ANNOUNCEMENT
PILOT PROJECT GRANTS 2014
Funding Opportunity

The Yale Center for Clinical Investigation (YCCI) is pleased to announce the 2014 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:

Translational and Interdisciplinary Research: This award is aimed at fostering interdisciplinary teams to work collaboratively on key experiments 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.

Outcomes, Research into Practice, and Community-Engaged Research: Ensuring that research is translated into practice is a difficult transition to navigate. This award is for comparative outcomes and community engagement projects that bridge the gap between science and the proven efficacy of treatments in order to translate these findings into practice.

Novel Clinical and Translational Methodologies: This award is to advance technologies *post* discovery with an eye toward preclinical development. The aim is to provide funding for mature new technologies that are clinically viable or for the translational advancement of medical devices/treatments. These projects should be able to generate data that will facilitate industry collaboration in order to move concepts into the healthcare market.

Established Cores: Yale has several world-class cores but conducting research that utilizes these technologies is costly. This award is for pilot projects using such established cores as flow cytometry, genomics, and imaging for research that will lead to the funding of full-fledged grants.

Emerging Cores: Core technologies change as science progresses. Proposals for projects that utilize Yale's emerging cores will fall into one of these categories:

- ***Center for Biomedical and Informational Technology (CBIT):*** Viable prototypes, animal or pilot clinical data, and a compelling business case enhance the successful commercialization of biomedical technologies. This award provides Stage 1 and Stage 2 awards to promising projects that can benefit from the expertise offered by CBIT, a collaboration between the Schools of Medicine, Management; Engineering and Applied Science; industry; and YCCI.
- ***Yale Center for Molecular Discovery (YCMD):*** For investigators interested in screening compounds but lacking the resources to carry out this research, YCCI is partnering with YCMD to offer this award for proposals of that demonstrate potential.
- ***Informatics:*** Epic is a powerful new tool in the clinical research arsenal that has yet to be harnessed. This award will involve collaboration with the Epic team and YCCI analysts for projects that utilize the EMR to conduct research utilizing the data it contains.

For questions, please contact:

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YCCI Pilot Projects in Translational and Interdisciplinary Research

YCCI invites applications from Yale faculty for new initiatives in translational and interdisciplinary research that focus on important aspects of human disease. Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies also is an important part of translational science. Investigators with translational and interdisciplinary research projects in all stages are invited to apply for funding. The goal is to foster new projects that bring together investigators from diverse disciplines to study important problems in clinical medicine. It is anticipated that funds will be used to assemble teams and generate preliminary data for compelling new grant applications that will sustain the proposed research activity.

Scope: Applications must propose new initiatives that combine Yale investigators from different disciplines to work on specific problems relevant to human disease. Examples of teams could include, but are not limited to the following: a population/community-based researcher and a clinical scientist, a laboratory scientist and clinical investigators, an evaluation researcher and a clinical scientist. Teams may include faculty from more than one department. Human-based research should be involved. The study must ultimately translate to treatment of a health problem or to improving community health. The proposed studies should allow researchers to generate preliminary data for submission of a research grant application.

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 his/her department chair describing the long term commitment to the applicant. Participation by two or more investigators from different disciplines is 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 will be accepted that include work with animal models of human diseases; however, such projects must move 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.   Although clinical studies can be supported, proposals for studies beyond the end of phase IIA are not eligible for consideration.

Funding and years of support: Investigators may request up to $50,000 per year for two years of funding totaling $100,000. It is expected that awards will be used to support individuals and to provide materials that will enable the development of integrated programs and generation of preliminary data. Awards are not renewable or transferable.

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. All applications must be submitted using the templates which are available online at the YCCI website.

Application Deadlines:
Due date for letters of intent: December 12, 2014
Due date for full applications: February 9, 2015
Earliest anticipated start date: March 15, 2015

YCCI solicits applications for support of community engaged or outcomes research across the translational continuum, as outlined below.

Patient-Centered Outcomes Research

These awards are intended to support highly meritorious projects that focus on developing pilot data for extramural application in patient-centered outcomes research. Patient-centered outcomes research is applied research that engages patients and/or stakeholders in the conduct of research focused on outcomes that matter to patients. It helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options. (See http://www.pcori.org/research-we-support/pcor/.) The purpose of this research is to provide information that will impact practice to improve outcomes. See: http://www.pcori.org/funding-opportunities/funding-announcements/upcoming-opportunities/ for particular areas of interest.

