

# CREID Network Pilot Research Program Informational Webinar for Applicants

October 19, 2023



# Pilot Program Contacts

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# Agenda

Time	Topic
45 min	CREID Network Overview and Structure
	Pilot Program Overview
	Submission and Review Dates
	Research Topics and What's Allowed
	Regulatory Information
	Eligibility
	CREID Research Center Collaboration
	Letter of Intent
	Application Package
	Budget
	Study Design and Statistics
	Review Criteria
	Post Award and Grants Management
	Capacity Building for Awardees
15 min	Questions

# CREID Network Overview

The NIH/NIAID-funded CREID Network is comprised of 10 Research Centers and a Coordinating Center operating in 30+ countries around the globe where emerging and re-emerging infectious disease outbreaks are likely to occur.

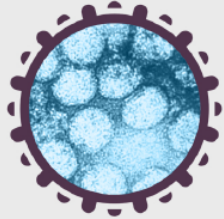
The CREID Network allows NIAID to focus resources on building a sustainable, scalable, adaptable rapid research response infrastructure to respond to unique situational requirements imposed by emerging pathogens.



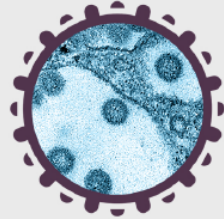
# CREID Priority Pathogens

## What are Priority Pathogens?

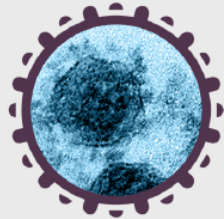
**Emerging infectious diseases** are those infectious diseases that have been recently discovered or exist and are increasing rapidly in incidence or geographic range.



**Flaviviridae** is a family of small, single-stranded, enveloped ribonucleic acid (RNA) viruses.



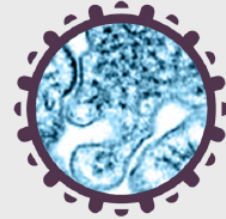
**Bunyvirales** is an order of more than 300 viruses which includes Rift Valley fever virus and Lassa virus.



**Coronaviruses** are a large family of viruses that can infect animals and humans.



**Filoviridae** is a virus family that can infect humans and non-human primates and cause severe hemorrhagic fever.



**Pathogen X** represents a pathogen that could cause an international epidemic or pandemic but is currently unknown to cause disease in humans.

**CREID**

Centers for Research in  
Emerging Infectious Diseases

# CREID Research Focus



Multidisciplinary teams of investigators at the Research Centers study

- Pathogen/host surveillance
- Transmission, pathogenesis and host immune response
- Develop reagents and diagnostic assays for emerging pathogens and vectors

# CREID Network Structure



# CREID Network Website



- Information and contact for each Research Center
- Research Study Dashboard
- Conference Dashboard
- Publication Dashboard
- Interactive Network Map

<https://creid-network.org/>





# Pilot Program Overview

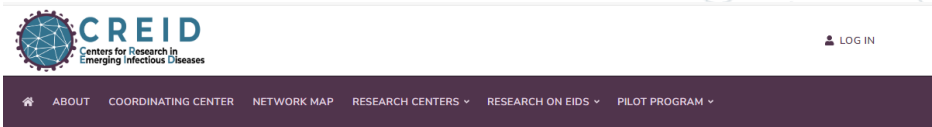
The CREID Network Pilot Research Program supports, trains, and mentors the next generation of emerging infectious disease researchers. This program aims to develop capacity for emerging infectious disease research around the world.



# Call for Applications

Please see CREID webpage for Call for Applications (and links to templates) for all details on the application process.

<https://creid-network.org/call-for-applications>



## CREID Pilot Research Program: 2024 Call for Applications

### Objectives and Research Priorities

The CREID Network Pilot Research Program supports, trains, and mentors the next generation of emerging infectious disease researchers. This program helps develop capacity for emerging infectious disease research around the world through the performance of scientific research projects.

