Overview Information

Funding Opportunity Title

2019 CCTS Pilot Translational & Clinical Studies Program: Secondary Analysis of Existing Datasets

Funding Opportunity Purpose

The purpose of this RFA is to foster innovative studies focused on secondary analyses of existing clinical and translational datasets that will provide new insights that could ultimately improve human health. Existing data sets may be:

1) Publicly available and accessible databases
2) Locally available databases generally accessible by faculty at The Ohio State University or Nationwide Children’s Hospital

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*

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<td>Posted Date</td>
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<td>Full Application Due Date</td>
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<td>External &amp; Pilot Council Reviews</td>
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<td>Notice of Award Date</td>
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*some dates may vary as a result of unanticipated delays

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Section I. Funding Opportunity Description

Purpose

The purpose of this request for applications (RFA) is to promote studies that will significantly advance new discoveries and accelerate the pace of clinical and translation research through secondary analyses of the large amount of existing data, from -omics and animal models of disease to data from clinical research studies and epidemiologic studies to that housed in clinical data warehouses. ‘Primary data analysis’ is limited to the analysis of data by members of the research team that collected the data, which are conducted to answer the original hypotheses proposed in a study. All other analyses of data collected for specific research studies or analyses of data collected for other purposes (including registry data) are considered ‘secondary analyses of existing data’, whether or not the persons conducting the analyses participated in the collection of the data. The primary goals of this RFA are to fund studies that will advance translational science by stimulating pilot testing of novel hypotheses and/or to generate innovative models, analytical tools and methods for secondary data analyses. The RFA provides an opportunity for investigators to conduct studies without investing in new data collection and promotes the development of new collaborative relationships among investigators. Desired outcomes of the funded research include a subsequent study to investigate the results further and lay a foundation for sustainable research; a publication and contribution to an evidence base that can be used by stakeholders for refining current approaches and interventions.

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.

This pilot grant mechanism supports discrete, well-defined projects using existing datasets and analyses that realistically can be completed within 6 months. Investigators should not underestimate the time and effort that may be necessary to curate or harmonize data. Investigators are encouraged to propose the analyses for which they have the most appropriate data. A partial listing of available datasets that may be used for re-organizing and re-analyzing is available on our website. New data collection efforts will not be supported under this RFA. Proposals using data that are either publicly available OR can be shared via a data use agreement are preferred.

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

- Innovative analysis of relevant existing datasets to address an existing hypothesis or problem in human health or behavior
- Enhance value of existing data and analysis capability, and strengthen the statistical power and rigor and reproducibility
- Merge similar datasets to allow cross-diagnostic, dimensional analyses such as single or multi-species datasets that incorporate health data from veterinary spontaneous disease models
- Combine or re-align datasets that include a range of participant ages to examine developmental factors or lifespan factors
- Use as part of a mixed methods approach or use to develop new statistical methodologies
- Evaluate trends over time and changes of phenomena over time
- Predict future trends using statistical forecasting techniques, predictive modeling or machine learning approaches
- Advance best practices and determine evidence-based practices for interventions
- Employ fresh perspectives with different disciplines utilizing new analytical tools, new theoretical perspectives, and new operationalization or methodological innovations

EVALUATION OF SECONDARY DATA:

Investigators are encouraged to propose the analyses for which they have the most appropriate and representative data. If investigators did not collect the data, it's important for them to become familiar with the data set: how the data...
was collected, what the response categories are for each question, whether or not weights need to be applied during the analysis, whether or not clusters or stratification need to be accounted for, etc. Other evaluable criteria include:

- Do the data apply to the population of interest?
- Do the data apply to the time-period of interest?
- Do the data apply to the geographic region of interest?
- Do the secondary data appear in the correct units of measurement?
- Do the data cover the subject of interest in sufficient detail and consistent with the problem definition? Are the existing data sets able to answer all of the study questions?
- Do the data lack specific information addressed in the proposal? How will information gaps be addressed by the proposed analysis of the existing data?
- Does the proposal acknowledge the limitations of the dataset and present ways to overcome them?
- What is the validity of the data collection methods used, sampling framework and procedures?
- Are the actual meaning of terms applicable to the proposed study and have there been any recent changes in terminology?
- Is there previous research on the topic using this secondary dataset?

