YCCI Yale Center for Clinical Investigation

ANNOUNCEMENT
PILOT PROJECT GRANTS 2017
Funding Opportunity

The Yale Center for Clinical Investigation (YCCI) is pleased to announce the 2017 round of pilot grants. YCCI's pilot program is a funding venue for conducting small-scale research projects to generate data that potentially could lead to further research and funding opportunities. YCCI will accept proposals in the following categories:

Clinical junior faculty pilot award: This award is intended to support junior clinician educator faculty who are interested in developing research as a component of their academic life. We anticipate the awardees will be very active clinicians, who would benefit from a period of protected time and resources to pursue research ideas. The primary aim of these awards is to provide early career pilot support and mentorship to allow a career trajectory which successfully integrates clinical care and research.
Award amount: Up to 20% salary support (up to the NIH cap) and $20,000 research support per year for up to 2 years.

Lifespan Research: This award is aimed at fostering interdisciplinary teams to work collaboratively on key research that may lead to the next phase of discovery. These projects should be strategically targeted to conduct research that will lead to the next step along the road to translation.
Award amount: Up to $50,000 research support per year for up to 2 years.

Community-Engaged Research: The purpose of this funding opportunity is to provide pilot awards to support community engagement projects. Community engagement can take many forms, as NCATS now defines community very broadly, including: patients (local and online communities); nonprofit organizations; faith-based communities; advocacy groups; governmental agencies; community-based clinicians (hospitals, practices, and clinics) and health care delivery systems; industry; and other entities.
Award amount: Up to $75,000 research support per year for up to 2 years.

Application Deadlines:
Due date for letters of intent: November 20, 2017
Due date for full applications: December 18, 2017
Earliest anticipated start date: January - February, 2018

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YCCI Clinical Junior Faculty Pilot Award

YCCI invites applications from Yale clinical junior faculty. This award is intended to support junior clinician educator faculty who are interested in developing research as a component of their academic life. We anticipate the awardees will be very active clinicians, who would benefit from a period of protected time and resources to pursue research ideas. The primary aim of these awards is to provide early career pilot support and to allow a career trajectory which successfully integrates clinical care and research. An emphasis will be placed on career development and mentoring plans, by successful senior clinical faculty capable of understanding the challenges of integrating very active clinical care with a robust translational research portfolio.

Scope: Awards, which provide salary, research funds, and mentorship will be made to a select number of junior faculty members who are committed to clinical care, but wish to incorporate clinical, community-engaged or translational research. Translational research includes basic science studies that are related to human disease, including studies that utilize animal models or in vitro studies such as cell cultures. Individuals must be nominated by a department chair, division head/section chief, or center/program director.

Eligibility requirements: This award is specifically for clinically active junior faculty considering the integration of clinical/translational research as a component of their long-term career objective. Only junior faculty who are at an early stage of their careers (assistant professor or equivalent) are eligible to apply. The applicant must have been a faculty member for no more than 6 years by the anticipated start date of January 1, 2018. This 6-year period is cumulative and includes all appointments as assistant professor, associate research scientist, lecturer, or instructor at any institution (any part time appointments and leaves of absence should be described and will be considered in calculating the total time at a faculty rank). Applicants must not have held an independent K career award, R01, or equivalent support or a departmental start-up package with substantial protected time. Applicants must be an MD or PhD with substantial clinical responsibility. MDs or PhDs without clinical responsibilities are not eligible for this award.

Funding available and years of support: Funds can be requested to cover up to 20% of an individual's salary (up to the NIH cap) and up to $20,000 of research support per year for a clinical, community-based, or translational research project for up to two years. A third year may be considered. Consideration will be based on progress and will require a departmental cost share commitment. Although the intent is to allow protected time of the clinician, YCCI (with prior approval of the department/center) will allow the flexible use of the funding to support research dedicated staff, such as a research coordinator or technician. The awardees will receive additional career development and mentoring support. Awards are not renewable or transferable.

