NEW PILOT FUNDING OPPORTUNITY

Title: Rapid Response COVID-19 Related Pilot Funding Research Opportunity

Available Funds (to date)**:** A maximum of $510,000, targeted to fund 19 awards ranging from $15k to up to $40k

RFA Release: June 1, 2020

Funding period: July 15, 2020 – June 30, 2021 (with documented deliverables within first 6 months)

Deadline for applications: June 15, 2020; 11:59pm

Funding Source: Multiple sources (listed in alphabetical order): Case COVID Task Force/NORD Family Foundation, Case Comprehensive Cancer Center, Center for AIDS Research (CFAR), Cleveland Brain Health Initiative (CBHI), Clinical Translational Science Collaborative (CTSC), Digestive Health Research Institute, and the Mary Ann Swetland Center for Environmental Health.

On behalf of the COVID Taskforce and multiple funding partners across Case Western Reserve University, the CTSC requests applications for pilot research funding from faculty at Case Western Reserve University, Cleveland Clinic, MetroHealth Medical Center, University Hospitals of Cleveland Medical Center, and the Louis Stokes Veterans' Administration Medical Center. **We believe that given the multifaceted nature of COVID-19, successful applications will be framed in the context of multi-disciplinary studies and thus encourage collaborative research that involves investigators from across the university and our institutional health system partners.** As a collective, we intend to award up to 19 pilot grants, with award amounts ranging from $15k to $40k, designated by each funding source. Indirect costs will not be allowed. Application will be submitted electronically no later than June 15, 2020; 11:59pm via InfoReady, https://cwru.infoready4.com.

In response to the SARS-CoV-2 pandemic the COVID Research Taskforce recruited 268 faculty with diverse interests. To support this effort, the Taskforce with the generous support of multiple sponsors, has created a Rapid-Response COVID-19 Pilot Award to support new research initiatives that will make immediate progress towards reducing the harm to individuals, groups, and society from SARS-CoV-2 and the COVID-19 pandemic. Together the funding partners seek shovel-ready applications that address a wide range of COVID-related questions including understanding and advancing knowledge on fundamental virology, immunology, evolution, natural history and pathogenesis of SARS-CoV-2; barriers and challenges in testing, tracing, diagnosis and treatment; impact of the pandemic on vulnerable populations (e.g., cancer patients, those with chronic conditions), health care workforce, health care utilization and impact on physical and mental health of the community. Projects focusing on the use of informatics and understanding disparities are encouraged. See Section 2 for topic areas sought by each funding group.

Priority will be given to projects that have a high impact on expanding knowledge or developing new knowledge on the COVID-19 pandemic and SARS-CoV-2. Ideally, these funds will be used to obtain preliminary data for an extramural grant submission related to COVID-19/SARS-CoV-2. **Projects that do not directly address or relate to COVID-19/SARS-CoV-2 will not be considered within this solicitation.**

To date, the following funding groups have joined in this initiative, providing one or more pilot grant opportunities. **Please see Section 2 for funding focus or desired projects for each group.**

CWRU COVID-19 Task Force / NORD Family Foundation (4 awards; $25,000 each)
Case Comprehensive Cancer Center (3 awards; $25,000 each)
Center for AIDS Research (CFAR)(2 awards; $25,000 each)
Cleveland Brain Health Initiative (2 awards; $15,000-$20,000 each)
Clinical and Translational Science Collaborative (CTSC) (5 awards; up to $40,000 each)
Digestive Health Research Center (2 awards; $15,000 each)
Mary Ann Swetland Center for Environmental Health (1 award; $15,000)

Case Western Reserve University will serve as the fiscal entity through which each award will be distributed and administered. Awardees will receive additional information regarding disbursement workflow.

SECTION I: GENERAL REQUIREMENTS (applies to all applications)

Applicants must read and follow all application instructions in this section as well as any funding source-specific instructions noted in Section 2.

