Michigan Institute for Clinical & Health Research (MICHR)

The Michigan Institute for Clinical & Health Research (MICHR) strives to develop and advance translational science - a field of study that aims to identify and overcome long-standing challenges in the translational research pipeline. MICHR examines translational research at a systems level with the goal of generating scientific and operational innovations that reduce translational barriers and improve the efficiency and effectiveness of all translational research. The ultimate goal of translational science is for health solutions to reach all people more quickly. MICHR provides myriad offerings to the research community that are focused on building and educating research teams; designing, funding, and implementing research studies; and disseminating research results. As a hub of innovation and experimentation, MICHR also rigorously evaluates and studies their offerings to ensure they produce the expected outcomes and impact and can be scaled and shared nationally. U-M established MICHR as a centralized resource to transform translational research in 2006, and an NIH Clinical and Translational Science Award (CTSA) has supported MICHR since 2007.

MICHR Facilities and Resources at the North Campus Research Complex: MICHR occupies 12,428 square feet of office, conference, lab, and media production space in a single-story building that is part of the North Campus Research Complex (NCRC). MICHR shares the NCRC with the IRB, administrative offices for the U-M Medical School Office of Research, the clinical trials office of the U-M Comprehensive Cancer Center, and the Innovation Partnerships office, creating a hub for clinical and translational research administration. Housing these resources in close proximity fosters communication, collaboration, and sharing of best practices among these units.

MICHR has software for media development, and a still image camera and digital audio recording device available for digital learning work. In addition, the North Campus Research Complex has a multi-media studio that can accommodate and facilitate webinar production and presentation, remote meeting access, and blended learning training techniques that combine online and face-to-face instruction. These resources provide faculty, trainees, and mentors with an enhanced learning and teaching environment while providing a strong learner-support system.

Office and Meeting Space: In addition to the MICHR resources mentioned above, all team members have individual workstations at MICHR, which include personal computers with access to secure high-speed internet. The MICHR office space also contains secure filing cabinets. Individual space is also available for faculty members who have main offices elsewhere but have effort associated with MICHR projects. To accommodate team meetings, focus groups, and advisory meetings, MICHR's administrative space includes six shared meeting rooms that accommodate 50 or more persons, a fully equipped training room that accommodates 40 persons, and multiple small meeting rooms that may be used for interviews and short video production.

MICHR has many programs that advance translational science:

Behavioral Research Innovation & Support Program: The Behavioral Research Innovation & Support Program (BRISP) provides support, consultation, and training to enhance rigor in conducting behavioral and social science research. BRISP is available to faculty and staff who are new to behavioral research as well as experts who are seeking the latest resources and guidance on conducting behavioral research. BRISP also provides support for career development and advancement of behavioral and social science research professionals through its consultation and training opportunities. BRISP collaborates with a network of units across campus to build a repository of educational resources related to behavioral research conduct. BRISP works closely with units that support clinical trial conduct to tailor processes to optimally support behavioral clinical trials.

Biostatistics Program: MICHR's Biostatistics Program offers consultation, collaboration, and mentoring throughout the lifecycle of a study. Services include study implementation, and abstract and manuscript development. MICHR's faculty and staff biostatisticians provide expertise in randomization scheme development and implementation, development and implementation of statistical analysis plans, data quality assessment, and database review. Biostatisticians will serve as study co-investigators, team statisticians, or statistical analysts.

Clinical Research Management: MICHR's Clinical Research Management (CRM) Program provides the highest quality operational support for single and multi-center clinical and behavioral studies in accordance with standard operating procedures, good clinical practice, and appropriate regulatory requirements. The CRM team includes certified clinical research professionals with experience in both clinical research and project management. CRM staff can be engaged to design project databases built for efficient collection, management, and analysis of research data. CRM also provides study monitoring services for clinical trials, with a focus on Investigational New Drug/Investigational Device Exemption (IND/IDE) required monitoring. In addition, CRM provides study teams with consultations focused on data management, quality management, and study management activities, as well as assistance with registration of clinical trials in the ClinicalTrials.gov Protocol Registration and Results System.

Community Engagement Program: MICHR's Community Engagement (CE) program fosters community-academic partnerships and community-engaged research (CEnR). CE develops, demonstrates, and disseminates strategies promoting translational science and the science of CEnR, and enhances the ability of community-academic partnerships to address community health priorities equitably across the state of Michigan. CE provides consultation, education, and funding to support research projects in community-engaged settings. CE services and funding are available to a broad base of partners, including academics, community members, health providers, and others engaged in collaborative research efforts to improve community and population health. MICHR also maintains strong and active relationships with community partners and organizations state-wide that work together to foster university-community research partnerships and facilitate specific CEnR projects.

Dissemination & Implementation Science Catalyst: The MICHR Dissemination & Implementation (D&I) Science Catalyst Implementation Science Network (ISN) connects researchers to promote more innovative dissemination and implementation research to close the gap between science and practice and ultimately improve care in our health systems and communities. It offers assistance for investigators pursuing implementation science learning opportunities including learning collaboratives, conferences, course offerings, and examples of career plans, frameworks, measures for K and R grants, and examples of U-M implementation studies. It also promotes novel and competitive implementation science-driven initiatives by providing funding opportunities, toolkits on D&I methods, and hosting forums to share and foster ideas about implementation science. Its efforts to build implementation science capacity in health systems and communities include: MICHR Community Research Studios, U-M BCBS Clinical Quality Collaboratives, Multimodal D&I Curricula, and Michigan Medicine Statewide expansion. The ISN comprises three components: 1) Spark - Leveraging talent to promote implementation science learning opportunities, 2) Seed - Promoting novel and competitive implementation science-driven initiatives, and 3) Spread - Building Implementation Science capacity in health systems and communities.

