



# CALL FOR PROPOSALS | Due October 16, 2020

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

### Special Solicitation for NIH Rapid Acceleration of Diagnostics – Radical (RADx-rad)

The Midwest Biomedical Accelerator Consortium (MBarC), an NIH Research Evaluation and Commercialization Hub (REACH), is a partnership program between NIH and funded institutions (led by the University of Missouri), aimed at accelerating the transition of discoveries originating from academic research into products that improve health. MBarC bridges the gap between academic research and industry by providing funding, training and resources to translational researchers to perform experiments and generate data that will attract funding from investors and strategic partners to continue commercialization of the technology. This special RADx-rad biosensing initiative aims to support translation of technologies for screening, diagnosis and monitoring of COVID-19 by incubating promising early stage MBarC projects.

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#### **PURPOSE**

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. The goal of 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 initiative also aims to support incubation of promising early stage projects** 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. **It is expected that projects funded through all REACH Programs, including MBarC, 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.

#### **\* RADX-RAD FOAS**

- Emergency Awards RADx-RAD: Screening for COVID-19 by Electronic-Nose Technology (SCENT) (**U18** Clinical Trial Not Allowed) [RFA-OD-20-017](#)
- Emergency Awards RADx-RAD: Novel Biosensing for Screening, Diagnosis and Monitoring of COVID-19 From Skin and The Oral Cavity (**Direct to Phase II SBIR (R44)** Clinical Trial Not Allowed) [RFA-OD-20-020](#)
- Emergency Awards RADx-RAD: Novel Biosensing for Screening, Diagnosis and Monitoring of COVID-19 From Skin and The Oral Cavity (**Fast-Track STTR** Clinical Trial Not Allowed) [RFA-OD-20-021](#)

#### **MBArc PROCESS**

Using proven methods and resources like the Concept to Clinic: Commercializing Innovation (C3i)/Coulter process, MBArc will identify innovative technologies, educate/train qualifying innovators, allocate funding to conduct feasibility studies and actively manage funded project progress toward predetermined milestones.

**MBArc will support each project funded through this opportunity with up to \$250,000 per year for up to 2 years.** Note that NIH plans to fund a total of 5-10 projects from the [REACH network](#).

#### **HOW TO APPLY – ELIGIBILITY AND REQUIREMENTS**

- All faculty are eligible to serve as Principal Investigator (PI). Co-I(s) and Collaborator(s), if required, must be from partnering MBArc institutions.
- The technology must be an idea or invention based on the applicant's institution's intellectual property.
- **To start your application process, request a meeting** with MBArc Lead Program Manager Jaya Ghosh (Email: [ghoshj@missouri.edu](mailto:ghoshj@missouri.edu); Phone: (573) 882-0522) to discuss next steps in submitting a proposal. For additional information about eligibility and application requirements, contact the Program Office for assistance.