

# Responding to the COVID-19 pandemic

A presentation to the  
Austin Health Care Council

**Ben G. Raimer, MD, MA, FAAP**  
December 17, 2020



# UTMB: A legacy of service

## Shaping health care outcomes for Texas, the nation and beyond

- Opened in 1891 as the state's first academic medical center
- Our mission: To improve health through patient care, research and health sciences education
- Today, we have four schools; a robust research enterprise; four campuses and 90 clinics in Southeast Texas; more than 13,000 employees across the state, including those in Correctional Managed Care; and an annual budget of more than \$2 billion.



# UTMB's Mission Focus

## Four Health Sciences Schools

- Fall 2020 enrollment of 3,446, a 47 percent increase in 12 years; Interdisciplinary education trains future health professionals to work as teams; advanced simulation technologies



## Robust research enterprise

- \$152 million in expenditures in FY20; Unique capabilities including the Galveston National Lab; World-renowned infectious disease expertise and vaccine development programs



## Comprehensive Health System

- From primary care to advanced tertiary care; four hospital campuses in three counties; lead trauma center for 9-county region



# Responding to COVID-19

## EDUCATION

- Faculty transitioned to all-online learning within days in the spring
- Hybrid model this semester to maintain academic progress
- Students adapted well through Match Day, commencements

## RESEARCH

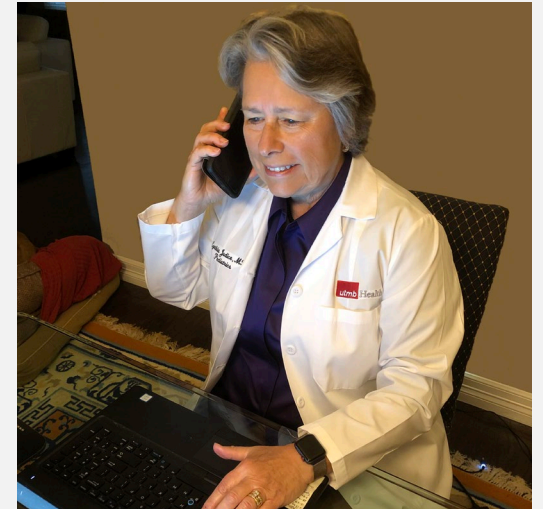
- GNL among first to receive SARS-COV-2 samples
- COVID-related research has attracted more than \$29M in funding so far
- Conducted clinical trials of novel treatments and vaccines



# Responding to COVID-19

## PATIENT CARE

- In collaboration with the GNL, created robust testing capacity that to date has completed more than 286,000 viral tests; More than 165 Texas counties served by UTMB testing
- Expanded our telehealth capability to handle routine care
- Dedicated clinics near each campus to care for COVID patients
- As of Friday, Dec. 11, UTMB has cared for more than 2,900 COVID patients in our hospitals
- Vaccine Preparedness Task Force overseeing administration of approved vaccines



# Overview of COVID Vaccine Development

**Alan D.T. Barrett, PhD, DSc (Hon)**

Director, Sealy Institute for Vaccine Sciences  
and Professor, Department of Pathology  
University of Texas Medical Branch at Galveston  
and

Director, World Health Organization Collaborating Center  
for Vaccine Research, Evaluation and Training  
on Emerging Infectious Diseases

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# Conflicts of Interest

- Director, **World Health Organization** Collaborating Center for Vaccine Research, Evaluation and Training for Emerging Infectious Diseases (part of Initiative for Vaccine Research (IVR), not Emergency Medicines)
- Member, Scientific Advisory Committee, **Coalition for Epidemic Preparedness Innovations (CEPI)** (supporting 12 COVID vaccine candidates)

# Overview of COVID vaccine development

## **FIRST GENERATION COVID VACCINE DEVELOPMENT**

- 350 candidates → 88 in preclinical + 54 in clinical trials → 13 in clinical trials in USA
- UTMB is supporting “discovery” and “preclinical” studies of vaccine candidates for non-UTMB entities in Galveston National Laboratory Biosafety Level-3 (BSL-3) facilities
- “Preclinical” studies by UTMB Office of Regulated Nonclinical Studies (ORNcS) = Good Lab Practices
- Three monoclonal antibodies evaluated → all progressed to clinical trials
- Multiple clinical trials by Sealy Institute for Vaccine Sciences (SIVS) Clinical Trials Program

