



Yale Center for Clinical Investigation

Fall 2013

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TAPPING INTO YALE’S RESOURCES FOR FUNDING, DESIGNING, AND LAUNCHING A STARTUP

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YCCI has been collaborating with Yale’s Office of Cooperative Research (OCR) to accelerate the translation of research discoveries from the laboratory to patients. The OCR partners with faculty members to determine the commercial potential of their inventions and discoveries. OCR also protects intellectual property by filing patents for faculty inventions; licenses faculty technology; and connects researchers with commercial partners.

This year, YCCI is expanding efforts in this area by working with the Yale Entrepreneurial Institute (YEI). YEI is a multidisciplinary entrepreneurial accelerator—a center for identifying, encouraging, mentoring, and launching ventures that emphasizes the lean startup model and is staffed by experts with scientific as well as business expertise. YEI’s programs are designed to support entrepreneurs at every stage in the startup process, from exploring ideas and learning the startup language to developing a business plan, attracting investors, and launching a business.

Through the OCR and YEI, faculty members, graduate students, and postdoctoral fellows can gain valuable insights into forming a startup; test the commercial potential of their research; find collaborative partners to launch a venture; and tap into funding and investment opportunities. YCCI supports these efforts, which are aligned with the aim of the National Center for Advancing Translational Sciences (NCATS)—to encourage partnerships with industry in order to speed the development of new therapeutics.

There are a number of opportunities for active researchers available through YEI. For example, a wealth of grant money is available to researchers through the government’s Small Business Innovation Research (SBIR) and Small Business Technology Transfer programs (STTR). Faculty members who form a startup around innovative research are eligible for up to \$150,000 in Phase I grant money and up to \$1,000,000 in Phase II. What’s more, awardees can receive matching grants of up to \$30,000 through the SBIR Acceleration and Commercialization Program from Connecticut Innovations (CI), allowing researchers to gather additional data, protect intellectual property, conduct market research, and more. Qualifying companies may apply for up to two of these CI grants per year.

The National Institutes of Health is looking for small companies working to improve patient health; speed the process of discovery; reduce the cost of medical care and research; and improve research and communication tools. The NIH is one of 16 agencies that award \$2.5 billion annually in SBIR or STTR grants to support small businesses to stimulate technological innovation aimed at developing products with commercial merit. The purpose of both programs is to move commercially viable ideas quickly through the “valley of death” to other funding sources.



Erika Smith, M.B.A.
Deputy Director,
Yale Entrepreneurial
Institute



Photo by Terry Dagradi

Director’s Corner

The National Center for Advancing Translational Sciences (NCATS) is promoting partnerships with industry to accelerate the development of new therapeutics. YCCI has embraced this concept by partnering with the Office of Cooperative Research (OCR) on pilot awards for promising translational projects that may ultimately become commercial products. We are also working with the Yale Entrepreneurial Institute (YEI) to bring new funding opportunities to the attention of investigators. YEI offers a number of opportunities related to research and boasts a staff with both scientific and business know-how. YCCI and YEI co-sponsored a symposium this fall on SBIR and STTR grants that sheds light on negotiating these programs. We hope that these efforts will speed up the process of bringing innovative discoveries from the lab to the clinic.

While we continue to point the way to funding sources for research, we also recognize the need to improve the quality of clinical research. We are devoting more resources to guide investigators through the complexities of clinical research by providing specialized expertise in regulatory issues and IND applications. Our quality assurance unit is expanding its capabilities with the addition of staff members to monitor research studies, and provide educational programs to help investigators understand increasingly complex regulatory requirements. Symposia held this fall were designed to help research faculty successfully navigate the complexities of conducting clinical research. Speakers from academic medical centers shared lessons learned, and discussed the policies and structures they have put in place to support best practices in research. We encourage you to join us for the last of the series in December. As always, please feel free to contact us for training opportunities and assistance with clinical and translational research studies.

Robert Sherwin, M.D.
YCCI Director

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For upcoming clinical research training events, see page 3.

YCCI EXPANDS QUALITY ASSURANCE & TRAINING EFFORTS



Jan Hewett, J.D., B.S.N.
Director of the HRPP

“We are here to drive the mission of research and be there for faculty.”



Susan Anderson, R.N., B.S.N., M.F.A.
YCCI associate director for education and quality assurance

“Our aim is to integrate services where possible in order not to duplicate efforts.”

