University-Operated Hospital Model Goodbye

Lloyd A. Jacobs, M.D.
Professor, President Emeritus

One should, I believe, from time to time, re-examine one’s most cherished beliefs and most deeply held presuppositions. This is difficult of course, not only because presuppositions may not be accessible to the conscious mind but also because beliefs and presuppositions provide a certain stability to life, a bit of respite from the external flux.

I have for many years cherished my belief that a hospital wholly operated by a university provides the best support for the teaching and research aspects of a medical school’s mission. My years at the University of Michigan solidified that belief and when I came to the Medical College of Ohio (MCO), then a freestanding health science university, it seemed entirely natural that it wholly owned and operated a hospital.

Indeed, MCO may be said to be and to have been “a model of its kind.” The model of which I speak now is well known: A College of Medicine and a hospital are structured as an integral whole; the College leaders also lead a great hospital. This structure is an American invention, and communities fortunate enough to possess a replica of this model are believed to enjoy higher quality of health care and greater general prosperity. This model, to which MCO conforms, was invented 125 years ago in Baltimore and consummated here in Toledo as the founders contemplated a great College of Medicine here in Northwest Ohio. The model celebrates a uniquely American reciprocity between knowledge and know-how, between principle and practice. It has been believed that it is precisely at the point of contact between the abstract and its application that learning and innovation flourish. But the second decade of the 21st century requires that we re-examine this successful and cherished model.

Much has changed in the interval since the model was invented. The business conducted in hospitals has changed dramatically. The capital required for the technological infrastructure of a hospital has increased a hundred fold.

The sources of revenue have changed from individuals or family payers to government agencies and insurance conglomerates. The business of medicine consists now of a complex of transactions which require a body of knowledge very different from the knowledge base of most medical colleges or physician practices.

More importantly, at least to the mission of a College of Medicine, are changes in the ways of teaching medicine to students and residents. More of the clinical exposure occurs in outpatient settings. The hospital
can no longer be looked upon as a laboratory (Halsted) because of the cost and complexity of the health care delivery there. Moreover, a modern view of medical ethics contradicts the idea of a “hospital as laboratory.” Finally, new modalities of teaching and learning are rapidly developing; most salient among them are virtual reality simulation techniques.

The purest examples of the “Hopkins” model are those Colleges of Medicine with university owned and operated hospitals, e.g.: Duke, Michigan, University of Toledo. There are many other successful models and some innovative models are under development; e.g., University of Nebraska. But one trend is clear; universities are insulating themselves from their owned or operated hospitals largely because of business risk¹. As that model becomes less ubiquitous, it cannot be over emphasized that solid, durable, mutually advantageous relationships between Colleges of Medicine and hospitals must, I believe, and can continue to be developed and constitute an important, nearly imperative goal. These relationships must be mutually beneficial, and share both risk and reward. Some viable form of joint operation is imperative.

Universities are beleaguered. The stressors are by now familiar: demographic changes, technological advances which threaten the historical pedagogical methods, decremental budgets at both federal and state levels, and a fundamental questioning of the value proposition of higher education and, oh yes, a huge investment in a risky business which is changing daily; namely the hospital business.

The result of my reflections is this conclusion: Universities should not, in the second decade of the 21st century own or solely operate hospitals. Relationships between Medical Schools and Hospitals should be celebrated and strengthened to enhance in every possible way the mission congruence and durability of the relationship. But the ownership or sole operator model is a risky anachronism and should be abandoned. Slow and carefully analyzed divestiture should be considered where appropriate. Innovative models of joint operation should be sought. The trend seems to me to be already underway and will probably continue for decades. But however long it takes, that is what the future holds. Rest in peace, old friend!


---

**University Research Funding Opportunities**

William S. Messer, Jr., Ph.D.
Vice President for Research

Robin Lanz
Grants Coordinator

We are pleased to provide an update on University Research Funding Opportunities (URFOs), our internal grants program offered by the Office of Research and Sponsored Programs. Administered by the Research Council, the program includes a wide variety of funding opportunities for new and established investigators in multiple disciplines. In the fall, faculty will receive a booklet describing the many programs in detail, the submission process and relevant deadlines. In this article, we will provide a brief overview of a few programs of relevance for faculty in the biomedical sciences.

