Educate, Fund, Connect, Support

MICHR continues to integrate education, funding, connections, and overall support to enable & enhance clinical & health research at the University of Michigan. Although we primarily serve as an important part of the Medical School, MICHR provides support and services for a wide variety of researchers 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.

Over the past year, in order to continue to meet the current needs and anticipate the future needs of these researchers, MICHR has expanded its Evaluation program, recruiting a new Associate Director. In addition, a new managerial position was created, with a focus on recruiting study volunteers.

MICHR also launched a new Research Navigator service to improve access to research services. The Navigator triages inquiries and provides end-to-end assistance to study teams traversing the University of Michigan research infrastructure, helping them navigate through regulatory processes and overcome hurdles. The immediate goal is to respond effectively to investigator inquiries by providing timely guidance, while the long-term goal is to improve U-M clinical and translational research processes by identifying and removing process barriers. This role has already begun to serve as a source for institutional change, as the Navigator has worked with other units to make frequently requested resources more available.
North Campus Research Complex Update

The North Campus Research Complex (NCRC) has been open for more than two years. The 174-acre, 30-building research complex formerly occupied by Pfizer was purchased by the University of Michigan in 2009. MICHR was one of the first occupants of the NCRC, in April 2009, and has welcomed many more departments as they moved in throughout the following year. Fifty-four groups now occupy the NCRC, with more than 660 employees who represent areas such as the Cancer Center Development Office, Research and Grants Office, Health Services Research, and DNA Sequencing as well as individual researchers. The close proximity of these groups, along with the clinical research administration “hub” created the previous year, support communication, collaboration, and sharing of best practices, allowing the clinical and translational research supported by MICHR to thrive.

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:

**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:

**Expanded Biostatistics Consultation and Analysis Capacity**
To address the growing needs of the research community at the University of Michigan, the Biostatistics Core has strengthened its capacity. The team now has six key faculty and five staff biostatisticians and epidemiologists, and is enriched through engagement of additional faculty from other schools as needed. Along with the Research Development Core, this program has assisted 135 investigators with grant proposals in the current project year, spanning nine schools and colleges at U-M. Forty-one percent of the projects submitted and reviewed so far have received extramural funding.

*This expansion of the Biostatistics Core contributes to the CTSA Strategic Goal #1.*

**Deployment of New Informatics Collaboration and Research Tools**
To further reduce barriers to cross-consortium collaborations, MICHR is working toward making three new systems available to researchers. MICHR made REDCap, an electronic data capture system that is secure, HIPAA compliant, and web-based, available to its researchers; moved forward with its implementation of i2b2, an innovative clinical research tool that helps researchers more effectively identify potential research subjects for clinical trials; and is currently working to launch OpenClinica to expand the portfolio of tools available to clinical and translational researchers.

The launch of i2b2 at U-M represents a collaboration project between MICHR and the Health System. Since beginning the pilot implementation last year, rollout to active users has begun, and the system can now access data from more than three million potential research participants.

*The availability of these systems contributes to CTSA Strategic Goal #3.*
Significantly Expanding Clinical and Translational Research Training by Revising the Dental School Curriculum

Three major accomplishments in the Education and Mentoring arena in the past year include creating a new health disparities program, launching a new virtual home for study coordinators, and integrating clinical and translational research training into the Dental School curriculum so that all DDS students are exposed to clinical and translational research. According to Dr. Will Giannobile, Director of Academic Programs for the Dental School, “after participating in the MICHR TL2 program, one of our dental students saw how important such training was for all health professionals and proposed that all DDS students receive clinical and translational research education. This major curricular change … would not have been possible without the support of MICHR.” The Dental School agreed to pilot a new curricular standard, with the full program rolling out in fall 2011. These activities contribute directly to CTSA Strategic Goal #2.