## **SECOND GENERATION COVID VACCINE DEVELOPMENT**

- Just getting started



# COVID clinical trial networks

- **National, including USA**
  - NIH COVID 19 Prevention Network (CoVPN)
  - Evaluates drugs, antibodies and vaccines
  - **UTMB a member**
  
- **World Health Organization**
  - Solidarity Clinical Trials Network
  - Clinical trials having problems getting started
  - **UTMB a member ?**

# Sealy Institute for Vaccine Sciences Clinical Trials Program – **Drugs and antibodies**

- Adaptive Covid-19 Treatment Trial (**ACTT** #1 and #2): SIVS was #4 of 72 clinical trial sites worldwide activated for ACTT studies.
  - Evaluation of **Remdesivir** → Emergency Use Authorization approved by FDA (co-PIs: Susan McLellan, MD and Richard Rupp, MD).
- Accelerating COVID-19 Therapeutic Interventions and Vaccines (**ACTIV**) #3: A monoclonal antibody study (**LY3819253 [Eli Lilly/AbCellera Biologics]**) in outpatients (PI: Laura Porterfield, MD) → Emergency Use Authorization approved by FDA

# Sealy Institute for Vaccine Sciences Clinical Trials Program – Vaccines

- Two vaccine clinical trials ([Pfizer](#) and [Moderna](#)) have been conducted by the SIVS Clinical Trials Program (PI: Richard Rupp, MD for both studies)
- UTMB one of the few institutions that can undertake two COVID clinical trials concurrently as we have two facilities 26 miles apart.
  - Pfizer vaccine (volunteers enrolled 12 years of age and older)  
Emergency Use Authorization approved by FDA
- Approached to evaluate 7 other candidate COVID vaccines in clinical trials; expect to do 3+.
- Two upcoming adult COVID vaccine studies starting early 2021.
- Planning to undertake several children's COVID vaccine studies

# If you would like more information:

Contact us for more information:

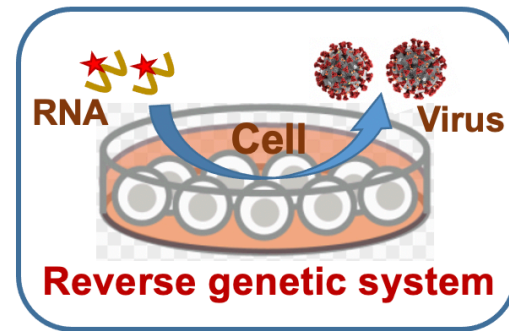
- Alan Barrett: [abarrett@utmb.edu](mailto:abarrett@utmb.edu)
- SIVS Clinical Trials Program Email: [sivsctp@utmb.edu](mailto:sivsctp@utmb.edu)
- **Galveston Primary Care Pavillon: 409-772-5278**
- **Bay Colony Clinical Trials Facility: 832-340-2313**

# Develop core technology for COVID-19 diagnosis, vaccine and antiviral

## Impact on research community.

Our reverse genetic system has been shared around the world: CDC, FDA, NIH, state health departments, and universities. The technology has been licensed to many pharmaceutical companies.

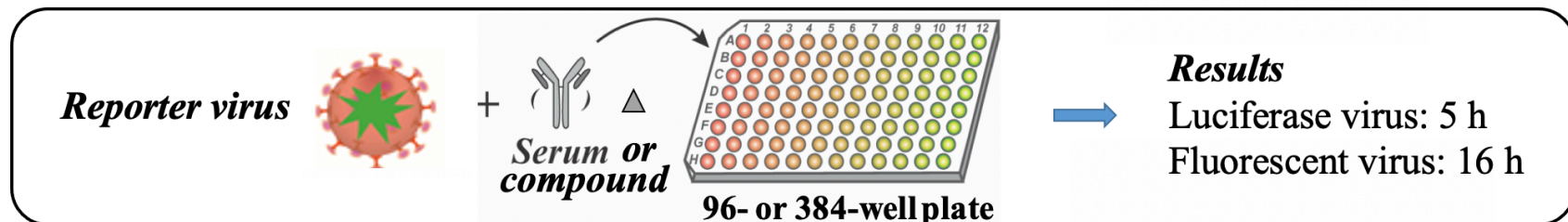
**Diagnosis.** Reporter virus for serodiagnosis: CDC, New York State Department of Health, medical centers, and diagnostic companies (e.g., Q<sup>2</sup> Solutions).