For the 2015-2016 academic year, the following funding opportunities will be available:

- deArce-Koch Memorial Endowment Fund in Support of Medical Research and Development
- Biomedical Research Innovation
- STEM Research Innovation
- Interdisciplinary Research Initiation Award
- Phase 0 SBIR/STTR
- Publications Subvention Program
- Summer Research Awards and Fellowships
- Visiting Faculty Researcher

All programs are open to full-time, tenure-track faculty, although the Summer Research Awards and Fellowships program is available only for faculty on nine-month contracts. Some programs, such as the deArce-Koch Memorial Endowment Fund, are targeted toward junior faculty, while others, such as the Biomedical Research Innovation program is focused on established investigators.
The deArce-Koch Memorial Endowment Fund supports medically related research and development projects. Originally established by a bequest from Helen C. Ponton deArce in memory of her husband Alfred Koch, Sr. and her son Alfred Koch, Jr., the program awards up to $25,000 for one year to advance professional careers, improve position for external support or provide assistance in developing a promising research program. Preference will be given to untenured, tenure-track faculty although proposals from tenured faculty will be considered. The deadline for applications will be January 19, 2016.

The Biomedical Research Innovation program is focused on high impact and innovative proposals in the biomedical sciences. Awards up to $50,000 for one year will be available to generate preliminary data sufficient for R01 type grant proposals. Letters of intent will be due December 1, 2015 and will be reviewed by the Research Council with possibility of involving external reviewers. A limited number of full proposals will be solicited with a due date of January 19, 2016. The program is directed to established researchers and senior faculty.

The STEM Research Innovation program funds high impact and innovative proposals in any STEM discipline. Awards up to $50,000 for one year are intended to generate preliminary data sufficient for R01 type grant proposals. Like the Biomedical Research Innovation program, letters of intent will be due December 1, 2015 and will be reviewed by the Research Council with possibility of involving external reviewers. A limited number of full proposals will be requested with a due date of January 19, 2016. The program is directed to established researchers and senior faculty.

The Interdisciplinary Research Initiation Award program targets collaboration between at least four faculty members from two different disciplines supporting a program of excellence. The program provides up to $100,000 for one year to allow generation of preliminary data sufficient for submitting an externally-competitive grant proposal. A Research Council subcommittee will review proposals initially, with a limited number to be forwarded for evaluation by external reviewers. The program focus is the development of a cohesive research group that can emerge as nationally competitive. The proposal deadline is December 14, 2015.

The Phase 0 SBIR/STTR program supports efforts of faculty to participate in the development of a proposal to an SBIR/STTR research project. Up to $8,000 is available for collaborations with a small business in the development of an SBIR/STTR proposal. There is no deadline; proposals are accepted at any time. The Vice President of Research and the Associate Vice President of Technology Transfer will review applications. The program encourages faculty to work with the local small business community.

The Publications Subvention program helps faculty advance their careers through the publication of scholarly manuscripts by academic presses. Up to $1,200 is available to improve the publication’s quality, increase the book’s marketability and affordability, or respond to press requirements. There is no deadline; proposals are accepted at any time.

The Summer Research Awards and Fellowships program provides support for nine-month faculty members’ research projects, creative projects, and scholarly activities. Junior faculty receive preference for this award, however, proposals from established faculty will be considered. An exciting development for this Academic Year is the addition of $150,000 in support for this program! This development has allowed the maximum award to be increased to up to $20,000 for eight-month project duration. The program’s main intent is to support projects that will enhance faculty members’ research and scholarship, as well as lead to external support opportunities. The deadline for applications will be January 19, 2016.

The Visiting Faculty Researcher brings expert practitioners and faculty from outside northwest Ohio to collaborate with a University faculty member on a problem of mutual interest. Up to $5,000 will be provided to the visiting faculty member who must agree to spend at least six consecutive weeks at UT. This program is designed to enhance the University’s relationships with other colleges and universities. The proposal deadline is January 19, 2016.