Today’s research landscape is hemmed in by requirements that can be both confusing and onerous. In order to promote the highest quality of clinical research and to help investigators meet the intensified demands of regulatory agencies, YCCI is increasing its offerings of educational programs regarding compliance as well as expanding its compliance support staff.

One such program is “Conducting Clinical Trials: Lessons Learned and Useful Tips,” a series of presentations on relevant research issues from the perspective of faculty members. The symposia features presenters from academic medical centers who have learned from firsthand experience with FDA audits, financial conflicts, and negative press related to clinical research. The series has been under way since October; its speakers have shared lessons learned and discussed the policies and structures they put in place to support best practices in research. The series kicked off with **Emma Meagher, M.D.**, associate professor of medicine and pharmacology and associate dean for human research at the Perelman School of Medicine at the University of Pennsylvania, who spoke about Penn’s response to the 1999 death of Jesse Gelsinger during a clinical trial of gene therapy. These corrective measures included the development of a training and certification program for clinical research coordinators; creating standard operating procedures for investigators; developing risk-adjusted monitoring plans; making improvements in the IRB process together with a shift to a service-based culture; and instituting financial conflict-of-interest training for investigators.

Paul DeLuca Jr., Ph.D., provost and vice chancellor for academic affairs at the University of Wisconsin–Madison, spoke on “Clinical and Translational Research: Lessons Learned at the University of Wisconsin–Madison” on October 30. The school ranks among the top public universities in research expenditures. DeLuca presented four cases, illustrating problems and solutions put in place to handle conflicts of interest; privacy/security issues with manufacturers’ representatives; discerning whether the Family Educational Rights and Privacy Act (FERPA) or the Health Insurance Portability and Accountability Act (HIPAA) applies to the study; and safeguarding the security of protected health information (PHI) after an investigator had her smartphone stolen.

The series continued with **Kara Morgenstern, J.D.**, associate general counsel at the University of Michigan, who spoke about FDA audits. The series will conclude on December 4 with **Robert Califf, M.D.**, vice chancellor of clinical and translational research at Duke University, whose presentation is titled “Getting to the Truth: Research and the Learning Health System.”

To register, visit www.yale.edu/training; browse courses by course owner and select CTSA/YCCI; select clinical trials.

YCCI is collaborating with the Human Research Protection Program (HRPP) and the Office of Research Administration to develop well-rounded training programs and events. Efforts with the HRPP include designing a comprehensive training program for study coordinators, and the joint development of good clinical practice (GCP) training. GCP is designed to ensure the protection of human subjects as well as to preserve the accuracy and credibility of clinical trial data. Failure to comply with GCP requirements can lead to various consequences, including damage to individual or institutional reputation, disqualification, debarment, fines, and even incarceration.

In addition to the GCP training available on our website (see <http://ycci.yale.edu/education/stafftrain/gcptraining.aspx>), YCCI recently (and for the past several years) sponsored GCP training on the FDA’s GCP regulatory requirements. The training is led by **Brian P. Bennett**, who has 20 years of experience in clinical training and development. YCCI and HRPP have also been working on a FAQ document to answer questions about clinicaltrials.gov from a regulatory standpoint.

The HRPP recently completed a site visit with the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in connection with Yale’s application for reaccreditation. About 85 interviews were conducted with investigators, study coordinators, and institutional leadership – an exhaustive effort that also involved preparation prior to the visit. Yale had only one observation out of 62 possible citations – an outstanding result, according to **Jan Hewett, J.D., B.S.N.**, director of the HRPP. The HRPP is taking steps to correct this insufficiency, which had to do with knowledge of the regulatory definition of a UPIRTSO, or unanticipated problem involving risks to subjects or others. If the AAHRPP finds the remediation sufficient, Yale’s accreditation will be approved for another five years.

“Both YCCI and HRPP want to become more effective by working jointly across the institution,” said Hewett, noting that the relationship between the two programs is enormously collaborative. “Our aim is to integrate services where possible in order not to duplicate efforts,” said **Susan Anderson, R.N., B.S.N., M.F.A.**, YCCI associate director for education and quality assurance.

This approach is used increasingly often, as the institution seeks to identify high-risk areas and understand how programs may be able to overlap in monitoring and auditing research studies, in order to develop a more comprehensive university-wide compliance program.

Hewett pointed out that while institutional review boards (IRBs) are a fundamental component of the HRPP, they are only one unit under the organization's umbrella. The HRPP also has substantial responsibilities for community outreach, education, and compliance. "We are here to drive the mission of research and be there for faculty," she said. "An important part of our broader mission is the support and management of conducting research efficiently and in a compliant manner."

