Centers for Research in Emerging Infectious Diseases (CREID) Network

Pilot Research Program
2024 Call for Applications (Round 4)
Release: October 10, 2023

SUBMISSION AND REVIEW DATES

Call for Applications Release	October 10, 2023
Webinar for Applicants	October 19, 2023, 10am ET
Deadline for Questions	October 26, 2023, 5pm ET
Response to Questions Available	November 1, 2023
Deadline to contact Research Center for collaboration	November 10, 2023
Deadline for Letter of Intent (LOI)	December 5, 2023, 5pm ET
Deadline for Full Application	January 31, 2024, 5pm ET
Notification of Award	March 29, 2024
Earliest Start of Award	May 1, 2024

Call for Applications 2024: Synopsis

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

Scientific research project topics could include but are not limited to 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; and studies aimed at detailing human immune responses to new or emerging infectious agents. Preliminary data are not required.

https://creid-network.org/pilot-program

Email: info@creid-network.org

Contents

1. Pilot Research Program Overview

1.1 Background

The Centers for Research in Emerging Infectious Diseases Network (CREID Network) is funded by the NIH's National Institute of Allergy and Infectious Diseases (NIAID) and is comprised of 10 Research Centers (RCs) and a Coordinating Center (CC) operating in regions around the globe where emerging and reemerging infectious disease outbreaks are likely to occur. Multidisciplinary teams of investigators conduct pathogen/host surveillance; study pathogen transmission, pathogenesis, and immunologic responses in the host; and develop reagents and diagnostic assays for improved detection of important emerging pathogens and their vectors. For more information about the CREID Network, please visit its website (https://creid-network.org/). For more information on the pathogens and diseases being studied as part of the CREID Network, please visit the pathogens page on the website (https://creid-network.org/pathogens).

CREID Research Centers

- American and Asian Centers for Arboviral Research and Enhanced Surveillance (A2CARES)
- Center for Research in Emerging Infectious Disease-Epidemiology, surveillance, pathogenesis (CREID-ESP)
- Center for Research in Emerging Infectious Diseases-East and Central Africa (CREID-ECA)
- Coordinating Research on Emerging Arboviral Threats Encompassing the Neotropics (CREATE-NEO)
- Emerging Infectious Diseases: Southeast Asia Research Collaboration Hub (EID-SEARCH)
- EpiCenter for Emerging Infectious Disease Intelligence (EpiCenter)
- Pasteur International Center for Research on Emerging Infectious Diseases (PICREID)
- United World Antivirus Research Network (UWARN)
- West African Center for Emerging Infectious Diseases (WAC-EID)
- West African Research Network for Infectious Diseases (WARN-ID)

CREID Coordinating Center

The CREID Coordinating Center (CREID CC) is a partnership between RTI International (RTI) and the Duke University Human Vaccine Institute. Serving as the operational hub for the CREID Network, the CREID CC team offers expertise in supporting administration and management of data and scientific programs. The CREID CC administers the Pilot Research Program, which is funded by NIAID under Award Number 1U01AI151378. View information about past awards on the CREID website https://creid-network.org/pilot-program.

1.2 Objectives and Research Priorities

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

Scientific research project topics could include but are not limited to 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; and studies aimed at detailing human immune responses to new or emerging infectious agents. Preliminary data are not required.

Additional examples of types of research this program would consider supporting include the following:

- Retrospective epidemiological study using already captured clinical data (secondary human subjects research) or other experimental data.
- Behavioral/social science studies on unique aspects of a particular clinical cohort nested within a parent study, but not a clinical trial.
- Characterizing pathogens or pathogen diversity from previously collected animal or vector specimens.
- Lab-based study answering a finite and well-defined hypothesis.

This program will NOT support:

- No human subjects research requiring a new IRB approval (rather than a modification of an existing IRB approval).
- No clinical trials: Please see this website for more information on the definition of clinical trials (https://grants.nih.gov/policy/clinical-trials/definition.htm).
- No vertebrate animal studies requiring a new IACUC approval (rather than modification of an existing IACUC approval).
- No areas outside of funding priorities such as HIV/AIDS-only and other topics not within scope of the CREID Network (e.g., brain disorders, addiction).
- No projects involving 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
- No research that falls within the categories of *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (https://www.phe.gov/s3/dualuse/Pages/InstitutionalOversight.aspx) or within the *United States Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework) (https://www.phe.gov/s3/dualuse/Pages/p3co.aspx).

Human Subjects Research:

- This program is **not** designed to support submission of **new** human subjects research, given the length of time required to receive Institutional Review Board (IRB) approval for new studies. Nor does this program support clinical trials (i.e., interventional trials). However, human subjects research is allowed within a limited scope, including research applications nested within a parent study with IRB approval already in place and requiring only a modification for the additional sub-study. In addition, clinical study research projects nested within a parent clinical trial are allowed if the Pilot application itself is **not** a clinical trial and no funds will go toward the parent clinical trial. Research involving stored specimens from human subjects is allowed provided the specimens are deidentified and cannot be linked back to the subjects. Please see the NIH definitions of a clinical research and clinical trial: (https://grants.nih.gov/grants/glossary.htm#ClinicalResearch)
- For more information on human subjects research, please visit the National Institutes of Health (NIH) website: https://grants.nih.gov/policy/humansubjects.htm.

Vertebrate Animal Research:

- This program is **not** designed to support submission of **new** vertebrate animal research studies, given the length of time required to receive Institutional Animal Care and Use Committee (IACUC) approval for new studies. However, animal studies are potentially allowed within a limited scope, including research

projects nested within a parent study with existing IACUC approval in place and requiring minor to no modification for the proposed pilot project study.
- The primary collaborating RC will be required to provide Animal Welfare Assurance to the awardee institution and the RC IACUC is subject to an audit and approval by RTI to support vertebrate animal work under the Pilot Award.
- For more information: https://olaw.nih.gov/guidance/vertebrate-animal-section.htm

1.3 Principal Investigator 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 at least one of the 10 CREID Research Centers.

