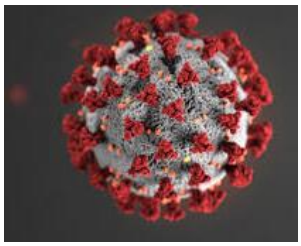
West Virginia Clinical and Translational Science Institute

Pop-Up COVID-19 Funding Opportunity



DEADLINES:	QUICK LINKS
Letters of Intent: **Not Required** *Full Applications:* **Accepted on Rolling Basis until April 21, 2020** **CONTACTS:** **Camille Charlier, MS** Pilot Grant Program Coordinator ccharlie@hsc.wvu.edu	**Full Text Announcement** **Eligibility** **Application Instructions** **Human Subjects Protection** **Budget** **Review and Selection Process**

ATTENTION: WVCTSI-funded projects are NOT eligible for the WVU IRB Flex Model as per Page 2 of the Flex Model Procedures. Please see Table 2 below for details.

FULL TEXT ANNOUNCEMENT

Funding Opportunity Description

Coronaviruses are a diverse family of viruses that cause a range of disease in humans and animals, and there are currently no approved coronavirus vaccines or therapeutics. In January 2020, a novel coronavirus, COVID-19, was identified as the causative agent of an outbreak of viral pneumonia centered around Wuhan, China. Current information regarding confirmed cases is changing daily and can be found on the Centers for Disease Control and Prevention website (https://www.cdc.gov/coronavirus/index.html). Transmission characteristics and the associated morbidity and mortality are not completely understood, but there is clear evidence of human-to-human transmission. Many other aspects of the disease are also poorly understood, resulting in an urgent public health need to better understand COVID-19.

WVCTSI is accepting applications for clinical and translational research focusing on COVID-19.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is twelve (12) months.

Budget

The budget is limited to a maximum of $30,000 in total direct costs for twelve (12) months. Please see Application Instructions for detailed allowable expenses.

Eligibility Information

Last updated 4/7/20

- Principal Investigator (PI) **must hold a faculty appointment** or equivalent at the time the award is announced. Appointments can be held at CAMC Institute/WVU Charleston, Marshall University, West Virginia School of Osteopathic Medicine, and West Virginia University. Individuals holding postdoctoral fellowships or other positions that lack independent status are not eligible to lead pilot projects. VA investigators may apply and receive CTSI services, however, regulations do not permit CTSI to fund federal agencies.
- Note that Marshall University faculty members must hold an appointment in either the School of Medicine or the School of Pharmacy. Other Schools and Colleges at Marshall University are NOT currently eligible for WVCTSI Pilot grants.

Application Instructions

Format Specifications

- Font restrictions: Use a font size of 11-point or larger. The only acceptable fonts are the following: Arial, Helvetica, Palatino Linotype, or Georgia. *Please use one single font throughout the document.*
- Font color: Black only. Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch.
- Page Margins: Use standard paper size (8 ½" x 11). Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins. Specifically, do not enter the PI's name or page numbers in the margins (as was past practice with hard copy grant proposals). Do not include any information in a header or footer of the attachments.
- Page Formatting: Applicants are strongly encouraged to use only a standard, single-column format for the text.
- Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnote: You may use a smaller type size (9 or 10 point) but it must be in black, readily legible and follow the font typeface requirement. Color can be used in figures; however, all text must be in black, clear and legible.
- Page Limits: Although many sections of the grant application are described as separate sections, the page limits must be followed or the proposal will be returned without review and not considered for funding. In addition, the appendix should not be used to circumvent the established page limits.

Applications must emailed to Camille Charlier as a single PDF with PI's Department Chair copied on the email.

Note:

- Do not scan documents unless absolutely necessary as this results in excessively large files
- Do not submit a PDF Portfolio
  - Instead, please use the "Combine Files" feature in Adobe Acrobat or equivalent file management software.
  - If one of your PDF documents cannot be combined, export it and save it as a Word file first. Combine this new Word file with the rest of your application using the "Combine Files" feature.