**DATA USE & DATA SHARING PLANS**

Applicants who plan to utilize data not currently in their possession (i.e., they intend to use data originating from another party) must confirm via a Letter of Support the availability of the data and the willingness and permissibility of the original investigator(s) to share the data for the purposes of the secondary analyses, in accordance with all applicable rules for the protection of human subjects, which may include Department of health and Human Services regulations at 45 CFR Part 46, and other federal and state laws for the use of the data. Please provide a Data Sharing Plan and Data Use Agreement, as applicable.

**PUBLICATION PLANS**

A publication submitted to a peer-reviewed journal **within 1 year of project completion** is a desired outcome of this project. 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.

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**Section II. Award Information**

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<th>Funding Instrument</th>
<th>Pilot Grant</th>
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<td>Application Types Allowed</td>
<td>New</td>
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<tr>
<td>Award Budget</td>
<td>Applicants may request up to $15,000 Direct Costs. No indirect costs are allowed.</td>
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<tr>
<td>Funds Available and Anticipated Number of Awards</td>
<td>The CCTS has committed pilot funding for the 2019 cycle with a total available funding of $75,000. Funding will be available for 5 proposals, subject to a sufficient number of meritorious applications.</td>
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<td>IRB Submission, if study meets human subject study criteria.</td>
<td>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 IRB submission on or before September 8, 2019.</td>
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Award Start Date

Awarded proposals must meet several requirements prior to the start date. See Section V 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 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

1. Eligible Applicants

Eligible Individuals (Principal Investigator)

This program is primarily intended to support proposals from full-time PI-eligible faculty and research scientists with primary appointment at any college of The Ohio State University or at Nationwide Children’s Hospital. 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).

1. Only multi-investigator, multi-disciplinary teams and proposals are eligible. Interdisciplinary team building is a requirement and mentor/mentee opportunity is desired. This award allows for, but does not mandate, a multiple PI model.

2. Project team leaders must have principal investigator status at OSU or NCH. Eligibility information can be found at the Ohio State Office of Research website and the NIH website.

3. Principal Investigator (PI) and co-PI (if applicable) are considered as the administrative manager(s) for the application (and the award). For the purposes of this award, there needs to be a designated PI but 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 Investigator or Co-Investigator (Co-I). The PI will be primarily responsible for ensuring compliance with the scientific, safety, and ethical responsibilities of the grant award. For the PI, a history of successful extramural funding and/or leading a multidisciplinary research team will be considered a strength but not a requirement. PI will be responsible for all grant reporting and fiscal management.

4. PI Effort: All PIs must have a minimum of 5% effort without compensation and be fully vested in the project in both spirit and practice and contribute actively on the project.

5. Team Composition: Priority will be given to research teams spanning the spectrum of translational research (T1 through T4 stages), examples of which include teams of pre-clinical and clinical investigators, and clinical and population health investigators. Additional information on these stages can be found at https://ncats.nih.gov/translational/spectrum.

6. Required Training: Applicants, key personnel and significant contributors must complete both RCR training as well as GCP training (if the project involves human subjects) prior to submitting their full applications (September 8, 2019).

7. CCTS Membership: All members of the research team must be CCTS Members in order to apply. To become a member, please complete the CCTS Membership Form.

8. PIs are responsible for fulfilling reporting requirements as a condition of receipt and continuation of funds. Non-compliance of final and/or annual reporting could result in the rescission of funds by CCTS.

CO-INVESTIGATOR

9. A co-investigator must have the requisite research training/credentials/expertise to make a substantive contribution to the science of the study.

10. Study personnel such as research assistant, study coordinator or other staff needed for the conduct of the study may not serve as a Co-Investigator.
11. These awards will NOT support projects that are minor offshoots of ongoing research by a funded investigator or that simply provide bridge funding to previously funded investigators.

12. All personnel must be identified prior to the start date to replace any “to be named” positions proposed in the application.

Section IV. Application and Submission Information

This funding announcement will serve as the instructions and guidelines for the full application submission. Additional resources can be found on the CCTS webpage dedicated to this RFA.

Submission Process. Applications will be submitted through an online REDCap form, which can be found on the CCTS Pilot Program website for this RFA: [https://ccts.osu.edu/content/secondary-analysis-existing-datasets-2019](https://ccts.osu.edu/content/secondary-analysis-existing-datasets-2019). Chrome is the preferred browser for this REDCap Application Form. Submit your application by the date listed in Key Dates*.

