Tulane National Primate Research Center

Regional Biosafety Laboratory

Director

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Introduction

The Tulane Regional Biosafety Laboratory being built at The Tulane National Primate Research Center is a biosafety level three (BSL-3) facility. Research conducted in the facility will focus on the development of treatments, vaccines and diagnostics for emerging infectious diseases that occur naturally, such as Severe Acute Respiratory Syndrome (SARS) and against biological agents that have the potential for misuse for terrorism. The overall goal of research associated with this facility is to protect the health and safety of our community and the nation. This brochure provides information on what Tulane's Regional Biosafety Laboratory will be and perhaps more importantly what it will not be.

Biodefinitions

Biodefense: Defense strategies and technologies to protect against attacks with biological agents. Involves development of diagnostics, vaccines and therapeutics to diagnose, prevent, and treat infections as well as technologies to detect potential bioweapons.

Biosafety: Biological safety--safety from infectious agents or toxins. Generally refers to standards and procedures in research laboratories articulated in "Biosafety in Microbiological and Biomedical Laboratories" published by the Centers for Disease Control and the National Institutes of Health www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm.

Biosecurity: Biological security--protocols and procedures to secure biological agents.

Biological agent: An organism or compound produced by a living organism that has biological effects on other organisms.

Biohazard: Biological hazard--any biological substance that poses a threat to health of humans or animals.

Biotechnology: Any technology that utilizes biological systems or living organisms to make or modify products for specific purposes.

Biotoxin: A type of biological agent. A poison-- often used to refer to compounds produced by plants, bacteria and some animals that are highly toxic for other organisms.

Bioterrorism: The use or threatened use of biological agents for the purpose of inciting terror in a population.

Biowarfare: The use of biological agents in warfare.

Bioweapons: Biological agents processed to be useful as weapons on the battlefield. Requires significant processing of the biological agent beyond simply growing the organism or producing the biotoxin.

What Are Biosafety Labs?

Scientists use biosafety labs to safely and effectively study infectious and toxic materials. These state-of-the-art labs are designed not only to protect researchers from contamination, but also to prevent microorganisms from entering the environment. There are four biosafety levels (BSLs) that define proper laboratory techniques, safety equipment, and design, depending on the types of agents being studied:

BSL-1 labs are used to study agents not known to consistently cause disease in healthy adult humans. The work is generally conducted on open bench tops using basic safety procedures. No special equipment or design features are required.

Comment: A typical BSL-1 lab is a high school biology laboratory.

BSL-2 labs are used to study moderate-risk agents that pose a danger if accidentally inhaled, swallowed or exposed to the skin. Safety measures include access controls, specialized training for laboratory employees, personal protective equipment such as gloves and eye wear as well as biosafety cabinets, hand-washing sinks and decontamination of waste material.

Comment: Most of the TNPRC is BSL-2 lab environment, as are hospital laboratories.

BSL-3 labs are used to study agents that can be transmitted through the air and cause serious or potentially lethal disease. Research precautions include those indicated above for BSL-2 labs as well as respiratory protection, specialized ventilation and decontamination systems and showering when exiting the facility.

Comment: The TNPRC has had an operational BSL-3 facility for more than 15 years.

BSL-4 labs are used to study agents that pose a high risk of life-threatening disease for which no vaccine or therapy is available. Lab personnel are required to wear full-body, air -supplied "space suits" when working in the facility. The labs incorporate all BSL-3 safety features as well as having air-tight door seals and occupy safe, isolated zones within a larger building.

Comment: The Tulane Tulane Regional Biosafety Laboratory is NOT a BSL-4 laboratory. The closest BSL-4 laboratories are at the Centers for Disease Control (CDC) in Atlanta, Georgia, and at the University of Texas Medical Branch, Galveston, Texas.

Safety and Security

- Biosafety Level 3 (BSL-3) laboratories are explicitly designed to protect both the research scientists and the public from exposure to biological agents or biotoxins used in research. The design principle used to ensure the safety of the facility is described as a "box-within-a-box-within a box." This engineering principle has been utilized to safely design and operate these types of infectious disease laboratories for over 50 years. Research activities using infectious pathogens occur in chambers under negative pressure deep within the containment laboratory; these laboratories are in turn completely contained within the facility's outer building. Air leaving the chambers, laboratories and the outer building passes through multiple high efficiency particulate air (HEPA) filters. In fact, air leaving the building is cleaner than air coming into the building.

