

CREID Network: Pilot Research Program 2022 Call for Applications

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

Responses to Questions November 15, 2021

Question	Response
Regarding the CREID pilot program,	It is definitely acceptable to have an eligible Co-PI at the RC
is it expected/acceptable that there	that will co-lead study. Please just note that separate awards
be a budget for the RC collaborating	will have to be made to each of the Co-PI's institutions/
site that will assist the pilot site in	organizations in that case, with both awards combined totaling
establishing the study? I have an	the \$150K award limit. Also, both the Co-PIs must be
inquiry about a Co-PI study that	investigators that meet the award eligibility criteria. Please
would include a team member	also note there is a limit of up to two Co-PIs.
already associated with the CREID. The CREID member is a	
junior investigator/post-doc that will	
work with the international Co-	
PI/team on the study. I know Co-PIs	
are allowable but I wasn't sure if we	
could have the Co-PI already	
associated with the Center.	
Our research team is planning to	Contact information for each Research Center is on the CREID
apply for the CREID Research Pilot	Website on the Research Center pages. On the navigation
Program, and we couldn't find all	pane, you can find the list of each Research Center and their
the contact email for each Research	webpages.
center for collaboration. If you have	
their contact information, please let	
me know.	

Page 1



Question Response I came across The CREID Network The webinar and application guidelines are posted on the Pilot Research Program call for CREID website here: https://creid-network.org/pilot-program. applications, which supports, trains, and mentors the next generation of The purple navigation panel at the top of the page has a dropemerging infectious disease down menu for Research Centers. There you will find researchers. I understand a webinar webpages for each Research Center alongside contact was held on this application but I information. missed it. I would be grateful if the recorded version is sent to me via this mail. This will give me the opportunity to understand what's expected of me as an applicant. I will also want to find out the procedure in getting in touch with a collaborator from CREID to enable me to be in good standing for the application. I look forward to hearing from you. I am from an LMIC but currently I Please carefully review the eligibility criteria to determine your eligibility. Being from an LMIC is not the only eligibility criteria. am working as a post doc at university in the US. Am I still eligible as someone from LMIC even that I would execute the research during my post doc in the USA? To apply for the Pilot Research We require all applicants to have a formal collaboration with a CREID Research Center. Please contact one or more CREID Program 2022, I must have a collaboration with one of CREID PI's, Research Centers to discuss your research interests. Contact once I would be working from information is on the CREID Website on the Research Center another institution. Does this pages. collaboration must be established with someone in one of the research centers or with someone from the research sites would also be a possibility? I thought that would be interesting if I could collaborate with one of the research sites in the LMIC I am from, but I'm not sure if this would be a possibility according to the rules of the application. I have not received any grants listed Please carefuly review the eligibility criteria included in the under the following link in the NIH Call for Applications and discuss with the collaborating website: Research Center you will be applying under to determine if List of smaller grants & awards that you meet the requirements. maintain ESI status | grants.nih.gov Therefore, can I apply under the "New Investigator" category? Or is the LMIC category more suitable?

Updated: 11/15/2021



Question	Response
I need some assistance in identifying the category of eligibility for me. I have not received any grants listed under the following link in the NIH	Please carefuly review the eligibility criteria included in the Call for Applications and discuss with the collaborating Research Center you will be applying under to determine if you meet the requirements.
website: <u>List of smaller grants & awards that</u> <u>maintain ESI status grants.nih.gov</u>	
Therefore, can I apply under the "New Investigator" category? Or is the LMIC category more suitable?	
Does a project about Human Papillomavirus infections could be eligible and belong to the research priorities for the CREID program?	Please discuss this with the collaborating Research Center you will be applying under to determine if this falls under their research priorities.
 I am originally from Brazil and I was wondering if I would still be considered a LMIC candidate despite working in the US. Is it ok to have a collaboration with a CREID research site, or the collaboration must be with a CREID research center? Since I am from Brazil I thought it would be nice to collaborate with one of the research sites in Brazil. 	Please carefuly review the eligibility criteria included in the Call for Applications and discuss your interest in collaborating with one of the CREID research sites with one of the CREID Research Centers. Each Research Center is limited to supporting up to 3 applicants for this round of funding.
I wish to register for your pilot research program. Please kindly provide me with directions.	Please carefully review the requirements for the Pilot Research Program on the website (https://creid-network.org/pilot-program) and connect with one of the CREID Research Centers to determine collaboration opportunities.