For more information on any of the University Research Funding Opportunities, please contact either Dr. William S. Messer, Jr. (william.messer@utoledo.edu) or Ms. Robin Lanz (robin.lanz@utoledo.edu), secretary of the Research Council.

Our Department

The UT-COMLS Department of Pathology Aspires to Excellence in Clinical Service, Education and Research
Kenneth Hensley, Ph.D.
Associate Professor, Department of Pathology

Pathology is the science of the causes and effects of diseases. As such, Pathology is a discipline that sits at the nexus of clinical practice and academic medicine, diagnosis and therapy development. The University of Toledo College of Medicine and Life Sciences (UT-COMLS) Department of Pathology embodies this concept of pathology as an interdisciplinary pursuit, by balancing a wide variety of clinical and teaching responsibilities with several basic science and translational research programs.

The Department of Pathology at UT-COMLS maintains an exemplary accredited clinical laboratory (College of American Pathologists, (CAP) and Clinical Laboratory Improvement Act (CLIA)) including a number of specialty divisions such as Coagulation/Hemostasis, Electron Microscopy, Histocompatibility & Transplantation, Immunology, Molecular Diagnostics, and Serology/Immunology Labs that are usually found only at tertiary academic laboratories. A recent additional strength includes application of ultrasound-guided fine needle aspiration (US-FNA) for cytology. Although the department's primary mission is service related, as an academic laboratory, we are also immersed in the entire mission of the medical school.

The education of medical students and residents is a mission that we take very seriously in the Department of Pathology. Both students and educators are increasingly recognizing that pathology and laboratory medicine are integral parts of virtually every clinical specialty, and that this will only become truer in the years ahead. For this reason, at the national level, pathology is now being thought of as a genuine frontline, or primary care specialty. In FY2015 the Department of Pathology partnered with the Department of Radiology to institute a new combined pathology/radiology clinical clerkship for 3rd- and 4th- year medical students. This new clerkship has been approved by the UTCOMLS Executive Curriculum Committee as a required 3rd year core clerkship in FY 2016. This is a first-in-the-nation offering. Our medical school has routinely attracted numerous graduates to pursue the discipline of pathology as a career choice. Most recently, eleven graduating UT students chose Pathology as their specialty and matched with high quality pathology training programs including Ohio State, the University of Michigan, the Cleveland Clinic, the University of Pittsburgh, the University of Chicago, and Emory University.

The Department of Pathology has an active and internationally respected research enterprise. In 2015, Pathology faculty and residents published more than forty scientific manuscripts, case reports or book chapters and presented more than 50 lectures or other presentations at national and international venues. Currently there are active research initiatives in the fields of oncology, neuroscience, hemostasis, molecular genetics, microbiology, and organ transplant topics. The Department has extramural research funding to study rare or “orphan” genetic disease including Batten disease; and other grants that support research into motor neuron disease (amyotrophic lateral sclerosis); postural orthostatic hypertension (POTS); and to identify biomarkers for fatigue, traumatic head injury, and exposure to algal toxins.

The Department of Pathology is also committed to translational research. Translational research is intended to bridge knowledge gained in the laboratory to applications in clinical practice, the ultimate goal of which is to improve patient management. A large part of the translational enterprise is therefore aimed at developing better diagnostic methods and new medicines. Thus, for example, faculty in the Department of Pathology are currently developing next generation sequencing (NGS) panels for rapid high resolution HLA typing as well as microbial identification. In addition, prospective validation is currently underway for novel lung cancer risk and diagnosis tests utilizing NGS. These complex multi-analyte panels will utilize state of the art NGS internal standardization controls developed at UT-COMLS. These controls provide necessary analytical characterization and limits of reporting for each assay, consistent with the College of American Pathology and Center for Disease Control's Next Generation Sequencing - Standardization of Clinical Testing (NexStoCT) approaches to quality assurance for compliance with regulatory and professional standards.

