



Overview Information

Funding Opportunity Title

2019 CCTS Pilot Translational & Clinical Studies Program: *Artificial Intelligence and Machine Learning in Translational Science and Human Health*

Funding Opportunity
Purpose

The purpose of this RFA is to foster transformative research, innovative discovery, multidisciplinary and team science approaches using artificial intelligence and machine learning to advance translational science and ultimately improve human health.

The pilot-feasibility-incubation funding mechanism of the CCTS Pilot Translational and Clinical (PTC) Studies Program is funded by the National Institutes of Health (NIH) [National Center for Advancing Translational Science](#) and aims to deliver high-quality high-impact research supporting team science and generation of preliminary data to enable researchers to successfully compete for extramural funding. The goal of NIH NCATS is to transform [translational science](#) to get more treatments to more patients more quickly. The Ohio State CCTS seeks proposals that address scientific questions [consistent with the Center's mission](#) at any "stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public" as described in [NIH NCATS' Translational Science Spectrum](#).

Key Dates*

<i>Release Date</i>	September 14, 2019
Pre-Application Due Date	December 10, 2019, midnight
Full Application Invitations	December 15, 2019
Full Application Due Date	January 31, 2020, midnight
External & Internal Reviews	February & March 2020
Notice of Award Date	April 15, 2020
Earliest Start Date	June 1, 2020
Expected Publication Date	June 2022

*some dates may vary as a result of unanticipated delays

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Section I. Funding Opportunity Description

Purpose

Artificial Intelligence (AI) and Machine Learning (ML) provides an unprecedented opportunity to accelerate and revolutionize human health and the pace of clinical and translational science. The purpose of this request for applications (RFA) is to stimulate and support transformative, innovative, interdisciplinary pilot and early stage studies that will leverage the power and impact of artificial intelligence and machine learning in new fields and applications and/or brings a new approach to the design or implementation of AI solutions. Ideal CCTS pilot grant projects leverages the university's strength across all disciplines, can be completed in one year, are distinct from existing sponsored research, and are intended to form a basis for larger grant applications or commercialization.

The program seeks to nurture collaborations across different fields to build, test and refine AI and ML algorithms using a variety of data sources, which may include images, electronic health records, wearable devices, smart phones and other sensor-related technology, genetics and biology. There is no field of study restriction and these grants are open to all scientists including bioinformatics, computer programming, biostatistics, and other computer programming related disciplines. Research areas expected to benefit from AI include medical imaging analyses, diagnostics, genomics, vaccine design, large-scale integrative analysis of data, healthcare analytics, precision medicine, and public health, to name a few. In this RFA, the definitions of AI, ML, and deep learning (DL) are framed as follows:

- AI: A larger umbrella of computer intelligence; a program that can sense, reason, act, and adapt
- ML: A type of AI that uses algorithms whose performance improves as they are exposed to more data over time
- DL: A subset of ML in which multilayered neural networks learn from vast amounts of data

The mission of the Pilot Translational & Clinical Studies (PTC) Program of the OSU CCTS is to transform and advance the discipline of clinical and translational science at The Ohio State University and Nationwide Children's Hospital by catalyzing scientific innovation. A key component of this mission is to convene and support new teams, which include the authentic inclusion of community stakeholders at every level of the research process. Through the Pilot Translational and Clinical Studies program, we strive to improve health outcomes by funding meritorious pilot projects to generate preliminary data and refine research strategies for subsequent extramural grant applications or to develop the best approaches and methodologies to address complex translational and clinical research problems. AI and machine learning approaches have a host of applications throughout all stages of the translational science spectrum and will require new interdisciplinary collaborations, resources and strategies that are augmentative and complementary to human analyses and observations. We are committed to supporting the development of biomedical AI technologies and applications to improve human health. This pilot grant mechanism supports discrete, well-defined projects with emphasis on development of transformative machine intelligence-based systems, emerging tools, and modern technologies for diagnosing, predicting and recommending treatments for a range of diseases and health conditions. Another goal is to foster interdepartmental and interschool collaborations involving disciplines outside traditional computational fields such as but not limited to economics, law, education, business, public policy, sociology, philosophy, biology and medicine.