### Eligibility

The CREID Pilot Research Program is designed for researchers who are in the early stage of their careers, including applicants from lower and middle-income countries (LMICs) who are poised to lead research studies and postdoctoral fellows and investigators who fit within the NIH definition of New Investigator AND who establish a collaboration with one of the ten CREID Research Centers.

Each CREID Research Center can support three applications for submission for each round of applications and each applicant must collaborate with at least one of the ten CREID Research Centers. Interested applicants should contact Research Centers directly about their interest in collaborating. See Research Center pages for contact information.

### Administration

The CREID Coordinating Center administers and oversees the Pilot Research Program. Please email [info@creid-network.org](mailto:info@creid-network.org) to register for the Webinar for Applicants scheduled for October 19, 2023 at 10am ET. The recorded webinar will be posted to this website for viewing within 1-2 days after the webinar is held.

**CALL FOR APPLICATIONS**

**Application Forms and Templates**

- [1. Letter of Intent Template](#)
- [2. Application Template](#)
- [3. Biosketch Form](#)
- [4. Other Support Form](#)
- [5. Facilities and Resources](#)
- [6. Research and Related Other Project Information<sup>1</sup>](#)
- [7. Foreign Clearance Form](#)
- [8. Submission Checklist](#)
- [9. Budget Template<sup>1</sup>](#)
- [10. IRB Templates](#)
  - [• PHS HS Information<sup>1</sup>](#)
  - [• PHS Inclusion Report<sup>1</sup>](#)

<sup>1</sup> As an accessible PDF, this file cannot be opened in your web browser. Download the file and open with Adobe Acrobat.

# Submission and Review Dates

<b>Deadline for Questions</b>	October 26, 2023, 5pm EDT*
<b>Response to Questions Available</b>	November 1, 2023
<b>Deadline to contact Research Center for collaboration</b>	November 10, 2022
<b>Deadline for Letter of Intent (LOI)</b>	December 5, 2025, 5pm ET**
<b>Deadline for Full Application</b>	January 31, 2024, 5pm ET**
<b>Notification of Award</b>	March 29, 2024
<b>Award Start Date</b>	May 1, 2024

\*EDT = United States Eastern Daylight Time

\*\*ET = United States Eastern Time



# Research Project Topics (Examples)



- Many first and second round of proposals used stored samples from previous studies (e.g., blood, serum, viral isolates)
- Studies involve one or more of humans, vertebrate animals or other hosts, vectors (e.g., mosquitos), or pathogens
- Preliminary data not required
- Examples of Research Topics
  - Studies on pathogen transmission, emergence, or maintenance in an ecosystem
  - Pathogenesis
  - Characterization of viral antigens
  - Phylogenetics
  - Viral diversity
  - Sociological or behavioral influences on emerging or reemerging viral diseases
  - Development of reagents and diagnostic assays to improve detection of emerging pathogens
  - Studies aimed at detailing human immune responses to new or emerging infectious agents

# Human Subjects Research

- Program not designed to support submission of:
  - New human subjects research, given the length of time required to receive IRB approval for new studies
  - Clinical trials
- Human subjects research **is allowed** for those nested within a parent study with an IRB approval in place and requiring only a modification for the additional sub-study
  - Clinical research applications nested within a parent clinical trial are allowed if the application is not a clinical trial and no funds will go toward a clinical trial
- Research involving stored specimens from human subjects **is allowed** if specimens are *deidentified* and cannot be linked back to the subjects



# Vertebrate Animal Studies

- Program not designed to support new vertebrate animal research studies, given the length of time required to receive IACUC approval for new studies.
- Animal studies are allowed for those nested within a parent study with an IACUC approval in place and requiring only a modification for the additional sub-study.



