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Yoder prepares new efforts to spark the entrepreneurial spirit at the Indiana CTIS

Jan. 10, 2012

The ultimate goal of translational research is to bring research out of the lab and into practice. This goal involves navigating the path from basic science to clinical trials and also commercialization.

In order to strengthen efforts and bring clarification to this final step in the translational process, Mervin Yoder, M.D., Richard and Pauline Klingler Professor of Pediatrics at the IU School of Medicine, was appointed assistant dean for entrepreneurial research at the IU School of Medicine and associate director for entrepreneurship at the Indiana Clinical and Translational Sciences Institute. He assumed the position July 1.

"There was a strong sense that a faculty member who also was an entrepreneur would be an asset to encouraging investigators to consider disclosure of intellectual property," said Dr. Yoder, who is the founder of [a biotech company in Indianapolis](#). "They needed a liaison from within the faculty to connect peers to services at the Indiana CTIS, IU School of Medicine and IU Research and Technology Corp."

In the first major step in a three-part plan to turn up the dial on entrepreneurship at the Indiana CTIS, Dr. Yoder will oversee the publication of the "Faculty Inventor's Guide to Technology Transfer." This document, currently under development by Dr. Yoder in collaboration with the IURTC, will provide a straightforward "how to" guide to transforming an idea into a business or other commercial opportunity. The guide will be distributed widely among faculty, as well as given to all new investigators when they join the university, and is expected to be complete in late January.

"When you join the faculty as a researcher, everyone knows you're expected to make discoveries, publish papers and earn grants," Dr. Yoder said. "What nobody really talks to you about is technology transfer; it's simply never been emphasized. Going forward, I want to make sure all new faculty receive this guide so they're aware of all the opportunities available to them to be successful."

Dr. Yoder also aims to personally meet all new science faculty to talk about how thinking entrepreneurially can advance their career goals, as well as to share his personal experience with the intellectual property process.

The second step to increase faculty innovation at IU and the Indiana CTIS is a plan to replicate the process by which his own discoveries were launched into a successful biotech company. He says EndGenitor Technologies was founded only after a project manager from [BioCrossroads](#), which provides support, investment and development to the life science sector in Indiana, spotted an IP disclosure on file at IURTC on a new type of cell with the ability to grow new blood vessels. Together, he and the project manager secured enough investment from local angel investors to launch a startup, as well as attract the talent of Ron Henriksen, a former executive at Eli Lilly, to serve as CEO. The company is focusing on isolating endothelial stem cells from umbilical cord blood and collaborating with other companies toward a Phase I human clinical trial to test the safety of these cells in repair of blood vessels in human subjects with vascular disease.

No one laid out this process before his journey from researcher to



Mervin Yoder, M.D., Ph.D., associate director for entrepreneurship at the Indiana CTIS.

business development, Dr. Yoder said. As director of the Wells Center, he will test pilot a new process by which all research generated by center investigators will be submitted for review by the IURTC before publication. If the reviewer spots an idea with spin-off potential, he or she will flag the project's investigator to meet about intellectual disclosure or other commercial opportunities.

"Faculty inventors don't need to run the company," Dr. Yoder said, noting that many faculty fear the distraction from research that starting a business may entail. "We're the experts at scientific investigation; others with business experience will turn your idea into a product. You're basically serving as a consultant to provide the scientific fundamentals to the process."

About 250 investigators at the IU School of Medicine are funded by the National Institutes of Health, with thousands of journal articles published annually. Given such prestigious funds and prodigious output, he says the rate of intellectual disclosures should exceed its current level of 80 to 100 per year.

"The numbers simply aren't congruent. Clearly, we're not capturing all the opportunities that could exist," Dr. Yoder said. "We really want to start to spot 'diamonds in the rough' before they even reach the publication phase."

The final goal will be to integrate entrepreneurial spirit into the core curriculum by capitalizing upon opportunities presented by the two new master's programs in [translational science](#) and [clinical research](#) established by the Indiana CTSI.

To kick off the process, Dr. Yoder will speak this spring to postdoctoral students from a clinical trials course taught by Kurt Kroenke, M.D., director of the Indiana CTSI Research Education, Training and Career Development Program. The talk will be the first in what's expected to be a continuing effort to bring a message of intellectual innovation into the classroom.

"Until someone brought it to my attention, I simply wasn't thinking about intellectual disclosure or starting a company," Dr. Yoder said. "We really need to share this knowledge with graduate and postdoctoral students — they're the next generation. Promoting an entrepreneurial spirit in our young investigators will surely enhance the overall mission of the Indiana CTSI."

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Kacena explores drug with potential to safely heal bone defects

Jan. 10, 2012

After a serious traumatic injury, bone often won't heal. Each year, there are nearly a half a million "non-unions" — bone fractures that won't heal and require surgical intervention — and these unhealed fractures are extremely painful and debilitating.