Candidates from high-income countries must have a clinical or research doctorate (including PhD, MD, DO, DVM, ScD, DNS, PharmD, or equivalent degrees), and LMIC candidates must have at least a master's degree or equivalent and 4+ years of relevant research experience, with some exceptions.

Applicants must include information on which category of eligibility they fall under, along with their biosketch that clearly demonstrates eligibility under one of the below categories (see LOI instructions on page 9).

1. **LMIC Applicants**
   a. LMIC applicants with at least a master's degree or equivalent degree and 4+ years of experience.
   b. Applicant recommended by a CREID RC PI who does not fit any of the other criteria.
2. **Postdoctoral Fellows or Clinical Research Fellows**
   a. 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.
   b. Should have protected time to devote to the proposed research project.
3. **New Investigator / Early-Stage Investigator (ESI)**
   a. Not previously competed successfully as PI for a substantial independent research award. See the NIH website for more information on acceptable smaller grants and awards that maintain ESI status: https://grants.nih.gov/policy/early-investigators/list-smaller-grants.htm.

Both international and U.S. (domestic) researchers are eligible to apply, inclusive of those who have an official affiliation with a CREID Network RC and those who are not currently affiliated with the CREID Network.

- Unaffiliated applicants must establish a collaboration with a CREID RC. Additional information about each RC is included on the CREID Network website (https://creid-network.org/).
- As part of the full application, all applicants must submit a required Letter of Collaboration from the affiliated CREID RC Principal Investigator with whom they are collaborating.

Applying as Co-PIs

Up to two applicants can apply as Co-PIs for a single application; however, the budget ceiling remains the same ($150,000 in total costs). If the two applicants are from different institutions, each applicant must provide a detailed budget, with the total of the two budgets not exceeding $150,000 in total costs. In the application, Co-PI applicants will need to include a justification for the Co-PI approach and add a plan for managing the project jointly.

Upon award, both Co-PIs will be expected to attend all meetings, co-present on their award (e.g., poster, oral presentations), and jointly share responsibility for the entire scope of work.

1.4 Institutional Eligibility

RTI issues Pilot Program grant awards as subawards to the institutions of the selected Pilot award Principal Investigator(s) performing the research, not the sponsoring CREID Research Center home institution. As such, recipient institutions must be able to agree to US Government policies and regulations. Please see the NIH Grants Policy Statement for more information: https://grants.nih.gov/policy/index.htm.

Performance Sites

Each application is limited to **two** performance sites for their project. Once new sites have been approved through the Foreign Clearance process, NIAID will update the CREID CC parent award to add the new performance sites.

1.5 CREID Research Center Engagement

Each CREID Research Center can recommend up to three applications per round and each applicant must collaborate with at least one of the ten CREID Research Centers. Applicants must contact the RC they are interested in collaborating with as early as possible to ensure alignment with RC priorities and to confirm support prior to submission of the required Letter of Intent. RCs are encouraged to consider diversity, equity, and inclusion goals in their selection of applicants to move forward.

The application process is considered part of the Network capacity-building process for applicants. As a result, RCs are expected to work closely with selected applicants on their application package to provide support on grant writing, statistics, budgeting, data sharing, career development and mentoring plan and other application needs.

1.5.1 Joint RC Collaboration

Applicants can collaborate with more than one RC and should initiate this discussion when developing a collaboration for the application. One RC must be identified as the lead RC for purposes of submitting a Letter of Intent and the single application.

Useful Definitions:
https://grants.nih.gov/grants/glossary.htm

- **Principal Investigator:** Directs the project or activity being supported by the grant and is accountable to the recipient organization for the proper conduct of the project or activity… When multiple PIs are named, each is responsible and accountable to the applicant organization, or as appropriate, to a collaborating organization for the proper conduct of the project or program including the submission of all required reports.
- **Key Personnel:** The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.
- **Mentor:** A mentor is someone who makes a long-term commitment to the applicant career. They wear many hats—adviser, advocate, critic, instructor—to guide the applicant's research and help with professional development and advancement. Ideally, a mentor should be well known and well respected in the selected field and have essential qualities like being knowledgeable, open-minded, supportive, motivating, and a good listener. They must be able to communicate clearly, give appropriate project guidance, teach data analysis and interpretation, as well as encourage discussion of alternative paths. (Link to NIAID definition)
- **Collaborator:** Collaborators always play an active role in the research, and the position is sometimes defined interchangeably with co-investigator. As a loose guideline, think of a collaborator as a scientist whose distinct expertise complements the applicants, while a co-investigator shares the applicant's area of expertise and therefore contributes in guiding the scientific direction of the overall project. One provides unique expertise, the other umbrella expertise. (Link to NIH Team Roles)

1.5.2 RC Letter of Collaboration

When detailing the collaboration with two or more RCs, the required RC collaboration letter should describe the RC role, the role of any additional collaborating RC(s) (if applicable), and how the collaborations will benefit the applicant's proposed study and career goals.

