MISSION

To enable and enhance clinical & translational research.

(E^2=CTR)
Director’s Message

Kenneth J. Pienta, MD
Director, MICHRI
The Michigan Institute for Clinical & Health Research experienced a great deal of change in 2009 – all for the better.

Since taking the helm as Director of MICHR in late 2008, I have committed our talented faculty and staff to “enabling and enhancing clinical & translational research” to make the University of Michigan a world leader in translating scientific discoveries into real health gains.

In support of this mission, we have put in place a new leadership structure, secured additional institutional support to grow our many programs and services, become pioneers by being among the first to move to the new North Campus Research Complex, participated and contributed in several ways to the National Institutes of Health’s Clinical & Translational Science Award consortium, developed new partnerships and collaborations across the university, and have a clear roadmap to future growth and success.

Reorganization Completed
MICHR integrates education, career development, infrastructure, and support to catalyze research that spans the laboratory, the clinic, and the community. Serving first and foremost as an integral part of the Medical School, MICHR provides a full spectrum of clinical research support services for multiple entities across the health system and the university, including the Schools of Dentistry, Medicine, Nursing, Information, Social Work, Kinesiology, and Public Health; the Colleges of Engineering, Pharmacy, and Literature, Science and Arts; the Institute of Social Research, and the Life Sciences Institute.
In order to meet current and future needs of these and other stakeholders, MICHRI has undergone a comprehensive reorganization. Only a year ago, MICHRI consisted of 17 independent programs, all reporting directly to me. Attempts to coordinate and collaborate across programs were complicated by the sheer profusion of activities and the differing approaches of the programs. For instance, some programs consisted of faculty only, with no support staff; other programs consisted of staff only, with no embedded faculty leadership. I am now pleased to report that MICHRI has integrated these 17 programs into four major ‘working groups,’ dramatically increasing collaboration and communication:

- Clinical Research Management Working Group
- Research Innovation Working Group
- Outreach, Partnerships, and Implementation Science Working Group
- Education and Career Development Working Group

In addition, MICHRI now has representatives for:

- Child Health Initiatives
- Informatics and Information Technology
- Alliances and Collaborations
- Mental Health

Eight new faculty Associate Directors were recruited to oversee these vital areas. This group now meets with me every other week for 90 minutes, creating a strong, integrated ‘cabinet’ to ensure coordination across working groups. With the recent naming of a new staff Managing Director, MICHRI has completed its reorganization.
Move to North Campus Research Complex

In 2009, the University of Michigan purchased a 174-acre, 30-building research campus formerly occupied by Pfizer. The campus includes research laboratories, research and administrative office space, collaboration and training venues, and a cGMP manufacturing facility. This purchase provides an unprecedented opportunity for the creation of a transformational, interdisciplinary research campus. MICHR is playing a leading role in the creation of this new campus in two ways: first, MICHR is among the first occupants. MICHR clinical research service staff are now co-located with the IRB, clinical research billing, and Cancer Center Clinical Trials Office staff, creating a clinical research administration ‘hub’ allowing an unprecedented level of communication, collaboration, and sharing of best practices between these entities. In addition, I serve on the Research and Scientific Programming Committee for the new campus, and MICHR’s Associate Director for Informatics and Information Technology has been leading integration of informatics in the planning process.

Contribution to NIH/CTSA Consortium

MICHR was created by the Regents of the University of Michigan in November 2006, and received its Clinical and Translational...
Science Award (CTSA) nearly a year later. This five-year grant, the largest NIH award ever to the Medical School and the third-largest NIH award in the University’s history, builds on previous NIH investments to expand innovative programs and services in clinical research infrastructure and education.

Working together as a national consortium, CTSA institutions share a common vision to improve human health by transforming the research and training environment to enhance the efficiency and quality of clinical and translational research. The CTSA program is led by the National Center for Research Resources, part of the National Institutes of Health.