# Select Agent Studies



- **No projects are allowed involving culture or storage of Select Agent pathogens as defined by US CDC.** Contact the collaborating RC PI for guidance on how to determine if your proposed work falls under US CDC Select Agent Policy. <https://www.selectagents.gov/sat/list.htm>

# Eligibility Criteria

- **Lower- and Middle-Income Country (LMIC) Applicants**
  - LMIC applicants with at least a master's degree or equivalent degree and 4+ years of experience
  - **OR:**
  - Applicant recommended by a CREID RC PI who does not fit any of the other criteria
- **Postdoctoral Fellows or Clinical Research Fellows**
  - Applicants who hold a clinical doctoral degree (MD, DO, DVM, DNS, PharmD) must provide evidence of formal research training completed prior to submission of application
  - Should have protected time to devote to the proposed research project
- **New Investigator**
  - Not previously competed successfully as PD/PI for a substantial independent research award

Each applicant must collaborate with one or more CREID Research Center and meet one of these eligibility criteria





# Role of CREID Research Center



Contact RC for collaboration as early as possible, but no later than **November 10, 2023**

- Applications must demonstrate
  - The collaborating RC is meaningfully involved in the proposed research
  - Proposed research is closely linked to the work of the collaborating RC
- CREID Research Centers
  - Can recommend **three applications**
  - Are encouraged to consider diversity, equity, and inclusion goals in their selection of applicants
  - Provide a Letter of Collaboration for each applicant they support
  - Provide a mentor to the applicants
  - Provide support for applicant, such as with grantsmanship, biostatistics, study design, or other support

# Applying as Co-PIs

- Up to two applicants can apply as Co-PIs for a single application; budget ceiling remains the same
- If the two applicants are from different institutions, each submits a detailed budget
- **Limit of 2 research locations**
- Need to include Co-PI approach and plan for managing the project jointly



# Definitions of Team Roles



- **Principal Investigator (PI/Co-PI):** Directs the project or activity being supported by the grant and is accountable to the recipient organization
- **Key Personnel:** The PI and other individuals who contribute to the scientific development
- **Mentor:** A mentor is someone who makes a long-term commitment to the applicant career.
- **Collaborator:** Collaborators always play an active role in the research, and the position is sometimes defined interchangeably with co-investigator

# Letter of Intent (LOI)

- **Due: December 5, 2023, 5pm ET**
- Submit to [info@creid-network.org](mailto:info@creid-network.org)
- Include collaborating RC on email submission
- Letter of Intent
  - Complete the LOI template
  - Include biosketches
  - All details for LOI in Call for Applications (pg. 9)

Use LOI  
template  
available on  
the website



# Application Package

Use templates  
and checklist to  
ensure  
completeness

- **Due: January 31, 2024, 5pm ET**
- Submit to [info@creid-network.org](mailto:info@creid-network.org)
- Include collaborating RC on email submissions
- Templates available on CREID website
- Collaborating RC expected to support development of application
- Develop application with review criteria in mind
  - Application Process, pp 9-16
  - Application Review and Selection Process, pp 16-18



# Study Design

- **Clearly describe the following:**
  - Study population(s)
  - Comparison groups (e.g. treatment vs control)
  - Data to be collected (e.g. number of samples, origin or source, etc.)
  - Clearly describe any bioinformatics pipelines/workflows
    - Names and versions of software
    - Describe any enhancements or deviations from current best practices



# Statistical Methods

- **Clearly describe the following:**
  - Primary or principal outcomes that will be collected
  - Statistical analysis method that will be used to test hypotheses
    - Make sure the method is appropriate to how your data were measured (e.g. continuous vs discrete) and the statistical theory underlying the method (e.g. large sample theory)
  - Sample size justification
    - Statistical power analysis is best practice, but sometimes subjects/specimens are limited



# Data Management & Sharing

## NIAID Data Policy and Guidance

<https://www.niaid.nih.gov/research/data-sharing-guidelines>

### In your application...

Clearly define the datasets and software you expect to generate

Clearly describe how you will manage the data and software you create.

Outline a plan for depositing your data in a public repository upon publication of the work.

### Best Practices/Address Questions

What types of data and software will be generated?

How will you version control?

How will your data will be consistent with FAIR\* guidelines?





