Request For Applications (RFA)

Rapid Acceleration of Diagnostics – Radical (RADx-rad)

Novel Biosensing for Screening, Diagnosis and Monitoring of COVID-19 from Skin and the Oral Cavity

Background:

The REACH (Research Evaluation and Commercialization Hub) program is a National Institutes of Health (NIH) initiative that has created five new proof-of-concept product development hubs. The goal of the program is to accelerate the translation of ground breaking innovations to benefit human health into commercial products that improve patient care and enhance health. Kentucky's REACH hub is KYNETIC (Kentucky Network for Innovation & Commercialization).

This RFA brings together the KYNETIC REACH program and NIH issued Rapid Acceleration of Diagnostics (RADx) in response to the declared public health emergency issued by the Secretary, Department of Health and Human Services (DHHS), for the 2019 Novel Coronavirus (COVID-19). The Rapid Acceleration of Diagnostics - Radical (RADx-rad) is one of four RADx emergency initiatives providing an expedited funding mechanism.

KYNETIC will accelerate translation of academic innovations into biomedical products across the Commonwealth of Kentucky. Led by the University of Kentucky, the University of Louisville, and the Kentucky Cabinet for Economic Development on behalf of KY public universities, KYNETIC will fund translational research and will provide commercialization-related education and training, as well as feedback from various experts, including the NIH and their partners (see https://ncai.nhlbi.nih.gov/ncai/resources/other).

The KYNETIC program is not a traditional grant program, it is product-focused and requires business-case project management. Applicants who are invited to submit a full application will work with project managers and/or mentors to develop a product development plan and timeline. Receipt of funding for selected projects will be milestone-driven and KYNETIC staff will monitor project progress. There will be a competitive renewal evaluation (go/no-go decision) every year and non-progressing projects may be terminated and replaced with new projects.

Purpose:

The goal of KYNETIC REACH-RADx-rad is to solicit proposals for the development of novel, nontraditional approaches to identify the current SARS-CoV-2 virus or other markers of the COVID-19 disease that can be used in future outbreaks of COVID-19 and that could be applicable to other, as yet unknown, viruses. In early August, seven RADx-rad Funding Opportunity Announcements (FOAs) were published. Three of the FOAs in the RADx-rad initiative aim to support development of **"Novel Biosensing for Screening, Diagnosis and Monitoring of COVID-19 from Skin and the Oral Cavity"*.** These FOAs solicit applications for development of novel biosensing technologies that leverage the accessibility of human skin and the oral cavity for detection of biological, chemical and other biometric signatures of COVID-19.

While these FOAs call for relatively advanced projects, this **RADx-rad biosensing initiative also aims to support incubation of promising early stage projects solicited through the REACH Network** to advance early Feasibility and Proof of Concept (analogous to Phase I SBIR projects). This special solicitation for REACH projects seeks applications for biosensing technologies intended for the detection of volatile organic compounds (VOCs) emanating from skin and/or multiple (i.e., biologic, chemical and physical) biosignatures captured from the oral cavity in COVID-19. A total of 5-10 projects will be selected across all REACH hubs for funding at a level of up to $250,000 per year for up to 2 years. It is expected that projects funded through REACH will strongly demonstrate early feasibility of proposed R&D to position the projects for competitive SBIR/STTR Phase I or Phase II funding in the future.

Specific Objectives:

Biosensing and detection technologies submitted to this initiative should provide reliable associations between biomarkers emanating from skin or the oral cavity to patients with symptomatic and asymptomatic COVID-19. Leveraging the accessibility of human skin and the oral cavity, this FOA seeks (1) to advance novel biosensing

technologies that are innovative, safe, and effective, and (2) to implement such technologies into devices with integrated artificial intelligent (AI) systems for the detection, diagnosis, prediction, prognosis and monitoring of COVID-19 in clinical, community and everyday settings.

To this end, dedicated engineering and artificial intelligence systems are required. For skin monitoring, the device can include Electronic-nose (E-nose) technology or Gas Chromatography (GC). Thus, biosensing technologies targeting VOCs emanating from skin or the oral cavity will be referred to as **SCENT (Screening for COVID-19 by E-Nose Technology)**. **Oral biosensing devices** may consist of technologies that are thoroughly characterized as safe and effective in preclinical studies to conform to and perform in the oral cavity. Non-invasive, real-time, continuous or periodic measurements of VOCs and other biomarkers in breath, droplets, tissues and other samples emanating from the oral cavity as signatures of onset, progression, and resolution of COVID-19 are desirable.

Multidisciplinary collaborations are expected to ensure project success. Disciplines may include: Biomedical engineers, material scientists, biosensing experts, software engineers, chemists, dentists, clinicians, virologists, clinical trialists, biostatisticians, data analysts and other relevant experts in academia and industry.