- All employees who have access to or work with select agents are required by federal law to undergo a FBI background check and fingerprinting.

- The Tulane Regional Biosafety Laboratory has been designed in compliance with federal regulations set forth by the National Institutes of Health. These regulations govern the construction, use, security, inspection and certification of a BSL-3 laboratory, including the safeguards to ensure the proper containment and destruction of infectious agents.

- BSL-3 facilities have operated safely in the United States for more than 30 years.

- Before entering the laboratory area, employees are required to remove street clothing and put on protective clothing. When leaving, they must remove protective clothing and shower before changing back into street clothing. Protective clothing is sterilized before being laundered.

- The Tulane National Primate Research Center has operated a BSL-3 laboratory for over 15 years.

Frequently Asked Questions

- **Why are RBL laboratories needed?**

  The anthrax scare in the fall of 2001 made it clear that the United States was not appropriately prepared to deal with the potential misuse of biological agents by terrorists or with newly emerging infectious diseases such as SARS or avian influenza. As part of the federal response to these major human health problems, the Department of Health and Human Service's National Institute of Allergy and Infectious Diseases (NIAID) within the National Institutes of Health (NIH) devised a multi-faceted research program to address the issues. This program is known as the NIH/NIAID National Biodefense Program. The first component of the program involved establishing the intellectual infrastructure, consisting of teams of scientists who will do the work. These are known as Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases or simply RCE's. Each of ten regions in the country has, or will have, its own RCE. The second component of the program was the development of state of the art facilities for safely working with potential human pathogens. This included two large Biosafety Level 4 Laboratories (BSL-4) known as National Biocontainment Laboratories and 13 Regional Biocontainment Laboratories referred to as RBL's. Tulane University, through its Tulane National Primate Research Center, participates in two of the RCE's: one is led by the University of Texas Medical Branch in Galveston, Texas, and the other is led by Duke University in Durham, North Carolina. In addition, Tulane University was successful in obtaining one of the Regional Biocontainment Laboratories that will be used by Tulane scientists as well as by collaborative scientists within the RCE's to develop new vaccines, therapeutics, and diagnostics to protect the nation's population. The Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases and the National and Regional Biocontainment Laboratories (also referred to as Biosafety Laboratories) form the core of the National Institutes of Health's efforts to defend the population against biological threats.

- **Has there ever been an accident at this type of research facility in the United States that caused release of pathogens into the environment?**

  No.

- **How much will the project cost?**

  The estimated cost of the project is $25 million.

- **Who is paying for the project?**

  The cost of the RBL is being shared by the federal government and Tulane University. The federal government's share of $17.6 million comes from the Department of Health and Human Services through its National Institute of Allergy and Infectious Diseases, (NIAID) which is part of the National Institutes of Health (NIH). Tulane University's share, which is a required match, is $5.9 million.

- **When will construction of the RBL begin and be completed?**

  Many factors influence the starting and final completion dates. However, construction will be completed approximately two years after ground breaking which is tentatively scheduled for the Winter of 2006.

- **What kinds of animals will be used in the research, where will they come from, and how will they be cared for?**

  Rodents and nonhuman primates will be used in the research and are obtained from vendors that are licensed and inspected by federal government agencies. Fully licensed and trained veterinarians and animal caretakers under their direct supervision will administer humane care and medical treatment to the animals.

- **Will the results of the federally funded research carried out in the RBL be shared with the public?**

  Yes, it will. The goal of this national research program is to provide information that will guide the development of diagnostics, treatments, and vaccines to protect citizens against emerging infectious diseases and agents of bioterrorism. The results of all research carried out in the RBL will be published in the same manner as other NIH funded research results.

- **What will happen to the animals when they are no longer needed?**

  They will be humanely euthanized and disposed of through a federally approved process that renders all agents inert. No animal will leave the facility, and no incineration is needed.

- **How will biological agents be transported to and from the RBL?**

  The shipment of biological agents is governed by national and international regulations as well as those of the National Institutes of Health and the Centers for Disease Control and Prevention. Infectious agents are shipped in sealed capsules that are packed in highly durable, watertight containers. These containers are then packed in dry ice inside styrofoam boxes that fit into larger shipping boxes.

