COVID-19 PreClinical Research Discovery Fund (C19PcRDF) Application Guidelines 2020

Eligible

- Pre-clinical SARS-COV-2 related research including basic science/laboratory-based research and animal studies
- All full-time Johns Hopkins University Faculty (Fellow, house staff or student proposals must be submitted under the auspices of a full-time faculty member mentor as PI)
- **Projects that involve human research subjects <u>will not</u> be considered**

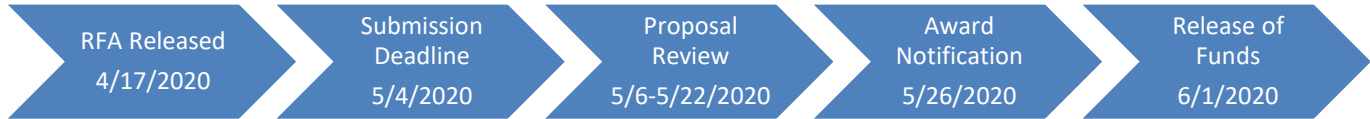|	
Budget	Up to $50,000.00 USD
Number Available	Maximum four projects will be funded
Funding Source	Johns Hopkins University
Grant Period	Six months, with a possible six-month no-cost time extension upon review
Application	hyperlink: C19PcRDF
	Web page https://hopkinsinfectiousdiseases.jhmi.edu/research/covid-19-preclinical-research-discovery-fund/
Submit Via Email	Submit the application and supporting documents via email, C19PcRDF@jhmi.edu
Contact	Email: C19PcRDF@jhmi.edu; Phone: 410-302-4753

COVID-19 PreClinical Research Discovery Fund, Application Guidelines 2020
Johns Hopkins University, School of Medicine

Tentative Project Timeline

Application Submission Deadline   Monday, May 4, 2020 at 11:59 PM
Anticipated Award Notification   On or before Tuesday, May 26, 2020
Award Start   June 1, 2020

RFA Released 4/17/2020 → Submission Deadline 5/4/2020 → Proposal Review 5/6-5/22/2020 → Award Notification 5/26/2020 → Release of Funds 6/1/2020

- **The application and review timeline may be altered due to unforeseen circumstances. Any alterations in the timetable will be conveyed via email to all applicants.**

Dissemination Plan

- University-wide web and email announcements will be sent at least twice for each application period.
- Any alterations to the program and the Request for Application will also be broadcast through these methods.
- C19PcRDF proposals and all application documents must be received by 11:59 PM on May 4, 2020.
- Applicants will be notified of acceptance or denial of the grant request on or before May 26, 2020.

Program Goals

The COVID-19 PreClinical Research Discovery Fund (C19PcRDF) is designed to accomplish the following goals

- To promote research by providing funds that will support projects focused on COVID-19 or SARS-CoV-2 pre-clinical research. Pre-clinical research includes animal, basic science, and laboratory-based research. **C19PcRDF will not support human subject translational clinical research or trials.**
- To encourage scientific impact, novelty and merit in experimental design.
    - Proposals funded will be geared for completion within six-months and demonstrable impact.
- To foster novel, cross-disciplinary collaborative pre-clinical research (as feasible) among schools of the Johns Hopkins University and with non-Johns Hopkins University research partners.
- To support projects with the potential for subsequent funding from other sources.

Eligibility

- Full-time faculty members of Johns Hopkins University.
- The grant is offered university-wide. Cross-discipline and cross-school collaborative research is encouraged. Any full-time faculty person from within Johns Hopkins University (JHU), including the schools of Medicine, Public Health, Nursing, Engineering, Applied Physics Lab, Business, and Arts/Sciences may apply.
- Only Johns Hopkins University faculty members holding a terminal degree (MD, DO, PhD, PharmD, DVM, or equivalent) may serve as Principal Investigator (PI).
- Hopkins-affiliated postdoctoral fellows, house staff, medical school students, PhD students, graduate students, and undergraduate students may not submit a C19PcRDF application. Still, they can coordinate with a faculty PI who submits and takes responsibility for the C19PcRDF proposal and execution. However, they may not be the PI.
- Current and previous awards and grants to the PI, such as NIH grants, do not impact C19PcRDF award eligibility.
- If a C19PcRDF grant is awarded, additional awards obtained after the distribution of C19PcRDF funds will not impact C19PcRDF funds.

Regulatory Requirements
- All C19PcRDF awarded projects involving animals must be approved by the Johns Hopkins University Institutional Animal Care and Use Committee (IACUC). Such projects will be carried out using the guidelines and policies developed by the IACUC.
- While advance approval by the IACUC is not a prerequisite for submission of a C19PcRDF application, investigators should be aware of the impact of these and other necessary administrative or regulatory reviews on the project timeline and feasibility. If an animal-based project does not meet with IACUC approval, C19PcRDF funding will be terminated and funds forfeited.