CCTS very strongly recommends involving a biostatistician in the application development process. The online application form will ask for the name of the biostatistician who either consulted on the proposal or serves as a member of the project team. For investigators without access to a biostatistician through their Department or Center, biostatistical support can be obtained through the convenient open office hours for biostatistics consultations at Prior Hall on Mondays: 9:00 am - 1:00 pm and Thursdays 1:00 pm - 5:00 pm.

Similarly for regulatory guidance on data involving human subjects that are individually identifiable, applicants are encouraged to contact Sandra Meadows at the IRB, CCTS Regulatory Program Manager, Robert Rengel or avail of IRB Walk-in Office Hours at the CCTS on Wednesdays, 12:30 to 3:30 p.m. or Thursdays, 9 a.m. to 12 noon. for assistance with any IRB-related questions. Our offices are on the 2nd floor at Prior Hall, Suite 260, 376 West 10th Avenue. Investigators are strongly encouraged to visit the CCTS website to search for and avail of other CCTS support services and resources.

Instructions for Application Submission

Online Submission Form

Within the online submission form, you may download the Full Application and prepare your responses and attachments prior to completing and submitting the online Full Application. Instructions for completing the form and returning to it at a later date are contained within the form’s “Instructions” section.

Please complete all sections of the online submission form, including:

- Principal Investigator(s) and Co-Investigator(s) Information
- Project Details
- Scientific Abstract: The abstract summary of the proposal for use by reviewers, review committee members and CCTS (250 word maximum).

Within the online submission form, you will be asked to upload a single PDF containing the following documents (in the order listed below):

- Research Strategy (5 pages)
- NIH biosketch for PI(s) and Co-I(s)
- Budget
- Budget Justification
- Project Timeline
- Acknowledgment of External Review
- Letters of Support from Department Chair(s) of PI(s) & contributors of datasets

Principal Investigator(s)

Please be prepared to provide the following information for project PI(s) in the online submission form: first name, last name, degrees, institution, school, department, division, rank, eRA Commons name, phone number, email, gender, race, ethnicity, diversity status. For more information about diversity status, please see “Revised: Notice of NIH’s Interest in Diversity.”
Project Details

Please be prepared to enter the following information in the online submission form:

- Project title
- Pilot Project Research Category 1 selection (standard NIH NCATS categories of pilot projects): pre-clinical research, clinical research, clinical implementation, public health
- Pilot Project Research Category 2 selection (standard NIH NCATS categories of pilot projects):
  - Method or Process Development
  - Mechanistic Basic to Clinical
  - Biomedical Informatics / Health Informatics
  - Outcomes Research, Health Services Research, and Comparative Effectiveness
  - Clinical Epidemiology
  - Clinical Trial
  - Digital Health
- Statement on CCTS Vision/Mission Alignment: Briefly explain how your project aligns with the vision and/or mission of the CCTS (see Overview & Section I. Funding Opportunity Description).

Full Application Research Strategy

Please submit an expanded description of the experimental plan.

- **Font size**: must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible when the page is viewed at 100%)
- **Type density**: must be no more than 15 characters per linear inch (including characters and spaces)
- **Line spacing**: must be no more than six lines per vertical inch
- **Margins**: Provide at least one-half inch margins (top, bottom, left, and right) for all pages. No applicant-supplied information can appear in the margins.
- **Text color**: must be black (color text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable)
- **Page Limit**: 5 pages (references are not subject to page limits)
- **Rigor, Reproducibility & Transparency (R2T)**. Applicants are required to address R2T concepts in their application. Please see the CCTS Rigor and Reproducibility in Research page for guidance.