- **Will local police, fire and rescue personnel need additional training to be able to respond to any emergencies that may result from the RBL?**

  Following the terrorist activities of past years, such as anthrax being released into the mail system, emergency personnel regularly receive emergency response training for biohazard emergencies.

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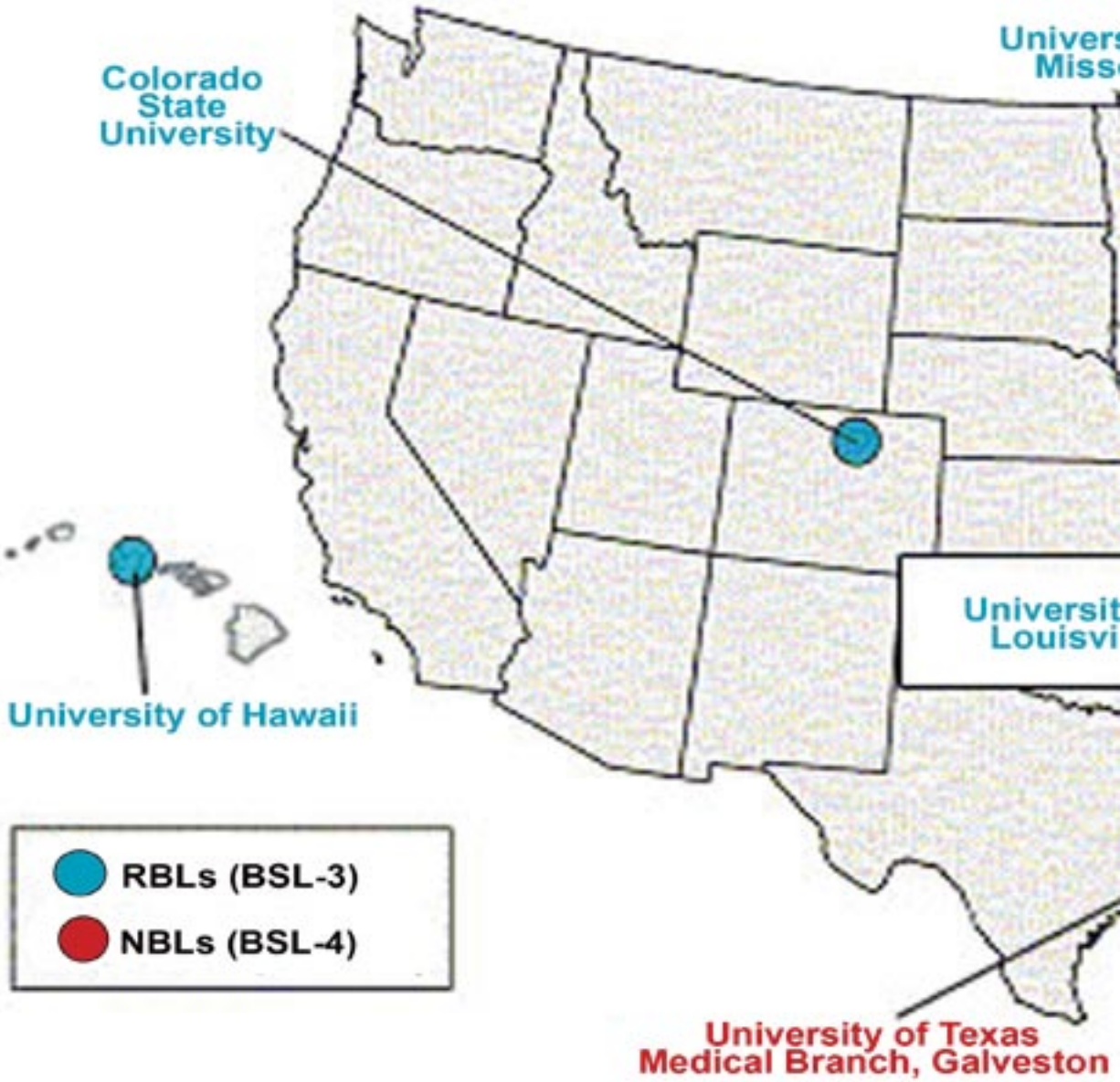