Each application must include a RC Letter of Collaboration from the RC contact PI. The Letter of Collaboration must address the following questions:

- How will the RC contribute to the development and success of the applicant?
- Will the proposed research study allow the applicant to expand their skill set?
- Is the proposed research study structured to establish linkages with in-country stakeholders?
- Will the proposed 12-month research study lead to a conference abstract or publication?
- Will the proposed research study establish the applicant as a mentor for other early career researchers?
- What is the long-term vision of the applicant as it relates to RC research priorities, in-country research needs and capacity, or other?
- Does this applicant and their proposed research study build the capacity at the Research Site for the RC?
- If the application includes Co-PIs, how will the Co-PI approach strengthen the proposed research study and ensure adequate skills building for both applicants?
- If the application includes more than one RC, identify the lead RC, describe the role of each RC and how the joint-RC collaboration will be managed, and how the joint RC collaboration will strengthen the research study and the applicant's career goals.

1.6 Funding

Awards will be made to the applicant PI home institution that will be managing the award in the applicant's name. These will be subawards made by RTI as part of its prime CREID CC NIAID award. Budget requests need to reflect the actual needs of the proposed project. If two applicants apply as Co-PIs, if selected, their institutions would each receive a subaward, limited to up to two performance sites/institutions, with the total funding for the combined award not to exceed $150,000.

Type	Period of Performance	Maximum Total Cost (Direct and Indirect)
Grant with milestones	12 months	$150,000 USD

1.7 Pilot Program Timeline

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2. Application Process

All applications must include the following elements (as applicable) in the order listed below. Page limits are noted where applicable. Failure to include a required element may result in the application not being reviewed. Where indicated, start each component on a new page. All applications must be in English.

Please review the Pilot Program Timeline for key due dates. Questions about the application process should be submitted by email to info@creid-network.org. The CREID CC will respond to the inquiry directly and post all questions and responses on the CREID Network website (https://creid-network.org/pilot-program).

The final application package (2 files) must be submitted via email to info@creid-network.org, no later than

Wednesday, January 31, 2024
5:00 PM Eastern Time

File 1. A single complied PDF of the specified application components
File 2. Budget with justification on downloaded fillable PDF template

2.1. Informational Webinar

The CREID CC will host an informational webinar on Zoom for interested applicants. The CREID CC will use this live webinar to discuss the application process and application package in detail and will include time for questions from participants. The webinar will be recorded and posted to the Pilot Program webpage for those unable to participate in the live session. **To register for the webinar, please email info@creid-network.org**. The CREID CC will send a Zoom link to access the webinar.

2.2 Letter of Intent

A Letter of Intent (LOI) must be submitted via email (info@creid-network.org) using the provided template, and the collaborating RC(s) must be copied on the LOI submission. The LOI must not exceed three pages, excluding the biosketches.

LOI submission includes:

- Completed LOI template.
  - Note: Applicants must provide any plans to conduct human subjects research and describe the parent study and the plan for receiving an IRB modification within 2 months of the award.
  - Note: Applicants must provide any plans to conduct vertebrate animal research and describe the parent study and the plan for receiving an IACUC modification within 2 months of the award.
- Biosketch of the applicant PI and Co-PI (if applicable):
  - Please use the NIH Biosketch template provided. NIH Biosketch Instructions (Non-Fellowship format): https://grants.nih.gov/grants/forms/biosketch.htm

The LOIs are for planning purposes only, and no response from the CREID CC is required to proceed with the full application. If any concerns or questions are identified upon review of the LOI, the CREID CC will contact the investigator(s) to share that information.

2.3 Application Format and Deadline

All application packages should be submitted as two PDF files: a **single** PDF file for the application; a **single** PDF file for the full budget and budget justification. All text should be in Calibri with a font size of no less than 11pt,

with normal text spacing required. All margins should be at least one-half inch. Inclusion of URLs to provide additional information is prohibited in all sections.

All required templates are available on the CREID Network website: https://creid-network.org/call-for-applications

2.4 Full Application Submission Requirements

The full application consists of the following components.

Item	Description	
Compile the following items for Application Package File 1 as a single PDF		
Application Template with Cover Sheet (*Template provided*)	Please be sure to include information on the organization managing the funds for the award. The cover sheet includes an abstract that will be used for public announcements about the program.	
Title and Table of Contents	Provide the title of the proposed project and a Table of Contents for the full Application.	
Study Personnel (*1-page limit*)	Demonstrate that the applicant PIs, collaborators, and other researchers are well suited to the project, have an ongoing record of accomplishments, and address how the study personnel will work together, including roles and responsibilities for each team member. The applicant should include a mentor in the personnel section; however, mentors should not request financial compensation for the role. All funds will go to the institution affiliated with the applicant.	
Resubmission Introduction *(1-page limit)*	If an applicant is resubmitting an application based on a previous round of the Pilot Research Program, the applicant must include a description of no more than one page that describes how comments from the previous scientific review have been addressed and any changes that have been made to the project. Reviewers will receive the Summary Review Statement the applicant received for the previous submission to assist in their evaluation of the resubmission.	
Specific Aims *(1-page limit)*	Per the NIH grant format, include a 1-page Specific Aims section that summarizes the goals and objectives of your research project. Specific aims and objectives should be clearly defined and sensibly tied to a definite research hypothesis/question. A clear endpoint or set of endpoints should be tied to each objective. Please see NIAID guidance on developing specific aims: https://www.niaid.nih.gov/grants-contracts/draft-specific-aims	
Research Strategy: *9-page limit*	**Study Rationale**	Projects should address an important problem, gap, or critical barrier to progress in the field of study. The project should address an area of need targeted by the CREID Network. All projects must be in line with the scientific mission of the CREID Network. Priorities specific to this Call for Applications are included in Section 1.2. See the CREID website for more information on each RC and the Network priorities (https://creid-network.org/).