- Principal Investigators (PIs) must have a PhD, MD, or equivalent doctoral-level degree and must have a faculty appointment at CWRU. Investigators may be based at any of the CWRU-affiliated hospitals, or in any School or College at CWRU.
- Co-PIs are permitted, but each applicant is allowed to submit only one application as PI or co-PI.
- While investigators can be collaborators on multiple applications, only one application will be accepted per PI (or team)
- The institution of record will be the PI's primary institution.
- Research projects must show significant progress by 12/15/2020, as documented through 6 month progress report and deliverables. Awards may be withdrawn at that time if progress is not demonstrated.
- If human/animal subjects are involved, approved IRB/IACUC # or a copy of IRB/IACUC application MUST BE INCLUDED with the application. Studies involving human subjects must include IRB approval before funds will be released and will not change the expectation for significant progress to be made within 3-6 months. The likelihood of gaining IRB approval in a timely manner will be considered as part of the Feasibility criteria.
  NOTE: Not all funding tracks permit animal studies, check the individual requirements table in Section 3.
- PI or Co-Investigator salary is not allowed.
- Indirect costs will not be allowed.
- Proposed project cannot have current funding, or only modest related intramural or extramural funding that will be enhanced by the pilot activities, representing a distinct sub-aim.
- All award funding must be spent by June 30, 2021; no-cost extensions will **not** be granted.
- All awardees must provide a mandatory 6-month progress report (no later than Dec 15, 2020) and one year final report (no later than July 15, 2021). Progress reports will be submitted through InfoReady, which will be forwarded to the respective funding group.

APPLICATION PROCESS:

- Application must be submitted electronically no later than June 15, 2020; 11:59pm via InfoReady, https://cwru.infoready4.com/
- Successful applicants will be notified by July 10, 2020, and if all requirements are met, funding could begin as early as July 15, 2020.
- Applicants must choose a primary funding "track" for which to apply. There is an option within the application to request being reviewed by a secondary funding group, but the decision to review secondary applications will be up to the funding group and is not guaranteed.
- Application must meet all general requirements unless an exception is noted within the specific funding group's requirements. Applications not meeting the requirements may be returned and not reviewed.
- Applicant's project must address the topic areas and other requirements of the individual funder to be considered by that funder.
- Awards will be based on a combination of meritorious proposals and priorities of the funder. Should there be no applications that meet the criteria set by a particular funding group, the funding group has no obligation to fund an application.

PREPARING YOUR SUBMISSION:

The InfoReady System will require the following information or documents to be provided or uploaded.

Please review the online submission form before preparing your final documents.
For all uploaded documents (as PDFs), please use 11 pt, Arial font with ½" margins.
Maintain margins and adequate spacing between paragraphs and note maximum length for each document.

- A short summary of the work directed to the lay public (500 characters including spaces – entered)
- Specific aims (maximum one page, uploaded as a PDF)
- Significance and urgency, specifically addressing how the project is related to COVID-19 (maximum one-half page, uploaded as a PDF)
- Research Strategy (**maximum 2 pages,** uploaded as PDF) that includes:
  A. Study design, hypothesis, expected results
  B. Study population
  C. Approach (recruitment/data collection, measures, analyses)
  D. Investigative team
  E. Feasibility
  F. Dissemination plan and next steps (i.e., extramural funding)
- References or provide URLS (max 10 references); please upload as part of the Research Strategy PDF.
- Study timeline and deliverables (reminder, applicants must show significant progress within 3-6 months), including plan and timeline for dissemination of research findings and for seeking extramural funding (maximum one-half page, uploaded as a PDF)
- Figures may be included as appendices; maximum 2 pages total for appendices
- If human/animal subjects are involved, approved IRB/IACUC # or copy of IRB/IACUC application MUST BE INCLUDED with the application as an uploaded PDF
- Detailed budget - please download and complete the NIH budget form (found on InfoReady COVID Pilot page). Note the fringe rate for staff salaries (if applicable) is the current non-federal rate of 33%.

- Budget Justification - provide description and rationale for each expense listed in the budget.
- NIH-format biosketches for senior/key personnel (max. five pages per biosketch; uploaded as a single PDF)
- Letter(s) of support/commitment (as applicable). Uploaded as a single PDF, maximum 5 pages/maximum 1 page per letter.

