URMC Department of Medicine, Infectious Diseases Vaccine and Treatment Evaluation Unit (VTEU) 2023-2024 Request for Applications

Stage I Abstract Deadline – November 30, 2023 Stage II Proposal Deadline – January 31, 2023

Purpose

To foster innovative new ideas and clinical, translational or basic science research projects related to the development of vaccines, therapeutics and diagnostics for infectious diseases.

Background

VTEUs have played a key role in the NIH NIAID effort to develop new and improved vaccines and therapies against infectious diseases for over four decades. They have conducted hundreds of clinical trials, many of which have contributed to the development of treatments and vaccine licensure to address new and emerging pathogens.

The University of Rochester VTEU within the Division of Infectious Diseases is seeking submissions from research faculty across the University for a one-year Pilot Award. Pilot awards are meant to develop preliminary data related to the fields of vaccinology, diagnostics and treatment of infectious diseases. These could include epidemiology studies of burden of disease or risk factors in special populations which would inform vaccine policy and the development of new therapeutic agents or targets. Clinical or pre-clinical studies may include assessment of host responses to disease, vaccines or therapeutics such as measurements of the magnitude or durability of immune responses or evaluation of new vaccine delivery systems and diagnostic platforms. Basic science projects which bridge a critical knowledge gap in human disease necessary to the development of new infectious diseases interventions will also be considered. Preferred infectious diseases subject areas include: respiratory or enteric pathogens, COVID, sexually transmitted infections or emerging infections (including antibiotic resistance).

Kay Dates:

- November 30, 2023 at 5:00 p.m. Initial abstracts of proposals must be received.
- December 15, 2023 Applicants from whom full proposals will be solicited will be notified.
- January 31, 2024, at 5:00 p.m. Full proposals must be received.
- February 28, 2024 Notifications of Award will be made.
- March 1, 2024 The anticipated start date.

Eligibility

Applicants must be faculty or fellows at the University of Rochester. Projects must should demonstrate the potential to lead to extramural funding (federal, state, or foundational).

Awards

Up to two (2) awards will be made for up to \$50,000 for one year in direct costs. Indirect costs are not allowed.

Application Process

The application process will take place in 2 stages. Stage 1 requires submission of a 1-page abstract of the proposed project. The abstract should list the principle investigator(s) and mentors (where applicable), describe the objectives of the proposed study, provide a brief description of the study design and conclude with an impact statement describing the relevance of the project to the development of vaccine, therapeutics or

diagnostics (there is no form template for the abstract portion). It is critical that research ideas are expressed in such a way that the reviewer can understand the ideas and appreciate their significance. Abstracts will be reviewed and applicants selected to submit full applications (3 pages).

Please submit your Phase I abstracts to Kaylee Streeter at <u>Kaylee Streeter@URMC.Rochester.edu</u> before or on **November 30, 2023, by 5 PM EST.**

Abstracts selected for Phase II, will be notified on **December 15th**, **2023**, and investigators will be asked to submit a full application (3 pages) before or on **January 31st**, **2024**, **by 5 PM EST**. Phase II applications are to be submitted as a single PDF document to Kaylee Streeter Kaylee_streeter@urmc.rochester.edu.

Full Application Requirements:

- □ VTEU Proposal sign-off form (Form provided)
- □ Modified PHS 398 face page (Form provided)
- □ Abstract
- □ NIH-format biosketch for PI, co-investigators and mentors
- □ Updated Other Support for PI or co-PI only
- □ Research Plan (limited to 3 pages):

Note: The Research Plan consists of items noted below, as applicable. It should be self-contained and include sufficient information to evaluate the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

- Specific Aims
- Research Strategy (Significance, Innovation and Approach)
- Timeline
- □ Human Subjects and Animals (no limit): *The Human Subjects and Animals Plan consists of items noted below, as applicable.*
 - Protection of Human Subjects
 - Vertebrate Animals
- □ Plans for Future Funding (short paragraph):
 - Provide a short outline of how the pilot will develop into a NIH or otherwise funded grant.
- □ Budget (PHS 398 Form provided)
 - Limited to \$50,000 direct costs
 - Provide a detailed description of supplies and other expenses within the form page
 - Funds may be used to support research supplies, equipment and expenses, travel to collect data and other non-faculty salary.
 - If applicable, identify other sources of support that will be used to complete the pilot project.
- □ Bibliography

Submission and Review Process

This is an internal competition for institutional funds. *ORPA review and sign-off is not required but departmental review and approval should be sought through the VTEU sign-off form.*

Proposals will be reviewed by a faculty committee and will be assigned a priority score in accordance with these 6 categories:

- Significance (including scientific premise and hypothesis)
- PI, Scientific Team
- Innovation
- Experimental Approach ability to complete the work in the 1 year time frame
- Responsiveness to mission of the VTEU
- Probability of future funding

A summary of the reviewers' comments will be provided once the review process has been completed

Award Process

VTEU will notify selected investigators via email by **December 15, 2023.** Funding will not be released until all UR and NIH regulatory requirements have been met including IRB, IBC and UCAR) (IACUC) approvals as applicable. Upon receipt of all required documentation, the VTEU will issue a formal internal Notice of Award.

Reporting Requirements

A semi-annual report 6 months after the project begins is required. The report should describe the progress made and note any delays or threats to the project. At one year, an annual or final written progress report is required also describing the progress made and note any delays or threats to completion of the project. If more time is needed to reach the project objectives, a justification for a no cost extension should be provided with a revised time line. Final reports must include the following:

- Status of the work supported by pilot grant
- · Statement regarding resulting grant applications, publications, presentations and inventions
- Update regarding plans for future funding resulting from the project

Should the PI's publish papers or receive an NIH or other grant related to the pilot after the final report is issued, the UR VTEU would appreciate being notified and VTEU funding should be acknowledged.

Inquiries:

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