

## **ANNOUNCEMENT**

### **PILOT PROJECT GRANTS 2008**

#### **- Call For Proposals -**

The Yale Center for Clinical Investigation (YCCI) is pleased to announce the 2<sup>nd</sup> round of pilot grant awards. The YCCI pilot program is aimed at stimulating : 1) the development of new translational and clinical interdisciplinary research teams that cut across the traditional boundaries of categorical disease centers; 2) the development of new technologies; and 3) the use of core resources.

**Applications for all categories are due by Thursday, March 6, 2008, by 1pm.**

**The Selection Committee will meet in late March, 2008 and finalists will be notified and funding initiated by July 1, 2008. Awardees must be prepared to start projects at that time, including obtaining all required approvals for projects.**

**YCCI invites proposals in the following areas:**

1. Pilot Projects in Translational and Interdisciplinary Research
2. Development of Novel Clinical and Translational Methodologies
3. Pilot Projects utilizing Core Technologies

***Each PI may submit only one proposal per category. Research must be in one or more of the categories described below:***

#### **Definition of Clinical and Translational Research:**

**Patient-oriented** research is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) studies on mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies for these types of research.

**Clinical research** is defined as including studies using human materials, patient records, etc, in which the patients are linked or identified, but the investigator does not necessarily interact with the patient. Any protocol requiring HIC approval would be considered clinical

research. Epidemiologic and behavioral studies, outcomes research and health services research are also included in this category. For present purposes, research with unlinked tissues or records, exempt from HIC review, are not considered clinical research.

**Translational research** is defined as the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. Included in this category is some research using animal models that represent the final steps in the development of human protocols or FDA filings. Also included are studies translating laboratory findings on diseases into studies of those diseases in humans and the development of the technological modifications needed to translate laboratory techniques into use in humans and the validation of these techniques in humans.

**Outreach.** This category includes research aimed at enhancing the adoption of best practices in the community. This is conceptually different from the translational research described above and identified separately as "outreach" activities.

Note that these are overlapping definitions. Essentially all translational and outreach studies meet the above-stated definition of clinical research. Some would also be patient-oriented research. This approach has been taken because it is sometimes necessary to identify patient-oriented research separately.

**For questions, please contact:**

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## 1. **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's faculty. We plan to offer ~ 3 grants. Each award will be up to \$25,000.

**Scope:** Applications should request seed money to explore novel methods that will enhance clinical and translational research studies and create new funding opportunities for Yale scientists.

**Eligibility requirements:** The only requirement is that the applicant is Yale faculty.

**Funding available and years of support:** Funding will be available for up to \$25,000 in total costs for a 12-month period beginning July 1, 2008. Proposals in the \$12-15,000 range are particularly encouraged in order to fund as many worthy proposals as possible. Support may be provided for salary, supplies, and other research-related expenses; funds may not be used to purchase equipment or for travel expenses (except as needed to reimburse clinical study participants). Award is not renewable or transferable.

### **Submission:**

**Candidates MUST use the application and budget templates.** Word and Excel copies of the templates can be downloaded from the YCCI website @ <http://ycci.yale.edu> under the Pilot Programs heading. Element of the application are included below:

1. Title page listing the name, title, address, telephone number, and email address of the candidate; and title of the project.
2. Candidate's NIH-formatted biosketch
3. Pilot project applications must include a research plan describing the project to be undertaken following the NIH format (i.e., Specific Aims, Background, preliminary Findings and Research Design and Methods). Maximum length is 5 pages.
4. Selected references. Maximum length is 2 pages.
5. Resources and environment. Maximum length is 1 page.
6. Full description of other support, including all current and pending sources of funds with amounts and dates for each for all sources. (external and internal, including any start-up funds) The team leader and other faculty participants should list their other research support, highlighting any support that is available for the proposed project.
7. Detailed budget and justification on NIH 398 forms. A budget section should be included with a justification of why the funds are necessary and how they will be used to promote innovative new science and secure applications for extramural funding.
8. An electronic copy of the application, the original application plus 15 copies must be **submitted to the YCCI by 1 PM on Thursday, March 6, 2008.**

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

- Scientific merit: Is the research proposed important and innovative?
- Funding: Is the research likely to establish the basis and rationale for a larger project and to result in a successful application for extramural funding by this larger project? Could the research be accomplished without funds from this RFA?

