



# Partnership for Research on Vaccines and Infectious Diseases in Liberia (PREVAIL)



## **VISION**

Improved global health through research



## **MISSION**

To conduct collaborative biomedical and public health research in accordance with best practices, to advance science, strengthen health policy and practice, and improve the health of Liberians and people worldwide.



## **VALUES**

**Respect:** Respect of staff, partners, and study participants. Respect encompasses tolerance of diverse people, cultures and ideas and subscribes to the principles of Good Participatory Practices.

**Integrity:** We protect our reputation by fulfilling our commitments, practicing fiscal responsibility, and adhering to the highest ethical standards of clinical research.

**Innovation:** We are flexible and encourage new solutions when challenged.

**Teamwork:** We accomplish more when we work together.

# PREVAIL GOVERNANCE STRUCTURE

The Liberian Ministry of Health (MOH) and U.S. Department of Health and Human Services established the PREVAIL agreement. Both Liberian and US representatives are involved in PREVAIL governance.



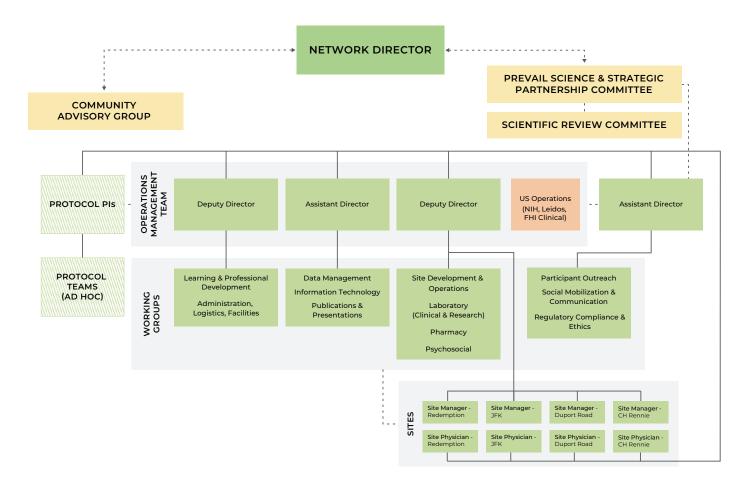
On the US team, the National Institute of Allergy & Infectious Diseases (NIAID) is responsible for the overall project objectives and technical input/guidance, while operations subcontractors assume responsibility for in-country logistics:

- Sourcing, procuring and shipping of materials and supplies
- 2 Hiring of administrative and facilities staff
- Managing facilities
- 4 Managing renovations projects

In addition, support for the following activities is provided:

- · Planning and preparation for the conduct of clinical laboratory operations
- · Data management, biostatistics and Data Safety Monitoring Board (DSMB)
- · Social mobilization and community engagement, social analytics and participant biometrics for study enrollment, working closely with local staff

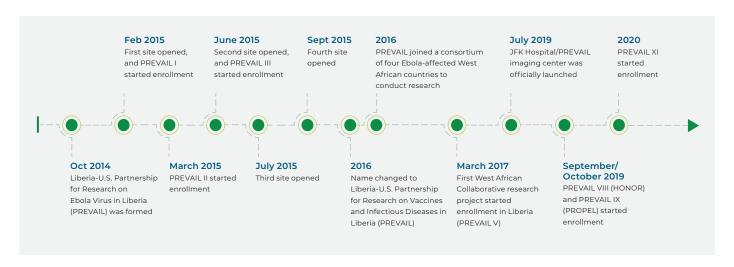
# PREVAIL ORGANIZATION STRUCTURE



## HISTORY OF PREVAIL

During the 2014-2015 Ebola outbreak in Liberia, collaborations between the Liberian government and international partners were essential to ending the epidemic. In 2014, the Liberia-U.S. Partnership for Research on Ebola Virus in Liberia (PREVAIL) was formed to conduct clinical research on Ebola therapeutics and vaccines.

To avoid another public health disaster, the Liberian MOH aimed to create a sustainable research infrastructure, including shifting the focus of PREVAIL from emergency response to a long-term research network and expanding the scope to include other diseases of public health importance in Liberia.



# **COMPLETED AND CURRENT STUDIES**

The focus of PREVAIL has expanded beyond Ebola to include other diseases of public health importance in Liberia.

STUDY NAME	DESCRIPTION	CLINICALTRIALS. GOV IDENTIFIER
PREVAIL I*	Double-blind, placebo-controlled RCT of an Ebola vaccine	NCT02344407
PREVAIL II*	RCT of the experimental treatment ZMapp	NCT02363322
PREVAIL III*	Observational natural history study of Ebola survivors and their close contacts	NCT02431923
PREVAIL III Substudy: Birth cohort	Evaluation of children born to Ebola virus disease (EVD)-survivor participants of the Ebola natural history study	_
PREVAIL III Substudy: CYTOF	Detailed immunological analysis in select survivors and close contacts	_
PREVAIL III Substudy: Neurology	Longitudinal follow-up study of neuropsychological sequelae of EVD in a subset of survivors and close contacts	_
PREVAIL III Substudy: Ophthalmology	Longitudinal ophthalmologic follow-up study of a subset of survivors and close contacts	_
PREVAIL III Substudy: Viral persistence in semen	Assessment of the persistence of Ebola virus in the semen of adult male participants after resolution of the acute illness	_
PREVAIL III Substudy: Viral persistence in the CNS	Assessment of the persistence of Ebola virus in the central nervous system (CNS) of adult participants after resolution of the acute illness	_
PREVAIL IV	Double-blind, two-phase, two-arm trial RCT of GS-5734 among male Ebola survivors with persistent Ebola virus RNA in their semen	NCT02818582
PREVAIL V (PREVAC)	Quadruple blind, placebo-controlled RCT of two Ebola vaccines	NCT02876328
PREVAIL VI	Observational study of the genetic factors underlying Ebola risk and response	NCT03098862
PREVAIL VII	Clinical trial to evaluate the persistence of Ebola viral RNA in the eyes and assess the response to cataract surgery of Ebola survivors	NCT03309020
PREVAIL VIII (HONOR)	Observational cohort study to understand the impact of HIV infection on people in Liberia	NCT03733093
PREVAIL IX (PROPEL)	Prevalence of malaria in Liberia	_
PREVAIL XI: The PREVAIL COVID-19 Observational Study (PCOS)	An observational cohort study of individuals who test positive for SARS-CoV-2 and of exposed individuals who test negative to describe characteristics and course of infection	_