These defects can result from tumor resection, infection, motor vehicle crashes or wounds from war, such as high-energy blast injuries. Modern medicine has come up with bone healing treatments, but they have a number of serious problems. Sometimes they regrow too much bone causing pinched nerves. Recent reports also indicate that current treatments may increase the risk of cancer.

Melissa Kacena, Ph.D., assistant professor of orthopedic surgery at the Indiana University School of Medicine, is the co-inventor of a pending utility patent on a compound with potential to re-grow bone with fewer side effects. With early support from Indiana Clinical and Translational Sciences Institute, Dr. Kacena has been investigating the effect of a drug used to treat patients with blood disorders on bone repair. Early laboratory tests suggest this compound prompts more regulated bone formation by controlling both bone growth and destruction.

In early 2012, she received more than \$3.4 million from the National Institute of Arthritis and Musculoskeletal and Skin Diseases to support this research.

"To maintain a skeleton, you need a balance between bone destruction and construction," Dr. Kacena said. "These things are normally in balance; however, the bone healing drugs currently on the market mostly stimulate growth."

During the normal process of bone repair following a fracture, a layer of cartilage forms and mineralizes into an irregular "bone matrix" or "woven bone." However, this substance is weaker and less regular than normal bone and must be broken down by the body before it can be replaced by stronger, more regular, "well-contoured" bone. The only compounds currently approved by the US Food and Drug Administration to treat such injuries are a class of drugs known as bone morphogenetic proteins — BMP2 and BMP7, specifically — which stimulate bone growth but not the counterbalancing bone destruction. Unregulated bone growth can pinch nerves, inflame surrounding tissue or inhibit motion.

"These drugs are very effective at bone formation but lack a remodeling component," Dr. Kacena said.

The compound under investigation by Dr. Kacena is unique in its stimulation of both osteoblasts, which create bone, and osteoclasts, which destroy bone. The original discovery prompting this research came from a separate study on rheumatoid arthritis and juvenile idiopathic arthritis, which revealed that osteoclast lineage cells also have receptors that react to the compound under investigation.

With Tien-Min Gabriel Chu, D.D.S., Ph.D., associate professor of restorative dentistry at the IU School of Dentistry, Dr. Kacena is developing a mouse model to further test the compound's effect on bone using a challenging bone healing model.

"What we're tackling here is the most challenging bone healing problem — a critically sized segmental defect in a weight-bearing bone which requires medical intervention, including a surgical scaffold stimulated by drugs to prompt new bone formation," Dr. Kacena said.

Previously, the drug had been tested only in rats due to the extremely small and delicate scaffold required to stabilize bone in mice. The ability to test the



Melissa Kacena, Ph.D.

drug in genetically altered mice will be a key step in understanding how the drug functions as well as advancing it toward human clinical trials. Developing this model is supported by nearly \$100,000 from the Indiana CTSI Collaboration in Translational Research Grant and Pediatric Sciences Project Development Team programs.

"While we still have much work to optimize the model and demonstrate efficacy," Dr. Kacena said, "should the mouse data be compelling, the work can move quickly into human clinical studies."

The IU Research and Technology Corp. recently filed domestic and international use patents on the mouse model and drug, respectively, she added, noting that the compound has seen to possess potential to advance to the second phase of clinical trials faster than most drug development projects because of existing FDA approval for its use in blood disorders.

"The university wouldn't have put the resources behind the patent application if they didn't think they could get some benefit," she said. "This is really a quickly translatable project since it won't require as many safety and toxicity screenings."

Annual sales for the drugs currently on the market to treat non-union bone fractures total more than \$700 million.

Other support for the drug development project, separate from support for the mouse model, included \$75,000 from the Indiana CTSI CTR Grant Program in July 2010 and \$9,000 from the Indiana CTSI Core Pilot Grant Program in January 2011. In addition to NIAMS, the rheumatoid arthritis and juvenile idiopathic arthritis project that promoted the drug development project has been supported by \$24,000 from the Indiana CTSI Pediatric Sciences PDT in November 2008 and \$7,650 from the Core Pilot Grant Program in January 2011.

Dr. Kacena also holds a KL2 training award from the Indiana CTSI supporting investigations into this research.

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"Survivor"-style course kicks off translational science program

Jan. 10, 2012

This semester marks the next major step in the Indiana CTSI's goal of training the next generation of translational researchers with the official launch of its new master's program in translational science.

The program represents an important step forward in the integration of translational and clinical science into the academic curriculum. Students participating in the program will kick off their studies Thursday, Jan. 12, with an innovative course, "Quantitative Aspects in Translational Research," designed to train medical and basic researchers to collaboratively solve problems in translational research.

