Bentivoglio Family Foundation COVID-19 Johns Hopkins Discovery Fund, COVID-19 Vaccine-related Research Fund (C19VRF) Application Guidelines 2021

Description

• To provide funds for clinical or translational research to optimize community vaccine uptake and understand vaccine safety and effectiveness in persons underrepresented in the initial clinical trials of SARS-CoV-2 vaccines, such as persons of under-represented minority, ethnic, or social groups, pregnant women, persons with prior severe allergic reactions, immunosuppressed patients, and children.

• To provide funds for clinical or translational research of survivors of COVID-19 for whom the risks and benefits of SARS-CoV-2 vaccines are incompletely understood, particularly in those individuals with ongoing signs and symptoms.

• To provide funds for clinical or translational research to understand the virologic and immunologic correlations of protection from disease, prevention of transmission and vaccine response duration with different SARS-CoV-2 vaccines (e.g., mRNA, adenoviruses platforms, and others).

• Projects with a solely basic science basis will be returned and not reviewed.

Eligible

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)

Budget

Up to $50,000.00 USD

Number Available

Maximum three projects will be funded

Funding Source

The Johns Hopkins University School of Medicine through a gift from the Bentivoglio Family Foundation

Grant Period

12 months, with a possible 12-month no-cost time extension upon review

Application

Online hyperlink C19VRF
URL: https://hopkinsinfectiousdiseases.jhmi.edu/covid-19-vaccine-related-research-fund/

Submit Via Email

Submit the application and supporting documents via email, C19VRF@jhmi.edu

Submission Deadline

Monday, February 22, 2021

Contact

Email: C19VRF@jhmi.edu; Phone: 410-302-4753

Created 01/25/2021
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Project Timeline

Application Submission Deadline: Monday, February 22, 2021 at 11:59 PM
Anticipated Award Notification: On or before Monday, March 29, 2021
Award Start: April 1, 2021

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

- The request-for-application (RFA) will be distributed University-wide via web and email announcements
- Any alterations to the program and the Request for Application will also be broadcast through these methods.
- C19VRF proposals and all application documents must be received by 11:59 PM on February 22, 2021.
- Applicants will be notified of acceptance or denial of the grant request on or before March 29, 2021.
Program Goals

The COVID-19 Vaccine-related Research Fund (C19VRF) is designed to accomplish the following goals:

- To provide funds for clinical or translational research to optimize community vaccine uptake and understand vaccine safety and effectiveness in persons underrepresented in the initial clinical trials of SARS-CoV-2 vaccines, such as persons of under-represented minority, ethnic, or social groups, pregnant women, persons with prior severe allergic reactions, immunosuppressed patients, and children.
- To provide funds for clinical or translational research of survivors of COVID-19 for whom the risks and benefits of SARS-CoV-2 vaccines are incompletely understood, particularly in those individuals with ongoing signs and symptoms.
- To provide funds for clinical or translational research to understand the virologic and immunologic correlations of protection from disease, prevention of transmission and vaccine response duration with different SARS-CoV-2 vaccines (e.g., mRNA, adenoviruses platforms, and others).
- To encourage scientific impact, novelty and merit in experimental design with the demonstrable potential for significant clinical impact.
- Feasibility of project completion within 12 months.
- To foster novel, cross-disciplinary collaborative research (as feasible) among the Johns Hopkins University schools and non-Johns Hopkins University domestic and international 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 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 C19VRF application. They can still coordinate with a faculty PI who submits and takes responsibility for the C19VRF 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 C19VRF award eligibility.
- If a C19VRF grant is awarded, additional awards obtained after the distribution of C19VRF funds will not impact C19VRF funds.

Regulatory Requirements

- All C19VRF awarded projects involving human participants must be approved by a Johns Hopkins Institutional Review Board (IRB). Such projects will be carried out using the guidelines and policies developed by the Johns Hopkins Office of Human Subjects Research Compliance Team.
- All C19VRF 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 IRB or IACUC is not a prerequisite for submission of a C19VRF application, investigators should be aware of the impact of these and other necessary administrative or regulatory reviews on the project timeline and feasibility. If the project does not meet with IRB or IACUC approval, C19VRF funding will be terminated and funds forfeited.
- If this is a clinical trial, after the C19VRF award has been made and the project has received IRB approval, the research project must be registered at clinicaltrials.gov in a timely fashion.
Conflicts 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 C19VRF 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 C19VRF award and the disallowance of all study costs.