In that sense, the HRPP and YCCI are aligned in their goals. YCCI is expanding its quality assurance staff in order to help investigators conduct high-quality clinical research, as well as understand and comply with regulations related to conducting research. **LaToya Howard** has assumed increased responsibilities that include supervising the administrative aspects of the scientific review committees under the auspices of YCCI and the Yale Cancer Center along with coordinating YCCI's training programs for research staff. Howard has spent the last four years providing administrative support for these programs; she is knowledgeable about the challenges inherent in quality assurance for clinical research as well as ways to assist investigators and research staff in meeting those challenges. In her new role she will bring a wealth of experience in coordinating professional development for research nurses, coordinators, data managers, IRB staff, and other personnel involved in clinical research. "A robust clinical trials infrastructure is even more essential now in light of the increased volume of clinical trials at Yale and the complexity of conducting research," said Anderson. "LaToya has been an asset for YCCI and I'm delighted that her role is expanding."



Barbara Beckerman, MHA; LaToya Howard; Susan Anderson; Ariana Wiley; and Allison Gavaletz

Ariana Wiley, who was most recently a research assistant in the Clinical Trials Office, recently joined the Quality Assurance unit as an administrative assistant. **Barbara Beckerman**, MHA, and **Allison Gavaletz** are two new compliance coordinators responsible for auditing clinical research throughout the School of Medicine. Beckerman has 25 years of clinical research experience and has worked with YCCI since 2008 as a clinical research associate/internal auditor for YSM and the Cancer Center. Gavaletz joins YCCI after more than 10 years as a regulatory/senior research coordinator

at the Child Study Center. "I'm very excited to add these seasoned coordinators to our team," said Anderson. "They bring a wide range of experience in a range of disciplines and will be an asset in terms of providing oversight and educating investigators and research staff." ☼

Need Help with OnCore?

The rollout of EPIC and the continued implementation of OnCore, Yale's clinical research management system (CRMS), are paving the way to an integrated information technology environment that fully supports research. YCCI staff members are ready to assist you in resolving questions or issues you may have related to OnCore:

OnCore Department Support for Clinical Research
 Budget Building
 Training and System Management
 Biospecimen and Registries Management
 OnCore Reporting
 Hospital Billing Review
 Professional Billing Review

Kelly Anastasio	kelly.anastasio@yale.edu
Pat Fontaine	pat.fontaine@yale.edu
Tom Debski	thomas.debski@yale.edu
Helen Seow	helen.seow@yale.edu
Liat Modiano	liat.modiano@yale.edu
Charise Berghaus	charise.berghaus@ynhh.org
Kelly Anastasio	kelly.anastasio@yale.edu

If you have issues with protocol building or have any other questions please contact **Nicholas Licht**, at nicholas.licht@yale.edu, who oversees the build process for OnCore protocols.

Have other questions? Visit <http://oncore.yale.edu> to get the latest information on OnCore, including training documentation, contact information, new study setup forms, and more.

Events Calendar

• December 4, 4 p.m.

GETTING TO THE TRUTH: RESEARCH AND THE LEARNING HEALTH SYSTEM

Presented by Robert M. Califf, M.D.
 Vice Chancellor of Clinical and Translational Research, Duke University

Cohen Auditorium,
 Child Study Center,
 230 South Frontage Road

TO REGISTER, VISIT:

www.yale.edu/training

1. Browse courses by course owner; then select CTSA/YCCI
2. Select Clinical Trials.

Yale research staff members are invited to attend the sessions below on topics related to the logistics, ethics, and results of clinical research:

Coffee and Conversation

8:00 a.m., Cohen Auditorium
 Third Wednesday of each month
 (Coffee at 7:30 a.m.)

Lunch and Learn Series

Noon, Cohen Auditorium
 Second Thursday of each month
 (Lunch is provided.)

FOR THE SCHEDULE, VISIT:

ycci.yale.edu/education/stafftrain/index.aspx

TO REGISTER, VISIT:

www.yale.edu/training

1. Browse courses by course owner; then select CTSA/YCCI
2. Select Clinical Trials.

FOR MORE INFORMATION, CONTACT:

LaToya Howard at:
latoya.howard@yale.edu or call,
 203.737.3661

Research-in-Progress Meetings

These meetings feature presentations from YCCI Scholars and Investigative Medicine Program students, as well as trainees from the Medical Research Scholars Program (MRSP).