Item	Description	
	Significance and Innovation	State how the project has the potential to significantly address an important problem or critical barrier to progress in the field. A successful application will also describe how the proposed research meaningfully expands on existing research without overlapping current studies or the unique contribution of the project to the research community and how it will not replicate current studies but move beyond with an innovative approach or objectives.
	Approach and Methods	The overall strategy, methodology, statistical plan, and analyses should be well reasoned and appropriate to accomplish the specific aims of the project. A sample size estimate must be included and justification that demonstrates the adequacy of the sample size; one approach could be a power calculation. Address how potential problems will be resolved, identify possible alternative strategies, and include benchmarks for success.
	Data Management and Sharing Plan	Include a detailed data management and sharing plan. Please see the NIAID Data Management and Sharing Guidelines: https://www.niaid.nih.gov/research/data-sharing-guidelines Sharing unpublished data among Network collaborators is one of the core principles of the CREID Network. Awardees are encouraged to work with their mentor to establish infrastructure for the sharing of data that is not or will not be made immediately publicly available. The recommended infrastructure/repository for this type of data sharing is ImmPort (https://www.immport.org/home) or BV-BRC (https://www.bv-brc.org/), so the awardee is encouraged to set up a free account. Awardees may also propose an alternative infrastructure if one is available.
	Project Timeline	Applicants need to provide a detailed timeline for their project, including key milestones and activities over the course of the project. Your project timeline should consider the possibility of a delayed start due to US Government and regulatory approvals taking significant time. ***Please consider the impact of a 1–3-month delay in starting your project after the May 1, 2024, award date.***
References Cited (*no page limit*)	List the references cited in the Research Strategy (including URLs or DOIs if available) using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).	
Career Development and Mentoring Plan (*2-page limit*)	The applicant should provide a detailed description of their career development goals and objectives. The applicant should then describe the mentoring plan including what the mentor's expertise is and how that aligns with the applicant's career goals, how the mentor will help build the applicant's leadership and independence and meet their professional development goals; a communication plan for ongoing, active engagement with the mentor; and how frequently the applicant will more formally meet with the mentor.	

Item	Description
Research Performance Site(s) (*1-page limit*)	Applicants should describe how the project benefits from unique features of the scientific environment or collaborative arrangements. A description of study locations should also be provided including how each proposed site contributes to the study and how the applicant will use these sites to complete the study protocol. ***Limit of 2 performance sites per application***.
Vertebrate Animals Section (*3-page limit*)	Include a summary description of the parent study and IACUC approval information for the study (approvals numbers, dates of study, PIs, organization). For the Pilot Application, please describe these procedures specific to the proposed study: **1. Description of Procedures** Provide a concise description of the proposed procedures to be used that involve live vertebrate animals. Identify the species, strains, ages, sex, and total number of animals by species to be used. If dogs or cats are proposed, provide the source of the animals. **2. Justifications** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro). **3. Minimization of Pain and Distress** Describe the interventions to minimize discomfort, distress, pain, and injury. These include analgesia, anesthesia, sedation, palliative care, and humane endpoints. **4. Method of Euthanasia** Provide a justification for methods of euthanasia that are not consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If answer is "No" to the question "Is method consistent with AVMA guidelines?", describe the method and provide scientific justification in the text field provided. For more information: https://olaw.nih.gov/guidance/vertebrate-animal-section.htm For more information, please view this OLAW video: https://olaw.nih.gov/vas-e-module/story.html. ***The collaborating RC will be required to provide Animal Welfare Assurance for any foreign sites and the RC will be required to establish an Interinstitutional Assurance with RTI and will be required to complete an audit by RTI. The collaborating RC should provide additional guidance/support as needed to help applicants navigate this topic.***

Item	Description
Human Subjects Research (*4-page limit*) *Fillable templates provided; download to complete*	Include a summary description of the parent study and IRB approval information for the study (approvals numbers, dates of study, PIs, organization). For Pilot Applications proposing human subjects research, either exempt or non-exempt, applicants must address the following elements on the Protection of Human Subjects: • Risks to the subjects • Adequacy of protection against these risks • Potential benefits of the research to the subjects and others • Importance of the knowledge gained or to be gained • Country- / institution-specific ethics / IRB regulations addressed For more information on human subjects research and guidance on completing this section, please visit the NIH website: https://grants.nih.gov/policy/humansubjects.htm and Office for Human Research Protections website: https://www.hhs.gov/ohrp/regulations-and-policy/index.html. The collaborating RC partner should provide additional guidance/support as needed to help applicants navigate this topic.
Other Supporting Documentation (*Templates provided)*	Start each document on a new page with complete header information. Include only those components described within this Call for Applications; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.
	Research and Other Related Project Information. Complete the R&R Other Project Information Form. This form includes questions on use of human subjects, vertebrate animals, and environmental impact. For guidance on completing the form, please see G.220 - R&R Other Project Information Form (https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.220-r&r-other-project-information-form.htm). (*Fillable template provided; download to complete*)
	Biographical Sketch and Other Support. All applications must include: • Applicant PI(s) Biographical Sketch (*five-page limit*) • Applicant PI(s) Previous/Current/Pending Support (*include funding amount from each support source – no page limit*) • Key Personnel Biographical Sketches (*five-page limit each*) • Key Personnel Current/Pending Support (*no page limit*) • Mentor Biographical Sketch (*five-page limit*) Please see the NIH website for instructions on completing the Biosketch (Non-Fellowship) (https://grants.nih.gov/grants/forms/biosketch.htm) and Other Support form (https://grants.nih.gov/grants/forms/othersupport.htm).
	Co-PI Plan (only needed if applying as Co-PIs) (*one-page limit*)**:** If two applicants are applying as Co-PIs on the same application, include a plan that details: • What each Co-PI will contribute to the proposed research study • How the Co-PIs will jointly work with the affiliated RC • How the Co-PIs will jointly manage the proposed study