Project Topics

- Clinical or translational research to optimize community vaccine uptake and understand vaccine safety and effectiveness in persons underrepresented in the initial clinical trials of SARS-CoV-2 vaccines, such as persons of under-represented minority, ethnic, or social groups, pregnant women, persons with prior severe allergic reactions, immunosuppressed patients, persons with pre-existing conditions, and children.
- Clinical or translational research of survivors of COVID-19 for whom the risks and benefits of SARS-CoV-2 vaccines are incompletely understood, particularly in those individuals with ongoing signs and symptoms.
- Clinical or translational research to understand the virologic and immunologic correlations of protection from disease, prevention of transmission and vaccine response duration with different SARS-CoV-2 vaccines (e.g., mRNA, adenoviruses platforms, and others).
- C19VRF resources will be concentrated on generating clinical or translational research to generate pilot or more comprehensive data.
- Basic science or laboratory-based research or animal study approaches will only be considered if clearly a part of a clinical or translational research project.
- Proposals may be exploratory in nature.
- 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.
- Research may be domestic or international in focus.
- Research in people of underrepresented populations and communities is encouraged.

Examples of Proposals include...

- Innovative approaches to facilitate community uptake of vaccines developed in response to the COVID-19 pandemic.
- Understanding uptake of vaccines and vaccine effectiveness in persons of under-represented minority, ethnic, or social groups.
- Approaches leading to an understanding of vaccine effectiveness in persons of color, pregnant women, persons with prior severe allergic reactions, immunosuppressed patients, persons with prior COVID-19 disease, and children.
- Comparison between vaccine platforms of the virologic and immunologic correlations of protections from disease, prevention of transmission and vaccine response durations.
Monetary Support

- This program’s funding is through a gift of the Bentivoglio Family Foundation COVID-19 Discovery Fund to Johns Hopkins University. Solicitation, review and awarding of grants is managed by staff of the Division of Infectious Diseases.
- **Requests must be no more than $50,000 USD.** Requests exceeding $50,000 will not be reviewed.
- A realistic budget proportionate to the scope of the project must be included in the C19VRF application package. The budget must be submitted using the C19VRF Budget Template 2021. The budget must be submitted as an Excel document.
- 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 C19VRF application.
- **Total salary support should not exceed 50% of the total requested budget** unless there is 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 specific to the development of an assay, diagnostic test, or device. **Total laboratory supplies, equipment, and service costs should not exceed 50% of the total requested budget** unless there is strong justification for an additional level of laboratory supply, equipment, and service 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 will be released to the PI in the form of a Johns Hopkins University internal order number or cost center number.
- Funding will be for 12 months, with the award start date on or near April 1, 2021.
- At the end of the grant period or at the time of early termination, all unspent C19VRF funds will be returned to the Johns Hopkins University.

No Cost Extension (NCE)

- After completion of the grant award’s initial 12 months, the PI may apply for a no-cost time extension for up to an additional 12 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 24 months (two years).
- All grant extension requests must be submitted six weeks before the end of the initial 12-month project period using the C19VRF Award Extension Request form, which can be requested via email, C19VRF@jhmi.edu

How to Apply

- For the application and documents, go to the C19VRF webpage at https://hopkinsinfectiousdiseases.jhmi.edu/covid-19-vaccine-related-research-fund/
- Applicants are advised to review the document C19VRF Application Guidelines 2021 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 C19VRF Application Guidelines 2021, page 6, section Application Documents
- Refer to the section Documents Presentation and Formatting (page 8 of this document) for formatting requirements.
• Send the completed application, protocol, budget, letters of support, biosketch and other required documents as separate files, but attached to a single email to C19VRF@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 without the explicit permission of the C19VRF Manager.

• 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 protocol, biosketch, and letters of support into one large file.

**Letters of Intent**

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

**Application Form**

• Completion of the [COVID-19 Vaccine-related Research Fund (C19VRF) Application 2021](#) 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. In addition, 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 C19VRF@jhmi.edu

**Research Protocol**

• Submission of a research protocol is required. The following sections must be included:
  
  o Abstract (250 words maximum)
  o Introduction and Background (1 page maximum)
  o Specific Aims (1 page maximum)
  o Procedures and Methods (3 pages maximum)
  o If applicable, rationale for using animal models, animal sources, housing, adverse events, final disposition, and consideration of alternatives to animal research (1 page maximum)
  o Timeline of study activities (1 page maximum)
  o Benefits or Significance of the research (1 page maximum)

• A list of citations that support the research protocol project must be included as part of the protocol.

• **Please number the pages in the research protocol document.**

• Insert the protocol title and the name of the PI in the header.

• Create and save as a Microsoft Word or PDF document

• Send via email to C19VRF@jhmi.edu

**Biosketch**

• A current biosketch or résumé for known key members of the research team must accompany the application. This includes the PI and co-investigators. An [NIH-style biosketch](#) is the preferred option.