This call is specifically designed to solicit meritorious projects that will provide the pilot/preliminary data required to support a future highly competitive application for patient-centered outcomes research. Each application must identify a well-defined research question to be addressed in the future application that will request support of patient-centered outcomes research. Additionally, each proposal should describe the plan for engaging stakeholders (i.e. patients, caregivers, providers, etc.) in the research process in a meaningful way.

The pilot project typically would not include testable hypotheses, calculations of sample size and power, or other elements more appropriate for a full-scale study. The pilot application must specify collaborative and scientific activities to be undertaken through this funding mechanism and must explain how the data to be obtained will promote the success of the future application.

Research into Practice

The Research into Practice Award supports pilot grants that address the gap between what we know and what we do in practice, in order to develop interventions that require individual, organizational, or system behavior change in practice settings such as hospitals, health systems, community health centers, primary care, specialty clinics, and other ambulatory care settings. Investigators are encouraged to submit pilot studies that will test the effectiveness of implementing research-based clinical interventions, inclusive of evidence-based health promotion, prevention, diagnostic, treatments, and quality of life improvement interventions, in a variety of practice settings and communities. Pilots should be designed to measure 1) uptake and use of evidence-based knowledge by clinicians or other stake-holders, and 2) patient-centered or health outcomes. We are especially interested in projects that hold promise for future grant funding and/or are spread across several practice communities.

The purpose of this funding opportunity is to support innovative approaches to overcoming barriers to the use of evidence-based interventions in a variety of healthcare sites. The award is designed to provide researchers and clinicians with experience and evaluation data from an implementation project that strives to improve quality of care. We are seeking researchers and key stakeholders who are committed to implementing improvements in care delivery based on research evidence. Examples of topics include but are not limited to the following: hypertension screening and treatment; provision of family focused care; diabetes prevention; self-care management for chronic conditions; obesity prevention and treatment; care coordination; and pain management. These are only examples and we encourage proposals that address other healthcare topics for which there is a research base.

Community-Engaged Research

The IOM report recommended that "Community engagement …must be cross-cutting and embedded in leadership, implementation, research, and communication strategies across all levels of the CTSA program." The benefits of engaging patients and communities not only as consumers of healthcare, but as active partners in the full spectrum of translational research include, but are not limited to: identifying community health needs and priorities, providing input on relevant research questions, contributing to appropriate research design and methods, developing culturally–sensitive and ethical proposals, enhancing the recruitment and retention of research participants, and implementing and disseminating research findings more effectively. Most community engaged research has taken place in the later phases of translational research, so that there is less experience on how to identify and involve communities from the beginning research stages throughout the translational continuum. In addition, since the optimal ways to involve relevant communities in each stage of the translational process have not been defined, there is a need for community engagement to be addressed as a scientific problem, in order to identify best practices and most effective approaches in an experimental, data-driven fashion. Applicants should describe how patient and community engagement will advance the process of turning observations in the laboratory and clinic into interventions that improve the health of individuals and the public.

Community Engagement is critical to increase the reach, effectiveness, and implementation of clinical research efforts. This RFA is intended to support community-academic partnerships to perform pilot studies that will strengthen relationships and produce preliminary data for future competitive grant applications.

Two additional elements are required for proposals in this category:

Community Abstract (500 word maximum)
The community abstract provides you with an opportunity to express to a community-audience how you anticipate that this project can, in the long-term, impact the health of Connecticut residents. It should not be a reiteration of the Scientific Abstract but instead should tell a story that addresses the importance of this research, whose lives will ultimately be improved, and why. Your community abstract must include:
- Magnitude of the health issue. How many individuals are affected, what is the scope of this issue in the state, how are costs of health care impacted, etc.?
- Knowledge gap. What gap will your proposed research address; what will your project results tell us that is not already known?
- Community collaborators. Who are the stakeholders of this research project and how will they be involved in your research, what roles will they play? For investigations at the very early stages, engagement can be more limited to an initial conversation with a stakeholder about the applicability of the question to daily practice.
- Longer-term policy implications of your research. How might your research inform/impact organizational or public policies?
- Potential impact of this stream of research. How will this project, in the context of your larger research career, improve health?