**Selection criteria:** Criteria for selection include innovation and potential to provide new opportunities for clinical and translational research. Preference will be given to methods that would support interdisciplinary projects. Proposals will be evaluated for compatibility with the YCCI mission, merit, and feasibility for conduct. Junior investigators new to translational research are particularly encouraged to apply. Established investigators interested in developing a new area of clinical or translational research are also eligible for support.

**Additional Requirements:** The abstracts and names of all investigators funded through the Pilot and Collaborative Studies Program will be posted on the national CTSA website. In addition, all investigators must provide a progress report to the YCCI, and acknowledge the YCCI CTSA base operating grant in any publications resulting from the supported studies. The YCCI also requires that results of studies supported through the program be posted on the Yale YCCI website once the data have been published.

## 2. YCCI Pilot Projects in Translational and Interdisciplinary Research

YCCI invites applications from its faculty for new initiatives in translational and interdisciplinary research that focus on important aspects of human disease. 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 that will result in programs that are competitive for extramural funding.

**Scope:** Applications must propose new initiatives that combine Yale investigators from different disciplines to work on specific problems relevant to human disease. It is expected that teams will typically include laboratory and clinical investigators from more than one department and that human subjects will be involved. The study must ultimately translate to treatment of a health problem or to improving community health. Studies should allow clinical and translational researchers to generate preliminary data for submission of a research grant application.

**Eligibility requirements:** Full-time Yale faculty may submit interdisciplinary proposals. Participation by more than one investigator from different disciplines is required. Multiple Principal Investigators are strongly encouraged. Pre-clinical studies must include collaboration with clinical faculty who help with the ultimate application of the research to human disease. The project must move from studies in the animal model to testing in humans or test translation to the community.

### **Submission:**

**Candidates MUST use the application and budget templates.** Word and Excel copies of the templates can be downloaded from the YCCI website @ <http://ycci.yale.edu> under the Pilot Programs heading. Element of the application are included below:

1. Title page listing the name, title, address, telephone number, and email address of the candidate; and title of the project.
2. Candidate's NIH-formatted biosketch
3. Pilot project applications must include a research plan describing the project to be undertaken following the NIH format (i.e., Specific Aims, Background, preliminary Findings and Research Design and Methods). Maximum length is 7 pages.

4. Description of the interdisciplinary nature of the project, the structure of the team, and plans for collaboration. Maximum length is 2 pages.
5. Selected references. Maximum length is 2 pages.
6. Resources and environment. Maximum length is 1 page.
7. Full description of other support, including all current and pending sources of funds with amounts and dates for each for all sources. (external and internal, including any start-up funds) The team leaders and other faculty participants should list their other research support, highlighting any support that is available for the proposed project.
8. Detailed budget and justification on NIH 398 forms. A budget section should be included with a justification of why the funds are necessary and how they will be used to promote innovative new science and secure applications for extramural funding.
9. An electronic copy of the application, the original application plus 15 copies must be **submitted to the YCCI by 1 PM on Thursday, March 6, 2008.**

**Funding and years of support:** Investigators may request up to \$75,000 per year for two years of funding. It is expected that awards will be used to support individuals and provide materials that will enable development of integrated programs and generation of preliminary data. We plan to fund three awards each year, with funding available for up to two years at \$75,000 per year. Award is not renewable or transferable.

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

- Scientific merit: Is the research proposed important and innovative?
- Interdisciplinary nature: Does the research meet the criteria for being a new interdisciplinary disease-oriented program?
- Funding: Is the research likely to establish the basis and rationale for a larger project and to result in a successful application for extramural funding by this larger project? Could the research be accomplished without funds from this RFA?

**Selection criteria and process:** Reviews will be discussed at a meeting of the entire Pilot Grant Review Committee along the lines of an NIH Study Section. Criteria for selection include innovation, recognition of clinical opportunities, good basic science behind a truly interdisciplinary project, and ultimate translation to the community to benefit human beings.

**Additional Requirements:** The abstracts and names of all investigators funded through the Pilot and Collaborative Studies Program will be posted on the national CTSA website. In addition, all investigators must provide a progress report to the YCCI, and acknowledge the YCCI CTSA base operating grant in any publications resulting from the supported studies. The YCCI also requires that results of studies supported through the program be posted on the Yale YCCI website once the data have been published.

