostic samples submitted to USDA APHIS FADDL –early fall 2008
- Microarray analysis indicated 28/28 samples positive for Ebola Reston – October 2008
 - Upon preliminary identification, all materials related to the case were immediately transferred to the CDC Special Pathogens Branch (SPB) at the Emory Campus (Atlanta, GA) for further confirmation, and processing of samples in the BSL-4 facility
 - Microarray techniques used in the analysis developed by USDA APHIS FADDL scientists through APHIS Science Fellows program with supplemental funding by DHS
- Initial characterization work at CDC
- FAO, OIE, and WHO sent a team (including FADDL scientist) to the Philippines to advise and assist on public health recommendations and control of the infected swine – January 2009
 - The CDC tested 141 individuals and found 6 that had seroconverted.
 - Surveys of two farms with positive diagnostic samples revealed circulating virus remaining on one of the farms.



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Justification: Case Study of Ebola Reston

- Initial contact with Australian Animal Health Laboratory (AAHL) in Geelong, Australia - *Immediately after CDC confirmed diagnosis*
- Completion of paperwork necessary to transfer Select Agent from CDC to AAHL
 - Australian import permit IP09000204 was issued 3 February 2009 for the importation of the virus. On May 6 2009 we were advised of the issue of your Export License D414873 for the consigning of 6 vials of Ebola Reston virus to AAHL.
- Samples received by AAHL – Reagents 22 May 2009, isolates 12 June, 2009
- Expected results of pathogenesis studies at AAHL – Results from initial experiments were reported in November 2009.
- Isolates requested by NIH Rocky Mountain Laboratory (RML)
 - RML's intention is to develop a model for this strain in small swine
- **If the diagnostic samples from the Philippines had been received in the planned NBAF, analysis of the isolates could have been initiated immediately after diagnosis.**



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Current PIADC Mission



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DHS – Lead the unified national effort to secure America... protect against and respond to threats and hazards to the Nation

✓ *S&T: RDT&E to Support DHS Mission*

USDA - Provide leadership on food, agriculture... based on sound public policy, the best available science, and efficient management

✓ *Strategic Objectives for U.S. Agriculture:*
- *Enhance International Competitiveness*
- *Enhance Protection and Safety*

HSA of 2002; HSPD 5, 7, 9

ESF 11; HSPD 9 - NVS



Homeland Security



PIADC

To Protect U.S. Agriculture from the threat of FADs

Programs

- ✓ **USDA APHIS FADDL** – FAD diagnostics, NAHLN reference lab, FAD training, NAFMDVB
- ✓ **USDA ARS FADRU** – Generates scientific knowledge for FAD prevention, control and recovery - basic research, rapid diagnostics, countermeasures
- ✓ **DHS Scientific Programs** – Translational product development of countermeasure discoveries for FAD

Operations

- ✓ Provide outstanding service to science
- ✓ Protect people, property and the environment
- ✓ Be a trusted and valued employer and neighbor

DHS PIADC Science Mission

- Research conducted or sponsored by DHS at PIADC is focused on the development of FMD molecular vaccine candidates.
- Research is led or conducted by the Targeted Advanced Development (TAD) Program, a joint effort between the Office of National Lab's PIADC and the Chem-Bio Division's Agrodefense Program initiated in FY2005.
- The TAD partners with USDA Agricultural Research Service, academia, and industry scientists to develop lead vaccine and antiviral candidates for licensure and potential use by the USDA APHIS National Veterinary Stockpile.
- Additional investments include alternate vaccine platforms for FMD and basic and advanced research into vaccine and diagnostic technologies for other foreign animal diseases (FAD).
- The TAD Program has produced the first recombinant vaccine for a single serotype of FMD based on technology initially developed by USDA's Agricultural Research Service scientists at PIADC.
- In a public-private partnership with GenVec, Inc and PerOs, Inc. DHS is pursuing conditional licensure, and eventually full licensure for this first vaccine.



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FMD Molecular Vaccine

- **1st Generation FMD Molecular Vaccines**
 - FMD vaccine platform requirements:
 - Does not require use of live FMDV in manufacturing
 - Single dose
 - Protection in 1 week
 - DIVA compatible
 - Domestic production
 - In parallel develop deep pipeline of 2nd, 3rd, 4th, 5th, etc. FMD vaccine serotype/subtype candidates and partner with USDA APHIS on vaccine technology transition agreement and transition points.
 - Potential to stockpile master seed for further subtypes to enable rapid manufacture and licensing of additional vaccine in the event of an outbreak.