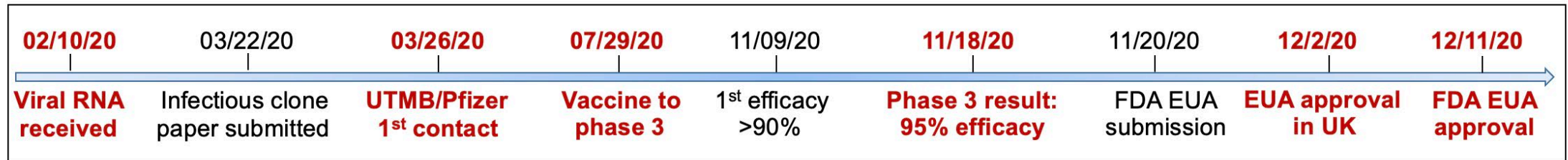
## Basic research. UTMB first to demonstrate (i) spike furin cleavage site is key to viral pathogenesis and (ii) a dominant spike mutation D614G enhances viral fitness in the upper respiratory tract and neutralization susceptibility.

**Antiviral.** Reporter virus to develop therapeutic antibodies, biologics, and small molecule drugs. Partners: Gilead, UTHealth, and others.

**Vaccine.** Reporter virus to evaluate vaccine efficacy. Support Pfizer and other vaccines. Develop UTMB's own vaccines.