### 3. YCCI Pilot Projects Utilizing YCCI Core Technologies

Increasingly, both translational and clinical research requires access to core facilities that are equipped with expensive instrumentation and operated by highly-trained staff members. Well run core facilities not only contribute to the quality and productivity of the research but also ensure patient safety. The YCCI and the School of Medicine have therefore invested funds for the expansion of existing core facilities and for the acquisition of new technologies for clinical and translational research.

An important goal of YCCI is to enhance clinical and translational research by encouraging and supporting collaboration between experts in cutting-edge technologies and

clinical/translational researchers who need access to those technologies. In support of this goal, YCCI is offering pilot funds to support work needed for clinical and translational research projects, particularly projects that are likely to lead to extramural support based on the preliminary data.

**Scope:** This support can only be used to pay for core resources. The goal is to provide funds for to conduct pilot studies and generate data that will support the development and submission of extramural proposals. Projects that have not received extramural funding, but are in the final stages of completion but which require additional data are also eligible for these funds.

**Eligibility requirements:** Full-time Yale faculty may submit proposals. Multiple Principal Investigators and interdisciplinary projects are encouraged. These funds are not intended for and cannot be used to support work done completely within the PIs own laboratory. Pre-clinical studies must include collaborations with clinical faculty who will help with the ultimate application of the preclinical research to understand, diagnose or treat human disease. The project must either facilitate translation from studies in animal model systems to testing in humans or facilitate translation of clinical studies into the broader community.

**Submission:**

**Candidates MUST use the application and budget templates provided by the YCCI.**

Word and Excel copies of the templates can be downloaded from the YCCI website @ <http://ycci.yale.edu> under the Pilot Programs heading. The elements of the application are listed below:

1. Title page listing the name, title, address, telephone number, and email address of the candidate and the title of the project.
2. Candidate's 2 page NIH-formatted biosketch
3. Project collaborator (s) NIH-formatted biosketch
4. Pilot project applications must include a research plan describing the project to be undertaken. This must follow the NIH format (i.e., Specific Aims, Background, Preliminary Data (if available), Research Design and Methods). The maximum length is 5 pages.
5. Selected references. Maximum length is 2 pages.
6. Resources and environment. Maximum length is 1 page.
7. Full description of the candidates' other support, including all current sources of funds and all pending applications, with amounts and dates for all sources. Both external and internal sources must be listed, including any start-up funds. The team leader and other faculty participants should list their other research support, highlighting any support that is available for the proposed project.
8. Detailed budget and budget justification on NIH 398 forms. A budget section should be included with a justification of why the funds are necessary and how they will be used to promote innovative new science and to secure applications for extramural funding. We encourage you to apply only for the funds that you will need to obtain adequate pilot data or the data needed to complete your initial project, whether this amount is \$500, \$5,000, or \$15,000. If using a core with pre-determined fees for services, indicate the number and type of analyses and the cost per analysis. Generally, these core facilities have personnel costs built into the fees so no personnel costs should be listed.
9. Letter of Support from Director of Core (s) to be utilized. As specific funds allocated under this program are to be used EXCLUSIVELY to pay the cost of core services, a letter of support from the director of the core to be utilized is required. The letter should indicated

that the director has reviewed the proposal and agree that the proposed use of core services is well justified and scientifically sound.

10. An electronic copy of the application and hard copies of the original application plus 15 copies must be **submitted to the YCCI by 1 PM on Thursday, March 6, 2008.**

**Funding and years of support:** Funding will be available for up to \$15,000 in total costs for a 12-month period beginning July 1, 2008. The awards are not renewable or transferable. The number of awards to be made will depend upon the number of proposals received and the caliber of projects submitted. These funds are designed to provide you with the pilot data needed for the preliminary results section of your proposal for extramural funding, or to complete an initial, unfunded study.

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

- Scientific merit: Is the research proposed important and innovative?
- Interdisciplinary nature: Does the research meet the criteria for being a new interdisciplinary disease-oriented program?
- Funding: Is the research likely to establish the basis and rationale for a larger project and to result in a successful application for extramural funding by this larger project? Could the research be accomplished without funds from this RFA?

**Selection criteria and process:**

Your application will be evaluated according to the following criteria:

*Significance.* How might your project lead to improved treatment or prevention of a specific disease or improve the health of the general population? Will this research lead to a better understanding of the basic mechanisms of a disease? How will the endpoints in the proposed research move your project from the bench to the bedside? If the research is exploratory rather than hypothesis-driven (often the case with genomics and proteomics research), why is current knowledge insufficient to justify pursuing exploratory research rather than testing a specific hypothesis?