This document should be organized as follows:

1. **SIGNIFICANCE**
   - The project must demonstrate significant scientific merit and provide a vision of how it could evolve to a more substantial body of work. Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. Successful applications will address a critical knowledge gap and represent a key step toward improvement in health, treatment or prevention of disease.
   - Describe the general strengths and weaknesses of the prior research being cited as crucial to support the application. Consider discussing the rigor of previous experimental designs, as well as the incorporation of relevant biological variables.
   - Must include a clear and concise hypothesis statement and how the research question relates to the significance of the proposed work (up to 200 words).
   - Translational Research and Human Health Impact: All studies must include a clear translational, human or clinical element. Please comment on how the proposed work fits the definition of Translational Research and demonstrates translation from discovery to practice, including a proposed next step toward translation along the translational science spectrum. All applications must concern disease mechanisms with clear, near term implications for diagnostics, therapeutics or prevention.
   - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. Describe how the concepts, methods, technologies, treatments,
services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

2. INNOVATION

☐ Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe how the innovation has potential for extramural funding or commercialization.

☐ Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.

☐ Explain any novel refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

3. APPROACH

☐ Dataset descriptions - describe the data set, the variables that will be used, sample inclusions/exclusions, etc. Include information about the capabilities and limitations of the dataset, data analyses and how the results will be interpreted as well as any resource sharing plans as appropriate. Explain how the data in the data sets are of sufficient quality to address the specific aims of the study. Include plans to control or account for potential biases and deficiencies in data sets (e.g., missing, inconsistent or implausible data; misclassification and information bias; selection bias; potential confounding). Include data management plan and prepare to upload relevant data use agreement(s).

☐ Be sure to include explicit statements of aims and corresponding hypotheses. A clear and well-written hypothesis statement is a requirement and expectation.

☐ Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.

☐ As applicable, ensure that the research question is relevant and in line with the needs/priorities of stakeholders, including those directly affected by the disease or condition. Engagement of patients and communities in every phase of the translational process is an important goal of our CTSA sponsor NIH NCATS – please visit this website for more information - https://ncats.nih.gov/ctsa/action/goal2. Also, please review this article titled, Community Engagement in Research: Frameworks for Education and Peer Review at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2901283/pdf/1380.pdf

☐ Provide evidence of feasibility of completing the aims and objectives of this project within 6 months. Describe any strategy to establish feasibility.

☐ Rigor, Reproducibility & Transparency: Emphasize how the experimental design and methods proposed will achieve robust and unbiased results.

☐ Explain how relevant biological variables are factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex.

4. PLAN FOR EXTRAMURAL FUNDING

☐ Describe how this work will set the stage for future, extramural support and a specific plan of obtaining extramural funding after successful completion of the pilot study. Please note that establishing commercialization potential is another favorable result of the pilot study.

☐ This should include what this project will provide with regard to the likelihood of the type of grant (including proposed project length, agency, and date of submission) that will be targeted.

5. PLAN FOR PUBLICATION

☐ Describe your specific plan of submission of a manuscript after successful completion of the pilot study since this is a desired outcome of this pilot grant within one year of completion.

☐ This should include names of peer-review scientific journals under consideration.

6. REFERENCES CITED

☐ Provide a bibliography of all references cited. Each reference must include the names of all authors, the article and journal title, book title, volume number, page numbers, and year of publication.
References are outside of page limit.

NIH Biosketch

The biosketch provided for the PI(s) and each Co-Investigator must conform to the NIH Biosketch requirements. Please visit the CCTS website for further guidance.

Budget and Justification

Applicants may request up to $15,000 Direct Costs. Awards are limited to 6 months in duration. Applicants should utilize the PHS398 Form Page 4: Detailed Budget for Initial Budget Period to submit their budget. This form can be downloaded from the Full Application online submission form.

Budgets are very specific to any given project and represent the financial implementation of the scientific aims and administrative needs of the proposed research.

- Salary and fringe support for faculty are NOT permitted.
- Research staff personnel: Salary and fringe support for research staff, students, graduate students, clinical trainees, post-doctoral and clinical fellows are permitted. Justification of support to enable the performance of outlined investigation is required.
- Travel to research conferences are not permitted under this mechanism.
- 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 another review for possible forfeiture of the award.
- Publication costs may be covered as a special incentive of the award based on specific criteria such as within 12 months from study close-out.
- Consultant Costs may be considered in unique circumstances and must be discussed with Pilot Program Administrator for leadership approval in advance of the submission.
- Indirect costs are not allowed.

Justification. All budget expenses should be well justified. Please see the NIH Guidelines for more information on what should be included in a detailed budget justification. If funding is not requested in any particular category, please indicate “Not Applicable.” For example:

PERSONNEL

CONSULTANT COSTS

Not Applicable.