# Budget

Award Type	Period of Performance	Maximum Total Cost (Direct and Indirect)
Grant with milestones	12 months: May 1, 2024-April 30, 2025	\$150,000 USD

- Budget ceiling remains same if one or two Co-PIs
- Include travel funds for 3-day Annual Meeting in Rockville, MD
- Equipment over \$20,000 requires quote
- If pre-payment required, please include in budget justification
- Include payment schedule in budget justification
- **Limit of 2 research sites/subawards per application**

# Review Criteria

## Scored Criteria

Research Rationale, Strategy, Feasibility

Significance and Impact

Personnel

Environment

Research Center Collaboration Plan

Career Development & Mentoring Plan

Resubmission Revisions

## Unscored Criteria

Budget

Vertebrate Animals

Protection of Human Subjects

Inclusion of Women, Minorities, Children

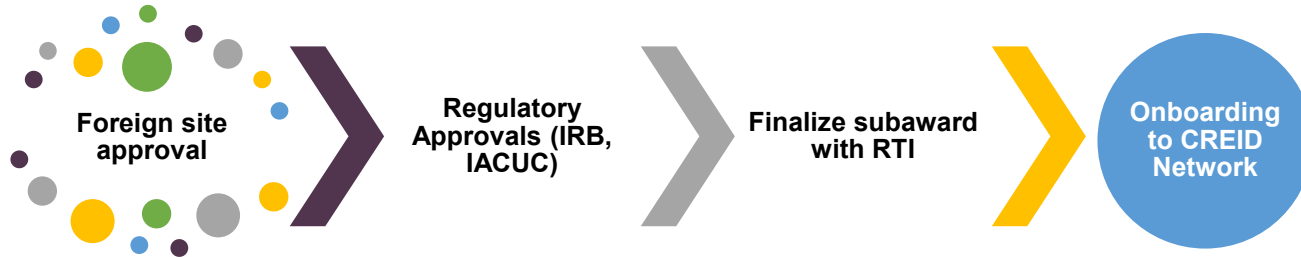


# Use Application Template & Checklist!

- The Application Template follows required sections
- The Application Submission Checklist helps ensure completeness
- Submit checklist with your Application



# Post-Award and Grants Management



- US Government Foreign clearance can take 1-3 months
- RTI initiates subaward process once foreign clearance and regulatory approvals are in place
- RTI incorporates grant requirements that flow down from the prime NIH award
- Negotiations can take weeks or months to complete, so you should accommodate these delays in your research study timeline
- Appropriate institutional officials need to be closely engaged for this negotiation process
- Delays in responses to RTI contract staff can delay establishing subaward