Projects proposed under this announcement could involve, but are not limited to, the following approaches or areas:

- Diagnostic classification using one or more data sources, such as images, EHR data, wearable devices, mobile health and public / private data sources
- Computer vision or robotic and image guided surgery
- Personalized imaging and treatment as well as in-home noninvasive patient monitoring and improving performance and health behaviors (health-promoting apps)
- Early-stage development of software, tools, and reusable convolutional neural networks
- Prospective evaluation of decision support algorithms in the clinical environment or natural-language processing and predictive modeling
- Design, development and/or dissemination of AI systems, innovative algorithms, software, methods, and computational tools to enhance analysis of complex medical images and data to enhance early detection,

reduce diagnostic errors, select appropriate treatment, or improve the quality and efficiency of medical imaging

- Clinically meaningful and/or predictive behavioral ‘digital biomarkers’
- Software as a Medical Device (AI/ML-Based SaMD) development
- Next generation AI technology inspired by neuroscience, cognitive science and behavioral science

A publication submitted to a peer-reviewed journal **within 1 year of project completion** is a desired outcome of this grant. Any publications resulting from awards funded under this RFA must include an acknowledgement of the [CCTS grant citation](#), source(s) of shared data and any funding sources which supported the initial data collection. Applicants should discuss co-authorship plans with original and/or contributing investigator(s) prior to submitting an application.

Section II. Award Information

Funding Instrument	Pilot Grant
Application Types Allowed	New
Award Budget	Applicants may request \$25,000 to \$50,000 Direct Costs. No indirect costs are allowed.
Funds Available and Anticipated Number of Awards	The CCTS , along with Office of Research , Technology Commercialization Office and Translational Data Analytics Institute have committed pilot funding for this RFA with a total available funding of \$225,000. Funding is subject to a sufficient number of meritorious applications.
Award Project Period	June 1, 2020 – May 31, 2021 to coincide with CTSA grant year of the CCTS. Projects must be completed by May 31, 2021.
IRB Submission, if study meets human subject study criteria.	CCTS is supported by the National Institutes of Health National Center for Advancing Translational Sciences (NIH/NCATS) via the Clinical and Translational Science Award (CTSA) Program. As such, CCTS is required to submit documentation based on IRB approval for each applicable pilot project that has been recommended for funding. NCATS requires IRB approval and all related documentation at least 30 days before the project start date. To accommodate this timeline, we require projects invited to advance to the next round to complete their IRB submission of on or before January 31, 2020.
Award Start Date	Awarded proposals must meet several requirements prior to the start date. See Section VI Application Review Instructions. NIH / NCATS (the sponsor of the CTSA Program that funds the CCTS) has a policy applicable to all CTSA-sponsored projects that involve human subjects and/or vertebrate animals. Full pilot applications identified by comprehensive review as meritorious for funding will be subject to NIH review and prior approval prior to release of funds. Documentation for this federal review will be collected from applicants and submitted after acceptance of the award if selected for funding. If the NIH/NCATS declines such approval, the CCTS will not be able to support the project.

Section III. Eligibility Information

Eligible Individuals (Principal Investigator & Team)

This program is primarily intended to support proposals from faculty who qualify as a Principal Investigator (PI) according to The Ohio State University or Nationwide Children’s Hospital Policy. All PI(s) must have an eRA Commons account. Note that for the purposes of this award and in the language of this RFA, the roles of Principal Investigator (PI) and Co-Principal Investigator (Co-PI) are equivalent. These are distinct and have different requirements from the roles of the Co-Investigator (Co-I). This award allows for, but does not mandate, a multiple PI model. Please review the FAQs on CCTS Pilot Grants on our website for additional information.

Section IV. Pre-Application Submission Guidelines

This pilot program involves a two-phased application process: a Pre-Application and a Full Application.

Phase One: A Pre-Application is *required* by this mechanism. The FAQs on CCTS Pilot Grants available on our website will serve as the instructions and guidelines for both Pre-Application and Full Application submissions.