Item	Description
	Facilities, Other Resources, and Existing Equipment (*template provided*): Describe the facilities, equipment, and other resources available for performance of the proposed project at each proposed site. Describe how containment facilities are appropriate for the proposed research. Indicate whether Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable.
	US Government Foreign Clearance Form (*template provided*). Applicants must complete the Foreign Clearance form. This form is required by the US Government to gain approval to conduct research at a foreign research site. If your research will be conducted in more than one foreign research site, please fill out a form for each site. Please ensure that the form is correctly filled out with the information about the institution overseeing the implementation of the award and administering the funds for the award, as well as correct information on human and/or vertebrate animal research. If the institution that will oversee the implementation of the award is different from the institution that will administer the funds and are located at separate foreign sites, please complete separate USG Foreign Clearance forms for each and identify their respective roles clearly. ***Definition of Foreign Component for Foreign Clearance Form:*** *The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are: collaborations with investigators at a foreign site anticipated to result in co-authorship; use of facilities or instrumentation at a foreign site; or receipt of financial support or resources from a foreign entity. Foreign travel for consultation is not considered a foreign component.*
Letters of Support (*2-page limit per letter*)	**(Required) Letters of Institutional/Organizational Support** *(two-page limit per letter)***:** Provide a letter (or letters, if applicable), signed by the appropriate organization official, reflecting the institution's commitment to the completion of the study, including protected time of the applicant to complete the study, laboratory space, equipment, and other resources available for the project. Include confirmation that the institutions can accept US Government funding and agree to the required US Government policies and regulations. If you are based at a foreign institution, the letter must include language confirming the institution can comply with the NIH Policy released September 15, 2023 and clarified here: NOT-OD-23-182: NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreements
	(Required) Letter of Collaboration from CREID Research Center PI *(two-page limit)***:** Provide a signed letter from the lead collaborating CREID RC contact PI that will demonstrate that the PI has the support or resources necessary for the proposed work. See Section 1.4 for questions the RC PI must address in the Letter of Collaboration.

Item	Description
	(Required) Letter from Research Center Mentor (*two-page limit*): Provide a signed letter from the designated RC mentor that demonstrates how the mentor will support the applicant as outlined in the mentoring plan.
	(If applicable) Letter from Primary Scientific Mentor (if different than RC mentor) (*two-page limit*): Provide a signed letter from the designated scientific mentor that demonstrates how the mentor will support the applicant outlined in the mentoring plan.
	(If applicable) Biosafety Letter (two-page limit): If you are planning to conduct research with hazardous agents, provide a signed letter from the entity biosafety professional (facility, laboratory, institution) where the work is to be conducted. The letter should document the rigor of the training, biosafety and biosecurity programs at the entity and the proficiency of the proposed investigative team.
Abbreviations	List of Abbreviations, Acronyms, and Symbols**:** Provide a list of all abbreviations, acronyms, and symbols used in the application
Checklist (*Template provided*)	Please complete and submit the submission checklist for the application. The checklist is intended to assist applicants to ensure that they submit a complete application package.
END of Components for Application Package File 1. Provide all applicable above as a single complied PDF with Table of Contents and continuous page numbers.	

Provide the following item as Application Package File 2	
Research and Related Budget and Budget Justification *Fillable template provided; download to complete*	A full budget, with total costs of no more than $150,000 (USD), must be submitted on the budget form available on the CREID Network website. • A budget justification which describes the labor and other direct costs necessary to complete the project must be included here. The budget should reflect direct and indirect costs for the 1-year period of award. The budget should include travel costs to attend the 3-day CREID Network Annual meeting in the Rockville, MD, area. If you plan to travel to another site or lab as part of your research study, please include those costs in your budget, staying within the budget ceiling of $150,000. • If you plan to purchase a piece of equipment, please note that any equipment purchases over $20,000 require a supplier quote and NIH approval upon award and prior to purchase. • Foreign institutions should use 8% as the standard indirect rate. • If two applicants apply as Co-PIs for a single application, the budget ceiling remains the same ($150,000 in total costs). If the two applicants are from different institutions, each applicant must provide a detailed budget, with the total of the two budgets not exceeding $150,000 in total costs. Each institution will receive a subaward for their portion of the project. No third level subawards can be established, so RTI will establish a subaward with each institution if there are two institutions involved in the application. • Because CREID Pilot Program funding is available as a subaward of the prime CREID CC NIAID award to RTI, all subawards will be subject to the same US Government policies and restrictions as the award for the CREID CC. • If your institution does not have adequate funds for a cost-reimbursement award (with monthly invoicing) and requires pre-payment of funds during the award year, please note this in your budget justification and outline a payment schedule that will function for your project.

3. Application Review and Selection Process

3.1 Review Criteria

To determine scientific and technical merit, all applications will be evaluated by a peer-review committee according to the following scored criteria.

3.1.1 Research Rational, Strategy, and Feasibility

- Are the project aims achievable and will they advance scientific knowledge or technical capacity?
- Are the Specific Aims clearly defined and tied to a research question(s)?
- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Are the potential problems, alternative strategies, and benchmarks for success clearly laid out and sufficiently addressed?
- Is the study, as proposed, likely to be completed in the designated time period and with the available budget?
- Is the statistical plan appropriate for addressing the research questions, given the design of the study?

- Are the sample size calculations clearly described and is the proposed sample size adequate given the goals of the study?

3.1.2 Significance & Impact

- Does the project address an important problem or a critical barrier to progress in the EID field consistent with the mission and objectives of the CREID Network?