Awardees supported by this pilot funding are eligible to apply for an individual K award. If such an application is successful, the awardee will be required to give up YCCI salary support. In rare instances, it may be possible to keep the YCCI research support, provided that funds are available and the project is distinct from that supported by the individual K award. Projects that involve human subjects research or live vertebrate animals will also need to be approved by the NIH before we can release funds for the research component of the proposal. The second year of funding is contingent on satisfactory progress during the first year.

Application Process: Letters of intent may be submitted by visiting http://www.ycci.yale.edu/. Applications must be submitted using the templates which will be available online at the YCCI website.

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Lifespan Research Pilot Program

The Yale Center for Clinical Investigation (YCCI) is pleased to announce a new program in lifespan research and a call for pilot grant proposals with a lifespan research perspective. As in YCCI's other research initiatives, YCCI's pilot grant program in lifespan research provides a funding mechanism for conducting small-scale research projects that will generate data to inform subsequent research and grant applications.

Lifespan research brings a developmental perspective to questions of individual differences in aging, susceptibility to diseases, the impact of early stressors and adversity across the developmental process, and the intergenerational transmission of risk for diseases. Lifespan research aims to understand the developmental origins of disease to better achieve earlier diagnosis and intervention, and lessen the impact of disease as people age. Lifespan research also seeks to recognize risk factors in childhood and adolescence that increase the risk for diseases of either greater severity or earlier expression in adulthood. Applications in this area may use existing longitudinal datasets with data from different life epochs. Translational research using preclinical animal or human models that address longitudinal, lifespan questions may be included with a clear explanation of relevance for the prevention or treatment of a health problem. Lifespan research is inherently interdisciplinary in that questions may bring together, for example, researchers in childhood diseases and those focused on aging. The goal of this new pilot grant initiative is to foster new projects that bring together investigators from diverse disciplines to study important lifespan research questions that are relevant to clinical medicine across the developmental process. It is anticipated that funds will be used to assemble teams and generate preliminary data to inform compelling new grant applications that will sustain the proposed research activity.

Scope: Applications must propose new research initiatives that combine Yale investigators from different disciplines to work on specific problems from a lifespan perspective. Examples of teams could include, but are not limited to, the following: a developmental and geriatric researcher partnering around a longitudinal dataset focused on aging that includes measures from earlier developmental periods; or an internist and pediatrician focusing on chronic diseases such as asthma with the origins in childhood. Teams should include faculty from more than one department. The proposed research must be human-based research or if not human-based research, should clarify its relevance for the prevention or treatment of a health problem. The proposed research should specify the data to be collected and how it will be used for submission of a larger research grant application.

Eligibility requirements: Full-time Yale faculty members at the assistant professor level or higher may submit proposals. Faculty at the level of lecturer, instructor, and associate research scientist are eligible with a letter of support from his/her department chair describing the long-term commitment to the applicant. Participation by two or more investigators from different disciplines and a lifespan developmental perspective are required. Multiple Principal Investigators are strongly encouraged. Pre-clinical studies must include collaboration with clinical faculty member(s) who will help with the ultimate application of the research to human disease. Proposals that include work with animal models of human disease will be accepted; however, such projects must clarify how the results will inform planned studies in humans.

Funding and years of support: Investigators may request up to $50,000 for January 1, 2018 to December 31, 2018, with the option of renewal for $50,000 for a second year of funding. It is expected that awards will be used to support individuals and to provide materials that will enable the development of integrated lifespan research programs and generation of preliminary data. Awards are not transferable. Renewal for the second year will depend on progress in the first year. Two awards will be made in the first year of the program, and it is anticipated that two awards will be made annually. Projects that involve human subjects research or live vertebrate animals will also need to be approved by the NIH before we can release funds for the research component of the proposal.

Application Process: Letters of intent may be submitted by visiting http://www.ycci.yale.edu/. Only invited applicants will be allowed to submit a full proposal. Applications must be submitted using the templates which will be available online at the YCCI website.