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Adenovirus-Vectored FMD Vaccine Development Program

Project: Project History (1st candidate FMDV Serotype A24)

2001	USDA ARS (Plum Island) discovery that an adenovirus-vectored FMD prototype vaccine for serotype A24 conferred protection in swine
2003	Transfer of Plum Island Animal Disease Center facility from USDA to DHS
2004	USDA ARS single dose A24 prototype vaccine protects cattle at 1 week post-vaccination; DHS initiates science program (Targeted Advanced Development)
2005	DHS completes first cattle study using commercially viable adenovirus platform (GenVec; AdA24)
2008	First Ad-FMD vaccine safety (non-challenge) test conducted on US mainland; cattle study to meet regulatory requirements
2009	(1) USDA CVB approves master seed vaccine virus and manufacturing cell line (2) Additional safety studies completed on US mainland
2010	(1) Completed study in lactating cattle and demonstrated absence of vaccine virus in milk (2) CVB stated efficacy study results were acceptable for demonstrating minimum expectation of efficacy

DHS NBAF Science Expansion

- The NBAF will allow for the expansion of the existing TAD product development model at PIADC by:
 - expanding the numbers of FAD agents studied;
 - expanding development of countermeasures for multiple FAD's, evaluating and developing novel delivery methods of those product types;
 - providing a national capability for vector borne and zoonotic disease research involving large livestock;
 - enhancing opportunities for industry engagement in the advanced development pipeline and improving probability of successful technology transitions



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DHS NBAF Science Expansion

- The NBAF will include a unique pilot production facility which will accelerate existing countermeasure development efforts.
 - Current facility plans include a Biotechnology Development Module (BDM) which will be capable of vaccine master seed production (pilot scale*) and scaling up production of small lots of candidate countermeasures.
 - This new space will eliminate the need for DHS to contract out to private industry for some parts of the countermeasure development process and will allow DHS and USDA researchers to develop countermeasure technologies to a point attractive as an investment to the animal biologics industry.
 - To date, DHS has awarded \$7M to private industry for the development of the FMD vaccine master seed. At NBAF, the majority of this work could be done by federal scientists in the BDM, allowing for more efficient use of federal resources.

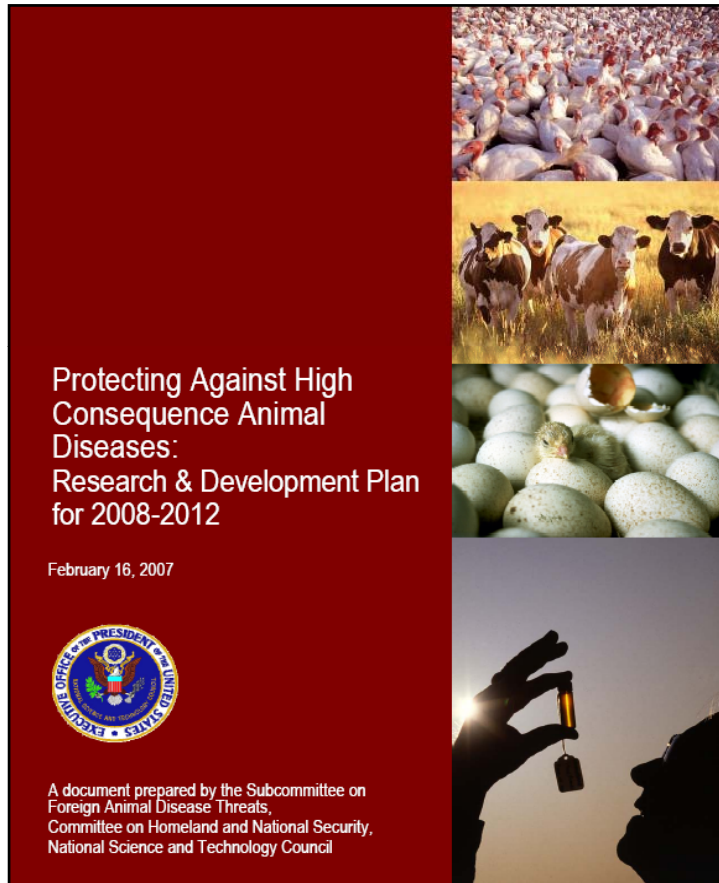
* This will not include vaccines that require the use of live FMD virus



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Interagency Strategic Planning



- *A Joint DHS and USDA Strategy for Foreign Animal Disease Research and Diagnostic Programs.* DHS and USDA formed a partnership to develop a joint research and diagnostic program to protect against the intentional or accidental introduction of foreign animal diseases (FAD), with an initial emphasis on foot-and-mouth disease (FMD). Report submitted to the U.S. House of Representatives' Appropriations Committee for DHS, 2005.
- *Protecting Against High Consequence Animal Diseases: Research and Development Plan for 2008-2012.* DHS and USDA supported the development of this plan, prepared by the Subcommittee on Foreign Animal Disease Threats (FADT), Committee on Homeland and National Security, National Science and Technology Council (January 2007).
- A follow-up to the 2008-2012 FADT R&D plan is under development.