# Enable Pfizer's vaccine development



nature

Article

## Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults

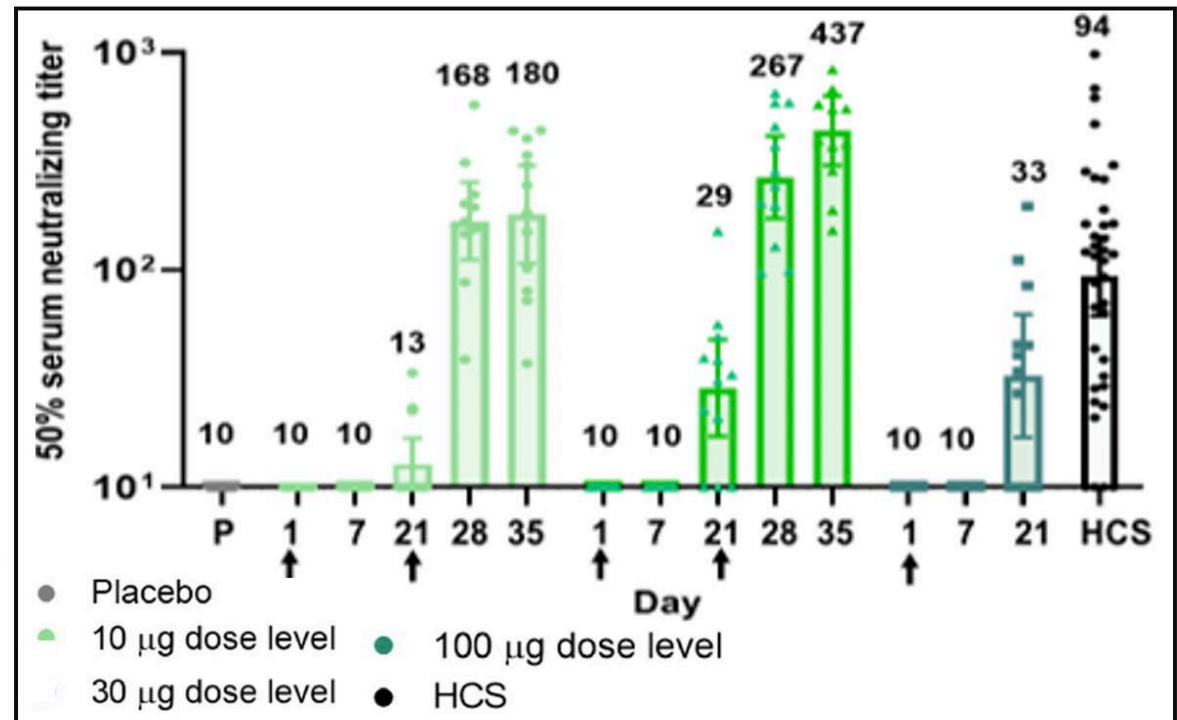
nature

Article

## COVID-19 vaccine BNT162b1 elicits human antibody and T<sub>H</sub>1 T cell responses

The NEW ENGLAND JOURNAL of MEDICINE

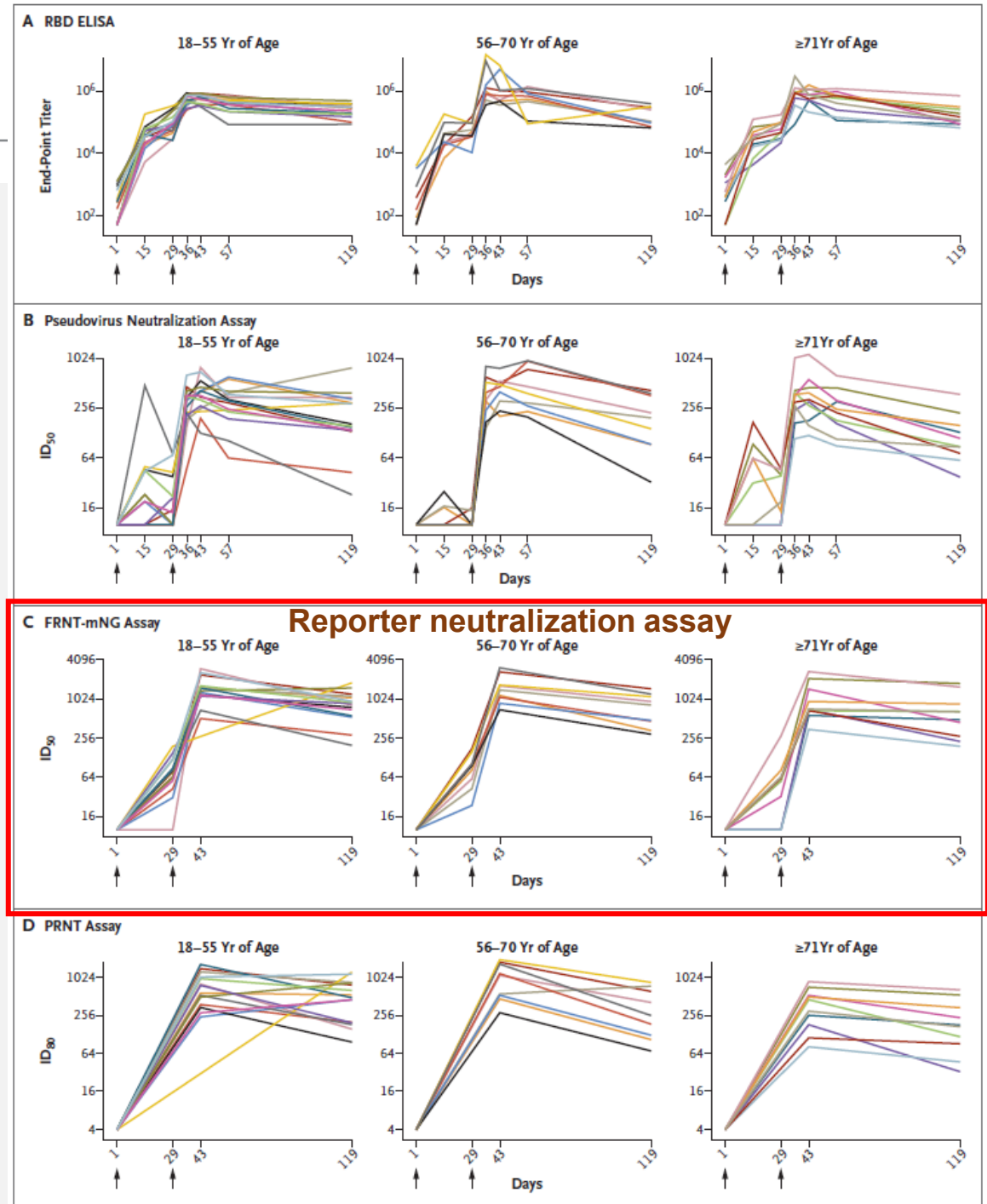
Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates



