YCCI PILOT PROJECT GRANTS
2024 Funding Opportunity Announcement

The Yale Center for Clinical Investigation (YCCI) is pleased to announce this request for applications for 2024 Pilot Program project grants. The YCCI Pilot Program offers funding opportunities towards new and innovative, scientifically meritorious projects to collect critical preliminary data for submission of extramural grant / funding opportunities and to promote the publication of research findings.

YCCI invites investigators with Yale faculty appointments to submit applications demonstrating new initiatives research focusing on important aspects of human disease. *Innovative proposals across the translational research spectrum are welcome*. Certain research areas are of special interest, pertaining to the goals and priorities of YCCI, and applications in these areas are encouraged. These Special Emphasis Areas are:

Translational Science: Projects that generate scientific and operational innovations that overcome longstanding challenges along the translational research pipeline constitute Translational Science. These include scientific, operational, financial, and administrative innovations that transform the way that research is done, making it faster, more efficient, and more impactful. Projects that involve application to humans of discoveries generated from basic research studies in the laboratory or with preclinical models are encouraged. Proposals may involve diagnostics and therapeutics to medical procedures and behavioral changes. Research aimed at enhancing the adoption of best practices in the community as well as studies of cost-effectiveness of prevention and treatment are also within the scope of this emphasis area. Small scale, particularly early (Phase I-ii) clinical trials will be considered but importantly, these trials must be ready for initiation since delay in the initiation of the award will not be permitted and the study must be completed over the course of the award. Emphasis is place on fostering new projects that bring together investigators from diverse disciplines to study important problems in clinical medicine, and generate scientific, operational, financial, and administrative innovations that transform the way that research is done, making it faster, more efficient, and more impactful.

Dissemination and Implementation Research (D&I): Proposals that address gaps between health sciences research, clinical practice, and population health are sought. The studies may propose building a knowledge base about how health information, interventions, and how new clinical practices and policies are communicated and implemented in public health and health care delivery settings. Among the areas of interest are studies that seek to improve health care delivery by "de-implementing" or lessening the use of strategies and interventions that are not evidence-based, have been prematurely widely adopted, yield sub-optimal benefits for patients, or are harmful or wasteful.

Community and Health Equity Research: Proposals regarding Community and Health equity research may interrogate the dynamic, cumulative, and interrelated structures of power, environmental conditions, and economic systems that produce inequities in health between different populations. This field of special emphasis also identifies, promotes, and leverages community-informed protective factors that are traditionally undervalued and understudied. Projects that are responsive in this area may have goals of improving clinical trials participation, expanding outreach and access to diagnosis and treatment resources and tools and improving response speed to public health challenges in the affected community. These research goals may be achieved through engagement or partnership with community organizations, patients, public health agencies, advocates, policymakers, or other groups throughout the research process.

Application Deadlines:
Due date for full applications: May 6, 2024
Earliest anticipated award date: July 15, 2024

For questions, please contact:
YCCI Research Administration Team
YCCI_Funding_Opportunities@yale.edu

Eligibility

Eligibility requirements: Full-time Yale faculty members at the assistant professor level and higher may submit proposals. Faculty at the level of lecturer, instructor, and associate research scientist are eligible with a letter of support from their department chair describing the long-term commitment to the applicant.

Both Junior and Senior faculty with broad collaborations are encouraged to apply. Women and investigators from diverse backgrounds are strongly encouraged. Multiple Principal Investigators is permissible.

Proposals will be accepted that involve preclinical or laboratory studies however, such projects must demonstrate a clear and immediate path from studies in the animal model to studies in humans. Projects that test translation from initial clinical studies into broader clinical trials or use in the broader community are also encouraged. Clinical studies can be supported, but **proposals for studies beyond the end of phase IIA as defined by the NIH are not eligible for consideration, and clinical trials must have completed regulatory approvals needed for initiation prior to funding decisions**.