Dissemination plan and Future considerations (500 word maximum)
Please include a plan that addresses how and when your project results will be disseminated to/with your stakeholder/community partner and/or other specific clinical practice, community or policy audiences. This plan should be developed early in the process with your stakeholders. Note: the sophistication of this plan should match the scope of your project and care should be taken for careful interpretation of results.

This plan should also address next steps: What is the next step in your research project trajectory and what are your plans for acquiring funding? If applicable, please address how your research might inform/impact organizational or public policies.

Eligibility: 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 also eligible but during the review process we will be evaluating the commitment from the department. Additional requirements are outlined on the last page of this announcement.

Multiple Principal Investigators and participation by two or more investigators from different disciplines are encouraged where appropriate, but are not required. Community-based collaborations are encouraged where appropriate, but are not required.

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. All applications must be submitted using the templates which are available online at the YCCI website.

Award and Award Period: Investigators may request up to $25,000 per year for two years of funding totaling $50,000. It is expected that awards will be used to support individuals and provide materials that will enable the development of integrated programs and generation of preliminary data for extramural funding applications. Awards are not renewable or transferable.

Application Deadlines:
Due date for letters of intent: December 12, 2014
Due date for full applications: February 9, 2015
Earliest anticipated start date: March 15, 2015

YCCI Development of Novel Clinical and Translational Methodologies Pilot Projects

Pilot funding for the development of novel clinical and translational methodologies will be made available to all of Yale faculty to advance technologies *post* discovery towards pre-clinical or clinical development. Funds may be requested to mature new technologies with a strong promise of being introduced for use with humans in the short term (<5 years). Funds may be used to mature methods that clinically validate characterization or diagnosis of human subjects, or for the translational advancement of medical devices or treatments of human diseases. Methodologies that are not traditionally technologically based, but have strong promise of being introduced for use with humans in the short term, are also eligible for funding (e.g. new methodological approaches to problems in research ethics, biostatistics, clinical trials design, bio-medical informatics, novel approaches to implementing community-based research/outcomes studies.)

Scope: Applications should request seed money to mature novel methods that will enhance clinical and translational research studies and create new funding opportunities for Yale scientists. The scope does not include basic research or discovery activities (e.g., model development, screening), but may include toxicity assessment, formulation, or field testing.

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 also eligible but during the review process we will be evaluating the commitment from the department. Additional requirements are outlined on the last page of this announcement.

Application Process: Applicants should submit no more than a ½ page proposal with a single line budget and, a brief biosketch. The proposal title should reference an "OCR number" for a submitted invention disclosure and include a copy of the complete invention disclosure as an exhibit in the proposal. These proposals in the letter of intent format will be reviewed and then as many of the selected applicants that can be scheduled on a single day will be invited to give a short presentation (format to be provided by YCCI) to the review committee, which will make final funding decisions shortly thereafter.

Award and Award Period: Funding will be available for up to $20,000 in total costs for a project duration not to exceed 12 months. Proposals in the $10-15,000 range are particularly encouraged in order to fund as many worthy proposals as possible. Support may be provided for supplies and other "direct" research-related expenses; funds may not be used for salary support or to purchase commercially available equipment or for travel expenses (except as needed to reimburse clinical study participants). Proposals that seek to support work done by commercial third parties who can provide services (e.g., efficacy or safety data, engineering prototypes, commercial grade software) and briefly state the next translational steps leading from a successful outcome will be highly regarded.

Application Deadlines:
Due date for letters of intent: December 12, 2014
Due date for full applications: applications will be presented in person as a slide presentation
Earliest anticipated start date: March 15, 2015

As human research projects become more complex, the incorporation of state-of-the-art imaging and/or genomic technologies is integral to successful translational science research programs. However, the high cost of high-tech experiments are often obstacles that prevent biomedical research from moving along the translational science spectrum toward better human health.

Yale School of Medicine is the home of many high-tech research cores including the Positron Emission Tomography (PET) Research Center, the Magnetic Resonance Research Center (MMRC), FACS Facility (Flow Cytometry), CyTOF Facility, and the Yale Center for Genomic Analysis (YCGA).