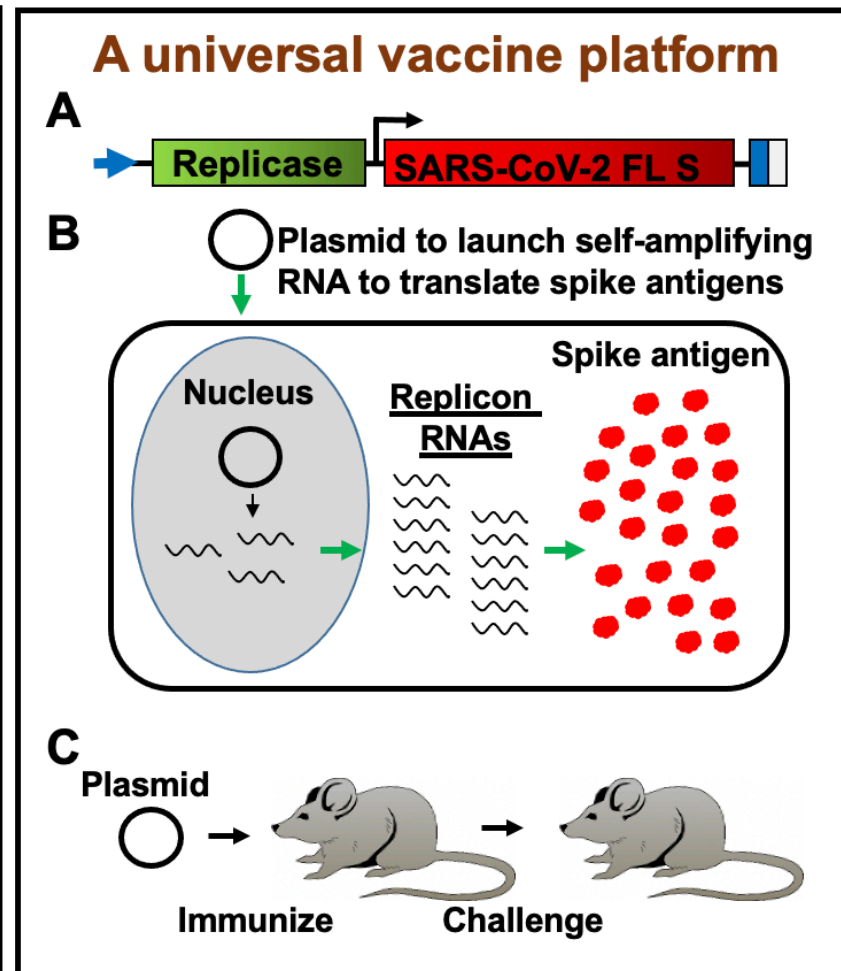
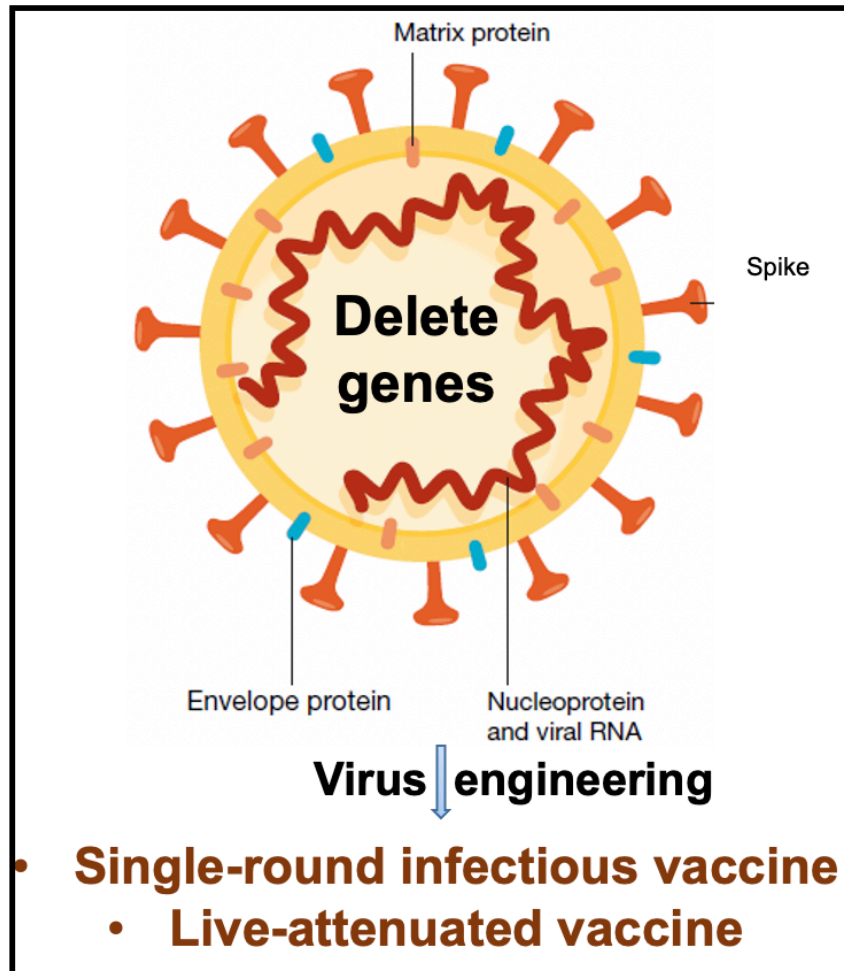
# Enable Moderna's vaccine study