The Department of Pathology recently has initiated collaborations with industry partners to develop conceptually novel new drug candidates that may slow neurodegeneration in Batten disease, traumatic head injury, Alzheimer’s disease and glioma. Our major effort in this area revolves around a class of compounds called lanthionine ketamine derivatives, invented and patented by department faculty. These compounds now are being developed through funding from Johnson and Johnson Innovations, Takeda Pharmaceuticals and other partners with the goal of moving this technology forward toward human clinical trials for neurodegenerative conditions.

The Department of Pathology seeks to expand collaborations with colleagues in other departments. In 2015 we initiated exciting new collaborations with the Departments of Emergency Medicine and Neurosurgery to identify biomarkers of traumatic brain injury. In one such project, in collaboration with the UT-COMLS Emergency Medicine Department, we are collecting and analyzing saliva samples from local high school football players who suffer sports-related concussions to develop a test that might indicate whether they should refrain from head-trauma prone activities. In other projects we are working the Department of Neurosciences to develop salivary markers of fatigue, and in other collaborative projects we are testing experimental therapeutics for their ability to reduce neural damage from facial and head trauma.
Clinical Research Snippets

Anand B. Mutgi, MD
Sadik A. Khuder, PhD

Spices have been an integral part of cooking cultures around the world and have a long history of use for flavoring, coloring, and preserving food. According to the NPD Group, around 56% of U.S. households keep hot sauce in their kitchens. However, the evidence relating consumption of spicy foods and health benefits is lacking. This month we highlight a recently published study addressing the benefit of spices on various health outcomes.

The China Kadoorie Biobank is a prospective cohort study of over half a million adults (aged 30-79) from 10 geographically diverse areas across China. The participants, who were enrolled in 2004-2008 and followed for a mean of 7.2 years, were asked about the frequency of eating spicy foods during the past month and the sources of spices usually used. A chili pepper was the most commonly used spice in the population.

A statistically significant inverse association between spicy food consumption and total mortality was reported. Compared with participants who ate spicy foods less than once a week, those who ate spicy foods...
1 or 2 days a week showed a 10% reduction in total mortality and those who consumed spicy foods 6 or 7 days a week showed a 14% reduction in total mortality. Spicy food consumption was inversely associated with the risks of death due to cancer, ischemic heart diseases, and respiratory diseases. These associations were less evident in men than in women. In addition, more frequent consumption of spicy foods in women was also significantly associated with a reduced risk of death due to infections. The inverse associations of daily spicy food consumption with death due to cancer, ischemic heart diseases, and diabetes were stronger in the fresh chili group than in the non-fresh chili group.

In discussing the limitations of the study, the investigators acknowledged that consumption of spicy foods was self-reported and may be correlated with other dietary habits and lifestyle behaviors. Consumption of chili pepper may be accompanied by an increased intake of oil, carbohydrate-rich foods, and water to relieve the burning sensation. Moreover, spicy food consumption may be correlated with socioeconomic status. Moreover, people with chronic disease might abstain from spicy foods.

Despite these limitations, the findings of this study are in line with previous evidence showing potential protective effects of spicy foods on human health. Capsaicin is the main active component of chili pepper. The beneficial roles of capsaicin have been extensively reported in relation to anti-obesity, antioxidant, anti-inflammatory, antimicrobial, anticancer, and antihypertensive effects, and in improving glucose homeostasis in experimental or small sized epidemiological studies. Therefore eating spicy food more than once a week, as part of a daily diet, is beneficial, and could lower the risk of mortality due to cancer, cardiovascular and respiratory diseases.

Scientific Advisory Panel to Offer Assistance with IRB Applications

Roland Skeel, M.D.
Chair, Biomedical IRB

Investigators planning to do human subject research face a host of problems getting started with their project. One problem is moving their good research idea to a scientifically valid protocol and then completing the Investigational Review Board (IRB) application in order to satisfy ethical principles of respect for persons, beneficence and justice and to meet regulations set by the federal government, by the state, and by the University of Toledo.