Eligibility:

This RFA is open to all faculty, staff, trainees, and students at all participating public Universities and community colleges within Kentucky. Non-faculty applicants must identify a faculty member who is willing to sponsor their application. Multiple Principal Investigators (up to three) are permitted. Applications should involve technologies or ideas that originate from within one of the participating public universities or community colleges that have pending intellectual property or are eligible for patent protection, copyright or some other mechanism for intellectual property protection. Technologies that are already licensed to a company are not eligible. Clinical trials (by NIH definition) are not allowed.

Budget and Duration:

Requests for $250,000 (total costs) per project, over a period of 1 year, will be considered. Projects are eligible for a one year renewal.

Important Dates (anticipated):

Pre-application deadline:	September 4, 2020
Full applications invited:	Approximately September 10, 2020
Full application due:	Approximately October 15, 2020 (by invitation only)
Full application presentations:	To be determined (mid-November, 2020)
Award start date:	January 1, 2021 (anticipated)

Pre-application Instructions

KYNETIC-Rapid Acceleration of Diagnostics – Radical (RADx-rad)

Novel Biosensing for Screening, Diagnosis and Monitoring of COVID-19 from Skin and the Oral Cavity

Format: The pre-application must be submitted as a single PDF document consisting of the sections shown in the table below. Please prepare the documents in Word, convert to PDF, and compile into a single PDF document.

Section	Format	Limit
Cover page	Part of fillable pre-application form.	1 page
Demographic information	Part of fillable pre-application form.	No limit (please complete for each PI/Co-PI)
Product description	Part of fillable pre-application form. Must have at least 0.75-inch margins, 12-point Calibri font, and single spacing in main text.	**2 pages** (including any figures and tables)
References cited	Part of fillable pre-application form.	**10 references**
Other Support	Part of fillable pre-application form.	No limit
OPTIONAL: PI & key personnel biosketch(es)	Any (e.g. NSF, NIH)	5 pages per person

In addition to these application forms, please submit a **non-confidential abstract** (maximum of 250 words) as an editable **Word document**. The abstract may be shared with industry representatives and investors, so please ensure that the abstract does not contain any proprietary information. If you have questions or need assistance composing your abstract, please contact Sarah Andres or Jessica Sharon (kynetic@louisville.edu) or Kendra Stenzel (kynetic@uky.edu).

Submission Deadline: Submit your pre-application as a single PDF file to either kynetic@louisville.edu or kynetic@uky.edu by **5:00 PM (Eastern time) on Friday, September 4, 2020**.

Questions & Assistance: KYNETIC staff can answer questions about this RFA and assist you with various aspects of the pre-application preparation. We encourage informal inquiries about whether an idea or product would be suitable for this program. If necessary, we may be able to help find a suitable collaborator and/or faculty sponsor (for non-faculty applicants). Email kynetic@louisville.edu or kynetic@uky.edu with questions or to set up an appointment to discuss the KYNETIC grant pre-application or your idea.

Cover page: Complete the form as indicated.

Demographics: Complete the form as indicated.

Product description: This section should be 2 pages or less. Answer each question below:

1. Describe the product/idea you are proposing. Does it address an unmet clinical need?
2. Describe the market for this product and any competitive products currently in use or development.
3. How is your product unique and is it patentable? If not patentable, is other proprietary protection likely?

4. In broad terms, how do you plan to use the funds? Describe for the first $250,000 AND up to $500,000.
5. Briefly explain any specific expertise and experience the PI and/or team have that will help this project.

References cited: Up to 10 literature references may be listed, but this is optional.

Other support: List past, present, and pending support relevant to the proposed product. Or state "none".

Biosketches: A biosketch or resume for the PI and other key personnel may be included, but is optional.

Pre-application Review Procedures

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Administrative review of pre-applications:

The KYNETIC hub staff will review pre-applications to determine if they are responsive to the RFA and may exclude any that are unsuitable for this program.

Scientific and commercialization review of pre-applications:

Responsive pre-applications will be reviewed based on various criteria, including scientific merit, clinical relevance, intellectual property (IP) position, market potential, and time to market. Pre-application reviewers will include faculty with scientific, clinical, and/or entrepreneurship expertise, plus Technology Transfer staff who will assess patentability and commercialization potential.

Next steps:

All applicants who submit a pre-application will be notified of the outcome (invited or not invited to submit a full application) on or around September 9, 2020. Those who were not invited will receive a brief description of why their pre-application was not selected and will be encouraged to meet with KYNETIC hub staff to discuss the possibility of resubmission. Invited applicants will receive further instructions regarding preparation of the full application. Submission of a full application will involve additional training in research commercialization and working with mentors to create a detailed product development plan. While a Research Disclosure Form is not required to submit a pre-application, completion of this form will be required prior to full proposal submission. Final funding decisions will be made following review by the KYNETIC External Review Board (ERB) and by the NIH Technology Guidance Committee (TGC).