The emphasis on problem-solving through teamwork will be reinforced by the course's design, which is patterned after a research version of the reality show "Survivor," with lecture titles such as "Marooned Survivor: Translational Island," "Building Tribal Alliances" "The Final Immunity Challenge." This focus will be on how to navigate the treacherous waters involved in turning a research idea into a clinical reality.

After a four-week section on mastering the terms and language of clinical and translational science, students will use their newfound knowledge to work backward from identifying a clinical problem to designing an experiment to tackle its most urgent questions. Students will then band into research teams or "tribes" in which they're asked to work out the details of their experiment, including preparing a short grant application and an oral presentation.

The ultimate goal of this "simulation approach" to education will be to provide students the analytical skills needed to anticipate and predict outcomes of translational research as well as secure support for their work. Subjects will include learning to create systems maps and mathematical constructs of their research problems; conduct systematic investigations of disease; and communicate effectively with scientists both within and outside their primary discipline.

The course will be led by Robert Bies, Pharm.D., Ph.D., associate professor of medicine and medical and molecular genetics at the IU School of Medicine and director of the Indiana CTSI Disease and Therapeutic Response Modeling Program. The course will also serve as a high-profile forum for translational researchers to present cutting-edge research and expose students to world-class investigators outside their institution. Presenters will include Dr. Bies; Jamie Dananberg, M.D., vice president for translational medicine at Eli Lilly & Co.; Sorrell Schwartz, Ph.D., professor emeritus at Georgetown University; and Mark Payne, M.D., professor of pediatrics and medical and molecular genetics at the IU School of Medicine.

For more information about the master's program in translational science, visit [this page](#) or contact Carrie Hansel at cahansel@iupui.edu.

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Indiana CTSI Opportunities -- January 2012

Postdoctoral (K Scholar) Awards in Translational Research

The Indiana Clinical and Translational Sciences Institute is seeking applicants for research fellowships in clinical-translational research. Clinical research includes epidemiological studies, clinical trials or other investigations involving human subjects. Translational research consists of either "T1 research" (interface of basic science to human studies) or "T2 research" (interface of human studies to the community). Eligible candidates must fall into one of two categories:

- Clinician-scientists with a doctoral degree (physicians, nurses, dentists, pharmacists, clinical psychologists, optometrists, veterinarians, allied health care professionals, etc.)
- Basic scientists with a PhD who are doing translational research that has high potential for early translation into impacting patient care

This award requires two co-mentors who are faculty investigators from at least two different disciplines (preferably a clinician and a PhD-scientist). Applicants must be full-time junior faculty or research scientists eligible to apply as principal investigator on an NIH grant or career development award but who have not yet been a principal investigator on an R01 or equivalent grant. Postdoctoral clinical or research fellows are not eligible to apply unless institutional arrangements have been made for a full-time faculty or research scientist appointment by summer 2012. Benefits include partial salary support, tuition and fees for required and elective coursework, pilot research monies and travel funds to attend the national CTSA young investigator meeting.

Applications must be submitted by **Wednesday, Feb. 1**. Awards will begin July 1. For complete application information, including eligibility guidelines and forms, visit www.indianactsi.org/grants, log in using your institutional username and password and select "CTSI Young Investigator Award in Clinical — Translational Research — 2012.02."

Questions to Donna Burgett at 317-630-7447 or dburgett@regenstrief.org.

Predocutorial (T Trainee) Awards in Translational Research

The Indiana Clinical and Translational Sciences Institute is seeking applicants for predoctoral training awards in translational research. Eligible candidates are second- or third-year predoctoral graduate student at one of the CTSI partner institutions: Indiana University, Purdue University or the University of Notre Dame.

Translational research refers to the process by which research in the lab translates into patient treatment (i.e.: "bench to bedside"). Translation may involve (T1) applying discoveries made during research to the development of clinical trials and studies in humans or (T2) carrying out research aimed at enhancing the adoption of best practices, or both.

Benefits include an annual stipend of \$24,500 (comparable to other pre-doctoral training positions), as well as partial tuition and fees for coursework relevant to the applicant's research, mentoring with a faculty member whose research program includes peer reviewed extramurally funded clinical or translational research and the opportunity to network with other pre and post-doctoral trainees, program mentors and allied researchers from multiple institutions in Indiana. This award also includes travel support to attend a national meeting with similar trainees from 40 other medical schools and research institutions.

For complete application information, including eligibility guidelines and forms, visit www.indianactsi.org/grants, log in using your institutional username and password and select "CTSI Predocutorial Training Awards in Translational Research — 2012.02 (TL1)."

Applications must be submitted by **4 p.m. Wednesday, Feb. 1**. Funding is renewable for an additional year based upon progress attained. Questions to Colleen Gabauer at 765-494-9256 or ictsi@purdue.edu.

Community-Based Research Grants — Request for Applications

The Indiana Clinical and Translational Sciences Institute Community Health Engagement Program is requesting applications to support community-based research projects.