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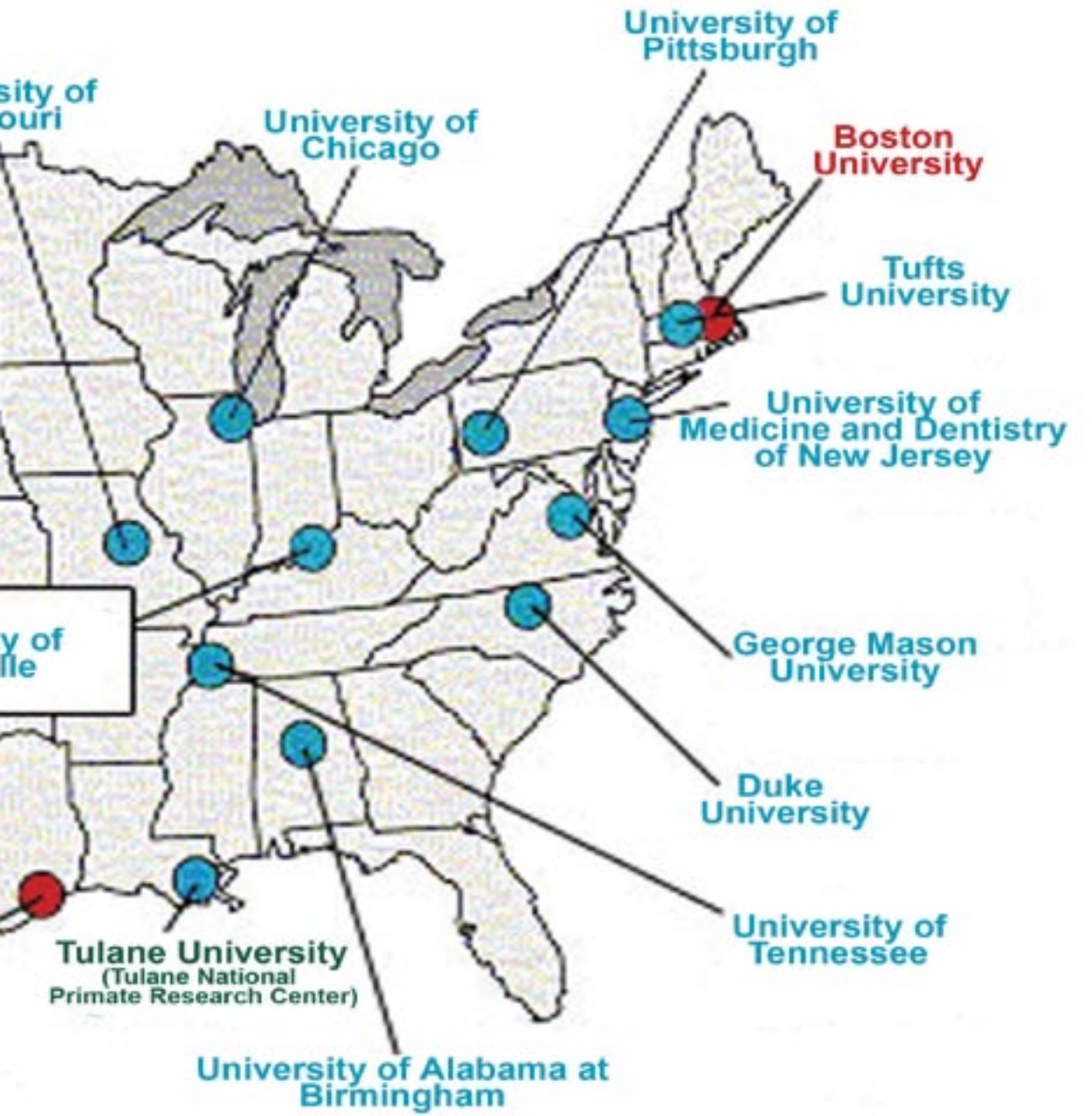

- **What will be studied in the RBL?**

  Tulane University scientists and collaborating scientists from other institutions will study a variety of pathogens including bacteria, viruses, and biotoxins. The goal of these studies is to develop drugs, treatments, vaccines and new diagnostic tests to combat these microorganisms so that they no longer pose a threat to public health.