Please follow the detailed instructions below:

- Table 1 items are required for ALL applications.
- Table 2 items are required as applicable to your project.

If you have any questions, please contact us prior to submission.

Table 1. Required Content for ALL Full Applications

SECTION	DESCRIPTION	CONTENT LIMIT
Face Page	Use the Pop-Up COVID-19 Application Template.	N/A
Project Abstract	Use the Pop-Up COVID-19 Application Template.	30 lines or less
Approach/Research Strategy	Use the Pop-Up COVID-19 Application Template. Include the sections below	Up to 6 pages total (see breakdown below)
	A. Specific Aims/Objectives State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.	1 page max
	B. Research Plan Organize the Research Plan in the specified order and using the instructions provided below. Start each section with the appropriate section heading: Hypothesis, Background, Significance, Innovation, and Approach.	5 pages max
	1. Background Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.	
	2. Hypothesis Clearly and briefly define the hypothesis of the project.	
	3. Significance • Explain how the project is of translational significance. • Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice. • Describe how relevant concepts, methods, technologies, treatments, services, or preventative interventions will be changed if the proposed aims are achieved.	
	4. Innovation • Explain how the application challenges and seeks to shift current research or clinical practice paradigms. • Describe any novel, theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s). • Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.	
	5. Approach • Describe in detail the overall strategy, methodology, sample selection and size, subject/patient enrollment, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. • Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. • If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the	

	proposed work. Clearly describe how each partner will be engaged in the development and/or implementation of the pilot study.	
References	Use the Pop-Up COVID-19 Application Template to list cited literature. Given the length of the application, investigators should strive to provide a relevant, although not exhaustive bibliographic review.	No limit
Budget & Budget Justification	Use the Pop-Up COVID-19 Application Template. For all funding cycles, the budget is limited to a **maximum of $30,000** in total direct costs with a performance period of **twelve (12) months**. **Refer to the Budget section below for allowable and unallowable costs.**	No limit
NIH Biosketch	Please follow the NIH "Biosketch instructions – non-fellowship" link and use the NIH "Blank biosketch format – non-fellowship" to format each biosketch.	5 pages each
Letter of Support	Given the current workload and stress related to COVID-19**, a Letter of Support is not required BUT Department Chair should be made aware of investigator's intent to apply for funding, and carbon copied on email submission.**	

Budget

General

- Personnel: if possible, please name co-investigators or postdoctoral associates in your budget justification. Naming an individual in the budget justification does not represent a commitment on your part to hire that individual.
- Equipment: equipment costs (which are equal to or greater than $5,000 single unit purchase price, useful life of one year or more) must be justified via a vendor quote for the item(s) you are requesting.
- Travel: Conference Travel is NOT permitted for this funding opportunity. For field work and other research-related travel, please provide detailed information about the number of people making each trip, its duration, and other information.
- Materials and Supplies: provide a list of the general types of expendable materials and supplies that will, in your estimation, be required to carry out the research you are proposing. Supplies should be broken down into common categories.
- Publication/Documentation/Dissemination Costs: $1,000.00 maximum.
- Consultants: provide justification for the rate. If travel and subsistence costs are not factored into the consultant(s) cost, these should be justified separately, but still be considered a part of the total cost of the consultant(s).
- Subcontracts/Subawards: most of the justification for a subcontract should come from the sub award partner(s). Please refer to Section VII. Clinical and Translational Pilot Grants Program Contact to determine who you should contact if you have any additional questions regarding subcontracts/subawards.
- Other Direct Costs: Provide quotes, catalog prices, or other published information to justify proposed rates for other costs.