REVIEW PROCESS:

- Proposals will be reviewed by a scientific review committee developed for each funding group, comprised of reviewers identified by the funding group, as well as members of the SARS CoV-2 Taskforce, representing the basic, clinical and population sciences. The CTSC staff will provide administrative oversight to each committee and the review process to ensure a standardized review process.
- Reviews will be conducted using NIH-style scoring methods, scoring (1) significance, (2) investigators, (3) approach, (4) feasibility, (5) overall impact.
- The committee will take into consideration the following:
    o Clear articulation of the problem being addressed by the proposed project
    o Demonstration of how the proposed work will directly contribute to developing new knowledge on the COVID-19 pandemic and SARS-CoV-2.
    o Significance, innovation and timeliness
    o Expertise of the investigative team and evidence of commitment of investigators and stakeholders to collaborate
    o Feasibility
    o Evidence of tangible deliverables, a timeline, and plans for future funding
    o Likelihood of future success
    o Budget and Budget justification
- As a reminder, should there be no applications that meet the criteria set by a particular funding group, the funding group has no obligation to fund an application.

REPORTING GUIDELINES

- All awardees must provide a mandatory 6-month progress report (no later than Dec 15, 2020) and one year final report (no later than June 30, 2021). Progress reports will be submitted through InfoReady, which will be forwarded to the respective funding group.
- As a reminder, applicants must show significant progress by 6 months; if not, funding may be withdrawn at that time.

QUESTIONS

Any questions, please contact Dr. Elaine Borawski or Ms. Anna Matos at the CTSC Community and Collaboration Core at COVID-Pilot@case.edu or at 216-368-5776.

SECTION 2: FUNDER-SPECIFIC DESCRIPTIONS AND REQUIREMENTS

This section provides information on each of the funding tracks for this pilot funding opportunity. For each track the number of awards and amounts of each award are provided, along with a description of the funder and the projects they are seeking, examples of projects that they might be interested in (but usually not limited to these examples) and any special requirements that differ from the general requirements described above.

Within InfoReady, you will be asked on the first page of the application to identify which funding track you would like to apply to. **Applicants may only choose one track.** However, there is an option within the application to request being reviewed by a secondary funding group, but the decision to review secondary applications will be up to the funding group and is not guaranteed.

Funding Track: COVID Task Force / NORD Family Foundation

Number of Awards: 4
Amount of Each Award: $25,000

Description: With support from the Nord Family, the School of Medicine is providing seed funding for highly innovative and potentially impactful proposals that will center on development of drugs or treatments that can limit the viral spread within the population, including but not limited to emergency support for local virus testing needs by research laboratories able to provide assays for the detection of antibodies.

Types or Examples of Projects:

- Development of drugs or treatments that can limit the spread within the population
- Support for research laboratories able to provide assays for the detection of antibodies
- Drug development and repurposing of existing therapeutics and identification of promising targets

Special Requirements: None (See General Requirements)

Any additional reporting requirements: None (See General Requirements)

Funding Track: Clinical and Translational Science Collaborative

Number of Awards: 5
Amount of Each Award: up to $40,000 with sufficient justification

Description: The primary goal of the COVID-19 Pilot Award is to support and encourage collaborative clinical and translational research aimed to better understand the SARS-CoV-2/COVID-19, particularly as it relates to clinical/health care delivery and impact on population health. Projects that focus on the use of informatics, novel research methods, or address behavioral health and community/population/public health outcomes are strongly encouraged.

The CTSC Pilot Award program is designed to stimulate and promote new translational research, new research collaborations, and novel research ideas. The goal of this funding is to promote innovative research teams capable of interacting across institutions, schools, and disciplines to generate novel ideas and data on translational research

projects. The NIH-CTSA defines translation as "the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes."

Types or Examples of Projects:

- Factors that help understand health disparities in the prevalence and severity of COVID-19 disease
- Informatics solutions to identify, trace, diagnosis or treat cases
- Healthcare system responses and strategies to address barriers and facilitators in the treatment of high-risk populations
- Research on how the COVID pandemic has effected health care services and the subsequent impact on treatment of other disorders and diseases (e.g., opioid overdoses, cardiovascular disease, and other chronic and rare diseases)
- Research to understand the broad impacts of COVID-19 (e.g., school closures, food insecurity, anxiety, social isolation) on development; substance use; other mental and physical health concerns and disability
- Research to understand system- or organizational-level responses to identify, prevent, or mitigate the impact of COVID-19 in settings that serve vulnerable populations
- Internet interventions, remote psychological support, mHealth-eHealth-telehealth based treatments, psychology-oriented digital tools and apps in the COVID-19 emergency
- Innovative engineering solutions to protective gear development
- Research on effective training programs for healthcare workforce as it related to COVID-19
- Impact of health care delivery service changes (e.g., telehealth) on patient-reported outcomes and providers; quality of care

Special Requirements of the CTSC:

- Applications must clearly identify a clinical or translational research project.
- Strongly encourage applications that:
  - Involve interdisciplinary teams of investigators that span across the university and our health care partners;
  - Promote interactions between basic scientists (including engineering), clinical scientists and population health scientists; and
  - Engage research collaborations with community partners and organizations.
- No animal studies.
- No funds will be provided for faculty salaries, secretarial personnel, equipment, computers, tuition, travel, dues and membership fees, per diem charges for hospital beds, and patient care costs (with the exception of patient/study participant costs).