- **Who will provide oversight of the RBL?**

  The RBL will be owned and operated by Tulane University. Only personnel trained in biocontainment procedures and authorized for work with these agents will be allowed into the RBL. Agencies involved in regulatory oversight for the RBL include the Centers for Disease Control and Prevention, United States Department of Agriculture and the National Institutes of Health.

- **What security plans will be in place to keep the building safe?**

  The RBL building will be constructed in accordance with federal standards. A variety of security measures will be in place to keep the building and its contents safe.

- **What type of security clearance will the workers in the laboratory need?**

  Clearance for all employees in the building will be determined by the Tulane National Primate Research Center and will also be consistent with institutional and federal government mandated regulations and standards. For example, all employees working with select agents in the RBL are required to undergo a federal background check.

- **What are your evacuation plans if something leaks from the building ?**

  The Tulane National Primate Research Center has an emergency response plan currently used for various disasters, including hurricanes, fire, floods and other natural disasters. Evacuation procedures associated with the new RBL have been incorporated into our current emergency response plan. It is worth noting that our existing BSL-3 laboratory remained operational and secure during and after Hurricane Katrina.

- **Why was Tulane University's Tulane National Primate Research Center chosen as one of the sites for a RBL?**

  The Tulane National Primate Research Center has a long history of infectious disease research using nonhuman primates. In addition, the Tulane National Primate Research Center has an existing BSL-3 facility that has been in operation, without incident, for over 15 years. Our scientific expertise along with our experience with infectious disease research using nonhuman primates was a major reason we were selected.

- **What is the Tulane National Primate Research Center's experience in working with a BSL-3?**

  The Tulane National Primate Research Center has operated a BSL-3 laboratory for over 15 years. Among other currently planned RBL sites in the country, we are uniquely qualified to operate this new BSL-3 laboratory because of our past experience.

- **Where is the RBL building going to be located?**

  The RBL will be located on the grounds of the Tulane National Primate Research Center which is located in Covington, Louisiana.

- **Are there plans for other buildings near the RBL?**

  The Tulane National Primate Research Center has a complete Master Plan that includes the new RBL and a variety of other buildings in the same area. At present, the TNPRC has funded construction and renovation projects involving three other buildings in the same area.

- **What will be the benefits to the community from the laboratory?**

  The research will benefit the community as new treatments and preventive vaccines against emerging and reemerging infectious diseases will be developed. The actual building of the RBL will have a significant economic and community impact as well. In addition to the construction jobs that will be generated, permanent jobs at all levels, including lab technicians, scientists and administrative staff, will be created to operate the RBL.

- **Can anyone visit the RBL building?**

  Once the RBL is operational, access is restricted to those specifically trained and authorized to enter the facility.

Selected BioInformation and Nonhuman Primate Web Sites

Animal Welfare Act
www.nal.usda.gov/awic/legislat/usdaleg1.htm

Association for Assessment and Accreditation of Laboratory Animal Care
www.aaalac.org

American Association for Laboratory Animal Science
www.aalas.org

National Institute of Allergy and Infectious Diseases
National Biodefense Effort
www2.niaid.nih.gov/biodefense

Centers for Disease Control and Prevention
Bioterrorism Agents/Diseases
www.bt.cdc.gov/agent/agentlist.asp

FAQ for Select Agent Program
www.cdc.gov/od/sap/faq

Federal Rules for Transporting Agents
http://bmbl.od.nih.gov/appendc.htm

RDS
http://www.rds-net.org.uk/

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NIAID Funds Construction of Biosafety Laboratories

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, today announced funding for the construction of two National Biocontainment Laboratories (NBLs) and nine Regional Biocontainment Laboratories (RBLs). "These awards to build high-level biosafety facilities are a major step towards being able to provide Americans with effective therapies, vaccines and diagnostics for diseases caused by agents of bioterror as well as for naturally occurring emerging infections such as SARS and West Nile virus," says Health and Human Services Secretary Tommy G. Thompson.

One-time grants of approximately $120 million each will fund construction of the NBLs, while the RBLs will receive one-time grants of between $7 and $21 million each in construction funds. Each institution is also required to provide matching funds.

In February 2002, an outside panel of experts provided guidance to NIAID on its biodefense research agenda and identified the insufficient amount of biosafety level 3 (BSL-3) and BSL-4 lab space as a significant barrier to progress.