Application Deadlines:
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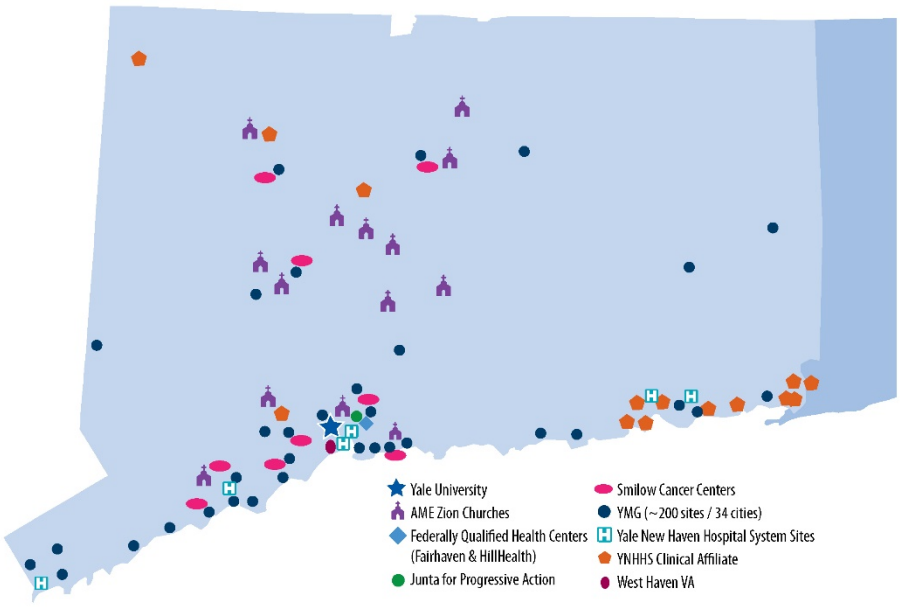
Pilot Projects in Community-Engaged Research

The purpose of this funding opportunity is to provide pilot awards to support community engagement projects by groups of Yale investigators. Community engagement can take many forms, and the partners can include organized groups, agencies, institutions, clinical practices, or individuals. We have a particular interest in engaging stakeholders in the state of Connecticut and/or regionally. However, the definition of community by NCATS is broad and may include community members including church groups, civic leaders and civic organizations, hospitals, companies, schools, other academic medical centers, among others.

Scope: The rationale behind this proposal is that strategies to address the problems that affect the health and welfare of the community can be best addressed by its stakeholders. They are able to identify the problems and provide insights into the causes and develop ways to resolve them with investigators whose expertise in study design, methods of analysis, and disease processes can be utilized. Our interest is to develop collaborative projects in which community groups work with Yale investigators to address problems that are of recognized importance. With this funding opportunity, we plan to support pilot awards for groups of investigators that will study and develop strategies to address problems that are identified by Yale investigators and community groups as having high impact and can be improved. The goal of this funding opportunity is to support the organization and work of new small research groups with expertise in these areas with the objective of developing mature research programs involving community engagement. Each award should include two to four interactive pilot projects but the number of pilot projects and investigators may be determined by the investigative group based on research objectives.

The format of this opportunity involves creation of small groups of community representatives and Yale investigators (2-4) who will self-organize around an important health related problem. The health problem must also be identified by community members as important and the investigators must be willing to develop the project in collaboration with community members. Application is open to both new and established partnerships. If an investigator wishes to apply but has yet to develop a community partnership, YCCI can assist in connecting the investigator group to possible community partners to identify potential collaborators and enable the interactions. YCCI already has several established partnerships which may be incorporated post award. See list on page 6:



YCCI established partnerships:

- **Center for Research and Engagement** (CRE) was originally developed as a part of the former Robert Wood Johnson Foundation (RWJF) Clinical Scholars Program. This program provides education for the next generation of investigators conducting high-impact community-engaged research. The goal of CRE is to facilitate the collaboration of community organizations and researchers to design and implement research projects on topics identified as priorities by the New Haven community. It will also provide a framework for multidisciplinary initiatives and models of engagement and will disseminate successful strategies geared to building a healthier New Haven, improving care delivery systems, and implementing impactful health policy. The CRE will also assist community-based stakeholder organizations, working in partnership with a Yale researcher or team, by assessing their readiness and capacity for research engagement and then providing consultation and resources to address challenges.
  http://medicine.yale.edu/ycci/researchspectrum/collab/commresearch/cre.aspx