We encourage all faculty and staff to attend.

Noon, TACN203
 (Lunch is provided.)

• December 9

• January 13

• January 27

• February 10

• February 24

• March 10

TO FIND THE LIST OF PRESENTERS AND PROJECTS, PLEASE VISIT OUR WEBSITE AT: ycci.yale.edu/education/lectures/schedule/index.aspx

Third Annual Scholar Day Retreat

A half-day event for students, trainees, Scholars, and faculty members who are participating or interested in clinical or translational research.

Noon, TAC Auditorium

• April 1



Judy L. Harris, c.p.c.
Director, Medical Billing Compliance

The Medical Billing Compliance Department oversees, develops, implements, and provides ongoing maintenance of the medical billing compliance program.



Kathy Engle
Senior Compliance Auditor

The 2013 Office of Inspector General (OIG) Work Plan has been released by the U.S. Department of Health and Human Services (HHS). The OIG is responsible for detecting and preventing fraud, waste, and abuse among 300+ programs administered by the HHS, as well as maintaining and improving the operations of the programs.

Investigators receiving payment for their research from any HHS program may be subject to OIG inspections. Some of the major programs under the HHS that fund research programs conducted at Yale include: the National Institutes of Health (NIH); the Centers for Medicare and Medicaid Services (CMS); the Food and Drug Administration (FDA); and the Centers for Disease Control and Prevention (CDC).

The following areas were noted in the 2013 work plan for investigators funded by the NIH and/or CDC:

1. NIH – Equipment Claims by Grantees (NEW): Review whether NIH grantees' claims for equipment purchases are in compliance with the special terms and conditions set forth by the Recovery Act of 2009 and applicable federal requirements.
2. NIH – Human Subjects Protection Practices of National Cancer Institute Extramural Grantees Collecting Biospecimens (NEW): Determine the extent to which informed consents for biospecimen research studies comply with human subjects protection regulations, and the extent to which PIS and IRBS take measures to address unique risks associated with this type of research.
3. CDC – Oversight of HIV/AIDS Prevention and Research Grants (NEW): Assess whether the CDC's oversight of HIV/AIDS prevention and research grants was conducted in accordance with federal regulations and HHS policies.
4. NIH – Colleges' and Universities' Compliance with Cost Principles: Evaluate colleges' and universities' compliance with selected cost principles issued by OMB Circular A-21, "Cost Principles for Educational Institutions."
5. NIH – Extra Service Compensation Payments Made by Educational Institutions: Assess whether payments for extra compensation charged to federally sponsored grants, contracts, and cooperative agreements by educational institutions complied with Federal regulations.
6. NIH – Use of Data and Safety Monitoring Boards (DSMBs) in Clinical Trials: Determine the extent to which DSMBs monitor data in clinical trials, and how and to what extent the NIH is ensuring that grantees comply with NIH policy for DSMBs in multisite clinical trials.
7. NIH – Inappropriate Salary Draws from Multiple Universities: Evaluate whether faculty members working on NIH grants were inappropriately drawing salaries from multiple universities.
8. NIH – Cost Sharing Claimed by Universities: Determine how universities are meeting cost sharing requirements. Of particular concern is possible misuse of the Cost Accounting Standards (CAS) exemption to directly claim costs that are normally treated as Facilities and Administrative (F&A) costs.

For investigators billing routine care costs or drugs under a clinical trial to Medicare and Medicaid, some of the clinical areas highlighted under the 2013 work plan are:

1. Ophthalmological Services – Questionable Billing (NEW): Review Medicare claims data to identify questionable billing claims for ophthalmological services during 2011.
2. Electrodiagnostic Testing – Questionable Billing (NEW): Review Medicare claims to identify questionable billing for electrodiagnostic testing (including electromyograms and nerve conduction tests).
3. Patient Safety and Quality of Care – Claims for and Use of Atypical Antipsychotic Drugs Prescribed to Children in Medicaid (NEW): Review medical records to determine the extent to which patients 18 years of age or younger had submitted Medicaid claims for atypical antipsychotic drugs during a selected timeframe; and determine the extent to which the drug claims were submitted for off-label uses (when the drug is prescribed for a condition not listed on the product's label) and for indications not listed in one or more of the approved drug compendia.