"With input from the scientific community, we have crafted a biodefense research agenda emphasizing rapid translation of basic findings into real products," says Anthony S. Fauci, M.D., NIAID director. "Although the agenda is ambitious, America's scientists have the commitment, creativity and energy equal to the task. The new laboratories will give these dedicated scientists space to conduct this critical research, and equally important, they will be able to conduct it safely."

The overall objective of the NBL construction program is to provide funding to design, construct and commission comprehensive, state-of-the-art BSL-4, BSL-3 and BSL-2 laboratories, as well as associated research and administrative support space; the RBL construction program will provide funding for similar facilities containing BSL-3 and BSL-2 labs. The BSL labs will be designed and built using the strictest federal standards, incorporating special engineering and design features to prevent microorganisms from being released into the environment. Numerous safety and decontamination features provide multiple layers of protection for lab workers and the surrounding environment.

The NBL and RBL sites were selected based on multiple factors, but primarily on the scientific and technical merit of the applications as assessed by peer review and on the applicant's ability to contribute to the overall NIAID biodefense research agenda. The NBLs and RBLs will complement and support the research activities of NIAID's recently awarded Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (see http://www.niaid.nih.gov/newsroom/releases/HHS_RCE.htm). The biosafety labs also will be available and prepared to assist national, state and local public health efforts in the event of a bioterrorism or infectious disease emergency.

NIAID is a component of the National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services. NIAID supports basic and applied research to prevent, diagnose and treat infectious diseases such as HIV/AIDS and other sexually transmitted infections, influenza, tuberculosis, malaria and illness from potential agents of bioterrorism. NIAID also supports research on transplantation and immune-related illnesses, including autoimmune disorders, asthma and allergies.

Tulane Receives $13.6 Million for Biosafety Lab

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Tulane University has received a $13.6 million grant to construct a new building at the Tulane National Primate Research Center where scientists will develop treatments and vaccines for emerging infectious diseases and germs that bioterrorists may use to attack the United States. The funding from the National Institute of Allergy and Infectious Diseases (NIAID), one of the National Institutes of Health, will be used to build a Regional Biocontainment Laboratory. The largest of the eight national primate centers, Tulane is the only one to receive this funding.

Tulane University President Scott S. Cowen says the multi-million dollar grant is critically important as the United States continues to improve its defenses against bioterrorism. "The fact that Tulane University is being awarded this grant acknowledges that our scientists are among those at the forefront of this area of research. The senior leaders of the health sciences center and the primate center have worked very hard to establish Tulane's expertise in this field and their efforts are being recognized nationally."

"Tulane University will supplement the initial award with an investment of almost $5 million", says Paul Whelton, senior vice president for health sciences at Tulane. Tulane anticipates additional NIH funding to purchase cutting-edge equipment. Tulane scientists and the NIAID have agreed to a 20-year cooperative agreement in which they will collaborate on projects related to biodefense and emerging infectious diseases.

"This grant provides the funding for a larger, state-of-the-art laboratory where our scientists and collaborators from the National Institutes of Health and other academic institutions can study ways to protect the nation from misuse of disease agents by terrorists," says Whelton. "The grant represents an economic boon for our area by bringing many high-paying new jobs here."

"The Tulane National Primate Research Center has had a nationally acclaimed infectious diseases research program since its founding in 1964 and a biosafety level 3 laboratory for about a decade", says Andrew Lackner, the center's director. Located on about 500 acres of land 35 miles north of New Orleans in Covington, the primate center currently employs about 220 people, including 27 doctoral-level scientists, and houses about 5,000 nonhuman primates.

"Our research programs have grown dramatically," Lackner says. "This new regional biosafety lab will expand greatly our existing biocontainment capabilities to support the recently funded Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research."

The infectious diseases program at the Tulane National Primate Research Center currently focuses on HIV/AIDS, malaria, Lyme disease, West Nile virus, tuberculosis, microsporidiosis and other diseases. These are multidisciplinary studies involving investigators in multiple divisions at the primate center and collaborators from elsewhere at Tulane and other institutions. The Tulane Regional Biocontainment Laboratory plans research projects investigating additional infectious diseases, including SARS, botulism, plague, tularemia and brucellosis.

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Note: The original $13.6 million award has been increased by NIH to $21 million.

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