\*Initiated during the Ebola epidemic

# RESEARCH COLLABORATORS

PREVAIL is committed to conducting relevant collaborative research with institutions that can sponsor their own studies, while benefiting from and contributing to this research capacity.

## Examples of collaborating organizations include:

- · ELWA Hospital in Liberia
- · Emory University
- · JFK Memorial Medical Center
- Liberian Ministry of Health programs (e.g., National Malaria Control Program, National AIDS Control Program, CH Rennie Hospital, Duport Road Health Center, Redemption Hospital)
- $\cdot\,$  London School of Hygiene and Tropical Medicine
- · NIAID Division of Intramural Research
- · NIH National Eye Institute

- · National Public Health Institute of Liberia (NPHIL)
- · Stanford University
- · University of Liberia
- · University of Minnesota
- · US Centers for Disease Control and Prevention
- West African Consortium for Re-emerging Pathogens (WACREP)
- · World Health Organization (WHO)

# INFRASTRUCTURE - THE "WARM BASE"

The "warm base," funded by PREVAIL, consists of the essential core clinical research resources for sustainable research capacity and outbreak readiness across the existing clinical sites:

- · Core complement of research staff trained in clinical research practices (i.e., ICH GCP)
- · Facilities for initial and follow-up research participant visits
- · Clinical laboratories (hematology, chemistry, serology) and biospecimen storage areas
- · Specialized ophthalmology and neurology clinics
- · Pharmacy operations
- · Administrative and research operations offices

Additional facilities include the NPHIL's Liberia Institute for Biomedical Research (LIBR); an imaging center providing access to CT scanning, x-rays and ultrasound at JFK Medical Center; and a research lab and biorepository.

## For each of these research locations, the warm base includes stable operational infrastructure:

## Clinical research site operations

- · Internet service
- Email and cell phone connectivity
- · Videoconferencing
- Uninterrupted and safe electrical power with regularly maintained backup generators
- · Water availability
- Functional waste management (including hazardous waste) and cleaning services
- Equipment calibration and maintenance
- · Rental cars
- Furniture
- · Office supplies
- Facility renovation and maintenance

## Clinical lab capacity

- Chemistry (ACE Alera & ACE Axcel)
- Hematology (Abbott CELL-DYN Ruby)
- Coagulation (Stago STA Compact Max)
- Urinalysis (Siemens CLINITEK Status+ Analyzer)
- Automated ELISA (Bio-Rad EVOLIS)
- HIV confirmation (Bio-Rad Geenius HIV 1/2 Supplemental Assay)
- · CD4 counter (BD FACSPresto)
- · RT-PCR (Cepheid GeneXpert)
- · Nexcelom cell viability counter

- Ophthalmology clinic capacity
- Imaging capacity
  - · CT scanner
- Human resources management
- Staff training
- → Travel support for site staff
- Accounting and financial management of sites
- Information technology management
- Supply chain, including cold chain, logistics

# **PREVAIL STAFF**

PREVAIL staff represent a diverse set of specialties to support clinical research and include a leadership team to assist with oversight. The list below provides an example of the positions within the staff.

STAFF	EACH CLINICAL RESEARCH SITE	LIBR	CENTRALIZED
Director (MD or MD/PhD)			<b>✓</b>
Deputy and Assistant Directors (Admin, Clin Ops, DM, Collaborations and Partnerships)			<b>✓</b>
Site physicians	<b>✓</b>		
Study nurses	<b>✓</b>		
Psychosocial staff	<b>✓</b>		<b>✓</b>
Pharmacists			<b>✓</b>
Study coordinators	<b>✓</b>		
Community outreach staff			<b>✓</b>
Participant trackers			<b>✓</b>
Data management staff			<b>~</b>
Regulatory affairs staff			<b>~</b>
Laboratory technicians	<b>~</b>	<b>✓</b>	
Biostatistics/Data analysis staff			<b>✓</b>
IT staff	<b>✓</b>		<b>✓</b>
Clinical site managers	<b>~</b>		
Clinical facility managers	<b>~</b>	<b>~</b>	<b>✓</b>
Administrative staff			<b>✓</b>
Security personnel	<b>~</b>	<b>~</b>	

# PREVAIL RESEARCH SITES:

- John F. Kennedy Medical Center (JFKMC)
- 2. Redemption Hospital
- 3. AMD Administration Office
- 4. Duport Road Health Center
- **5.** Liberia Institute of Biomedical Research (LIBR)
- 6. CH Rennie Hospital
- **7.** Phebe Hospital (pending expansion)





For more information, please contact the PREVAIL team at info@prevailcr.org.