*Approach.* What are the specific aims and hypotheses, and what methods will be used to address them (please do not provide unnecessary details of laboratory methods)? What is the rationale for the proposed experimental approach as opposed to other potential strategies? How will the data be analyzed? What are the expected outcomes, and what would be done next if the expected outcomes are observed? What would be done next if the expected outcomes are not observed?

*Preliminary data.* This is less important than significance and innovation, especially for junior investigators. However, preliminary data can be important if you are proposing an untested method or if the hypothesis has very little support in the literature.

*Need for support.* The goal is to use these funds to initiate promising new projects, not to support ongoing research that already has extramural support. We recognize that "K" awards have limited non-personnel budgets and welcome applications from those with such awards. If you have other support, what is unique about the proposed project compared to the funded project(s)?

**Additional Requirements:** The abstracts and the names of all investigators funded through the Pilot and Collaborative Studies Program will be posted on the national CTSA website. In addition, all investigators must provide a progress report to the YCCI and must acknowledge

the YCCI CTSA base operating grant in any publications resulting from the supported studies. The YCCI also requires that results of studies supported through the program be posted on the Yale YCCI website once the data have been published.

## **Eligible YCCI Cores:**

### **1. Yale MR Research Center**

Contact: Douglas Rothman or R. Todd Constable

[douglas.rothman@yale.edu](mailto:douglas.rothman@yale.edu)

[todd.constable@yale.edu](mailto:todd.constable@yale.edu)

### **2. Yale PET Center**

Contact: Richard E. Carson, PhD, Yu-Shin Ding, PhD, or Henry Huang, PhD

[richard.e.carson@yale.edu](mailto:richard.e.carson@yale.edu) 203-737-2814

[yu-shin.ding@yale.edu](mailto:yu-shin.ding@yale.edu) 203-785-4297

[henry.huang@yale.edu](mailto:henry.huang@yale.edu) 203-785-3193

<http://petcenter.yale.edu/research/collaborators.html> or by email [pet.center@yale.edu](mailto:pet.center@yale.edu)

### **3. Center for Cell & Molecular Imaging**

Contact : Michael H. Nathanson or Al Mennone

[michael.nathanson@yale.edu](mailto:michael.nathanson@yale.edu)

[al.mennone@yale.edu](mailto:al.mennone@yale.edu)

### **4. Psychiatry SPECT Imaging**

Contact: Julie K. Staley, PhD

203-932-5711x3324 or [julie.staley@yale.edu](mailto:julie.staley@yale.edu)

### **5. Electron Microscopy Facility, Center for Cell and Molecular Imaging (CCMI)**

Contact: Marc Pypaert

[marc.pypaert@yale.edu](mailto:marc.pypaert@yale.edu), Phone 785 3681

### **6. The CINEMA Laboratory**

Contact: Derek Toomre

[derek.toomre@yale.edu](mailto:derek.toomre@yale.edu)

### **7. Immune Monitoring**

Contact Person: Lesley Devine, PhD ([lesley.devine@yale.edu](mailto:lesley.devine@yale.edu))

<http://info.med.yale.edu/labmed/imcf/>

### **8. Flow Cytometry Facility**

Contact: Mark Shlomchik

[mark.shlomchik@yale.edu](mailto:mark.shlomchik@yale.edu)

### **9. Keck Lab**

Contact: Ken Williams

[kenneth.williams@yale.edu](mailto:kenneth.williams@yale.edu)

### **10. Yale Pathology Tissue Services**

Contact: David Rimm

[David.Rimm@Yale.edu](mailto:David.Rimm@Yale.edu)

<http://www.yalepath.org/YPTS/index.htm>

**11. Center for Chemical Genomics**

Contact: Janie Merkel, Ph.D.

[janie.merkel@yale.edu](mailto:janie.merkel@yale.edu) 432-5930

[http://cgp.yale.edu/chemical/chem\\_info.html](http://cgp.yale.edu/chemical/chem_info.html)

**12. Biostatistical Support of YCCI**

Contact: James Dziura

[james.dziura@yale.edu](mailto:james.dziura@yale.edu)

**13. Biomedical Informatics Core**

Contact: Perry Miller or Pradeep Mutalik

[perry.miller@yale.edu](mailto:perry.miller@yale.edu)

[pradeep.mutalik@yale.edu](mailto:pradeep.mutalik@yale.edu)

**14. Core Laboratory of YCCI**

Contact: Li Wen or Ralph Jacob

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