• In addition, 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 or résumé. This includes research nurses, study coordinators, lab personnel, technicians, etc.
Please number the pages in the document.
We will not accept CVs.
Create and save as a Microsoft Word or PDF document. Send via email to C19VRF@jhmi.edu
Send each biosketch or résumé as an individual file. Do not combine multiple biosketches or résumés into a single file

Letters of Support
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 C19VRF@jhmi.edu

Budget
Please review the section Monetary Support (page 5 of this document) prior to completing the budget proposal.
All proposals must be accompanied by a budget formatted using the C19VRF Budget Template 2021. 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 $50,000 USD.
Create and save the budget as a Microsoft Excel document. Do not save the budget as a pdf document.
Send via email to C19VRF@jhmi.edu
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 protocol 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 research team member on the application and budget.
Under the section Personnel on the budget, list only those persons slated to receive salary support from the C19VRF 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.

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• Applicants are strongly encouraged to direct budget questions to the C19VRF Manager (410-302-4753 or C19VRF@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 principal investigator, and project title should be in the header, in the top right-hand corner of each page of the research protocol.

Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes/Endnotes
• 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.

Photographs and Images
• 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 C19VRF will assign an application number. This number will be used on all future C19VRF communication with the applicant.
- Applications will be scored by senior 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:
  - Relevance to C19VRF goals (page 3 of this document) and COVID-19 vaccines
  - Scientific impact, novelty, and merit in the experimental design
  - Feasibility of project completion within 12 months
  - Collaboration between investigators and JHU schools
  - 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:
  - C19VRF 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.
  - Application materials will be distributed to individual faculty reviewers for preliminary scoring. Reviewers will submit written feedback regarding applications they have scored.
  - The C19VRF Advisory Board will meet to discuss all applications, assign a final score to applications, and discuss funding awards.
  - The C19VRF Director will finalize the award, including funding. All funding decisions are final.
  - Applicants will be notified in writing of acceptance or rejection of the grant proposal on or before March 29, 2021.
  - The PI and a representative of the C19VRF will sign a written agreement outlining the terms of the award.
  - The C19VRF grant start date will be on or near April 1, 2021. The start and end date of the 12 month period will be included in the C19VRF 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

- Feedback to applicants after peer review is viewed as essential by C19VRF. All applicants will receive written feedback via the C19VRF Review Summary Statement
- The meaning of numeric designations will be indicated on the C19VRF Review Summary Statement.

Post Award Requirements

- Financial Management
  - The PI will forward to the C19VRF Manager the name and email of the PI’s budget analyst.
  - The budget analyst will create a non-sponsored SAP account solely for the use of C19VRF award funds.
  - The account number will be forwarded to the C19VRF Manager for funds transfer. The transfer of funds is dependent on the timely creation of an account in the Johns Hopkins University SAP system.
  - At the end of the funding period, the budget analyst will submit a SAP YTD Transactional Detail Report for the fiscal years covered by the project dates. The report is to include all revenues and expenditures, G/L breakdown, and all rows. The report is to be extrapolated into MS Excel and submitted to the C19VRF Manager.
Failure to submit the **SAP YTD Transactional Detail Report** will result in termination of funding, with the balance returnable to the C19VRF.

- **Written Reports**
  - At six-months following fund dispersal and at the end of the grant period, awarded PIs or their designees will submit a written progress report using the online form found at [COVID-19 Research Response: Mid-grant Survey](https://hopkinsinfectiousdiseases.jhmi.edu/covid-19-vaccine-related-research-fund/).
  - Information from all C19VRF awarded projects is compiled into regular reports presented to the JHUSOM Dean and Vice Deans.

- **Publication Requirements**
  - The publication of research is strongly encouraged.
  - All publications resulting from research using C19VRF resources are required to cite the C19VRF 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 Bentivoglio Family Foundation COVID-19 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 C19VRF. Failure to do so will result in the termination of the project and forfeiture of remaining funds. Protocol changes must be submitted to the responsible Johns Hopkins University regulatory body.

- The C19VRF may suggest revisions to the application, protocol, research plan, budget, IRB application, or other study documents pre or post-award.

**Contact Information**

- The C19VRF encourages applicants to communicate with our staff concerning our programs, resources, and granting process.

**Contact Us**

COVID-19 Vaccine-related Research Fund (C19VRF)

Phone: 410-302-4753

Email: [C19VRF@jhmi.edu](mailto:C19VRF@jhmi.edu)

Web page hyperlink: [C19VRF](https://hopkinsinfectiousdiseases.jhmi.edu/covid-19-vaccine-related-research-fund/)

URL: [https://hopkinsinfectiousdiseases.jhmi.edu/covid-19-vaccine-related-research-fund/](https://hopkinsinfectiousdiseases.jhmi.edu/covid-19-vaccine-related-research-fund/)