- **Cultural Ambassadors -** YCCI recognizes that broadening community participation in clinical research involves linking investigators directly to resources in the community. To facilitate this, YCCI has partnered with Junta for Progressive Action and the African Methodist Episcopal Zion (AME Zion) Churches across Connecticut to ensure that clinical trial participation reflects the diversity of the population and will benefit patients in the community and beyond. Junta is the oldest Latino community based non-profit organization in New Haven and the AME Zion Church is New Haven's oldest African American congregations. YCCI's goal in developing both partnerships is to help increase the participation of the Hispanic and African American populations in clinical trials. Representatives of Junta and AME Zion Church serve as Cultural Ambassadors to Yale's research programs. They act as expert resources, advising Yale investigators how best to raise awareness of clinical research and engage the community.
  http://medicine.yale.edu/ycci/community/research/ambassadors.aspx

- **Collaborations with Other Institutions** - Yale is an active participant in two regional CTSA collaborations: (i) NYCON, a regional consortium of CTSAs in the states of New York and Connecticut, that shares best practices in research and training and works to foster the use of social networking; and (ii) the New England Regulatory Group, a voluntary forum comprised of CTSA representatives from Boston University, Dartmouth, Harvard, Tufts, the University of Massachusetts, and Yale. These groups meet quarterly to explore common issues, interests, and concerns related to research participants, and emerging regulatory requirements.
  http://medicine.yale.edu/ycci/researchspectrum/collab/institutions.aspx

- **Collaboration with Puerto Rico to Expand Education and Clinical Trials** - This partnership was developed to facilitate the research and training collaboration between Yale and Puerto Rico. As more than half of Connecticut's Hispanic population is of Puerto Rican descent, this collaboration presents a unique opportunity to examine environmental factors that affect diseases such as cancer and diabetes, which have a high impact on the Hispanic population.
  http://medicine.yale.edu/ycci/researchspectrum/collab/institutions.aspx

- **Industry: OCR and CBIT: YCCI's partnership with the Office of Cooperative Research (OCR)**. Yale is committed to, and has a history of, successful licensing and commercial development of intellectual property arising from its research. OCR's mission is to facilitate the translation of Yale research into products and services that benefit society, with many local companies licensing cutting-edge Yale research. Over the last 15 years, OCR has helped to launch more than 50 companies, based on discoveries from Yale labs that have collectively raised $5 billion in equity capital. The OCR pharmaceutical pipeline includes four drugs that are on the market to treat HIV/AIDS, Hepatitis B, ADHD and cancer, as well as 18 drugs or vaccines that are in various stages

of clinical trials and an additional 18 that are in preclinical development. The medical device and diagnostic pipeline includes five diagnostic technologies that are on the market, an additional 8 diagnostics and devices in clinical testing, and 5 in development.
http://ocr.yale.edu/

- **Center for Biomedical & Interventional Technology (CBIT)**, is co-led by Peter Schulam, MD, PhD (Professor and Chair, Department of Urology) and Mark Saltzman, PhD (Professor of Biomedical Engineering), and was created with the specific goal of catalyzing biomedical team science by facilitating the formation of multi-disciplinary teams to advance the development of innovative medical devices. CBIT has two interrelated missions: education of the next generation of clinical, engineering, and business leaders and support of these future leaders by aiding in their efforts to commercialize products for unmet clinical needs. CBIT fosters the creation of multi-disciplinary teams of faculty, staff members, and students and connects them with the funding and expertise they need to advance their projects. In its first year as an active center, with support and services from YCCI, CBIT has already worked with more than 100 multi-disciplinary teams, including more than 400 individuals from Yale College, the Schools of Engineering, Management, Medicine, Nursing, and Public Health, and YNHHS.
http://medicine.yale.edu/cbit/