Conflict of Interest
- At the time of application, before funds are awarded, and throughout the project period, it is the responsibility of the PIs and all members of the research team to report any financial or fiduciary interest that might appear to present a conflict of interest to the C19PcRDF and the University Office of Policy Coordination, using the JHU disclosure system.
- The presence of a conflict of interest does not disqualify investigators from receiving this award but will require the review and management of this conflict by the Committee on Outside interest, and notification of the Grant Review Committee
- The failure of any research team member to disclose all outside interests could result in the termination of the C19PcRDF award and the disallowance of all study costs.

Project Topics
- C19PcRDF provides funds for critical pre-clinical COVID-19 or SARS-CoV-2 research. **C19PcRDF will not support human subject clinical research, trials, or any project with a direct human component.**
- Proposals should be using basic science/laboratory or animal study approaches.
- Proposals may be exploratory in nature.
- C19PcRDF will support proposals that may have the potential for human translational research that may impact the dissemination, diagnosis, treatment, and outcomes associated with COVID-19 disease.
- Research must demonstrate a hypothesis with the potential for human COVID-19 disease impact.
- Collaborative research within the Johns Hopkins community is encouraged, as feasible.

Examples of Proposals include...
- Innovative approaches to facilitate understanding of SARS-CoV-2 viral pathogenesis
- Approaches that interrupt host cell biosynthesis of viral particles or virally-driven immune responses
- Development of pilot data that lead to novel methods leading to improvements in diagnosis or management of COVID-19

Monetary Support
- Funding of this program is through an initiative by the Johns Hopkins University.
- **Requests must be no more than USD 50,000.** Requests exceeding $50,000 will not be reviewed.
- A realistic budget proportionate to the scope of the project must be included in the C19PcRDF application package. The budget must be submitted using the *C19PcRDF Budget Template 2020*. Funds may be used only for support of research conducted primarily at Johns Hopkins institutions. **Subcontracts with outside institutions or facilities are permitted, but should not exceed 50% of the total requested budget.**
- Funds may be used for staff salary or student stipends. If salary support is requested for an individual, that individual must be listed as a member of the research team on the C19PcRDF application.

- **Total salary support should not exceed 50% of the total requested budget** unless there is a strong justification for an additional level of salary support. Justification for exceeding the 50% cap is to be submitted in the form of a written letter and appended to the application package.
- Funds may not be used for travel.
- Funds may be used for supplies, equipment, and laboratory services.
- Funding will be for six months, with the award state date of June 1, 2020.
- At the end of the grant period or at the time of early termination, all unspent C19PcRDF funds will be returned to the Johns Hopkins University.

No Cost Extension (NCE)
- After completion of the initial six months of the grant award, the PI may apply for a no-cost time extension for up to six months. This extension period is to allow for the completion of research projects.
- Beyond one NCE period, no additional NCEs will be considered. Hence, the maximum time allowed for completion of the research project is 12 months.
- All grant extension requests must be submitted six weeks before the end of the initial six-month project period using the *C19PcRDF Award Extension Request* form, which can be requested via email, C19PcRDF@jhmi.edu.

How to Apply
- For the application and documents, go to the C19PcRDF webpage at https://hopkinsinfectiousdiseases.jhmi.edu/research/covid-19-preclinical-research-discovery-fund/
- Applicants are advised to review the document *COVID-19 PreClinical Research Discovery Fund (C19PcRDF) Application Guidelines 2020* before completing the application and supporting documents.
- Download and complete the application as directed.
- Download the required supporting documents and complete. Explanations for the use of these documents may be found in the *C19PcRDF Application Guidelines 2020*, page 4, section *Application Documents*
- Refer to the section **Documents Presentation and Formatting** (page 6 of this document) for formatting requirements.
- Send the completed application, project description, budget, letters of support, biosketch and other required documents as separate files, but attached to a single email to C19PcRDF@jhmi.edu before the published deadline. If the documents exceed the email file size, send the remaining documents in a second email.
- **NOTE: Once submitted, application documents cannot be changed.**
- Non-electronic submissions will not be accepted.

Application Documents

To maintain the integrity and formatting of each document, complete and save documents as individual files. **Do not combine multiple documents**, such as the project description, biosketch, and letters of support into one large file.

Letters of Intent
Due to the accelerated pace of this announcement, we will not seek or accept Letters of Intent (LOI).