Submission Process. Pre-Applications will be submitted through an online REDCap form, which can be found on the CCTS Pilot Program webpage dedicated to this RFA. **Chrome is the preferred browser for this REDCap submission form.** Submit Pre-applications by the date listed in Key Dates*. After pre-application proposals are reviewed, some projects will advance to the next round and invited to complete a **Full Proposal** by January 31, 2020.

Section V. Full Application Submission Guidelines

Phase Two: Full Application

Full proposals will not be accepted without invitation.

The FAQs on CCTS Pilot Grants will serve as the instructions and guidelines for Full Application submissions.

Submission Process. Full Applications will be submitted through an online REDCap form, shared with investigators in the email they receive acknowledging their meritorious pre-applications and invitation to submit Full Applications only. **Chrome is the preferred browser for this REDCap submission form.** Submit Full Applications by the date listed in Key Dates*. Additional resources can be found on the CCTS webpage dedicated to this RFA. **IMPORTANT:** Please note that you are required to include a Lay Summary as part of the full application. You could also choose to prepare a 5 minute video which explains your proposed project to a general (lay) audience. Lay Summary (written or visual) must minimize jargon and promote readability and understanding at a nonscientific lay level. Please see the FAQ section on the website for additional instructions.

Section VI. Application Review Process & Criteria

The full application will be sent to a minimum of two external reviewers with expertise in fields relevant to the science in the proposal. Additionally, proposals may be reviewed by trained community reviewers through a new community reviewer training program of the CCTS. Do not submit any confidential or proprietary information through this application. All applications will be scored on each of the review criteria using NIH 9-point scale along with written reviews. Full proposals will be subject to a NIH-type study section assessment and interactive discussions based on the submitted written feedback from external reviewers, institutional context and the overall relevance to the mission of the CCTS. The review committee (CCTS Pilot Council and ad hoc experts) will make recommendations on funding priority of best scored proposals. All external and internal reviewers will be asked to disclose any relationships to the grant applicant. Please check all criteria to be compliant, competitive and successful.

Review Criteria

Applications will be assigned an Impact Score (NIH 9-point scale) corresponding to the overall scientific merit of this pilot proposal taking into account qualifications of research team, scientific approach and significance as well as overall impact. Complete details about our scientific and other criteria can be found in our FAQ document.

Section VII. Award Administration Information

Anticipated Announcement and Award Dates

Meritorious applications will receive formal notice in the form of a Notice of Award provided to the applicant. Any costs incurred before receipt of the NOA are at the recipient's risk. Any application awarded in response to this RFA will be subject to terms and conditions listed in the NOA as well as federal requirements found on the [Award Conditions and Information for NIH Grants](#) website. A completed and signed CCTS Pilot Award Acceptance Packet which includes a Fiscal Information Form is required following the NOA. **Initial release of funds, "award activation", will be contingent upon timely receipt of all required documents and verification of research regulatory approvals.** In the event that additional intra/extramural funds are secured to support the study outlined in your application during the submission or post-award phase, you must notify Dr. Tanya Mathew at

Tanya.mathew@osumc.edu.

Please refer to Part 1. Overview for dates for peer review, advisory council review, time needed for NCATS prior approval and earliest start date. Section II. Award information summarizes funds available and number of awards. This program has an accelerated nature and only a 12-month funding period. As a milestone driven funding program, grants are managed internally through the CCTS and funds will not be transferred to the awardee's cost center.

Regulatory Approvals

All lines of investigation supported by the CCTS Pilot Program require appropriate regulatory approvals by the CCTS Regulatory Program Manager (IRB and IACUC, as applicable). These approvals must be in place in advance of human subjects research and the project must remain in good standing throughout study implementation.

Project Milestones & Timeline

As a milestone-driven funding program, if the team does not make sufficient progress within 3 months of the award, they may be subject to referral and review by leadership for possible forfeiture of the award.

Section VIII. Agency Contacts

Scientific/Research & Grant Management Contact

Please review the FAQ document on our website for complete details. If you have any additional questions, please contact:

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