Supporting a New National Network of Depression Centers

MICHR, in collaboration with the U-M Depression Center, was selected from five competitive proposals as the National Network of Depression Centers (NNDC) Data Coordinating Center. This network capitalizes on not just local MICHR resources, but the national consortium, because almost all network sites are CTSA institutions. The Data Coordinating Center is building a central database for electronic data capture of all assessments for two protocols. The first protocol is a long-term, multi-center patient registry to collect data in patients with depression who are treated in routine clinical care with repetitive transcranial magnetic stimulation (rTMS). Sixteen NNDC sites, 13 of which are CTSA institutions, will participate. The second protocol is a set of self-assessment instruments to be administered by 18 NNDC members, 16 of which are CTSA institutions. This initiative is particularly relevant to both CTSA Strategic Goal #1 and Strategic Goal #3.
Increasing Efficiencies and Reducing Administrative Burden

In the past year, MICHR made enhancements in efficiency and service. Michigan Clinical Research Unit (MCRU) leadership developed a new, bundled rate for industry-sponsored protocols utilizing MCRU services. The previous budgeting system had several drawbacks for both MICHR and study teams. Because each service was charged at a different rate, there was a high administrative burden both for MICHR and for investigator teams. The new bundled rate enhances MCRU’s sustainability by recovering applicable costs for industry-sponsored studies, while enhancing efficiency. The resources freed up by the reduction in administrative processing and invoicing time have been reinvested to improve service in other areas of MICHR.

These new efficiencies contribute to CTSA Strategic Goal #1.

Providing Specialized Core Resources for the Creation of New Devices

In the last year, U-M’s Medical Device Design and Prototype Laboratory made 85 device and diagnostic prototypes using rapid prototyping equipment funded by MICHR. One device that has gone on to small-scale manufacture in the past year is a novel device for research on pain sensitivity. This device enables clinical and translational research by creating a standardized, hand-held device that can be used at multiple clinical sites to conduct standardized pain sensitivity protocols. The device is being used in support of fibromyalgia research.

These resources assist investigators with early translational ideas, a key contribution to CTSA Strategic Goal #5.

Influencing State Law to Improve Community Wellness

During the past year, the CTSA was leveraged to obtain a new NIH RC4 grant, a new “Roadmap to Achieving Health Equity in Michigan” was published, and MICHR’s partnership with community policy advocates resulted in passage of a new state law. MICHR developed a “Policy 101” training and policy guide template, which led to working with a community-based organization partner, who then testified at the Michigan Legislature. The result of the testimony was a new Cottage Food Law. This new law allows individuals to make certain types of food items in home kitchens and then sell them in places like local farmers markets and roadside stands. This increases options for homemade foods for communities in need of better diets and also provides a potential income source.

This is a direct example of how CTSA-supported activities can directly improve the health of our communities, aligning with CTSA Strategic Goal #4.
Launching a Novel Contracting Demonstration Project to Establish Best Practices

A major accomplishment of the past year was the launch of a new contracting demonstration project. In order to improve the contracts/award processes, focus group discussions were held with study team members at every level. Study coordinators, research and division administrators, faculty, and the Division of Research Development and Administration project representatives offered their insight in guiding the strategic implementation process. The Contracting Deployment Committee held its first meeting in December 2010 and is charged with developing and endorsing an implementation plan. The committee consists of faculty and administrative leadership within several Medical School departments and will serve as an advisory board through spring 2012. This team has identified baseline metrics, and under the direction of the project manager a web-based data collection and process tracking system has been created to facilitate the collection of necessary metrics across the campus. Additionally, a stakeholder working group has been formed to further develop partnerships with clinical research teams from a diverse scope of departments and centers, and to engage the assistance of additional staff that are most familiar with the current research administrative workflow and barriers. Lastly, partnerships with early adopting divisions and departments have been identified and will assist with collecting baseline metrics and test the recommendations from the Working Group and Deployment Committee.

This work is directly relevant to CTSA Strategic Goal #1.

Testing a Novel Approach to Enrolling Participants in a Biorepository

We launched a major new project, the MICHR Genomic DNA BioLibrary, intended to expand the impact of the Specimen Processing and Biorepository Laboratory. This new research project focuses on the development of an innovative system for informed consent, collection, storage, and use of genomic DNA and related data. The five-year goal is to establish a collection of more than 100,000 genomic DNA samples with secure links to personal health information.