While we serve the Medical School, health system, and university, we also support the strategic goals of the CTSA consortium, which are to:

**Goal 1:** Build National Clinical and Translational Research Capability
**Goal 2:** Provide Training and Improving the Career Development of Clinical and Translational Scientists
**Goal 3:** Enhance Consortium-Wide Collaborations
**Goal 4:** Improve the Health of our Communities and the Nation
**Goal 5:** Advance T1 Translational Research

Here are highlights of the ways we have contributed to the CTSA strategic goals over the past year:

**Clinical Research Management Strategic Assessment**
MICHR made concrete steps to initiate a major transformation of the institution’s clinical and translational research capability by completing the first-ever, comprehensive institutional analysis of the health system’s clinical research management enterprise.
This in-depth assessment was supported through a new institutional commitment complementing MICHR’s Evaluation Key Function, and included staff working together for six months. The assessment was conducted by the Health System’s Strategic and Enterprise Analysis group, whose portfolio of responsibilities includes developing the Health System’s funds flow model and exploring the business case for the purchase of the new North Campus complex described above. The analysis consisted of 125 interviews of faculty, staff, and administrators, the findings of which were further validated through a survey (>600 respondents from active research teams). In addition, market analysis and benchmarking data were collected. The process was informed by the expertise and experiences of MICHR’s Biostatistics, Ethics, and Regulatory Support Key Functions. The results and specific recommendations are now being shared with institutional leadership, and MICHR will continue to champion the next phase of the project, which includes an implementation roadmap. Results will be disseminated to other CTSA institutions as appropriate.

**Expanding Research Education to Enable Team Science**

MICHR continues to implement innovative approaches to training the next generation of team scientists by reaching beyond the traditional physician-investigator. This year MICHR’s Education Key Function significantly expanded its program in Patient Oriented Research Training for Clinicians (PORT). This program teaches front-line clinicians how to partner with investigators to develop and conduct research inspired by real clinical problems. The program initially focused on allied health professionals such as physical and occupational therapists. It has now been expanded to include hospitalists. This program has been highly successful as noted by increasing interest from a variety of disciplines, national recognition resulting in partial
funding via the Paralyzed Veteran’s Association, and a recently published overview of the program. Another program is the Post-Doctoral Translational Scholars Program, which takes basic science doctorates and exposes them to a clinical or community setting by linking them with a clinical research team or public policy mentor. Based on the career paths of some of our most successful translational researchers, the third cohort of this program continues to be diverse with individuals from Neurology, Psychiatry, Engineering, Rheumatology, Urology, Life Sciences, and the Institute for Women and Gender. By complementing our KL2 and TL1 programs with these innovative offerings, MICHR is creating the full spectrum of multidisciplinary research team members needed to address the translational research challenges of the future.

**Partnering Across the Consortium with New Informatics Tools**
MICHR has played a national leadership role in the area of informatics collaborations. MICHR’s Associate Director for Informatics and Information Technology, co-chaired the CTSA Informatics Key Function Committee through October 2009. MICHR faculty and staff continue to support the university-based caBIG Data Sharing and Intellectual Capital Knowledge Center as well as participate in the NCRR-supported multi-institutional CIRWP and Physio-MIMI informatics development projects. MICHR is now leading a pilot implementation of i2b2 at the University of Michigan to provide institutional support for cohort discovery, multi-institutional query capability, and translational research that includes future integration of NCIBI bioinformatics and biomedical informatics tools. The pilot will include an in-depth evaluation of i2b2 in the context of the NIH-funded Physio-MIMI project.
Translating Results to Communities Through Outreach, Partnerships, and Implementation Science Program

MICHR has focused on translating results into community settings through new partnerships and innovative service delivery models. For example, within the Community Engagement Key Function, a new key partnership was formed this year with the National Nursing Practice Network, a network of 70 hospitals in 26 states, with a goal to improve patient care by promoting and implementing evidence-based practice through a collaborative model of shared learning and participation. In addition to new partnerships, MICHR has provided infrastructure for developing new models of service delivery.

The program for Quality Improvement in Complex Chronic Conditions (QUICCC) has established a tested, scalable model to link clinicians to patients and lay caregivers in a community setting, the CarePartner model. QUICCC’s success is an example of building and testing models that bring the best of academic medicine out to the communities we serve in a sustainable, cost-effective way. The CarePartner model utilizes automated, telephone-based symptom reporting from both patients and family members, and follow-up intervention from informal caregivers, including friends or family outside the patient’s home, to improve disease management. This year QUICCC established two regional demonstration programs of the CarePartner model for chronic illness care: (1) Blue Cross and Blue Shield-funded demonstration in 10 primary care practices around Michigan for patients treated for depression in primary care; and (2) VA-Office of Rural Health funded demonstration of the CarePartner model supporting VA patients with diabetes, depression, or
heart failure. Also, QUICCC began recruitment for a VA-funded CarePartner trial, initiated a second trial of CarePartners for cancer symptom management, and submitted a grant to AHRQ in conjunction with U-M hospitals to evaluate a similar system within UMHS.