Funding

- Awards of up to $50,000 (direct costs) for up to 18 months may be requested. Projects will be reviewed after 6 months, and remaining funds will be contingent upon satisfactory progress at the time of this review.
- The awards may be used for all expenses related to the costs of the research proposal including salaries, clinical costs, use of Core services, and supplies.
- Awards do not include indirect costs.
- The level of funding awarded to successful applicants will be determined after review of the budget and budget justification.
- Awards are not renewable or transferable. Funds must be used in accordance with the approved budget and budget year. Carryover is not permitted and No Cost Extensions will not be granted.
- Cost sharing is allowed.
- Subcontracts with outside institutions are unallowable.

Application and Review Process

All applications must be submitted by the deadline with no exceptions. Copies of the application templates can be downloaded from the YCCI website at http://ycci.yale.edu under the Pilot Programs heading. The application template must be used to apply for this award. For proposals containing a clinical trial (see https://grants.nih.gov/policy/clinical-trials/definition.htm) any and all required regulatory approvals including those from IRB and ancillary committees or the FDA are required to be completed prior to any award funds being issued. If these have not been completed by the time of application, it is strongly encouraged that applications include a regulatory path and timeline for obtaining regulatory approvals and completion prior to the earliest start date of the award.

Review Process:

Important elements in the review process will be:
- Significance: Does this study address an important problem in the proposed area of research? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced?

What will be the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field?

- Scientific merit: Does the proposed research explore creative, original and potentially transformative concepts? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area?
- Approach: Are study design, methods and analyses adequately developed, well-integrated and appropriate to the aims of the project? Does the applicant acknowledge potential pitfalls and consider alternative strategies? Does the applicant identify the next steps in research or clinical endeavor to move the concept forward?
- Academic achievements to date. Does the candidate have rigorous training in the proposed area of research? Is the candidate's academic, clinical and research record of high quality as it pertains to the proposed research?
- Outcomes/Funding: Has the applicant provided a plan or set of criteria by which to judge whether the proposal has been successful? If this project is successful, would it likely lead to external peer-reviewed funding? Could the research be accomplished without funds from this RFA?
- Budget: Can this project be completed with the funds requested? Does this project provide cost sharing approaches?
- Timeline: Can any necessary regulatory approvals/process for the conduct of this project be obtained/completed feasibly within the award period? Is it possible/likely to achieve the proposed aims during the award period?

Selection criteria and process:
Applications will undergo a rigorous review by an in-person meeting of a multi-disciplinary committee patterned after an NIH study section peer review process to ensure that all pilot projects are of high methodological quality and can answer the scientific question proposed. Criteria for selection include significance, approach, innovation, recognition of clinical opportunities, strong project design, good basic science behind a truly interdisciplinary project, and ultimate translation to the community to benefit human beings, environment, and investigators. Pilot studies should have a clear path forward along with criteria for go/no go decisions, next steps if the pilot is successful, and a plan for reporting negative results if not successful. Pilot project metrics may include the generalizable translational solutions developed; demonstration of feasibility accomplished; enumeration of pilot projects funded, along with a rationale of methodological quality of trial design when applicable and performance, measured for instance by power calculations; measures to minimize bias; measurement of impact, not only in publication or further funding obtained but also impact on one or more extant translational roadblocks; and plans for implementation or dissemination. The number of awards to be made will depend upon the number of proposals received and the caliber of projects submitted.

Requirements for Regulatory Approvals

Awardees must obtain all regulatory approvals (e.g. IRB, IACUC, or Radiation Safety and meet all compliance requirements prior to receiving funds and maintain approvals during the entire length of the award. We strongly encourage pilot applicants to begin the IRB/IACUC process at the time of submission to ensure there is adequate time to complete the research study. This includes obtaining a "non-human subjects" designation from the IRB, if applicable.

Requirements for Reporting and Dissemination

The abstracts and the names of all investigators funded through the YCCI Pilot Program will be posted on the YCCI site and may be posted or submitted to the national CTSA website.

Progress report will be required at least annually with updates requested as needed for our grant renewal reporting and evaluation functions.

Investigators must acknowledge the Yale Clinical and Translational Science Award (Award Number: UL1TR001863 from the National Center for Advancing Translational Science (NCATS), a component of the National Institutes of Health (NIH) in any publications including abstract and presentations or patents resulting from the supported studies.

All publications must be compliant with the NIH Public Access Policy and submitted to PubMed Central.