Scope: YCCI solicits applications from Yale faculty for translational and clinical research projects that utilize the resources and expertise found in the PET Center, MMRC, Flow Cytometry, CyTOF, or YCGA. Projects must pursue a clear and significant scientific opportunity in translational or clinical science area and demonstrate a path toward extramural funding capable of sustaining an imaging- or genomics-based translational science project. Awards will be used for services provided by the above referenced cores only. Research projects that require additional data for publication but have not received extramural funding will also be considered.

Core leader contact list:

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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 also eligible but during the review process we will be evaluating the commitment from the department. Additional requirements are outlined on the last page of this announcement.

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. All applications must be submitted using the templates which are available online at the YCCI website.

Award and Award Period: Investigators may request up to $20,000 in total costs for a 12-month period. Awards are not renewable or transferable.

Application Deadlines:
Due date for letters of intent: December 12, 2014
Due date for full applications: February 9, 2015
Earliest anticipated start date: March 15, 2015

Pilot Projects Utilizing New Emerging Core Technologies

Consistent with the NCATs mission to bolster translational science through collaborations that capitalize on existing strengths within academic research centers, YCCI is pleased to highlight three new emerging core technologies. These cores include the Yale Center for Biomedical and Interventional Technology (CBIT), Yale Center for Molecular Discovery (YCMD), and the Electronic Health Record (EHR). ***All funding in this category can only be utilized to cover services in the awarded core. Payments for services will be made directly to the core.***

Yale Center for Biomedical and Interventional Technology (CBIT)

CBIT is an interdisciplinary initiative to foster greater innovation in medical technology. It is a consortium of engineers, clinicians, scientists, innovators and entrepreneurs designed to help incubate, support, implement, and potentially bring to market novel technical approaches to address under-met clinical needs.

Successful applications for extramural support of the commercialization of biomedical technology are enhanced by effective prototypes, animal or pilot clinical data, and a compelling business case. CBIT can provide expert mentorship and support to interdisciplinary teams and support key value-creating milestones that enhance applications for external funding. This program provides Stage 1 Awards coupled with CBIT mentorship, to help achieve initial objectives, which will be followed by Stage 2 Awards.

Scope: This support can be used to pay for prototypic activity, animal and clinical evaluation, and creation of a strong business strategy. Appropriate business planning activities include engaging regulatory and clinical consultants, conference attendance for market research, and support for expert consultants. Proposals are to be product focused; proposals to fund basic science are not appropriate. Project teams are expected to create a compelling SBIR, STTR or similar application at the end of the Stage 2 Award.

Stage 1 proposals will primarily be reviewed based on the significance of the unmet clinical need and the viability of the proposal.

Stage 2 Proposals will be evaluated based on:
1) Does the project team have the diversity of required skills?
2) How compelling is the market need?
3) How approachable is the likely regulatory path?
4) How attractive is the project likely to be to SBIR granting agencies, angels and VCs (fundraising plan)?
5) Will the product be reimbursable and adoptable?
6) Can YCCI resources make a critical difference in the success of the program?

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 also eligible but during the review process we will be evaluating the commitment from the department. Additional requirements are outlined on the last page of this announcement.

Application Process: Pre-Applications may be submitted by visiting http://www.ycci.yale.edu/. Pre-Applications and Applications must be submitted using the CBIT specific templates which are available online at the YCCI website.

Award and Award Period: Stage 1 funding of $1,500 will be available for three months of work and Stage 2 funding will be available for up to $50,000 in total costs for a 12 month period. While applicants can submit to Stage 2 without a Stage 1, applicants are highly encouraged to apply for and participate in Stage

1. The number of awards to be made will depend upon the caliber of the projects submitted. These funds are designed to provide the pilot data needed for extramural funding. Awards are not renewable or transferable.

Application Deadlines:
Pre-application: December 12, 2014
Earliest anticipated start date for pre-application: January 1, 2015
Full application: ~~March 20, 2015.~~ June 19th, 2015
Earliest anticipated start date: ~~April 15, 2015~~ July 31th, 2015

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Yale Center for Molecular Discovery (YCMD)

The Yale Center for Molecular Discovery (YCMD) is an unparalleled resource for investigators whose translational research projects focus understanding biological mechanisms and disease targets. YCMD provides biology and chemistry services to the Yale community. Drawing on the extensive and diverse experiences of their staff, YCMD offers expertise as well as access to small molecule compound and siRNA collections and instrumentation for high throughput assay design and execution. The Center also offers a range of medicinal, computational and synthetic chemistry services. Through staff expertise in the field of drug discovery and access to state of the art equipment, YCMD can provide collaborations with investigators that promote the advancement of projects through hurdles that sometimes limit promising research in academic settings. Awards will be made for collaborative projects with the YCMD.