**Translating Ideas to Innovations and Innovations to Markets**

The Novel Methodologies Key Function grew through stronger partnerships this year, with both the Michigan Center for Oral Health Research (MCOHR) and the Medical Innovation Center (MIC). Exemplifying a multidisciplinary, innovative approach, MIC, a program of MICHR, accelerates translation by uniting clinicians with engineers and entrepreneurs. MIC supports fellows from business, science, and engineering backgrounds and immerses them in clinical contexts; this year’s cohort launched two medical device companies.

Three products were commercialized (pyloric clamp, pathology tray, patient safety software). MIC’s work has resulted in 12 incremental invention disclosures to the Office of Technology Transfer. The strength of the program was recognized through the award of a $2M grant from the FDA to launch a Pediatric Device Consortium, which will further strengthen the MICHR Pediatric Research Program. Also, MIC launched a Medical Entrepreneur Internship, an unpaid, no credit opportunity for student volunteers to participate in medical innovation projects in the very early stages.

These translational innovations are further enabled through MICHR’s support of Translational Technical Cores, such as
MIC’s prototyping lab, which provided access to equipment and mentoring for a Biomedical Engineering graduate capstone design class with great success. In fact, one of the resulting project teams has continued their work with a provisional patent on further prototype development. Approximately 60 individual devices and tools have been designed and manufactured this year.

In addition, the MICHR Pilot and Collaborative Grant Key Function continued to enable the full spectrum of translational science. This year MICHR and the Coulter Foundation jointly sponsored a research project resulting in a successful new biotech startup. HistoSonics recently launched an Ann Arbor-based start-up with $11 million in venture capital. This company has been formed to commercialize histotripsy, an ultrasound approach utilizing cavitation rather than heat to destroy unwanted tissues. The first clinical application will be in BPH (benign prostate hyperplasia). About 400,000 patients suffering from the condition are treated surgically every year. Histotripsy’s efficacy for additional applications is being explored. Potential applications include thrombolysis (clot breakup), kidney stones, uterine fibroids, breast lesions, and brain tumors.

New Partnerships and New Collaborations
During the past year, MICHR continued to expand its ability to serve investigators through new partnerships. To qualify as a MICHR partner, arrangements must meet specific criteria. First, MICHR provides the partner with quantifiable resources. In many cases these resources leverage economies of scale normally inaccessible to smaller centers. For instance, MICHR
provides the support of skilled financial administrators, project managers, and web designers to some partners. Others have benefitted from the infrastructure of the MICHRI Pilot Grants program. In exchange, the partner provides access to specialized expertise, training, facilities, or funding opportunities for MICHRI investigators. For example, new partnerships this year have increased investigators’ access to oral health expertise and specialized dental research facilities, expertise in stem cell research, and biomedical engineering expertise and prototyping equipment. Each partnership is formalized through a signed memorandum of understanding and is renewable annually. Through these partnerships, MICHRI has created a model that leverages the unique strengths of both partners and creates new opportunities for innovation. In the past year, MICHRI formalized six new partnerships, for a total of 13.

MICHR has also worked over the past year to strengthen its collaborations with the Comprehensive Cancer Center and Specialized Project of Research Excellence (SPORES) in ways that leverage resources and promote best practices. Two specific examples of such partnerships are in our Clinical Research Unit and our Biomedical Informatics Key Function. Over the past year, the Nurse Manager of the Clinical Research Unit has worked with Cancer Center administration to develop standard job descriptions and competencies for research nurses, to allow cross-training and enable efficiencies through sharing of staff. When a vacancy arose in the MICHRI specimen processing core, we made an arrangement for staff to ‘float’ between Cancer Center and MICHRI facilities as needed, providing coverage, while reducing the overall number of FTEs supporting these endeavors. Similarly, the MCRU 2 U staff has supported 11 protocols in the past year that were conducted jointly with the
Cancer Center, including conducting joint initiation meetings to streamline the investigator experience. In the Bioinformatics program, the Comprehensive Cancer Center and MICHR have jointly developed and supported Velos, enhancing the capability of this tool and making it available to research teams across campus. A unified governance committee with both Cancer Center and MICHR representatives guides the priorities for further development of the system. These are concrete illustrations of new efficiencies made possible by the flexibility of the CTSA structure and the collaborative approach at Michigan.