This work holds the potential for significant impact for our translational researchers, and advances CTSA Strategic Goal #5.
MICHR Continues to be Fully Engaged in the National CTSA Consortium, With 52 Faculty and Staff Members on 14 Out of 17 Committees

In addition to program leads and managers, key staff leaders from outside MICHR participate in consortium activities, demonstrating the consortium’s influence throughout the institution. During the past year MICHR had a particular focus on national activity in ethics, children’s health, and community engagement. In addition to national consortium activities, MICHR joined the Midwest CTSA consortium to promote partnerships in education and bioinformatics programs. U-M has also established a strong presence in the Society of Clinical and Translational Science, which was formed to support the CTSAs and the infrastructure for translational science as a whole. Former Director Ken Pienta served as the Vice President and Dr. Riba is a member of the SCTS Board of Directors.
MICHR contributes to the national understanding of research barriers in children’s health through a national survey executed by the C.S. Mott National Children’s Poll and led by Children’s Health Initiatives Working Group member Matthew Davis, MD. The survey has begun to provide unique insights relevant to children’s health research. The survey has added questions to assess parental perceptions of children’s health research and barriers to having children participate in studies. We anticipate the results will help investigators understand the best way to obtain informed consent and increase the number of pediatric subject enrollees.

Service Growth
During the reporting period overall, MICHR continued its growth, supporting 888 investigators, an increase of 18% over the previous period. During the reporting period, 132 active federal grants have benefitted from MICHR resources, a 15% increase. In addition, 149 publications arising from work supported by MICHR appeared in peer-reviewed journals this year, more than double the previous year’s output.

Growing Partnerships in the Pilot Grant Program
This program continues to promote multidisciplinary collaborations by bringing together partners from across the university. MICHR uses institutional funds to match funds provided by the applying investigator’s department, school, or center. At the onset of the CTSA, departments, schools, colleges, and centers participated to fund this unified program. The list continues to grow and now includes more than 95 units that have partnered with the Pilot Grant Program. In the past year, 82 grant applications have been submitted to the PGP. Of these, 21 proposals were funded for a total of $1.12 million dollars. Matching funds received from our collaborators equaled $477,169. To date, 53 proposals have been completed, 18 manuscripts have been published, and extramural funding obtained based on the pilot work funded by MICHR equals approximately $37.2M. This represents a 70% increase in extramural funding since the last report.
Srijan Sen Applies Genomics and Genetics to Advance Depression Research

If you suffered from depression in the 1970s – and if you sought help for your depression – you probably would have been put on medication and undergone psychotherapy. It would have taken 2-6 weeks for the medication to help you get better, if it was going to help. If you didn’t see an improvement with the combination of medication and psychotherapy, your doctor would have tried different drugs in what was basically a practice of trial and error to find out which drug, if any, worked for you. If your depression persisted, a more involved option was electroconvulsive therapy (ECT), which basically induces a seizure and may cause memory loss.

You might be surprised to learn that now, 30-40 years later, treatment options for depression remain about the same as they were in the 1970s. A depressed patient today has no higher odds of getting better than he would have back in the 1970s, says Srijan Sen, MD, PhD. About 30% of patients have some sort of treatment resistance, and an even larger percentage don’t respond to the first drug prescribed by their doctors.

However, with the recent advances in genomics and genetics, that may soon change. “The advances in genetics and genomics over my 10 years involved have been pretty dramatic. My PhD was looking at two genetic variants in 400 people, and it took me four years to do that. And now that work would take about a week or so to do,” Sen says. He adds that technology has advanced to the point that researchers are now looking at a million different variants in huge populations. Scientists are beginning to ask questions they didn’t have the means to ask in the past. “Before we were asking questions and focusing on one gene, and humans have some 23,000 genes,” he says. “Now we are starting to look at all the 23,000 genes at once and try to find answers that way.” Sen says that’s a better way to conduct psychiatric research rather than trying to select one particular gene to test for, since researchers really don’t know yet the biological pathways underlying depression.

Dr. Sen is a researcher and an Assistant Professor at U-M’s Department of Psychiatry. He has studied at Cornell and Yale in addition to his work at the University of Michigan. His parents are medical researchers, and a career in research seemed like a natural fit for him. He became interested in psychiatry after learning about relatives who had psychiatric issues. We don’t know much about what goes wrong with the brain in mental illness, he says, and that makes psychiatry interesting to him.