- "**Learning Health Care system" to support community practice** - Clinically, Yale is the largest referral center in southern New England, with >1,200 university and affiliated physicians providing advanced care in >100 specialties. Close partnership between YSM and Yale-New Haven Hospital (YNHH) has made it possible to develop nationally visible centers of excellence in fields such as Alzheimer's disease, cancer, cardiovascular medicine, diabetes, minimally invasive surgery, neurosurgery, organ transplantation, adult and child psychiatry, and pulmonary medicine. YNHH has 1,540 beds and is the nation's ninth largest hospital, and its parent organization (Yale-New Haven Health System) has affiliated with >3,000 community physicians throughout the state, allowing clinical researchers to draw upon a large, diverse population of patients with a significant percentage of underrepresented minorities.
https://www.yalemedicine.org/

The studies may be focused in the New Haven community but may also have broader applications including the State of Connecticut and other regions are encouraged. Collaborations with other CTSAs are also encouraged. The following is a list of health problems that have been identified as priorities by community members, but any health-related problem may be studied.

- Opioid addiction among all age groups
- Reducing recurrent emergency room visits
- Implementation of diabetes management in the home
- Economic burdens of chronic medical conditions
- Stress disorders in young children
- Environmental health
- Asthma prevention and treatment
- Substance abuse including tobacco prevention
- Obesity and metabolic syndrome
- HIV/AIDS prevention
- Violence and crime prevention
- Pregnancy care among those at high risk
- Teen pregnancy and prevention of sexually transmitted infections

The scope of work may be determined by the investigative team. Behavioral, laboratory based, clinical studies, and social science methods may be utilized. The application should fully describe the target audience(s) involved in participatory activities and this description should include efforts to involve women, historically underrepresented minorities, and individuals from underrepresented or underserved communities.

Eligibility requirements: Full-time Yale faculty members at the assistant professor level or higher may submit proposals. Faculty at the level of lecturer, instructor, or associate research scientist are eligible with a letter of support from his/her department chair describing the long-term commitment to the applicant. Each award should include 2-4 interactive pilot projects but the number of pilot projects and investigators may be determined by the investigative group based on research objectives. Engagement of community is a required element of the proposal. If the investigative team already has an identified partner, the application must describe past accomplishments achieved through the existing partnership. If a community partner has not been identified, the YCCI will facilitate the engagement of community members and investigators involved in those awards chosen for support are expected to work interactively to complete the research objectives.

Funding and years of support: Investigators may request up to $75,000 for January 1, 2018 to December 31, 2018, with the option of renewal for $75,000 for a second year of funding. Awards are not transferable. Renewal for the second year will depend on progress in the first year. Two awards will be made in the first year of the program. Projects that involve human subjects research or live vertebrate animals will also need to be approved by the NIH before we can release funds for the research component of the proposal.

Application Process: Letters of intent may be submitted by visiting http://www.ycci.yale.edu/. Applications must be submitted using the templates which will be available online at the YCCI website.

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Application and Review Process

Letters of intent may be submitted by visiting http://www.ycci.yale.edu/. Only invited applicants will be allowed to submit a full proposal for the Lifespan Research Pilot Program. Applications must be submitted using the templates which will be available online at the YCCI website.

All full applications must be submitted by the respective 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.

Review Process:
Important elements in the review process will be:

- Significance: Does this study address an important problem in clinical and/or translational 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?
- 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?

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.

Additional Requirements

- **Awards are not renewable or transferable. No cost extensions will be permitted.**
- The abstracts and the names of all investigators funded through the Pilot and Collaborative Studies Program will be posted on the YCCI site and may be posted or submitted to the national CTSA website. In addition, a full 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: UL1 TR001863 from the National Center for Advancing Translational Science (NCATS), a component of the National Institutes of Health (NIH) in any publications or patents resulting from the supported studies.
- 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. Projects that involve human subjects research or live vertebrate animals will also need to be approved by the NIH before we can release funds for the research component of the proposal.
- Awards do not include indirect costs.
- Applicants may submit applications for multiple projects for a single mechanism provided that each project is different. Applicants may not submit identical projects to multiple pilot funding mechanisms.
- Cost sharing is allowed.
- Foreign subcontracts are unallowable under this mechanism, and research at foreign sites will require approval by NCATS prior to an award.
- Applicants may not request salary support for themselves or Co-PIs; salary support is allowable for research staff