Scope: The goal of funding is to position Yale research for new, highly-competitive grant applications, or enable key experiments required to further commercialization opportunities. Pilot funding can be used to develop assays towards the goal of achieving robust assay statistics (S/B >5, Z' > 0.05) when screened against a library of 5,000 bioactive and Yale-synthesized compounds as assay development validation prior to a screening campaign. This validation will demonstrate a strong secondary assay workflow to assess signal interference, toxicity, specificity, and potency. The hits obtained would be expected to demonstrate that a structure-activity relationship may exist for the compounds and chemically attractive scaffolds might be found in a full validated screen. Larger proposals may include screening against diversity libraries. Structure-Activity-Relationship studies draw upon the Center's strengths in design, synthesis and analytical chemistry to generate series of compound analogues with the goal to improve potency and pharmacokinetic properties of validated chemical scaffolds. An alternative non-screening approach using structure-based drug design (SBDD) and computational chemistry strategies may be possible for those targets possessing a quality crystal structure. Proposals will be evaluated on the potential to impact a therapeutic disease area, the novelty of their approach and their likelihood for success under this funding mechanism.

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 also eligible but during the review process we will be evaluating the commitment from the department. Applicants are highly encouraged to work with the Center in development of their proposal to ensure compatibility with Center resources. Additional requirements are outlined on the last page of this announcement.

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 are available online at the YCCI website.

Award and Award Period: The awards in this category are partnered, with 50% funding from YCCI and 50% from YCMD. The total request must not exceed $40,000, with the request for reagent purchase not to exceed $12,000. All funding in this category can only be utilized to cover services in the awarded core. Payments for services will be made directly to the core. Awards are not renewable or transferable.

Application Deadlines:
Due date for letters of intent: December 12, 2014
Due date for full applications: February 9, 2015
Earliest anticipated start date: March 15, 2015

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Pilots for Studies using Electronic Health Records

The third core provides access to the wealth of information collected in the electronic health record (EHR). With widespread adoption of electronic health record (EHR) systems across the nation, this new resource has the capacity to transform both clinical care and research. Yale's EHR, is in place across the entire Yale New Haven Health System and this unified database will begin to be available to translational science and clinical investigators.

Biomedical informatics is a critical CTSA focus for enabling and advancing translational research, which is increasingly data intensive, and requires collaboration across many communities, including healthcare, research, and public health. Additionally, the increasing amounts and types of data (e.g., genetic, imaging, clinical, economic, environmental, behavioral, patient reported) need to be integrated to generate knowledge. Epic, Yale's electronic health record, is a resource for both clinical care and research. Awards will be made for pilot projects that utilize and extract clinical data from Epic for research purposes but proposals from all areas using Electronic Health Records are welcomed.

Scope: Support provided through this award can be used for the collection or analysis of data sets from electronic medical records or the validation of cohort data. Funds are intended to provide support for the collection of pilot data required for the preliminary results section of a proposal for extramural funding, or to complete an initial, internally funded study.

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 also eligible but during the review process we will be evaluating the commitment from the department. Additional requirements are outlined on the last page of this announcement.

Application Process: Applicants should submit a letter of intent by the LOI deadline. Letters of intent should include a ½ page project proposal with a single line budget and a brief biosketch. Smaller projects may be awarded based on the letter of intent. Larger projects, however, will be invited to submit a more

comprehensive application for review by the committee. Applications must be submitted using the templates which are available online at the YCCI website.

Award and award period: Funding will be available for up to $10,000 in total costs for a 12-month period. Applications with a minimal request for funding or no funding but for informatics support are of particular interest.

Application Deadlines:
Due date for letters of intent: December 12, 2014
Due date for full applications: February 9, 2015
Earliest anticipated start date: March 15, 2015

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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. Applications must be submitted using the templates which are 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 TR000142 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.
- 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