The NEW ENGLAND JOURNAL of MEDICINE

Durability of responses after SARS-CoV-2 mRNA-1273 Vaccination



# UTMB's Vaccine Platforms





# NIH-funded Centers for Research on Emerging Infectious Diseases

- NIH planning began 4 years ago in response to the Zika outbreak; goal to anticipate and respond to outbreaks before they spread internationally
- Applications submitted in May 2019
- 10 Centers selected for funding from an international applicant pool in May, 2020
- UTMB is the home of 2 of these 10 centers
- Goals include identifying likely sites and agents of virus emergence to intervene before pandemic spread can occur

## NEWS RELEASES

Thursday, August 27, 2020

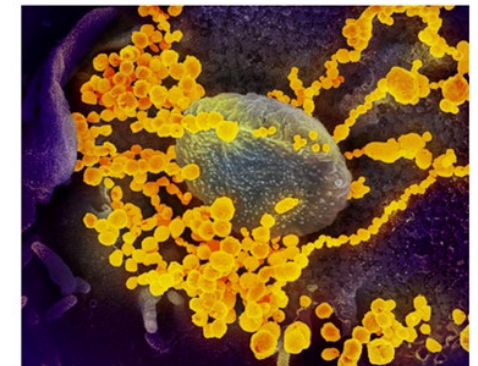
### NIH establishes Centers for Research in Emerging Infectious Diseases



The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, today announced that it has awarded 11 grants with a total first-year value of approximately \$17 million to establish the Centers for Research in Emerging Infectious Diseases (CREID). The global network will involve multidisciplinary investigations into how and where viruses and other pathogens emerge from wildlife and spillover to cause disease in people. NIAID intends to provide approximately \$82 million over five years to support the network.

“The impact of the COVID-19 pandemic serves as a potent reminder of the devastation that can be wrought when a new virus infects humans for the first time,” said NIAID Director Anthony S. Fauci. “The CREID network will enable early warnings of emerging diseases wherever they occur, which will be critical to rapid responses. The knowledge gained through this research will increase our preparedness for future outbreaks.”

Each Center in the network will involve collaborations with peer institutions in the United States and 28 other countries. Research projects will include



This scanning electron microscope image shows SARS-CoV-2 (round gold objects) emerging from the surface of cells cultured in the lab. SARS-CoV-2, also known as 2019-nCoV, is the virus that causes COVID-19. The virus shown was isolated from a patient in the U.S. Image captured and colorized at NIAID’s Rocky Mountain Laboratories (RML) in Hamilton, Montana. *NIAID*



# WEST AFRICAN CENTER

For Emerging  
Infectious Diseases

Scott C. Weaver, PhD., Principal Investigator

### Additional UTMB Leaders:

- Slobodan Paessler, DVM, PhD, Pathology
- Robert Cross, PhD, M&I
- Andrew Routh, PhD, BMB
- Pei-Yong Shi, PhD, BMB
- Dr. George Golovko, PharmTox
- Susan McLellan, MD, MPH, Int. Med/ID

### International Partners:

- **Senegal:** Inst Pasteur, Dakar
- **Nigeria:** National Veterinary Research Institute, University of Jos Teaching Hospital
- **Sierra Leone:** Kenema Hospital, Njala University



# West African Center Objectives

- Organize surveillance for people with acute febrile illness in all 3 African countries to determine what viruses have the potential to emerge into human populations.
- Study the emergence of urban mosquito-borne viruses such as Zika, yellow fever and chikungunya from ancestral forest transmission cycles in eastern Senegal.
- Study viruses circulating in West African bats to find the sources of outbreaks such as 2014 Ebola, 2012-present MERS and Nipah (1998-present), as well as unknown viruses.
- Study Lassa fever virus to determine the reasons for the wide variation in mortality and disease severity, and how different virus strains circulating in rodents vary in human virulence