New Institutional Support and Service Growth
Over the past year, MICHR garnered new institutional support in several areas. First, the medical school provided two new FTEs to join the MICHR Investigator Assistance Program, which provides IND/IDE support. Second, the Faculty Group Practice committed a new allotment of $1.5 million annually for three years. This new program represents a key partnership with the University of Michigan Hospitals and Health Centers.

MICHR will pilot new service delivery models in seven high-impact clinical areas, with a goal of both strengthening clinical and translational research in these areas, and developing best practices and scalable models that can be generalized across the health system. In addition to these major new commitments, MICHR continued to expand service in the past year, with 753 investigators, trainees, and scholars directly benefitting from MICHR services, covering 485 distinct research projects. This represents a 14% increase in investigators served over the previous year.
The university has demonstrated very robust support for the CTSA, from multiple stakeholders across the university. First, the Medical School provides an annual unrestricted operating budget of $1.9M. In addition, the Dean of the Medical School has provided up to $1M annually to support our novel Postdoctoral Translational Scholars. The Executive Vice President for Medical Affairs has established a quasi-endowment of $10M, which provides approximately $600-800K annually in unrestricted disbursements, as well as support of our Informatics program in the amount of approximately $1.5M this year.

Perhaps the best demonstration of institutional support for MICHR is the Pilot Grant Program. The CTSA grant supports staff and faculty to administer the program, but all the grants are funded through a commitment of $1M annually from the Medical School Dean and matching funds from more than 30 participating schools, departments, institutes, and centers. The total amount disbursed by this program in the past year was $2.3M. The pool of partners contributing matching funds has grown each year since the program was instituted. Finally, the Medical School covers all space and facilities costs for MICHR, including bearing all costs of construction of a new Clinical Research Unit (completed last year) and all costs of moving MICHR staff to the new North Campus Research Complex as mentioned above. This year MICHR secured a new commitment of $1.5M annually for three years from the Faculty Group Practice of the Health System, as described above. This robust and growing institutional support has allowed MICHR to dramatically leverage its federal funds.
Looking Ahead

I’m very proud of what MICHR has accomplished over the past year. As we were getting a great deal of important work done, it also felt like we were setting a strong foundation for further growth – our reorganization, moving to the NCRC, establishing new partnerships, and assessing what needs to be done to improve the clinical research enterprise – all prepare us for getting more important work done to support researchers in their ongoing quest improve health and find cures.

As we look ahead to 2010 and beyond, I am confident that we have the talent, passion, and commitment to lead the way in creating an effective and efficient investigator-centered, clinical research infrastructure at U-M, with best practices that are transferable to the CTSA consortium and beyond.

Sincerely,

Ken Pienta, MD
Financials

Funding Sources

Expenditures

Note: due to overlapping fiscal calendars, all percentages are approximate
By the Numbers

distinct research projects supported

2008: 326
2009: 485
Increase: 49%

investigators, scholars, trainees, and others who benefitted from MICHR programs and services

2008: 659
2009: 753
Increase: 14%
By the Numbers

Pilot Grant Dollars Disbursed

- 2008: >3M (33/66 match)
- 2009: >2.4M (50/50 match)

20% increase from 2008 to 2009

Dollars Disbursed Directly to Trainees for Tuition, Salary, Stipends, and Research

- 2008: 1.9M
- 2009: 2.4M

26% increase from 2008 to 2009
potential research participants registered in UMengage.org database

number of publications generated by MICHR-supported research
Leadership

Ken Pienta, MD
Director

Teri Grieb, PhD
Managing Director

Brian Athey, PhD
Associate Director, Informatics and Information Technology

Deb Gipson, MD
Associate Director, Clinical Research Management
Dorene Markel, MS, MHSA
Associate Director, Alliances and Collaborations

Michelle Riba, MD
Associate Director, Mental Health

Blake Roessler, MD
Associate Director, Research Innovation

Tom Shanley, MD
MICHRR Associate Director, Child Health Initiatives

Marita Titler, PhD, RN
Associate Director, Outreach, Partnerships, and Implementation Science

Lynda Welage, PharmD
Associate Director, Education, Career Development, and Mentoring
1600 Huron River Drive
Ann Arbor, Michigan (visiting)

2800 Plymouth Road – Building 400
Ann Arbor, Michigan 48109-2800 (mailing)

Learn more about MICH at www.michr.umich.edu
or call 724.998.7474 to schedule a consultation.
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