Point of Care Technology Research Network

RFA-22-203
TECHNICAL ASSISTANCE WEBINAR

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National Institute of Biomedical Imaging and Bioengineering
Engineering the Future of Health
Point of Care Technology Research Network

Overarching Goal

The POCTRN catalyzes innovation in diagnostic technologies through a network model that enhances complementary strengths and builds multidisciplinary partnerships across scientific/technological, clinical, regulatory, and commercialization domains.
NIH Point of Care Technology Research Network

• PAST.PRESENT.FUTURE

2007 Award Recipients
• Point-of-Care Center for Emerging Neurotechnologies, University of Cincinnati
• Center for Point-of-Care Technologies Research for Sexually Transmitted Diseases, Johns Hopkins University
• Center for Point-of-Care Technologies for Disaster Readiness, University of California, Davis
• Center to Advance POC Diagnostics for Global Health, Program for Appropriate Technology in Health (PATH)

2012 Award Recipients
• Center for Point-of-Care Technologies Research for Sexually Transmitted Diseases, Johns Hopkins University
• Center for Innovation in Point of Care Technologies for the Future of Cancer Care, Boston University
• Point of Care Technology Research Center in Primary Care, CIMIT

2018 Award Recipients
• Atlanta Center for Microsystems Engineered Point-of-Care Technologies, Emory University
• Center for Point-of-Care Technologies Research for Sexually Transmitted Diseases, Johns Hopkins University
• Center for Innovation in Point of Care Technologies for HIV/AIDS at Northwestern, Northwestern University
• Center for Advancing Point of Care in Heart, Lung, Blood, and Sleep Diseases, UMass Medical School

COLLABORATION * CLINICAL TESTING OF PROTOTYPES * CLINICAL NEEDS ASSESSMENTS * TRAINING
Technology Research and Development Center (TRDC)

- The purpose of this funding opportunity announcement is to solicit Technology Research and Development Center (TRDC) applications for the Point-of-Care Technologies Research Network (POCTRN).

- Each TRDC will accelerate the:
  - Development
  - Validation
  - Deployment
  of point-of-care, home-based and other innovative testing technologies in a specific area of health research.

- The POCTRN TRDCs will merge scientific and technological capabilities and expertise with clinical need and market demand to address unmet testing, monitoring, and treatment demands.

- This opportunity is open to all applicants, including the existing POCTRN grantees and new applicants.
NIH STATEMENTS OF INTEREST

National Institute of Biomedical Imaging and Bioengineering (NIBIB)
National Heart, Lung, and Blood Institute (NHLBI)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institute on Drug Abuse (NIDA)
Fogarty International Center (FIC)
National Center for Complementary and Integrative Health (NCCIH)
National Cancer Institute (NCI)
National Institute of Biomedical Imaging and Bioengineering (NIBIB)

- The mission of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) is to transform through engineering the understanding of disease and its prevention, detection, diagnosis, and treatment.

- NIBIB supports new tools and technologies to improve human health within its internal laboratories and through grants, collaborations, and training.

- In the area of POC technologies, the NIBIB supports research that enables patient-centered health care through the development and application of point-of-care and home-based technologies.

- The NIBIB will support point-of-care and home-based technologies to detect, measure, and analyze biological information including molecular, genomic, cellular, clinical, behavioral, physiological, and environmental parameters at the site of patient care or within the home to assist prevention, diagnosis, treatment, and management of diseases.

NIBIB is interested in supporting Research Center(s) that are structured around emerging technologies, clinical needs and opportunities in the following example areas, but not limited to:

- Primary Care
- Emergency Preparedness
- Emerging Infectious Diseases
- Low-Resource Settings
- Ambulatory Care
National Institute of Allergy and Infectious Diseases (NIAID)

• NIAID conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.

• For more than 60 years, NIAID research has led to new therapies, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people in the United States and around the world. NIAID advances the understanding, diagnosis, and treatment of many of the world’s most intractable and widespread diseases.

NIAID is interested in supporting, by intellectual and technical input and guidance, POCTRN TRDC that are structured around emerging technologies, clinical needs and opportunities focused on advancing innovative point-of-care and home-based diagnostic technologies for emerging and re-emerging infectious diseases, sexually transmitted infections, and other research areas within its mission. Technologies to distinguish vaccine induced seropositivity from infections or to allow early detection or characterization of emerging variants conferring resistance to treatment are needed.
NIDA focus is to support the transition of scientific discoveries and engineering advances into tools to address the clinical and field research in the area of drug detection, screening and quantification with the goal of diagnosis, treatment, treatment monitoring and/or disease management. Additionally, devices aiding the determination of cause of death in cases of suspected drug overdose are of interest.

NIDA is interested in funding one center for the development, validation and/or adoption of point of care (POC) technologies in clinical and other settings where the point-of-need devices and assays will be deployed.

A NIDA POCTRN center is envisioned to incentivize the development of point of care (POC) technologies for substance use disorder (SUD) care continuum, including technologies explicitly designed to address challenges and barriers associated with SUD health disparities and low resource settings. For this purpose, the center will encourage the engagement of minorities, tribes, as well as justice system-involved groups during technology optimization and validation to better serve underserved populations.

Examples of POC technologies supported by NIDA could include, but are not limited to:

- POC technologies for drug quantification in blood, saliva, sweat or tissues with minimal or no sample preparation;
- POC technologies capable of analyzing 2 or more matrices without change in workflow;
- Reusable POC drug panels for rapid toxicology testing;
- Low-cost electrochemical, optical or calorimetric-based POC platforms for drug detection;
- PON technologies focused on rapid detection of emerging drugs of abuse and/or drug analogs;
- Technologies that enable processing of complex samples in point-of-need settings to facilitate the POC use of existing technologies.
The NHLBI supports development of technologies to detect, prevent, or treat heart, lung, blood and sleep (HLBS) disorders and clinical use of blood and all aspects of the management and safety of blood resources.