3.1.3 Personnel

- Do the background and expertise of the PI(s) and other key personnel demonstrate their ability to perform the proposed work?
- Are the levels of effort by the PI(s) and other co-investigators appropriate to ensure the successful conduct of the project?
- Do the PI(s)' and co-investigators' records of accomplishment demonstrate their ability to accomplish the proposed work?

3.1.4 Environment

- Is the scientific environment appropriate for the proposed research?
- Are the facilities and resources adequate to support the research requirements?
- Are the quality and extent of organizational support appropriate for the proposed research?

3.1.5 CREID Research Center Collaboration Plan

- Does the project fit within the RC's overall objectives or expertise?
- Is the RC guidance integrated into the project and are the roles and responsibilities between the applicant and the RC collaborators complementary?
- Is the collaboration plan appropriate for the overall success of the project?

3.1.6 Mentoring Plan

- Are the career development goals and objectives appropriate and justified?
- Is the plan for communication appropriate throughout the project timeline?
- Are the roles and responsibilities in the mentor-mentee relationship appropriate and reasonable?
- Will the applicant's professional development goals be adequately met through this award?
- Is the mentor sufficiently involved to help build the applicant's leadership and independence and to meet the applicant's professional development goals?
- Does the mentor's biosketch demonstrate appropriate expertise to mentor the applicant?

3.1.7 Resubmissions

- For Resubmissions, Reviewers will evaluate the application as now presented, taking into consideration updates made in response to comments from the previous scientific review.

In addition, the following unscored criteria will contribute to the overall evaluation of the application:

3.1.8 Budget

- Is the budget appropriate for the proposed research and within the funding limitations?
- Is there sufficient level of effort for the PI(s) to complete the research study as described?

3.1.9 Vertebrate Animals

- Is the proposed research involving vertebrate animals scientifically appropriate, including the justifications for animal usage and protections for research animals?
- Does the applicant adequately describe the following?

- Description of procedures
- Justification of species and numbers of animals used
- Minimization of pain and distress
- Method of euthanasia

3.1.10 Protection of Human Subjects

- Does the applicant adequately describe what they plan to do and how IRB / ethics board approval will be obtained?
- If they have any participant-facing activities, does the applicant address issues of confidentiality, data management, participant risks, and compensation?

3.1.11 Inclusion of Women, Minorities, and Children

- If the study involves the use of human subjects samples / data, does the sample population involve all relevant populations?

3.2 Programmatic Review

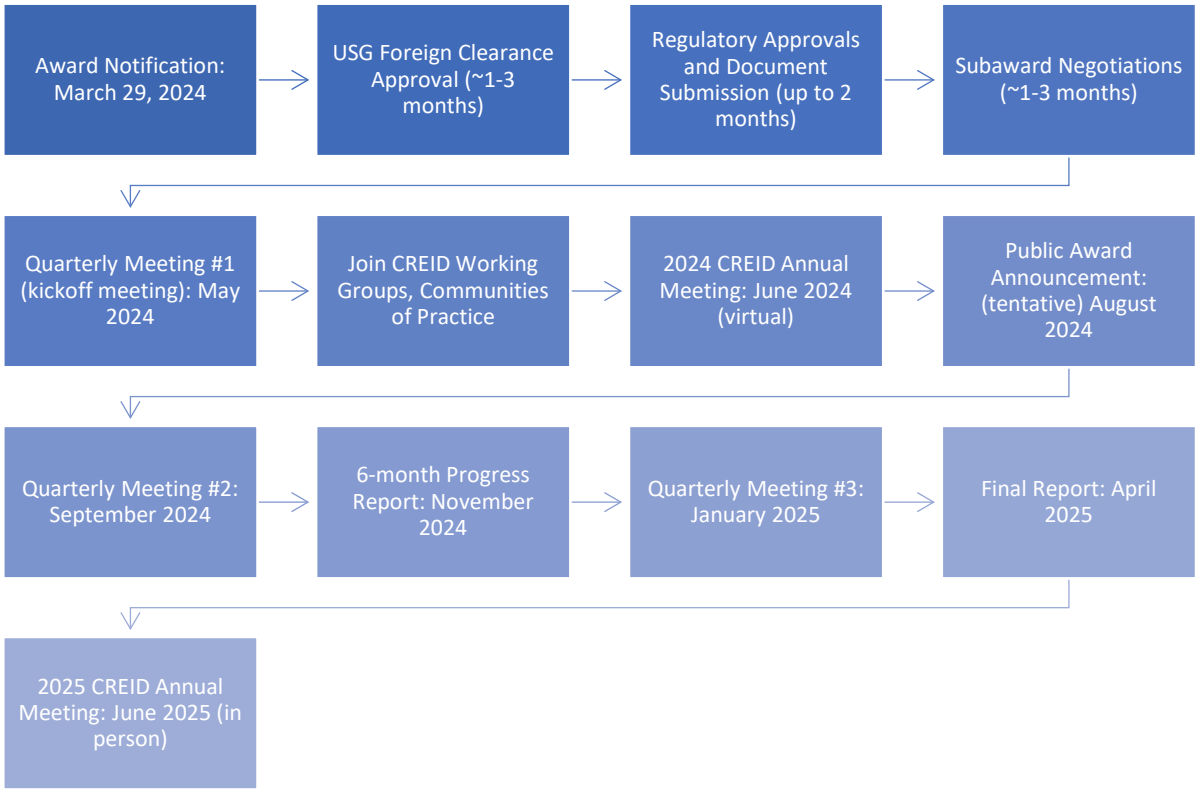
Following the Peer Review, the Programmatic Review of applications will be conducted by the CREID CC and the NIAID CREID Team. The CC, in collaboration with NIAID, will make funding recommendations using the following criteria:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the CREID Network, as evidenced by the following:
  - Relative impact
  - Program portfolio composition
  - Programmatic relevance
  - Adherence to the intent of the award mechanism
- Availability of funds

Final selection of research awards will be made by the CREID CC.