Project Timeline & Milestones

The Project Timeline & Milestones document will be included in the online submission form. Please fill out the timeline to define the proposed timeframe for project milestones. The application must include specific milestones and timelines for data analysis, manuscript(s) preparation and submission to peer review journals. Please be sure to describe time needed to attain regulatory approvals, to create any data management tools, to execute analyses according to the specific aims and any other milestones specific to your project. Include plans for presenting related abstracts at national meetings as well as extramural grant application(s).

Acknowledgement of External Review

The CCTS participates in a national CTSA External Reviewer Exchange Consortium* (CEREC) to improve fairness in the scientific review process and better match applicants with feedback from experts in their respective fields. Maintaining confidentiality throughout the peer review process is essential to allow for the candid exchange of scientific opinions and evaluations; and to protect trade secrets, commercial or financial information, and information that is privileged or confidential. Similar to the NIH peer review process, the CCTS is committed to protecting the integrity of and maintaining confidentiality in peer review. External reviewers must agree to uphold confidentiality at the beginning of the review process. Before submitting a Full Application, investigators will be asked to acknowledge that proposals will undergo external scientific peer review.

*CEREC is comprised of Harvard Catalyst; Medical College of Wisconsin; The Ohio State University; University of Alabama - Birmingham; University of Arkansas for Medical Sciences; University of California - Irvine; University of Southern California; University of Washington; Virginia Commonwealth University.
**Letter(s) of Support**

Letter(s) of support are required from the Department Chairs of the PI(s) to acknowledge awareness and support of the project as well as an acknowledgment of the minimum of 5% effort of the PI(s) without compensation. Applicants who plan to utilize data not currently in their possession (i.e., they intend to use data originating from another party) must confirm via a Letter of Support the availability of the data and the willingness and permissibility of the original investigator(s) to share the data for the purposes of the secondary analyses.

**Section V. Application Review Information**

**Scientific 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. Scientifically meritorious applications will also be assessed by external reviewers using these criteria:

- **Assessment of Significance, Impact and Relevance**: To evaluate significance, please consider whether the proposed project accomplishes at least one of the following:
  - Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, will scientific knowledge, technical capability, and/or clinical practice be improved?
  - Is there a strong scientific premise for the project? Will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- **Assessment of Qualifications of the Investigators and the Research Team**: A highly qualified research team should meet all of the following criteria:
  - Are the PI, collaborators, and other researchers well suited to the project? Do the investigators/collaborators for the project have appropriate skills, capability and training to complete the project? If the project is collaborative or multi-PI, do the investigators have complementary and integrated expertise?
  - Evaluation of status of prior pilot funding awards and the outcomes from those studies. If established researchers, have they demonstrated an ongoing record of accomplishments that have advanced their field(s) AND are they significantly changing research directions to be eligible for this pilot award?

- **Assessment of Approach; Scientific strength of research design and strategy**: In judging the scientific approach, please consider the following questions:
  - Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Does it include demonstration of feasible and generalizable translational research solutions, team science and interdisciplinary collaboration?
  - Are potential problems, articulated research barriers, alternative strategies, and benchmarks for success presented? Does the proposal meet expectations in rigor, reproducibility and transparency (i.e., rigorous experimental design, consideration for biologic variables, and authentication of resources)?

- **Assessment of Innovation**: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? In evaluating innovation, you might consider whether the proposal is novel in any of the following ways:
  - Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
  - Is there appropriate justification for the proposed work through literature citations, data from other sources, or, when available, from investigator-generated data?

**Additional Review Criteria**

- **Assessment of Alignment with CCTS Mission**: One of the goals of the CCTS Pilot Translational & Clinical
Special Considerations: Special consideration will be given to those projects that bring together investigators across partner institutions (Ohio State University & Nationwide Children's Hospital) or multiple colleges, investigate the operational principles underlying each step of the translational process, address scientific questions of particular importance to the health of our communities, including health disparities and health challenges across the life course, as well as applications that involve population health investigation, or innovative approaches to translational science.

- **Assessment of Project Milestones & Amount of Work proposed for each milestone:** Are they sharply defined, clear, specific and quantitative? Are they overly ambitious, insufficient or reasonable considering the team strength?