The NHLBI is interested in sponsoring a Center to facilitate clinical validation and adoption studies for technologies that can be deployed in low-resource settings.

The NHLBI Center will not support early-stage development of prototypes.

The NHLBI Center is anticipated to have the capacity to cover four main programmatic areas: heart, lung, blood, and sleep disorders. The applicant is encouraged to have co-investigators or collaborators with expertise in all four programmatic areas.

Examples of POC technologies supported by NHLBI Center could include, but are not limited to:

- POC technologies that can detect acute condition or deterioration of chronic diseases and facilitate clinical decisions, such as bleeding, thrombosis, pulmonary embolism, and heart failure decompensation.
- POC technologies that will enable continuous monitoring and management of chronic diseases at home, such as heart failure, chronic obstructive lung disease, asthma, and sickle cell disease.
- Integrated devices that can monitor multiple parameters, such as heart rate, respiratory rate, temperature, asthma status, blood pressure and sleep quality.
- Enabling, minimally invasive, biomarker detection technologies for early identification of HLBS diseases and disorders.
- Mobile applications and POC technologies for improving patient self-management, communications with health care providers, and adherence to treatment as well as to help clinicians monitor patients’ response to treatment and allow for clinical decisions.
The Fogarty International Center is dedicated to advancing the mission of the NIH by supporting and facilitating global health research conducted by U.S. and international investigators, building partnerships between health research institutions in the U.S. and abroad, and training the next generation of scientists to address global health needs.

The FIC is interested in facilitating research in a Center on the development, validation, and adoption of technologies to address global health problems.

Additionally, the FIC prioritizes collaborations with and training of LMIC researchers.

Technologies studied should be specifically suited for low resource settings and applicable to low- and middle-income countries (LMICs; as defined by the World Bank as low-, lower-middle-, or upper-middle-income economies).

Specific health areas of focus should be justified and highly relevant to priorities in LMICs.
The NCCIH supports the development and validation of technologies that can facilitate the integration of complementary and integrative health approaches into the points-of-care for diseases and conditions to enhance diagnosis, prevention, or treatment of diseases and/or associated symptoms, or promotion of well-being.

Complementary health approaches include a broad range of practices and interventions that are not typically part of conventional medical care and can be classified by their primary therapeutic input, including nutritional (e.g., special diets, dietary supplements, herbs, probiotics, and microbial-based therapies), psychological (e.g., meditation, hypnosis, music-based interventions, relaxation therapies), physical (e.g., acupuncture, massage, chiropractic manipulation, other force-based manipulations, or devices related to these approaches), or a combination of psychological and physical (e.g., yoga, tai chi, dance therapies, or some forms of art therapies, such as music-based interventions) input.

Examples of such technologies include, but are not limited to:

- Mobile devices or applications that can monitor the dose, intensity, duration and/or frequency of complementary approaches employed by the patients at POC.
- Technologies that can objectively measure pain or functional limitations due to pain, which would be treated by complementary approaches, at home or in primary care facilities.
- Technologies that can monitor or enhance physiological responses to complementary approaches at POC for the treatment of pain, fatigue, sleep disorder, mild to moderate depression, anxiety, or other symptomatic conditions.
- Development and testing of mobile health technology or nonmobile technology and methods to monitor or quantify pain, physical and/or emotional well-being, breathing, sleep, or whole person health.
The focus of the NCI in this initiative is to support the transition of scientific discoveries and engineering advances into tools to address clinical cancer research for assessment of cancer risk, cancer screening, early detection, prevention, diagnosis, treatment, treatment monitoring and/or disease management.

The NCI is interested in funding one center for the development, validation and/or adoption of point of care technologies in clinical and other settings where the point-of-care device and assays will be deployed.

The cancer POCTRN center is envisioned to incentivize the development of POC technologies for cancer care continuum, including technologies explicitly designed to address challenges and barriers associated with cancer health disparities and low resource settings. For this purpose, the center will encourage the engagement of minorities during technology optimization and validation to better serve underserved populations.

Examples of POC technologies supported by the NCI include, but are not limited to:

- POC technologies that work with non-invasive or minimally invasive samples
- POCTs for in vitro and in vivo imaging
- Portable platforms for near patient use
- Paper based POC platforms
- Printed sensor/electrode based POC platforms
- Smartphone-based platforms (beyond cell phone apps)
- Technologies that enable processing of complex samples, such as samples obtained by self-sampling, in the POC and point-of-need settings to quickly deliver results
Section II: Award Information

Funding Instrument
Cooperative Agreement

Application Types Allowed
New
Renewal

Funds Available and Anticipated Number of Awards
The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget
Application budgets are not limited but it is strongly recommended that applicants not request a budget of more than $1.2M in direct costs per year. Facilities and administrative costs requested by consortium participants are not included in the direct cost limitation.

Award Project Period
A project period of up to five years may be requested.
Key Dates:
Earliest Application Date: August 26, 2022
Letter of Intent Due: 6 weeks prior to application due date
Applications Due: September 27, 2022
AIDS Applications Due: January 7, 2023
Details and to apply: PAR-22-203
Section III. Eligibility Information

Foreign Institutions
Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply.
Foreign components, as defined in the NIH Grants Policy Statement, are allowed.

Letter of Intent
Prospective applicants are asked to submit a letter of intent 6 weeks prior to application due date
that includes the following information:
• Descriptive title of proposed activity
• Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
• Names of other key personnel
• Participating institution(s)
• Number and title of this funding opportunity
## Multi-Component Application

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