Application Form
- Completion of the COVID-19 PreClinical Research Discovery Fund (C19PcRDF) Application 2020 in its entirety, is required for all proposals.
- List key study team members known at the time of application. This includes the PI and co-investigators. If you request salary support for an individual, that individual must be listed as a member of the research team on the

application. If the specific individual is unknown at present, please list the research team roll on the application [example *Laboratory Technician*].
- Send via email to C19PcRDF@jhmi.edu

<u>Research Project Description (protocol)</u>
- Submission of a research project description is required. The following sections must be included:
  - Abstract (250 words maximum)
  - Introduction and Background (1 page maximum)
  - Specific Aims (1 page maximum)
  - Procedures and Methods (3 pages maximum)
  - If applicable, rationale for using animal models, animal sources, housing, adverse events, final disposition, and consideration of alternatives (1 page maximum)
  - Timeline of study activities (1 page maximum)
  - Benefits or Significance of the research (1 page maximum)
- A list of citations which support the research project description project must be included as part of the project description or as a separate document.
- **Please number the pages in the research project description document**.
- Insert the project description title and the name of the PI in the header.
- Create and save as a Microsoft Word or PDF document
- Send via email to C19PcRDF@jhmi.edu

<u>Biosketch</u>
- A current biosketch for known key members of the research team must accompany the application.
- Note: If you request salary support for an individual, that individual must be listed as a member of the research team on the application and you must provide their biosketch
- **Please number the pages in the document**.
- To conserve paper, we will not accept CVs.
- Create and save as a Microsoft Word or PDF document. Send via email to C19PcRDF@jhmi.edu
- Send each biosketch as an individual file. **Do not combine multiple biosketches into a single file**

<u>Letters of Support</u>
- Letters of support are strongly encouraged from collaborators and research partners, within and outside the University relevant to the project.
- Limit letters of support to 1-2 pages.
- Create and save as a Microsoft Word or PDF document.
- Letters of support are to be saved as separate documents. **Do not combine multiple letters of support into a single file.**
- Send via email to C19PcRDF@jhmi.edu

<u>Budget</u>
- Please review the section **Monetary Support** (pages 4 of this document) prior to completing the budget proposal.
- All proposals must be accompanied by a budget formatted using the *C19PcRDF Budget Template 2020*. The budget must include costs related to personnel, animal care, laboratory, and other study-related expenses.
- If funds are not requested for a particular category, enter a zero in the total column.
- Total funding requests are limited to USD $50,000.
- Create and save as a Microsoft Excel document.
- Send via email to C19PcRDF@jhmi.edu

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- Remember to include the *Project Title, PI, and Submission Date* at the top of the template.
- To gauge if the proposed budget corresponds to the project description and the costs are reasonable, **specific line items are to be listed on the budget.**
- Under the section *Personnel*, list the name of the person and the role on the research team; if unknown at the time of application, TBD (to be determined) is acceptable [example, *TBD laboratory technician*].
- If you request salary support for an individual, that individual must be listed as a member of the research team on the application.
- On the budget, under the section *Personnel*, list only those persons slated to receive salary support from the C19PcRDF funding. If a person is on the research team, but will not receive salary support, then do not list that person on the budget.
- For the sections *Animal Care; Laboratory Supplies, Equipment, and Services; and Other Expenses*, **provide specifics** regarding costing allocations. For example, under the section *Laboratory Supplies, Equipment, and Services,* the entry for a lab item should be, as an example: Pipettes (4 boxes, $20/box). In the total column, enter $80.
- *Animal Care* is defined as items related to the purchase and care of animals. Example: Care of Mice ($0.64 per cage/day x 15 cages x 10 days), $96.00 total.
- *Laboratory Supplies, Equipment, and Services* are defined as items necessary to complete the research but are not related to direct patient care, such as lab supplies and testing. Examples: 30 ml 2% EDTA solution (2 bottles, $80/bottle), $160 total; PCR testing (50 tests, $100/test), $5000 total.
- *Other Expenses* are defined as expenses that do not fit into the other categories. Example: Dell Laptop Computer to record study results (1 at $1500.00), $1500.00 total.
- **Funds may not be used for travel**
- On the budget template, do not delete rows or categories. Additional rows may be added within existing categories. Do not add new categories.
- Applicants are strongly encouraged to direct budget questions to the C19PcRDF Manager (410-302-4753 or C19PcRDF@jhmi.edu prior to final submission of the application.