Any additional reporting requirements:

- Team is required to participate in a 2.5-hour, professionally facilitated workshop within 30 days of funding aimed at helping teams adopt evidenced-based practices for successful teams such as development of a working agreement that clarifies roles, expectations, procedures for communication, data usage, etc.
- High level of engagement with CTSC throughout funding year; possibilities include:
  - Informational interviews for publication in newsletter, website, etc.
  - Be invited to present pilot results as part of a CTSC sponsored seminar

Funding Track: Case Comprehensive Cancer Center

Number of Awards: 3 awards
Amount of Each Award: $25,000

Description: The Case Comprehensive Cancer Center is seeking pilot projects to better understand the relationship of SARS-CoV-2/COVID-19 on cancer. Topics of interest include understanding the basic mechanisms of interactions between SARS-CoV-2 and cancer cells, co-morbidities of cancer and SARS-CoV-2 infection, and the impacts on treatment and clinical outcomes of SARS-CoV-2 infected persons with cancer. The goal is to better understand the impact of SARS-CoV-2 infection and its impact on cancer patients' disease progression, response to therapy, care delivery, or survivorship.

Types or Examples of Projects:

Aligned with the National Cancer Institute, the following focus areas are encouraged:
- Fundamental biological processes related to cancer
- Population-level determinants of occurrence and outcomes in cancer patients with SARS-CoV-2
- Impact on cancer related care delivery due to COVID-19 pandemic
- Impact of infection with SARS-CoV-2 on cancer prevention, early detection, screening, diagnosis and treatment
- Assessment of COVID-19 disease on the efficacy of anticancer agents, radiation treatments, and all other cancer treatment modalities
- Repurposing cancer therapeutics for the treatment of patients with COVID-19 disease

Special Requirements:
- There must be sufficient evidence of project feasibility, especially as it relates to the study of patient samples
- Projects must make sufficient progress within a 6-month period
- Multi-investigator projects are encouraged
- All funds for shared resources (SR) must involve Case CCC facilities unless the use of a SR at another NCI-funded institution is sufficiently justified
- PI must be a Case Comprehensive Cancer Center member to be eligible
- No funds will be provided for faculty salary support, travel, large/specialized equipment, journal subscriptions or society memberships, or renovations

Any additional reporting requirements: None (See General Requirements)

Funding Track: Center for AIDS Research (CFAR)

Number of Awards: 2
Amount of Each Award: $25,000

Description: In 1994, CWRU established the NIH-funded Center for AIDS Research (CFAR), which has been continuously funded for the past 26 years and has catalyzed research activities, recruitment, faculty development, and infrastructure support that clearly would not have occurred without the CFAR. Pilot projects should address the impact of SARS-CoV-2 infections on HIV patients. CFAR seeks studies to understand critical aspects of SARS-CoV-2

viral infection, replication, pathogenesis, and transmission and its interactions with HIV including production of molecular clones of SARS-CoV-2, reporter viruses and recombinant viral proteins

Types or Examples of Projects:
- Virologic and serologic surveillance studies of the distribution and natural history of SARS-CoV-2 viruses in people with HIV
- Impact of drugs of abuse on SARS-CoV-2 in the context of HIV
- Evaluation of immune responses to SARS-CoV-2 in people with HIV
- Evaluation of immunological risk factors in people with HIV

Special Requirements: Expect projects to show significant progress and be near completion by 6 months.

Any additional reporting requirements: None (see General Requirements)

Funding Track: Cleveland Brain Health Initiative

Number of Awards: 2
Amount of Each Award: $15,000-$20,000

Description: CBHI seeks to engage scientists and physician scientists across departments in each of our member institutions to develop collaborative, impactful research that will lead to improved brain health for the residents of northeast Ohio and beyond. In this RFA we seek to support collaborative basic neuroscience or mental health research that focuses on: (1) the effects of SARS-CoV-2 on the nervous system; or (2) the lasting impact of COVID-19-related sequestration or stress on human social behavior.