This request for applications will provide funds to academic and community partners to assist in the development and successful completion of collaborative, community-based research planning or implementation projects. Indiana CTSI CHEP support will range from \$1,000 to \$5,000 for planning projects and \$10,000 to \$20,000 for implementation projects during the 2011-12 fiscal year for this RFA.

For the purposes of this opportunity, community-based research will be defined as collaborative efforts with at least one community-based organization and one academic partner. Planning or implementation projects must be joint efforts pursuing one or more of the following objectives: (1) improve an important feature of health or health care, (2) perform a needed evaluation of a valuable health-related program, or (3) develop a relationship for a community-based implementation project that can lead to (1) or (2). Preference will be given to projects likely to lead to extramural funding that supports the continuation or expansion of the proposed project or results in intellectual property.

The application deadline is Monday, Jan. 30. Awards will be announced March 1. The final allocation amount will be based on the number and quality of applications received. No applications will be funded for more than \$20,000. Proposed project periods cannot exceed 12 months from the project start date, although applications for additional funding in the next year's funding cycle will be considered based on progress.

For complete application guidelines and forms, visit www.indianactsi.org/grants, log in using your institutional username and password and

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select "CHEP Community-Based Research Awards (CBR)". Questions to Emily Hardwick at (317) 278-2821 or ejhardwi@iupui.edu.

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Kovacs to lead clinical research; Bullock appointed Notre Dame liaison

Richard J. Kovacs, M.D., professor of clinical medicine, was appointed associate dean for clinical research at the Indiana University School of Medicine on Jan. 1.

In this role, Dr. Kovacs will oversee clinical research activities at the IU School of Medicine. This includes increasing the number of researchers engaged in clinical trial research at the IU School of Medicine and working with the school's hospital partners to increase patient enrollment in clinical research studies. He will also serve as an associate director with the Indiana Clinical and Translational Sciences Institute, a statewide partnership among Indiana University, Purdue University and the University of Notre Dame to turn scientific discoveries in the lab into new patient treatments and therapies in the health care system. Dr. Kovacs also is clinical director at IU's Krannert Institute of Cardiology.

Dr. Kovacs succeeds Rafat Abonour, M.D., professor of medicine and of pathology and laboratory medicine, who has served in the position since July 2005. He has been a passionate advocate for clinical trial research and served as the founder of the Indiana CTSI Office for Research Recruitment.

Dr. Abonour will continue in his role as a renowned oncologist and researcher specializing in multiple myeloma and gene therapy at the IU Melvin and Bren Simon Cancer Center.

Bullock to serve as Notre Dame liaison

Andrew Bullock, Ph.D., MBA, managing director of the Mike and Josie Harper Cancer Research Institute at the University of Notre Dame, has been appointed as a liaison for the Indiana CTSI at Notre Dame.

Dr. Bullock is an accomplished scientist and manager with experience in molecular biology and neuroscience. He is the author of successful research grants, animal and human use protocols and academic publications, as well as strategic business plans across multiple laboratory disciplines. Prior to joining the Indiana CTSI at Notre Dame, he served as a project manager for Naval Environmental and Preventive Medicine Unit 5 at the Naval Medical Center in San Diego, Calif. In 2007, he was deployed to a medical facility in Kuwait.

Dr. Bullock holds a Ph.D. from the Weill Graduate School of Medical Sciences at Cornell University and an MBA from the School of Business Administration at the University of San Diego. He succeeds Melanie DeFord, MSA, assistant director and associate professional specialist in the Department of Chemistry and Biochemistry, who will remain the liaison for the core facility program at Notre Dame.

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Richard J. Kovacs, M.D.



Andrew Bullock, Ph.D., MBA

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Indiana CTSI and CHEP to host annual events; CTSI cosponsors conference

The Indiana CTSI Community Health Engagement Program (CHEP) will present their Fourth Annual Community Advisory Council Meeting on **Tuesday, March 20**, at the Indiana Historical Society, 450 W. Ohio St., Indianapolis, IN. To register, please visit <https://redcap.uits.iu.edu/surveys/?s=a41LQ9>.

Mark Your Calendars! The Fourth Annual Indiana CTSI Meeting on **Monday, May 7**, at the University Place Conference Center and Hotel at IUPUI. This annual event provides an opportunity to learn more about the Indiana CTSI and its programs from state-, local- and national-level representatives, as well as hear from researchers supported by institute, explore poster presentations, and meet new colleagues and collaborators. Information about previous annual events is available on the Indiana CTSI [news page](#) under the drop down menu labeled "Meetings."

The Indiana CTSI will cosponsor the Second Annual American Delirium Society Conference **June 3-5** in Indianapolis. For more information, see the [event flier](#) or visit www.americandeliriumsociety.org.

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