4. Evaluation and Management (E/M) Services – Potentially Inappropriate Payments in 2010: Determine the extent to which CMS made potentially inappropriate payments for E/M services in 2010 and the consistency of E/M medical review determination. Review multiple E/M services for the same providers and beneficiaries to identify electronic health records (documentation practices associated with potentially improper payments).
5. Diagnostic Radiology – Medical Necessity of High-Cost Tests: Review Medicare payments for high-cost diagnostic radiology tests to determine whether they were medically necessary. Review the extent to which primary care physicians and physician specialists order the same diagnostic tests for the same treatment of a beneficiary.
6. Laboratory Tests – Billing Characteristics and Questionable Billing in 2010: Identify questionable billing for Medicare Part B (outpatient) clinical lab tests in 2010. Medicare pays only for lab tests ordered by a physician or qualified nonphysician practitioner who is treating a beneficiary.
7. Laboratory Tests – Part B Payments for Glycated Hemoglobin A1c tests: Determine the appropriateness of Medicare payments for the glycated hemoglobin test (HgbA1c). Medicare does not consider it reasonable and necessary to perform this test more often than once every 3 months on a controlled diabetic patient, unless documentation supports the medical necessity of testing in excess of national coverage determinations guidelines.
8. Patient Safety and Quality of Care – Off-Label Use of Medicare Part B Drugs: Review off-label and off-compensia use of certain outpatient Medicare (Part B) prescription drugs and determine the extent to which specified compendia provide support for coverage.
9. Drug Payments – Questionable Claims for HIV Drugs: Determine the extent of questionable billing for HIV drugs dispensed in 2010 under Medicare’s outpatient prescription plan (Part D).
10. Sleep Testing – Appropriateness of Medicare Payments for Polysomnography: Identify questionable billing patterns for Medicare sleep services provided in 2009 and 2010.
11. Sleep Disorder Clinics – High Utilization of Sleep Testing Procedures: Examine Medicare payments to physicians, hospital outpatient, and independent diagnostic testing facilities to determine whether they were “reasonable and necessary.”

Principal investigators (PIs) contacted by an inspector from an HHS program for audit should immediately contact **Judy Harris**, Medical Billing Compliance Officer, at judy.harris@yale.edu; and **Alice Tangredi-Hannon**, University Research Compliance Officer for the Office of Research Compliance and Education, at alice.tangredi.hannon@yale.edu. A copy of the entire plan may be viewed at <https://oig.hhs.gov/reports-and-publications/workplan/index.asp>. ❁

ACADEMIC MEDICAL CENTER PAYS \$1.5 MILLION TO SETTLE ALLEGATIONS OF RESEARCH BILLING MISCONDUCT

On August 28, 2013, the United States Attorneys’ Office announced that Emory University agreed to pay the United States and the State of Georgia \$1.5 million to resolve allegations of submitting false claims to Medicare and Medicaid from 2001 through 2010. According to the settlement agreement, Emory’s Winship Cancer Institute was accused of violating the National Coverage Determination (NCD) for Routine Costs in Clinical Trials through:

- Billing Medicare and Medicaid for clinical trial services that should have been billed to the clinical trial sponsors.
- Double-billing the same clinical trial services to clinical trial sponsors and to Medicare and/or Medicaid.

Under this settlement, Emory agreed to identify unallowable costs previously submitted for payment to Medicare, TRICARE, and

Medicaid within 90 days. The federal government is also entitled to recoup these overpayments, plus applicable interest and penalties.

Emory’s settlement illustrates Yale’s need to be proactive in evaluating a research study’s billing compliance. Since February 1, 2013, the OnCore/EPIC interface has been activated to assist investigators and departments with research billing compliance at Yale. Investigators starting a new clinical trial involving clinical services should contact the OnCore team to assess the need to use the interface prior to enrolling their first subject. If the team determines that the study should use the system, subjects must be activated in OnCore/EPIC soon after signing the consent form. ❁

Getting Started

- For help with study design, contact **Theresa Katz** at YCCI, theresa.katz@yale.edu, or visit: ycci.yale.edu/index.aspx.
- Investigators who have an idea they want to develop should contact **David Lewin, PH.D.**, OCR senior associate director of licensing at david.lewin@yale.edu. OCR can also assist in identifying local companies interested in collaboration.
- YEI has resources for evaluating the commercial potential of a business idea and other essentials for launching a successful startup. For more information, visit: yei.yale.edu, or contact **Erika Smith**, erika.smith@yale.edu.