The primary responsibility of the IRB is to assure that the ethical and regulatory standards have been met by the research application. Because this assurance is dependent in part on the scientific validity and rigor of the proposed study, at times it can be difficult for the IRB to be confident that a study meets these criteria. As a consequence, the IRB has proposed that it can do a better job if some investigator-initiated studies undergo a scientific review before coming to the IRB for its approval.

Dr. Akira Takashima has volunteered to set up a Scientific Advisory Panel to help in the review of selected investigator-initiated studies. Their role will be to review studies that the IRB believes their review would be facilitated by a prior scientific review. Several scientists (named below) have volunteered for this task. In addition to reviewing selected studies that the IRB requests they look at, they will also be available to investigators who wish their protocols to be reviewed prior to submitting to the IRB. We hope that this will be educational and will enhance the scientific – and thus the ethical – quality of human subject research.

The types of studies to be reviewed may be for convened IRB review or expedited review. They may be initiated by faculty, residents or students preparing for MSBS or PhD degrees, but not medical students, nursing students, or other undergraduate students. For the latter two groups, it is expected that the faculty mentor or advisor will provide rigorous review and critique prior to allowing the student to submit their study proposal and application.

We will be trying this method out over the next six months to see whether and how much it helps investigators. If it works well, it will become part of a permanent process used by the IRB. Anyone who has additional questions or suggestions is encouraged to contact either Dr. Skeel or Dr. Takashima.
Members of the Panel and their expertise are as follows:

Nicolas Chiaia (Neurosciences)

- Neurology and neurotoxicology
- Neurological disorders
- Brain injury
- Peripheral nerve injury

Keith Crist (Surgery)

- Nutrition
- Cancer biology
- Chemoprevention
- Neoplasia

Alan Goodridge (Biochemistry & Cancer Biology)

- Transcriptional regulation
- Regulation of metabolism & metabolic physiology
- Obesity & metabolic disorders
- Diabetes & endocrine disorders

Bill Gunning (Pathology)

- Microscopy applications
- Bleeding disorders
- Renal disease
- Low serotonin disorders

Beata Lecka-Czernik (Orthopaedic Surgery)

- Bone biology
- Bone disease and orthopaedic complications
- Diabetes
- Obesity

Akira Takashima (Microbiology & Immunology)

- Immunology
- Drug screening
- Skin disease
- Autoimmune disease and allergic disease

Kandace Williams (Biochemistry & Cancer Biology)

- Cancer biology
- DNA damage & DNA repair
- Genetic/genomic research protocols
- Genetically inherited cancers (e.g., glioblastoma & Lynch syndrome)

New Clinical Trials

An Evaluation of Rigid Sternal Fixation in Supporting Bone Healing and Improving Postoperative Recovery: A Prospective, Randomized Trial.
Dr. Bonnell - Surgery
Dr. Casabianca – Anesthesiology

A Randomized, Placebo-controlled, Prospective, Double-blind, Multicenter Phase 2/3 Study of the Efficacy and Safety of SANGUINATE™ for Reduction of Delayed Graft Function in Recipients of a Donor Kidney Transplant.
Dr. Ortiz – Surgery

---

**IRB Corner**

<table>
<thead>
<tr>
<th>July - August IRB Actions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>New Exempt NHSR</td>
<td>3</td>
</tr>
<tr>
<td>Expedited - New, Continuing, Amend.</td>
<td>85</td>
</tr>
<tr>
<td>Convened - New, Continuing, Amend.</td>
<td>4</td>
</tr>
<tr>
<td>IRB Administrative Actions</td>
<td>21</td>
</tr>
<tr>
<td>Internal Safety Reports</td>
<td>4</td>
</tr>
<tr>
<td>CIRB Approved for UT Enrollment</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>118</strong></td>
</tr>
</tbody>
</table>

---

**Contact Us**

Health Science Campus • Center for Creative Education Bldg.
2920 Transverse Drive, Floor 3 • Toledo, OH 43614
Phone: 419.383.6919 • [ClinicalResearch@utoledo.edu](mailto: ClinicalResearch@utoledo.edu)