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Is there an issue with a proposal, and what authorization is necessary to work with possible CCHF specimens (tick) in BSL-3, due to it being a US Federal Select Agent? These specimens will be used for isolation of nucleic acids for detection and sequencing CCHF, but not culturing or isolating the virus. Also note the possibility of CCHS was included in the original Research Center application, and they are out target sponsor, although they did not yet seek US Federal Select agent approval for working with CCHF as of yet.

There are no issues with applying for pilot funding in this case. The exemption request is a reasonable path forward as long as you follow the rules pasted below (sources linked at the bottom of the email) and can ensure compliance with DMID and with local entities prior to award. The CREID Network has multiple Approved Select Agent Entities that could receive and store material via approved transfer process if that is needed.

§ 121.5 Exemptions for VS select agents and toxins.

- (a) Diagnostic laboratories and other entities that possess, use, or transfer a VS select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:
 - (1) Unless directed otherwise by the Administrator, within 7 calendar days after identification of the select agent or toxin, the select agent or toxin is transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization or inactivation process;
 - (2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported;
 - (3) Unless otherwise directed by the Administrator, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization or inactivation process within 7 calendar days after delivery of patient care by heath care professionals has concluded; and
 - (4) The identification of the agent or toxin is reported to APHIS or CDC, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within 7 calendar days after identification.
- (b) Diagnostic laboratories and other entities that possess, use, or transfer a VS select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:
 - (1) Unless directed otherwise by the Administrator, within 90 calendar days of receipt, the agent or toxin is transferred in accordance with § 121.16 or destroyed onsite by a recognized sterilization or inactivation process; (2) The agent or toxin is secured against theft, loss, or release during the period between identification of the

Page 4



- agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported; and
- (3) The identification of the agent or toxin, and its derivative, is reported to APHIS or CDC. To report the identification of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 days of receipt of the agent or toxin. A copy of the completed form must be maintained for 3 years.
- (c) Diagnostic reagents and vaccines that are, bear, or contain VS select agents or toxins that are produced at USDA diagnostic facilities will be exempt from the requirements of this part.
- (d) Unless the Administrator by order determines that additional regulation is necessary to protect animal health or animal products, products that are, bear, or contain VS select agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:
 - (1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);
 - (2) Section 351 of Public Health Service Act (42 U.S.C. 262);
 - (3) The Virus-Serum-Toxin Act (21 U.S.C. 151-159); or
 - (4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 et seq.).
- (e) The Administrator may exempt from the requirements of this part an experimental product that is, bears, or contains a VS select agent or toxin if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation under this part is not necessary to protect animal health or animal products. To apply for an exemption, an individual or entity must submit APHIS/CDC Form 5. A written decision granting or denying the exemption will be issued. The applicant must notify APHIS when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.
- (f) In addition to the exemptions provided in paragraphs (a) through (e) of this section, the Administrator may grant a specific exemption upon a showing of good cause and upon his or her determination that such exemption is consistent with protecting animal health or animal products. An individual or entity may request in writing an exemption from the requirements of this part. If granted, such exemptions are valid for a maximum of 3 years; thereafter, an individual or entity must request a new exemption. If a request for exemption is denied, an individual or entity may request reconsideration in writing to the Administrator. The



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	request for reconsideration must state all of the facts and
	reasons upon which the individual or entity relies to show
	that the exemption was wrongfully denied. The
	Administrator will grant or deny the request for
	reconsideration as promptly as circumstances allow and will
	state, in writing, the reasons for the decision.
	[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct.
	16, 2008; <u>77 FR 61078</u> , Oct. 5, 2012; <u>79 FR 26831</u> , May 12,
	2014; <u>82 FR 6208</u> , Jan. 19, 2017]

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