Read more about Dr. Sen’s work and how MICHr has supported him at www.michr.umich.edu.
From my perspective serving as one of MICHR’s Associate Directors over the past year, I had a strong sense of the impact that we have on U-M’s research enterprise. Now that I am serving as Director, I am even more proud and even humbled by the stellar work we are fortunate enough to support across the university. Building on the strong foundation set by Ken Pienta, MD and Dan Clauw, MD before him, I am confident that MICHR will continue to improve and expand our support of faculty and their research teams.

I am grateful for both the federal and institutional support MICHR receives, and pledge to make the most of every dollar and all the resources at our disposal to further our mission of enabling & enhancing clinical & translational research. The NCRC provides a local environment for collaboration at the university, and the 60-member CTSA consortium provides collaboration opportunities nationwide – all providing endless possibilities for bringing scientific advances and breakthroughs within closer reach to impacting health outcomes.

Sincerely,

Tom Shanley, MD
Director, MICHR
Associate Dean, Clinical & Translational Research
Associate Vice President for Clinical & Translational Research
Janette Ferrantino Professor of Pediatrics
Professor, Pediatrics & Communicable Diseases
DISTINCT RESEARCH PROJECTS SUPPORTED

INVESTIGATORS, SCHOLARS, TRAINEES, AND OTHERS WHO BENEFITED FROM MICHR PROGRAMS AND SERVICES

PILOT GRANT DOLLARS DISBURSED

DOLLARS DISBURSED DIRECTLY TO TRAINEES FOR TUITION, SALARY, STIPENDS, AND RESEARCH

POTENTIAL RESEARCH PARTICIPANTS REGISTERED IN UMCLINICALSTUDIES.ORG DATABASE

NUMBER OF PUBLICATIONS GENERATED BY MICHR-SUPPORTED RESEARCH
Tom Shanley, MD
Dr. Shanley serves as MICHR’s Director, Associate Dean for Clinical & Translational Research, Associate Vice President for Clinical & Translational Research, Janette Farrantino Professor of Pediatrics, and Professor of Pediatrics & Communicable Diseases. His clinical interests include management of pediatric hypoxic respiratory failure, management of severe sepsis and septic shock, indications and use for CVVH, and post-operative cardiac management. His research interests include genomics of pediatric sepsis, regulation of host innate immune responses, pathophysiologic mechanisms mediating acute lung injury, mechanisms of immunoparalysis and relatedness to endotoxin- and cross-tolerance, phosphatase regulation of inflammatory cell signaling.

Teri Grieb, PhD
In a dual role, Teri Grieb, PhD, serves as MICHR Managing Director and leads the Office of Research in the Medical School as Senior Director of Research. In these roles, she partners with the Senior Associate Dean for Research and the Associate Dean for Clinical and Translational Research in advocacy for the research mission of the University of Michigan Health System. As the chief business and administrative officer for the research mission, Dr. Grieb is responsible for the operational and fiscal management of the Office of Research and its reporting units. She assists with devising and deploying strategic research initiatives; managing projects; and advising on policy, procedural, and operational issues for the research enterprise. Dr. Grieb also serves as the lead administrative liaison and primary staff interface between MICHR and the university, and representing MICHR to the NIH/CTSA consortium.

Brian Athey, PhD
Dr. Athey has recently been named “Chair Designate” of a planned new Department of Computational Medicine and Bioinformatics at the U-M Medical School. Co-founder of the U-M Center for Computational Medicine and Bioinformatics (CCMB) and Professor of Biomedical Informatics, he is also a Professor of Psychiatry and of Internal Medicine. He serves as Director of Academic Informatics of the Medical School. Dr. Athey has served as elected national co-chair of the (CTSA) Informatics Key Function Committee. He is PI of the U-M NIGMS Bioinformatics T32 Training Grant and PI of the NIH National Center for Integrative Biomedical Informatics (NCIBI.org) since its inception in 2005. Dr. Athey established the first nationwide Internet2 Visible Human Project demonstration under contract with the National Library of Medicine, was also PI of the DARPA Virtual Soldier Project.