Types or Examples of Projects:
- Study of the varying susceptibility of distinct phenotypes of differentiated neurons to SARS-CoV-2 in culture;
- Risk factors of psychological distress at the individual, family, interpersonal and cultural level (e.g., activity restriction and reduction of pleasant events; personality traits; hypochondria and cyberchondria; mental disorders; family characteristics; social support, etc.);
- Coping as a health professional during the epidemic (e.g., emotions, psychological burdens, anxiety, traumatic experiences, PTSD)

Special Requirements: Applicants must describe feasibility, and adequately describe containment if they are proposing to work with SARS-CoV-2. Applicants must be faculty of CBHI member institutions: Case Western Reserve University, Cleveland Clinic, Kent State University, Louis Stokes Cleveland VA Medical Center, MetroHealth Medical Center, Northeast Ohio Medical University, and University Hospitals of Cleveland.

Please note that this is the ONLY pilot opportunity for which faculty at Kent State University or Northeast Ohio Medical University may apply.

Any additional reporting requirements: None (See General Requirements)

Funding Track: Digestive Health Research Initiative

Number of Awards: 2
Amount of Each Award: $15k

Description: The Case Digestive Health Research Institute (DHRI) was established in July, 2015, and houses a robust organizational infrastructure capable of supporting and promoting interdisciplinary basic science, translational, and clinical digestive disease research.   The DHRI is accepting pilot project proposals aimed at better understanding the relationship of SARS-CoV-2/COVID-19 and digestive disease as further outlined below.

Types or Examples of Projects: In alignment with the NIDDK research areas of interest and the goals of the Cleveland DDRCC, the following focus areas are emphasized:

- Collection of biosamples that could inform the pathogenesis of COVID-19 associated gastrointestinal, or metabolic diseases;
- Studies to gather data from health care systems and ongoing clinical trials to better understand whether patients with COVID-19 and diseases in the mission of NIDDK have different outcomes based on underlying disease factors or therapies for their condition;
- Studies to identify risk factors that could lead to modification of therapy in high risk individuals such as patients with inflammatory bowel disease and other diseases within the mission of NIDDK that are treated with immunomodulators or biologic pathway inhibitors;
- Studies to identify novel pathogenic pathways and potential translational targets for the development of gastrointestinal and metabolic diseases associated with COVID-19 infection using relevant in vitro and in vivo studies of the gastrointestinal or metabolism system.

Special Requirements:

- Multiple-Investigator proposals are preferred;
- At least one Key Personnel on the proposal must be a full or affiliate member of the Cleveland DDRCC;
- No funds will be provided for faculty salary support, travel, large/specialized equipment, journal subscriptions, society memberships, or renovations.

Any additional reporting requirements:

- None (See General Requirements)

Funding Track: Mary Ann Swetland Center for Environmental Health

Number of Awards: 1
Amount of Each Award: $15,000

Description: The mission of the Mary Ann Swetland Center for Environmental Health is to study the complex interplay between the environment and health. The center places special emphasis on investigating the environmental determinants of health inequities to translate these findings into policies and practices that promote community and population health.

Types of Projects: We will support studies focused on environmental factors (i.e., built, physical, natural, social) influencing COVID-19 transmission and sequalae with priority given to studies focused on populations disproportionately burdened by COVID-19 such as African American populations.

Special Requirements:
- Team must include at least one faculty affiliate of the Swetland Center.

Any additional reporting requirements:
- Awardee must provide a seminar as a part of the Swetland Center Seminar series (date TBD).

SECTION 3: SUMMARY OF REQUIREMENTS
(where funding track requirements may be different from general requirements)

	NORD Family Foundation	CTSC	Cancer Center	Cleveland Brain Health Initiative	CFAR	Digestive Health Research	Swetland Center
Number of Awards	4	5	3	2	2	2	1
Award Amounts	$25k	Up to $40k	$25k	$15-20k	$25K	$15k	$15k
Permits animal studies	X		X	X	X	X	
Special Requirements		X	X	X	X	X	X
Has additional reporting requirements		X			X		X

NOTE: Details of this RFA are based on both CWRU and CTSC templates, as well as requirements and project ideas found in other publically available pilot program announcements.