# NIH Grants Management Seminar

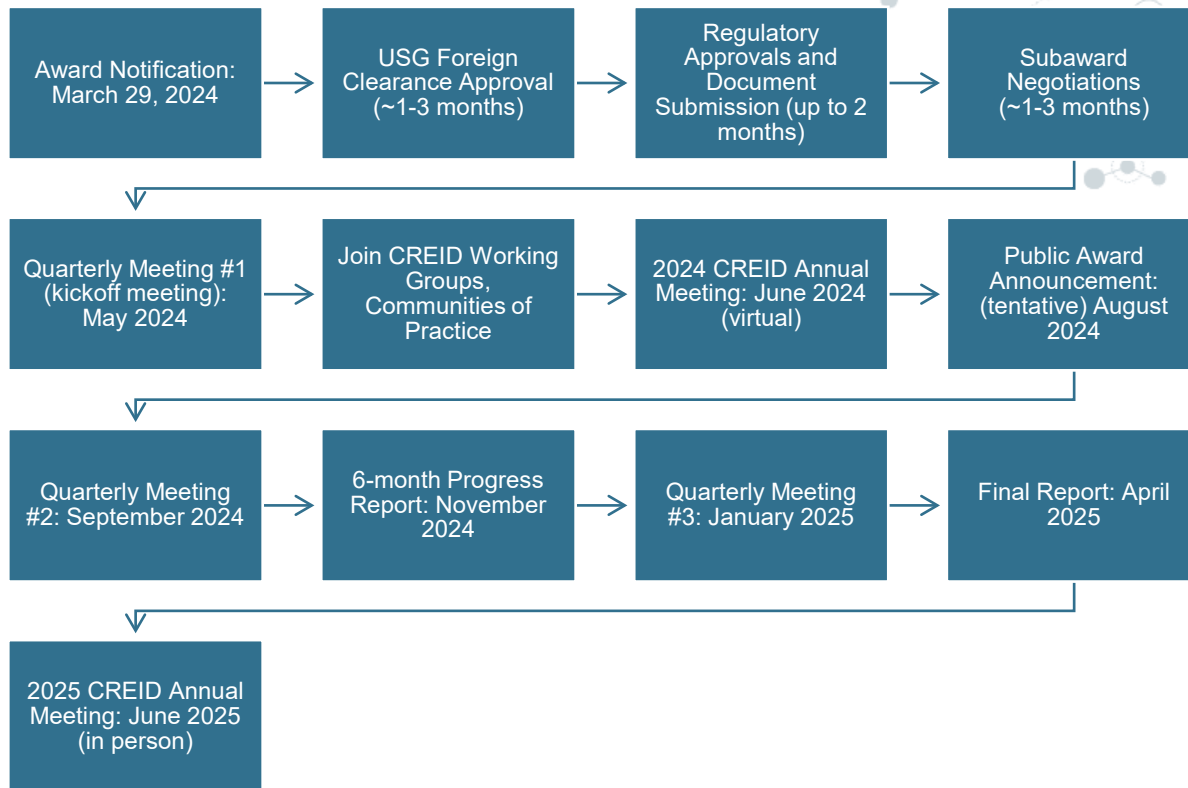
- NIH Virtual Seminar on Program Funding and Grants Administration
- Recorded sessions provide guidance on receiving and managing US Government funding
- <https://grants.nih.gov/learning-center/conference>



# Capacity Building Framework



# Pilot Award Year Timeline (tentative dates)



# 2023 Pilot Program Awardees

## Project abstracts on CREID website

PI(s) and Institution(s)	Award Title	Pathogen	Country	Collaborating RC
Ngu Abanda, PhD, <i>Centre Pasteur du Cameroon</i>	Reconstructing historical patterns of arbovirus transmission in Cameroon using serological data	Arboviruses	Cameroon	WAC-EID, with PICREID
Maria Martin, PhD, Carina Sen, MsC, <i>Instituto Nacional de Enfermedades Virales Humanas</i>	Pathogenic mammarenavirus and orthohantavirus in Argentina	Arenavirus Hantaviruses	Argentina	WAC-EID with CREATE-NEO
Christian Ranaivoson, PhD, <i>Association Ekipa Fanihy</i>	Development of a comprehensive serological, molecular, and genomic surveillance platform for potentially zoonotic bat-borne viruses in Madagascar	Henipaviruses	Madagascar	CREID-ESP
Miguel Garcia Knight, PhD, <i>National Autonomous University of Mexico</i>	Virome diversity across ecological niches in mosquito vectors	Arboviruses	Mexico, Uganda	EpiCenter with WAC-EID
Francesca Falconi Agapito, PhD, <i>Universidad Peruana Cayetano Heredia</i> Phillippe Selhorst, PhD, <i>Institute of Tropical Medicine Antwerp</i>	Application of mNGS to identify etiologies of acute undifferentiated fever in the Peruvian Amazon	Viruses causing acute undifferentiated febrile illnesses	Peru	EpiCenter
Bianca Bratuleanu, PhD, <i>Iasi University of Life Sciences</i> Sarah Temmam, PhD, <i>Institut Pasteur</i>	Arbovirus discovery and surveillance in Danube Delta Biosphere Reserve, Romania	Arboviruses	Romania, France	PICREID
Momoh Mambu, PhD, <i>Kenema Government Hospital</i> Nell Bond, PhD <i>Tulane University</i>	Cellular immune responses to rVSV-G-ZEBOV-GP vaccination in Ebola survivors in eastern Sierra Leone	Filoviruses	Sierra Leone	WAC-EID with WARN-ID, CREID-ECA, CREATE-NEO



# Questions

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CREID Coordinating Center