Documents Presentation and Formatting
> Software
- Application documents are to be submitted in their original software format (Microsoft Excel for the budget, Microsoft Word or PDF for all other documents). Handwritten applications will not be accepted

> Language
- All applications must be submitted in standard American English
- If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

> Font
- Arial or Calibri, 11-12 points, black type.
- A symbol font may be used to insert Greek letters or special characters
- 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
- Shadings or colors may not be used in text portions of the application

> Paper Size and Page Layout
- Use standard size (8.5" X 11") sheets of paper
- Use 1-inch margins on all sides (top, bottom, left, and right) for all pages
- Standard, single-column format for the text

- Single sided and single-spaced
- Consecutive number pages throughout the application in the footer, centered, on each page. Do not use suffixes (e.g., 1a, 1b)
- Do not include unnumbered pages
- Do not include additional blank pages
- **The submission date, principal investigator, and project title should be in the header, in the top right-hand corner of each page of the research project description.**

<u>Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes/Endnotes</u>
- Smaller type size is acceptable, but it must be in blank ink, readily legible and follow the font typeface requirement
- Footnotes or endnotes are to be consecutively numbered

<u>Photographs and Images</u>
- All photographs and other materials must be embedded directly within the application. Items glued or taped on the application will not be accepted.
- Up to six black-and-white images may be included if they are critical to the content of the application.
- The application must contain only material that reproduces well when photocopied in black-and-white

Review Process
- Upon submission, the C19PcRDF will assign an application number. This number will be used on all future C19PcRDF communication with the applicant.
- Applications will be scored by JHU faculty members with expertise in the field similar to that of the proposed research topic.
- All applications will be scored on a 1-5 scale in five areas:
  o Relevance to C19PcRDF goals and COVID-19 illness or SARS-CoV-2
  o Scientific impact, novelty, and merit in the experimental design
  o Feasibility of project completion within six months
  o Collaboration between investigators and JHU schools
  o Potential for subsequent funding from other sources
- Only complete applications received by the deadline will be reviewed. **Incomplete applications will be returned and not reviewed**
- The review process is as follows:
  o C19PcRDF Manager will review the application for completeness and compliance with the grant process, as outlined above. Document errors will be referred back to the applicant for correction.
  o Application materials will be distributed to individual faculty reviewers for preliminary scoring. Reviewers will submit written feedback regarding applications they have scored.
  o The C19PcRDF Advisory Board will meet to discuss all applications, assign a final score to applications, and discuss funding awards.
  o The C19PcRDF Director will finalize the award, including funding. All funding decisions are final.
  o Applicants will be notified in writing of acceptance or rejection of the grant proposal on or before May 26, 2020.
  o The PI and a representative of the C19PcRDF will sign a written agreement outlining the terms of the award.
  o The C19PcRDF grant start date will be June 1, 2020. The start and end date of the six month period will be included in the C19PcRDF written agreement.
- An additional review will not be permitted.
- Revisions after a rejection will not be permitted.
- **The application and review timeline may be altered due to unforeseen circumstances. Any alterations in the timetable will be conveyed via email to all applicants.**

Feedback
- As part of the mentoring objective, feedback to applicants after peer review is viewed as essential by C19PcRDF. All applicants will receive written feedback via the *C19PcRDF Review Summary Statement*
- The meaning of numeric designations will be indicated on the *C19PcRDF Review Summary Statement*.

Post Award Requirements
- Written Reports
  - Within three months of the release of funds, awarded PIs or their designees will submit a written progress report using the *C19PcRDF Interim Report* form.
  - The *C19PcRDF Interim Report* form will be forwarded to the PI or their designee six weeks before the due date.
  - Near or just after the completion of the six-month award or NCE extension period, awarded PIs or their designees will submit a written comprehensive review of the research project using the *C19PcRDF Final Report* form.
  - The *C19PCRDF Final Report* form will be forwarded to the PI or their designee six weeks prior to the due date.
  - Information from all C19PcRDF awarded projects is compiled into regular reports presented to the C19PcRDF Review Committee as well as the JHUSOM Dean and Vice Deans.
- Publication Requirements
  - The publication of research is strongly encouraged.
  - All publications resulting from research using C19PcRDF resources are required to cite the C19PcRDF as contributing sources of support. When publishing articles related to this research, the following language should be used in its entirety:

    This publication was made possible by support from the COVID-19 PreClinical Research Discovery Fund of the Johns Hopkins University School of Medicine. Its contents are solely the responsibility of the authors and do not necessarily represent the official view of the Johns Hopkins University School of Medicine.

- Any substantive changes to the original research plan or budget must be discussed with and submitted in writing to the C19PcRDF. Failure to do so will result in termination of the project and forfeiture of remaining funds. Project description changes must be submitted to the responsible Johns Hopkins University regulatory body.
- The C19PcRDF may suggest revisions to the application, project description, research plan, budget, IRB application, or other study documents pre or post-award.

Contact Information
- The C19PcRDF encourages applicants to communicate with our staff concerning our programs, resources, and granting process.
- **Contact Us**
  COVID-19 PreClinical Research Discovery Fund (C19PcRDF)
  Phone   410-302-4753
  Email   C19PcRDF@jhmi.edu
  Web page hyperlink   C19PcRDF
  Web page https://hopkinsinfectiousdiseases.jhmi.edu/research/covid-19-preclinical-research-discovery-fund/