- **Assessment of Project Feasibility within the proposed time-frame:** In evaluating the project feasibility, you may want to examine the Timeline and Milestones document submitted with the application and consider the following questions: Is the proposed project feasible within the award’s 6-month timeframe? Does the project include a realistic timeline given the experience of the research team?

- **Assessment of Clinical and Translational nature of the application:** Translational research applies findings from basic science to enhance human health and well-being. It aims to “translate” findings in fundamental research to clinical or public health practice. Does the project demonstrate the ability to be translational in nature?

- **Assessment of Clear Health Need & Gap:** Does the application identify a clear need pertaining to human health or human behavior?

- **Assessment of Imminence to Health Impact:** Does the application demonstrate a potential impact of the results on human health in the near future, preferably within the next 3 years?

- **Assessment of likelihood of leading to extramural funding or commercialization:** One of the goals of the CCTS Pilot Award Program is to enable investigators to obtain results that will support and inform an application to an external funder for a larger research study. To score this component, please consider the following: Will this funding enable the development of compelling new grant applications or other external funding that will sustain the proposed research activity? Are plans for grant submission for subsequent funding clearly outlined? Is it commercially viable? If applicable, is there a commercially viable innovation? If yes, is there a potential for acceleration with industry partnership?

- **Assessment of likelihood of Publication:** A manuscript is expected within one year of completion of this project. Will the project lead to a publication and contribution to scientific literature?

- **Assessment of Budget, Support Period & Justification.** Is the budget appropriate for the proposed work?

- **Assessment of Human Subjects or Animal Protection.** Are there any potential human subjects and/or animal protection concerns?

### NIH / NCATS Prior Approval

NIH / NCATS (the sponsor of the CTSA Program and thus the CCTS) has a policy applicable to all CTSA-sponsored pilot projects, especially those that involve human subjects and/or vertebrate animals. Full pilot applications identified by comprehensive review as meritorious for funding will be subject to NIH prior approval. Grant funds cannot be released until the NIH prior approval is obtained. Documentation for this federal review can be prepared in advance of the pilot award date listed in Part 1. Overview Information. If the NIH/NCATS declines such approval, the CCTS will not be able to support the project. Applicants are strongly encouraged to fulfill the NIH requirements thoroughly to avoid iterative submissions in response to NIH questions or concerns. The CCTS cannot extend the project period of the award in light of such delays.

The NIH requires prior approval of all pilot projects based on a discrete set of documentation as outlined below:

**Prior Approval of Research Involving Human Subjects.**

Requests for prior approval of planned research involving human subjects must be submitted in writing via the CCTS to NCATS before the proposed implementation of research involving human subjects. This requirement will go into
Effect as soon as selection, notification and acceptance of award is completed.

Documentation will be submitted to the NIH by an Authorized Organizational Official and must include the following:

- Certification that IRB approval has been obtained for the proposed research.
- Name of the grantee of the parent award, the name of the individual who is receiving the pilot award, the pilot awardee’s telephone number, email address, and NIH Biosketch.
- A summary (<500 words) of the pilot study being supported by NCATS pilot funding.
- The complete research protocol (IRB Human Subject Protocol) and applicable consent/assent/waiver documents.
- If the research protocol is considered an amendment or sub-study to a parent protocol, include a summary of the parent protocol with an explanation of how the NCATS-supported amendment or sub-study connects to it.
- If the entire parent protocol is included in the submission, that portion which is supported by NCATS funding should be clearly labeled as such.
- Certification that the pilot awardee and any Key Personnel directly involved in human subjects research have taken appropriate education in protection of human subjects.
- A line item budget for the proposed research.

REGULATORY REQUIREMENTS

- PIs must provide proof that all regulatory applications (IRB) have been submitted or approved by time of the submission of the full application for this CCTS pilot grant. If applicable, proof of any exempt status must be provided.
- Please note that all applicable projects that receive recommendation for funding must provide proof that the IRB application has been submitted by September 8, 2019. Please note that the Common Rule revisions have gone into effect. This is a new requirement to accommodate necessary timelines for submitting NCATS Prior Approval documentation (see section below on NCATS Prior Approval).
- If your project involves human subject research, all study team members must obtain CITI training or equivalent training in human research protections as well as GCP training (complete training requirements by September 8, 2019).
- Applicants are instructed to contact CCTS Regulatory Program Manager, Robert Rengel or IRB Walk-in Office Hours at the CCTS for assistance with any IRB-related concerns.
- This program has an accelerated nature and only a 6-month funding period.