# Coordinating Research on Emerging Arboviral Threats Encompassing the Neotropics



**Nikos Vasilakis, PhD**  
Contact PI  
UTMB



**Kathryn Hanley, PhD**  
Co-PI  
NMSU

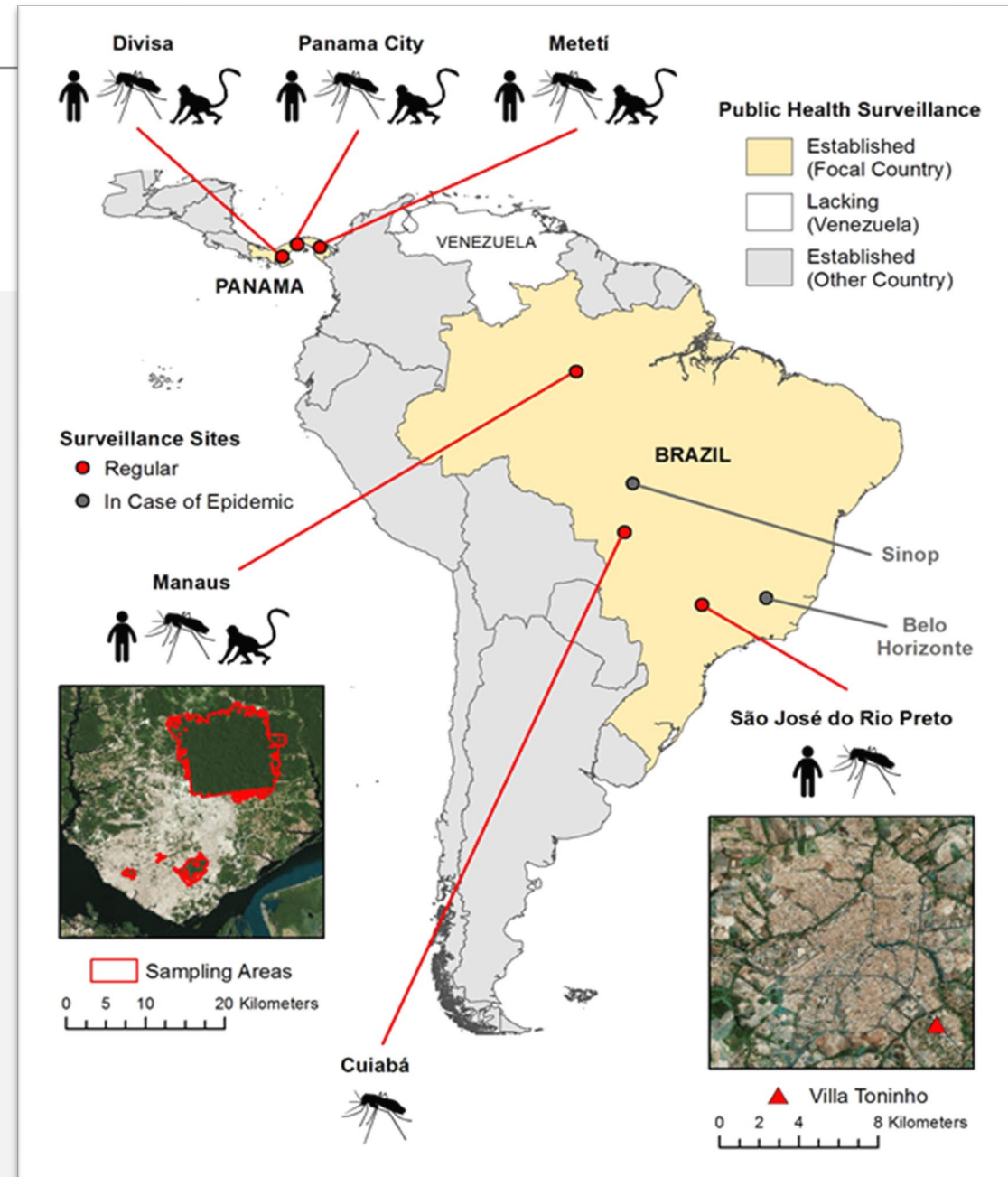
<https://www.utmb.edu/createneo/>



# Pathogen/Region of Focus

## MISSION STATEMENT:

*To anticipate and counter arbovirus emergence in the Americas via nimble and flexible surveillance coupled to cutting-edge modeling approaches*



**Thank you. Questions?**