4. Post-Award Process and Expectations

4.1 Award Process Overview



4.2 Award Notification Procedures

Successful applicants will be notified via email by the CREID Coordinating Center within the noted program timeline. Upon notice of award, applicants will be required to respond with their acceptance and intent to conduct proposed work.

4.3 U.S. Government Approvals and Foreign Clearance

U.S. Government approvals are required prior to initiating the Pilot Research Award or establishing a subcontract from RTI for the award.

- NIAID is required to submit any project foreign components through internal US Foreign Clearance system for approval before awards can be initiated. Applicants submit the USG Foreign Clearance forms as part of their applications. Awards that include foreign components are subject to U.S. State Department approval. Foreign Clearance can take 1-3 months (or more), or additional time if awardees require changing any submitted Foreign Clearance information.
- The CREID CC and/or NIAID may require additional documentation/information as it pertains to planned select agent research.

4.4 Regulatory Approvals and Documentation

4.4.1 Human Subjects Research

The RTI Institutional Review Board (IRB) defers oversight of any human subjects research funded by the CREID Pilot Program to the study IRB of record (https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-

site-research.htm). An IRB Authorization form must be signed by the IRB of record and the RTI IRB before human subjects work can be initiated.

Pilot awardees must submit all required regulatory documents and approvals to the CREID CC before funded research can be initiated no later than 2 months after the award notice. This includes IRB approval, study protocol, CITI certificates for key personnel, etc., as appropriate. Information on study location (US and Foreign), site contacts, and Federal Wide Assurance (FWA) number (for human subjects' research) will be required. For more information on FWA, please see the U.S. Department of Health and Human Services website: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html

4.4.2 Animal Research

Pilot awardees must submit all required regulatory documents and approvals to the CREID CC before funded research can be initiated.

RTI will facilitate Pilot Awardee communication with the NIH Office of Laboratory Animal Welfare (OLAW) to determine the specific OLAW requirements for their project. Pilot Awardees will complete and submit all required regulatory documents and approvals to the CREID CC and OLAW before funded research can be initiated, no later than 2 months after the award notice.

RTI Regulatory Affairs defers oversight of any vertebrate animal research funded by the CREID Pilot Program to the collaborating RC IACUC. An Interinstitutional Assurance (IIA) agreement must be signed between the collaborating institution and RTI's Regulatory Affairs specialist before animal research work can be initiated. To establish the IIA, RTI will conduct an audit of the RC institution's IACUC. These institutions must submit at a minimum:

1. IACCU members backgrounds/titles, roles, and length of service on the committee
2. The results and timing of the past two inspections of IACCU operations by a representative of the USDA.
3. The statement of Animal Welfare Assurance describing how the institution complies with PHS policy.
4. In the past five years, have there been any compliant investigations? If so, please describe with timing of events and outcomes.

4.5 Subaward Procedures

Once U.S. Government approval criteria and regulatory documentation are met, subawards will be made to each awardee by RTI (on behalf of the CREID CC) to the applicant's institution that is administering the funding. **These will be subawards issued by RTI from the prime CREID CC NIAID award, not the collaborating CRIED Research Center.**

If your application is recommended for funding, subaward negotiations will be held between your institution that is managing the subaward and RTI to establish the scope of the final project. All official negotiations of the budget, terms, and conditions of any resulting subaward will be conducted between the Business Official of your institution and the RTI Subcontracts Specialist. All subawards, and changes to all subawards that result in substantive changes to the budget, including major modifications of the awards and changes across cost categories, require approval from the CREID CC and NIAID.

4.6 Subaward Letters

If needed, RTI will issue initial subaward letters allowing for up to 10% of the total budget to be spent while full subaward negotiations take place, to allow awardees to initiate start-up activities.

4.7 Award Announcements

After a subaward has been executed between RTI and the Pilot Awardee home institution, awarded studies will be featured on the CREID Network website for the Pilot Research Program and as part of the CREID Network monthly newsletter. Announcements will include PI, home institution, collaborating CREID Research Center, and a synopsis of the project, based on the application abstract.

4.8 Invoicing

The subaward documents include invoice instructions the awardee institutions can use to submit for payment. Payment schedules will be defined during the subaward negotiations, which may include pre-payment, monthly invoicing, or quarterly invoicing.

The first invoice will require extra time for payment, especially for first-time awarded foreign institutions, as RTI accounting must conduct accounting set-up and ensure secure payment processing. Please plan accordingly and anticipate approximately one month processing time for first-time invoice payment.

4.9 Data Sharing

The project's data management and sharing plan should follow the NIAID Data Management and Sharing Guidelines: https://www.niaid.nih.gov/research/data-sharing-guidelines

Sharing unpublished data among Network collaborators is one of the core principles of the CREID Network. Awardees are encouraged to work with their mentor to establish infrastructure for the sharing of data that is not or will not be made immediately publicly available. The recommended infrastructure/repository for this type of data sharing is ImmPort (https://www.immport.org/home) or BV-BRC (https://www.bv-brc.org/), so the awardee is encouraged to set up a free account. Awardees may also propose an alternative infrastructure if one is available.

4.10 Reporting

One interim progress report (6-month) and a final report (12-month) will be required by each awardee PI or co-PI team. As part of these reports, and to comply with NIH policies, all Pilot Program Awardees are required to securely share electronic copies of all lab notebooks, data, and documentation that supports the research outcomes as described in the interim and final progress reports via private, limited access MS Teams/Sharepoint folders. The CREID CC submits its annual Research Performance Progress Report (RPPR) by March 1 each year as required by the terms of the prime award to RTI, and Pilot Program progress reports are required components of this report. The report template and links to private, secure folders for sharing electronic copies of lab notebooks, data and documentation will be provided by the CREID CC.