Anticipated Announcement and Award Dates

Please refer to Part 1. Overview for dates for peer review, advisory council review, and earliest start date. Section II. Award information summarizes funds available and number of awards.

Section VI. Award Administration Information

Award Notices

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.

Regulatory Approvals

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

Quarterly & Final Progress Reports. You will be expected to submit progress reports and a year-end report detailing the results, products and next-steps of your research – a template will be provided as will the deadline(s) for such reports. As part of project study close-out procedures, awardees will be expected to make a brief oral presentation of study findings to the CCTS Executive Committee. Awardees must submit an abstract to the annual CCTS Scientific Meeting within 2 years of the beginning of the CCTS pilot award.

Citation Requirements: Awardees are required, by law, to cite the CTSA Award number (UL1TR002733) on all products (publications, patents, presentations, posters) resulting from this award. According to National Institutes of Health (NIH) grants policy, all grantee publications (including research manuscripts, press releases and other publications or documents about research) that are funded by NIH, must include a specific acknowledgment of grant support. For example - “Research reported in this [publication/press release] was supported by the National Center for Advancing Translational Research of the National Institutes of Health under award number CTSA Grant UL1TR002733. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” If the publication, press release, etc. was supported by more than one grant, please reference all relevant grant numbers.

Quality Improvement and Program Outcomes Data Collection: In an effort to maintain our reporting requirements to NIH NCATS, improve the quality of the CCTS Pilot program and our commitment to optimize the services we provide to investigators, we collect and track post-award short term and long-term outcome metrics. We will be sending REDCap surveys occasionally to both applicants and awardees. Your timely participation in this effort will be greatly appreciated.

Compliance with the NIH Public Access Policy: Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central, upon acceptance for publication, of an electronic version of a final peer-reviewed manuscript resulting from research supported in whole or in part by the NIH. The staff of Prior Health Science Library can help investigators navigate the Public Access Policy processes.

Section VII. Agency Contacts

Scientific/Research & Grant Management Contact

If you have any questions regarding this RFA, please contact:

TANYA MATHEW, BDS, MS
Research Specialist & Pilot Program Administrator
Pilot Translational & Clinical Studies Program (PTC Program)
CENTER for CLINICAL & TRANSLATIONAL SCIENCE
Prior Hall, Suite 260, 376 West Tenth Avenue, Columbus, OH 43210
O: 614.366.5856 | tanya.mathew@osumc.edu | ccts-pilots@osumc.edu

CCTS Pilot Translational & Clinical Studies Program Co-Directors

VISH SUBRAMANIAM, PhD
Professor & Chair, Mechanical & Aerospace Engineering
Professor, Chemical Physics Program
College of Engineering
The Ohio State University

HENRY XIANG, MD, MPH, PhD
Professor of Medicine
Director of Center for Pediatric Trauma Research
Director of Research Core, Center for Injury Research and Policy
The Research Institute at Nationwide Children’s Hospital
Other CCTS Program Directors

SOLEDAD FERNANDEZ, Ph.D.
Director, CCTS Biostatistics, Epidemiology and Research Design (BERD) Core
Director & Research Professor, Department of Biomedical Informatics
Center for Biostatistics and Bioinformatics
The Ohio State University

GUY BROCK, PhD
Director, CCTS Biostatistics, Epidemiology and Research Design (BERD) Core
Deputy Director & Research Associate Professor, Department of Biomedical Informatics
Center for Biostatistics and Bioinformatics
The Ohio State University

SARAH MOORE, DVM, Diplomate ACVIM (Neurology)
Director, CCTS Comparative and Translational Medicine Program
Associate Professor, Neurology and Neurosurgery
Co-director, Clinical and Translational Neurology Laboratory
College of Veterinary Medicine Department of Veterinary Clinical Sciences
The Ohio State University

CCTS Director

Rebecca Jackson, MD
Director, The Center of Clinical & Translational Science
PI, NIH NCATS Clinical & Translational Science Award
Associate Dean of Clinical Research, Ohio State College of Medicine
Professor, Internal Medicine/Endocrinology, Diabetes and Metabolism
Professor, Physical Medicine and Rehabilitation
The Ohio State University