NBAF will be built in Manhattan, KS

Kansas State, Manhattan Campus

School of Veterinary Medicine and Sciences



Department of Animal Science and Industry



Biosecurity Research Institute

Manhattan, Kansas selected as site for NBAF after an extensive 3-year site selection process that included a thorough risk assessment, environmental impact assessment and security assessment

Located in proximity to research of NBAF-related missions in veterinary, agriculture, and bio-security research expertise and resources

Located in proximity to a major hub of the veterinary pharmaceutical industry

Located in proximity to the Biosecurity Research Institute, School of Veterinary Medicine and Sciences, College of Agriculture, and the Department of Animal Science & Industry

Strong community support from key stakeholders

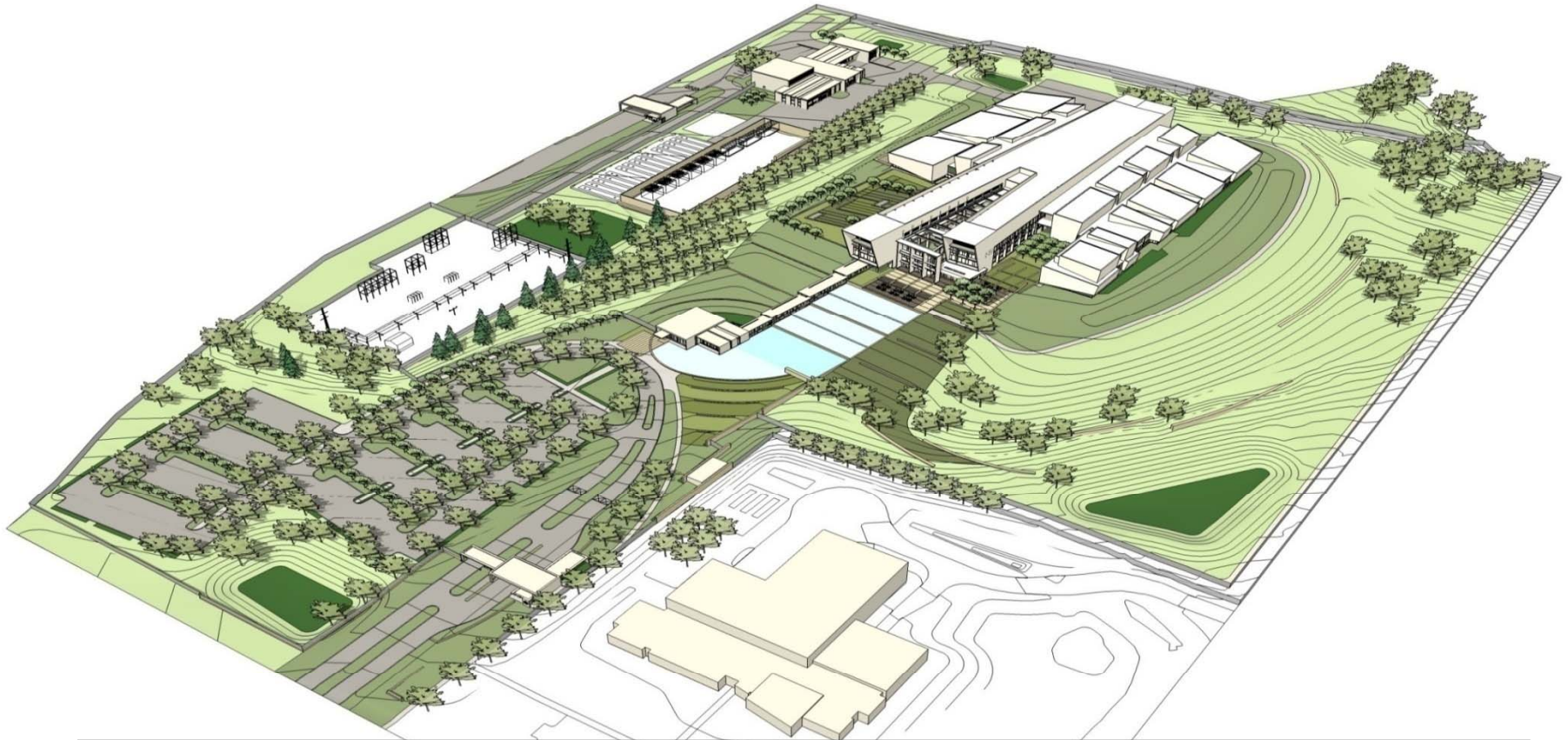


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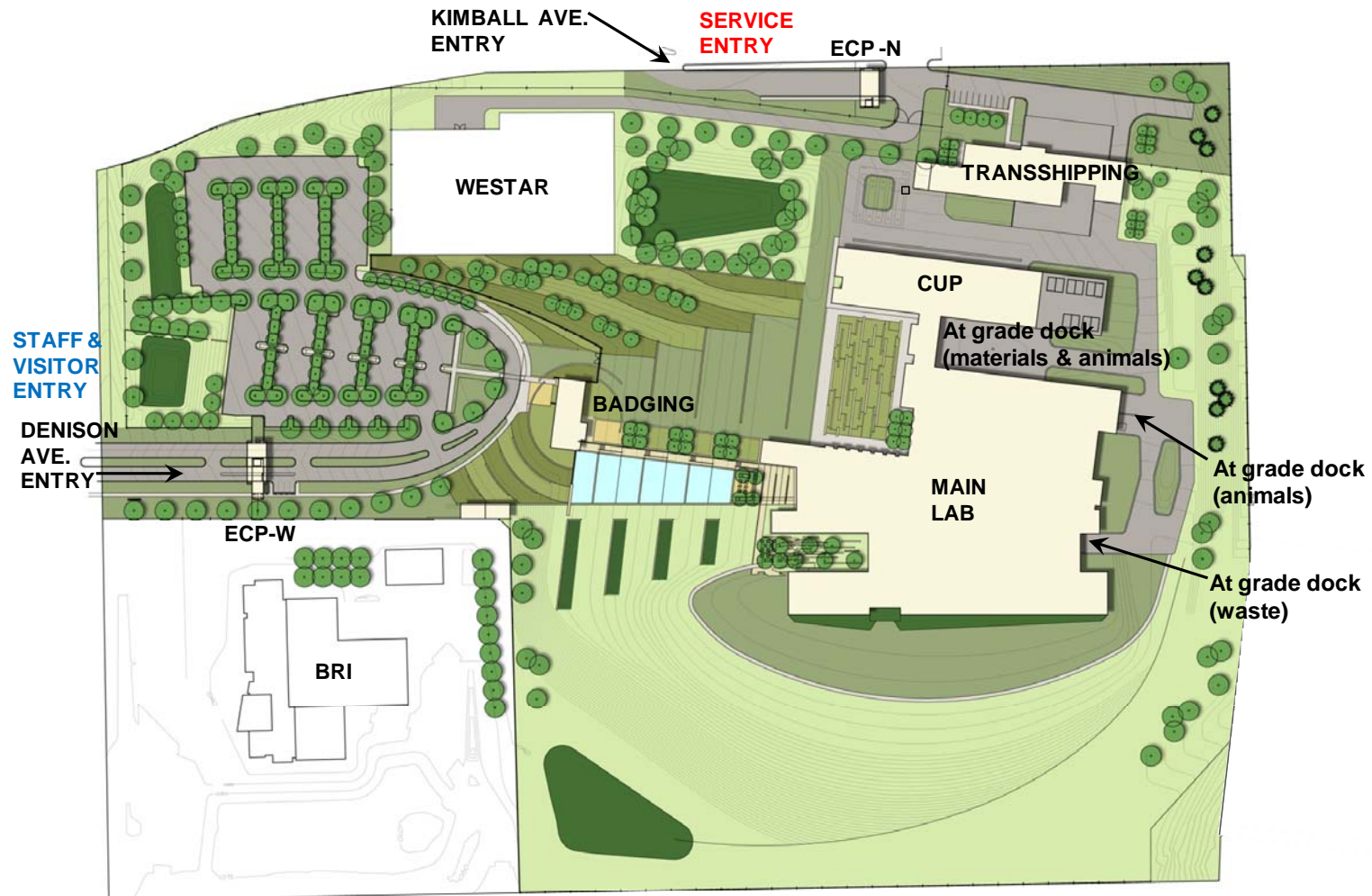
Site Concept Design

*Notional Subject to Change



- First BSL-4 facility in the U.S. for large animal research
- 500-520K gross square feet of research, animal holding and laboratory support spaces
- Hoteling concept and shared research space to provide optimum utilization of space and facility resources
- Space for vaccine development
- Entry Control Center, Central Utility Plant, transshipping and storage facilities

NBAF Site Plan



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Aerial view of NBAF Site from the east



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NBAF Project Status Highlights

- The NBAF site has been cleared and made ready for site work
- DHS has awarded a contract with the Federal Protective Service and has begun training guards for support during construction phase activities
- DHS, Kansas State University, State, Kansas Board of Reagents (KBOR), and others are completing the final stages of the land transfer process
- DHS awarded site preparation services contract to McCarthy Mortenson



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Information Sources

- NBAF Website
www.dhs.gov/nbaf
- Inquiries
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