Allowable Costs

- Funds are to be used for the conduct of the project, including supplies, subject payments, assays, etc.
- WVCTSI Pilot Grants allow up to 10% of an award to be used for PI salary support (including fringe benefits). Any salary support requested from the grant must be matched by the PI's home department in the form of matching funds. At this time, no faculty Co-I salary may be charged to the grant.
- Travel funds that are needed *for study conduct* are allowed, if essential. Travel to collect data or for

collaboration purposes can be justified separately in the budget section.
- Data analysis costs
- Research assistant salary support; applicants must account for fringe benefit costs when considering research assistant salary levels.
- Non-faculty personnel salary support
- Project specific specimen collection/analysis or testing
- Chemistry and biological lab supplies
- Purchase of cell lines, cultures reagents, etc.
- Animal purchase and housing costs
- Specimen collection/analysis or testing
- Participant reimbursement

Unallowable Costs
- Funding is not available for student support.
- Funding will not be awarded as bridge funding for ongoing, competitive projects.
- Conference travel
- Facilities and administrative costs, also known as indirect costs, are not permitted.

Table 2. Additional Content As Applicable

SECTION	DESCRIPTION	CONTENT LIMIT
Human Subjects Protection	**All Human Subjects studies must include:** The "Human Subjects Template for WVCTSI Funded Projects" form. **Reference information concerning NIH definitions of Human Subject research and Clinical Trials can be found here.** * Note: Clinical Trials MUST include a study timeline (Section 2.7)	N/A
Clinical Protocol AND Timeline	**Clinical Trials MUST submit a clinical protocol in addition to their Research Strategy. Protocol MUST include a clear timeline of the project.** • Please use the WVU IRB form "Investigator Initiated Protocol Template". Note that investigators can use templates from their home institutions, however this form is a free resource from WVU available to all partner sites. • WVU investigators can also use Protocol Builder, an online tool to build clinical protocols for a variety of study types. Please refer to the Protocol Builder section at the bottom of the WVU IRB Guidance page for additional information.	No limit
Vertebrate Animals	Please use NIH PHS 398 Continuation Page form(s) (Continuation Format Page) and the NIH Animal Welfare instructions. The following headers MUST be clearly labeled: • Description of Procedures • Justifications • Minimization of Pain and Distress • Method of Euthanasia	No limit
IRB/IACUC	IRB/IACUC approval or proof of submission is NOT required at time of application. However, full approval is expected within 60 days following award notification and required before funds can be released. **ATTENTION: WVCTSI-funded projects are NOT eligible for the WVU IRB Flex Model as per Page 2 of the Flex**	

	Model Procedures. Projects with an existing Flex approval are REQUIRED to resubmit their IRB prior to application to the WVCTSI Pilot Grant Program.	
Compliance	CITI certificates are NOT required at time of application. However, proof of compliance will be required before funds can be released.	N/A
	Human Studies – Non-Clinical Trials A minimum of one course from the "Human Research" curriculum group **Human Studies – Clinical Trials** A minimum of one course from the "Human Research" curriculum group AND the Good Clinical Practice (GCP) module. ***See NIH clinical trial criteria here.***	
	Vertebrate Animals Any course from the Animal Research curriculum groups as applicable to your project.	

Review and Selection Process

Only the review criteria described below will be considered in the review process.

A. Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

B. Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each.

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment
- Clinical Trials only – Study Timeline

An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

C. Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards
- Radiation Safety and Hazardous Materials
- Budget and Period of Support

As part of the scientific peer review, all applications:

- Will be assessed on the scientific and technical merit of the proposed project and relevance of the proposed project to outlined programmatic priorities.

Final funding decisions will be made by WVCTSI leadership taking into consideration programmatic priorities and availability of funds. Appeals of initial peer review will not be accepted for applications submitted in response to this RFA.

Award Notices

The formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant via email for successful applications.

Selection of an application for award is NOT an authorization to begin performance. Any costs incurred before receipt of the NGA are at the recipient's risk.

Reporting

PI's that receive a WVCTSI COVID-19 Pop Up Funding will be required to submit a progress report every three (3) months as defined by the project period of performance. A final progress report, invention statement and the final itemized expenditures are required for closeout of an award

Contact	Phone Number	Email
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