YCCI and OCR

OCR works with investigators to develop avenues for transitioning discoveries into commercial products. **David Lewin, PH.D.**, OCR senior associate director of licensing, identifies projects that can benefit from modest amounts of funding, which YCCI awards on an ad hoc basis to help move projects toward initial commercial development. "Our partnership with YCCI has been instrumental in moving new discoveries to the next step," said Lewin. "It allows us to get answers to questions we will inevitably be asked but don't otherwise have the resources to address."

Upcoming SBIR Events at Yale

Office hours with **Merrie London**, SBIR manager at Connecticut Innovations, will be held at:

Office of Cooperative Research
433 Temple St., New Haven

December 4 and 11, 1:00–4:00 p.m.

To reserve your spot, email: merrie.london@ctinnovations.com.

For more information, visit: www.yale.edu/ocr/sbir_officehours.html

Save the Date:

February 11–12, 2014

How to Apply for the SBIR Program with **Lisa Kurek**

For more information, visit: yei.yale.edu/funding-new-ventures

To learn more about YEI resources and educational programming, sign up for the monthly YEI newsletter at:



YEI and YCCI hosted a lunch symposium on November 6 with guest speaker **Lisa Kurek**, the program director of SBIR Impact NYC and a managing partner of BBC Entrepreneurial Training and Consulting. Kurek explained the basics of the SBIR and STTR programs, highlighting what investigators should consider when applying for these awards.

Both programs award funding to small businesses to develop products based on technological innovation. The small businesses must have research facilities and employees. The SBIR program

requires the principal investigator to have his or her primary employment (at least 51 percent) with the small business. Under the STTR program, primary employment with the business is not required, and grants are awarded for cooperative research, which is the development of technology between a small business and a partnering research university. While the STTR program requires collaboration with a nonprofit research institution, the SBIR program allows this requirement to be met through subcontracting. Faculty can meet the SBIR requirement of primary employment with the small business by serving as a consultant and appointing a postdoc to work for the company.

YALE SBIR SUCCESS STORIES

Vincent Pieribone, PH.D., professor of cellular and molecular physiology and of neurobiology, cofounded the New Haven-based company Marinus Pharmaceuticals in 2005, raising \$29.4 million in Series A financing in addition to receiving an SBIR grant. The company is dedicated to the development and commercialization of novel drugs to treat serious neurological, psychiatric and pain disorders.

Adam Wisnewski, PH.D., senior research scientist in medicine, has received multiple Phase I and Phase II STTR grants for his work with the New Haven-based startup L2 Diagnostics to develop innovative biomonitoring approaches to exposure surveillance for methylene diphenyl diisocyanate (MDI). This compound is used to make foams, coatings, and other products, but also leads to MDI asthma in exposed workers.

Michael Hodsdon, M.D., PH.D., associate professor of laboratory medicine and of pharmacology and associate director of the Yale Clinical Chemistry Laboratory, was awarded a Phase I SBIR grant for his work developing a rapid phenotypic method relying on mass spectrometry to detect carbapenemase activity. This test would help prevent outbreaks of drug-resistant bacteria, a major threat to global health. Hodsdon's New Haven-based startup, M/Z Diagnostics, includes **David Peaper, M.D., PH.D.**, assistant professor of laboratory medicine and director of the Clinical Microbiology Laboratory; and **Mandar Kulkarni, PH.D.**, who completed his postdoctoral fellowship at Yale.

OPPORTUNITIES FOR STUDENTS

The Venture Creation Program (VCP) at YEI is designed to help students turn that nugget of an idea into commercial gold with financial support, mentoring, and expert advice. Student startups at any stage in the inspiration process will be given consideration for admittance into the VCP. Many of these early-stage teams have gone on to secure coveted Summer Fellowships, in which they work to develop their newly honed ideas into successful businesses. Selected teams receive up to \$2,500 to develop their prototype or proof of concept, and are assigned a mentor. They are also provided with access to YEI consultants and corporate partners as well as a dedicated space in the YEI Incubator.

YEI has earmarked a portion of the VCP funding specifically for postdoc and graduate student researchers interested in launching ventures with faculty support. Contact **Erika Smith**, erika.smith@yale.edu, for an application and more information.

YCCI encourages faculty members and students to take advantage of the resources offered by OCR and YEI. Such new funding opportunities as SBIR and STTR are especially important in light of shrinking NIH budgets. These programs challenge investigators to think about their research in new ways that have the potential to speed the development of new therapies. 🌟