In addition to written progress reports, PIs (and Co-PIs if applicable) will give oral presentations at the CREID Network Annual Meeting and may be requested for Working Group, Communities of Practice, and Steering Committee meetings. If there are Co-PIs, both are expected to have joint responsibility, shared equally by both.

4.11 Citing CREID in Scientific Products

Pilot Program awardees are required to cite the CREID CC award number (1U01AI151378) and the assigned Pilot Program subaward number in all scientific products resulting from the work funded through this program, including conference presentations and posters, peer-reviewed journal articles, and other scientific endeavors.

5. Capacity-Building and Mentoring Resources

The Pilot Research Program will include capacity-building and mentoring activities and resources. Capacity-building and training activities will be implemented in partnership with the CREID RCs and will complement the mentoring activities proposed by each awardee with their mentor and affiliated RC. Activities and resources will include establishing a mentoring agreement between the awardee and their mentor, holding quarterly meetings between the CREID CC and the awardees, including the awardees and their mentors in CREID Network Working Groups, peer mentoring, capacity building webinars, and in-person events.

5.1 Needs Assessment

The CREID CC will conduct a needs assessment survey of awardees and their mentors at the start of the award period to determine webinar topics and other capacity-building priorities for the awardees.

5.2 Pilot Research Program Mentor

Each awardee has identified one or more mentors as part of their application. The CREID CC will provide an agreement that each party must sign to formally establish the mentoring relationship. The agreement will establish clear expectations for both the mentor and the awardee. This collaboration will provide a platform for the Pilot Program awardee to discuss their research ideas and receive critical feedback on how to strengthen their approach and to understand and avoid roadblocks. The mentor can also provide connections to others working on the same ideas for collaboration and help the awardee avoid duplication of effort.

The CREID CC will be available on an ad hoc basis to the mentors to provide guidance or support as needed.

The Pilot Program awardees may need statistical mentoring from a CREID CC or Network statistician for guidance on issues related to study design and statistical analysis. If needed, the CREID CC will identify a statistician to provide this guidance.

5.3 Quarterly CREID CC and Pilot Program Awardee Meetings

The CREID CC will convene awardees on a quarterly basis to check in on how their research is progressing and to ensure that the mentoring relationship is going well. The CREID CC will use this meeting to identify additional topics for capacity-building webinars. The first quarterly meeting will serve as the kickoff meeting for the program.

5.4 CREID Network Working Groups and Communities of Practice

CREID Network Working Groups and Communities of Practice are established under the auspices of the CREID Steering Committee to address scientific issues, undertake specific activities, propose and review issues, policies, and procedures of interest to the CREID Network, and to support knowledge exchange. Awardees and their mentors are invited to participate in the WGs and CoPs as part of the Pilot Program. Current CREID WGs and CoPs include the following:

- Outbreak Research Response WG
- Capacity Building and Sustainability WG
- Repository, Assay, and Data CoP
- Other CoPs TBD

5.5 Peer Mentoring

The CREID CC will facilitate peer mentoring by forming a cohort among the awardees so they can share information, ask questions, and discuss scientific research and career development issues with each other. The CREID CC will utilize Microsoft Teams to create a peer-to-peer mentoring community to foster and enhance real-time communications. Teams includes chat threads that can be designated for different conversations (e.g., biospecimen management, data analysis, quality assurance, specific viruses, such as Coronavirus, Flavivirus). The CREID CC Pilot Program coordinator will be part of these chat threads and will monitor the online engagement to identify and resolve issues that may arise.

5.6 Capacity-Building Webinars

The CREID CC will coordinate webinars several times a year utilizing Zoom to include formal training presentations and question-and-answer discussion sessions between CREID Network investigators and awardees on an area of interest. These webinars will be recorded for viewing later. Possible topics could include (1) protocol development; (2) high-quality data collection and processing; (3) efficient development of study materials, including manuals of operations, and training materials; (4) detailed project team training on all aspects of implementing a study; (5) use of data capture systems; (6) study data oversight, quality assurance, and monitoring procedures; (7) statistical analysis; (8) biospecimen tracking; (9) lab quality assurance; and (10) presentation skills.

5.7 CREID Network Annual Meeting

Pilot Program awardees are expected to attend and participate in the CREID Network Annual Meeting. The CREID CC will coordinate capacity-building and mentoring activities as part of the Annual Meeting. A Pilot Research Program session will be on the agenda for awardees to present on their research project. **2024 Pilot awardees will participate virtually in the 2024 Annual Meeting and in person at the 2025 Annual Meeting where the PI (both, if there are Co-PIs) will present results**. Mentoring activities could include speed mentoring sessions where investigators spend 10 minutes discussing a topic of interest with a senior researcher, then move on. These sessions will be held individually or in small groups of awardees paired with a senior researcher and may be held virtually as needed. Capacity-building activities could include a brief topic presentation or Q&A session followed by a mixer to allow early career and senior investigators the opportunity to connect on scientific areas of joint interest and develop mentoring relationships.

6. Pilot Research Program Evaluation

The CREID CC will evaluate the Pilot Research Program annually through a series of surveys conducted with the awardees, the mentors, and the CREID RC PIs. The evaluation will focus on the Pilot Program details and the

mentoring and capacity-building activities. The CREID CC will use this feedback to make changes to the program in future years.

The CREID Network External Advisory Committee will review the progress of the CREID Network annually, including the CREID CC, and will provide recommendations to NIAID.