Deb Gipson, MD
Debbie S. Gipson, MD is an Associate Professor, Division of Nephrology, Department of Pediatrics. Previously, she served as Associate Director for Community Engagement, Child Health Core, at University of North Carolina-Chapel Hill, where she was Associate Professor of their Kidney Center. Dr. Gipson received her MD from Indiana University, and an MSC from University of Washington. Her research focuses on 1) phase 1, II and III clinical trials and implementation research in nephrotic syndrome and 2) the neurodevelopmental and quality of life impact of chronic kidney disease in children. She uses a multidisciplinary approach in her research, including colleagues from pharmacology, pathology, psychology, psychiatry, education, radiology, biostatistics, and nephrology.

Kyle Grazier, PhD
Kyle L. Grazier is Professor in the Department of Health Management and Policy and in the Department of Psychiatry at the University of Michigan. With support from the NIMH, NIAAA, AHRC, the Robert Wood Johnson Foundation, the BCBS Foundation, and the Center for Healthcare Research and Transformation, he has studied the impact on health status and service use of structural and process changes in health care financing and resource allocation. She serves on CMS’ advisory board, the NIMH Services Review Panel, the CSR Dissemination and Implementation Review Panel, the NIGMS Technical Advisory Board, and is chair of the International Graham Prize Committee. She has also twice served as chair of the university’s Committee on Sustainable Health Benefits, co-chair of the M-Healthy Advisory Board, and is currently a member of the provost’s Faculty Budget Committee.

Michelle Riba, MD
Dr. Riba is a Clinical Professor in the Department of Psychiatry, Associate Chair for Integrated Medicine and Psychiatry Services, and Director of the PsychOncology Program and Associate Director of the University of Michigan Depression Center. Her specialty is Psychosomatic Medicine. Dr. Riba’s research interests include breast cancer and bone marrow transplantation, assessment, and treatment of distress. She is past president of the APA, AADPRT and AAP and representative to the WPA.

Blake Roessler, MD
Blake Roessler is an Associate Professor in the Department of Internal Medicine; an Associate Professor of Pharmaceutics; Director, Human Applications Laboratory; Director, Vector Core; and Director, Center for Gene Therapy. His specialty is Rheumatology, and his clinical interests include experimental gene therapy. Earning his MD from the University of Cincinnati, Dr. Roessler has a broad-based basic and clinical research program that is exploring many facets of chondrocyte biology and signaling. A current area of research emphasis is the development of Raman spectroscopy as a platform technology for diagnostic devices for a variety of musculoskeletal diseases.

Marita Titler, PhD, RN, FAAN
Dr. Titler is an Associate Dean for Practice and Clinical Scholarship, Rhetta Dumas Endowed Chair, University of Michigan School of Nursing and UMHS. Formerly, she was Senior Assistant Director at the University of Iowa Hospitals and Clinics (UIHC); Director of Research, Quality, and Outcomes Management in the Department of Nursing Services and Patient Care at UIHC, and Clinical Professor at the University of Iowa College of Nursing. Her research at UIHC focused on translation science, interventions to improve outcomes of adults with chronic illnesses, and dissemination of evidence-based practice guidelines for the elderly. In her role as Senior Associate Dean for Practice and Clinical Scholarship at the University of Michigan School of Nursing and UMHS, she also twice served as chair of the university’s Committee on Sustainable Health Benefits, co-chair of the NCQA Technical Advisory Board, and is chair of the International Graham Prize Committee. She has twice served as chair of the university’s Committee on Sustainable Health Benefits, co-chair of the M-Healthy Advisory Board, and is currently a member of the provost’s Faculty Budget Committee.

Lynda Welage, PharmD, FCCP
Dr. Welage is a Professor in the Department of Clinical, Social and Administrative Sciences, and Associate Dean for Academic Affairs, College of Pharmacy. Welage earned her Postdoctoral Fellowship at the Clinical Pharmacokinetics Laboratory Millard Fillmore Hospital in Buffalo, New York, a PharmD from State University of New York at Buffalo, and a BS in Pharmacy from the U-M College of Pharmacy. She is an active researcher educator whose career has focused on enhancing pharmacotherapy for critically ill patients, has published extensively, and received several national awards for her work. Dr. Welage was also instrumental in writing the education and career development section of the CTSA grant proposal, as well as in implementing the program after the award.
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