Education and Mentoring Group: The Education and Mentoring Group (EMG) provides multidisciplinary education, career development, and mentoring programs for clinical and translational research teams across U-M. Offerings include 1) mentored research programs comprising (1a) the Mentored Clinical Scientists Career Development Program (MICHR K), (1b) Predoctoral T32 training in translational science, (1c) Postdoctoral T32 training in translational science, and (1d) a pre-doctoral Summer Immersion program; 2) educational and training initiatives including (2a) a summer research immersion program to train new clinical research professionals; (2b) clinical trials training for faculty and staff, (2c) mentorship education and training, and also instruction in (2d) scientific writing, (2e) research methods, and (2f) responsible conduct of research; 3) research and evaluation studies to demonstrate the impact of our competency-based approach to education; and 4) consultation to other U-M units regarding educational initiatives. EMG

also provides the health community with access to online training resources through the Development, Implementation, and AssessMent Of Novel Training in Domain-based competencies (DIAMOND) portal. DIAMOND is a federated professional development platform that provides just-in-time training resources to clinicians and study team members that is tailored to their needs. Resources on the platform are curated from throughout the CTSA consortium.

EMG Facilities and Resources: The EMG has experience in the multimedia learning environment and can provide guidance to study teams regarding development of digital learning products. Our team of education experts can provide advice in the development of webinars, e-learning modules, and virtual learning and instruction.

Informatics Program: MICHR's Informatics team consists of staff who have specialized knowledge and experience in clinical research systems and processes. Informatics develops, implements, and supports informatics software for clinical research investigators and currently provides researchers with several web-based systems. For example, REDCap (Research Electronic Data Capture), is a secure web-based application designed to support electronic data capture for clinical research studies. REDCap provides an intuitive interface for data entry, audit trails, automated export and import procedures, and advanced features such as branching logic and calculated fields. In addition, Informatics has developed EMERSE (Electronic Medical Record Search Engine), which provides a self-service web-based tool for authorized users to search clinical notes from electronic medical records. Users can input their own terms or phrases and get results within seconds. The clinical notes include admission, discharge, and progress notes, as well as ambulatory care notes and notes from radiology, pathology, and other reports going back to 1998. Also, MICHR Informatics has developed UMHealthResearch (UMHR), a public website that allows participants to search for studies using various parameters and express interest in the studies that fit them. These volunteer participants create personal accounts with self-reported demographic and health information, and researchers create digital postings that describe their study and eligibility criteria. A matching algorithm continuously runs to link eligible volunteers with studies open for recruitment. UMHR currently has tens of thousands of registered volunteers interested in clinical research.

Interdisciplinary Research and Team Science Program: MICHR's Interdisciplinary Research and Team Science Program offers a variety of services to support teams in coordinating and advancing research ideas, securing funding, and elevating team functioning. MICHR offers engaging, facilitated Research Jams to help cross-disciplinary teams surface and prioritize shared research ideas, develop pilot projects, identify audiences and value propositions, and respond to funding opportunity announcements. For teams pursuing large-scale grants, MICHR provides strategic and personalized advice, proposal management, numerous resources and tailored templates, and grant editing.

MICHR IND/IDE Investigator Assistance Program: The MICHR IND/IDE Investigator Assistance Program (MIAP) provides comprehensive regulatory support, guidance, and education services to investigators involved in Food and Drug Administration (FDA) regulated clinical research. MIAP's primary focus is providing regulatory assistance to sponsor-investigators of drugs, biologics, and medical devices. This includes Investigational New Drug (IND) and Investigational Device Exemption (IDE) services such as: regulatory needs assessments; exemption rationale development; assistance with FDA meeting preparation; assistance with IND and IDE application submissions, including protocol and informed consent development; assistance with regulatory compliance, document preparation, and FDA contact and correspondence; sponsor-investigator training; and ongoing study assistance, including safety reporting, FDA annual report preparation, protocol amendments, and IND/IDE closeout.

Patient Partners Program: The goal of the Patient Partners Program is to reimagine the role of individuals with lived experience in health research, and build the capacity of individual patients, family members, caregivers, and researchers to create authentic research partnerships. To achieve this vision, the Patient Partners Program is working with patients to co-design a Patient Partners Academy curriculum. This academy will train faculty and patient partners in strategies that optimally engage patients in research, with the goal of increasing patient leadership in clinical and translational research to ultimately impact health. Patients will learn how to engage in the co-creation of study design, grant applications, study

conduct, and dissemination. The Patient Partners Academy will also prepare patients to serve as grant reviewers on study sections and mentors on career development awards.

Participant Recruitment Program: MICHR's Participant Recruitment (PR) Program provides a variety of services for research teams in need of support to recruit, enroll, and retain participants. PR offers consultations to assist with recruitment analysis and strategic planning, development of robust recruitment plans and timelines, and cost estimation. PR also offers assistance with the creation of professional quality marketing and advertising materials and with paid targeted social media advertising and community outreach. PR maintains the engaged volunteer registry, UMHealthResearch, which provides research teams with a database of >92,000 individuals interested in research participation and a portal through which they can advertise their studies. The tool recommends studies to participants based on topics of interest, medical conditions, and participants' responses to health profile questions.

Pilot Grant Program: MICHR's Pilot Grant Program offers funding for projects that propose addressing a common cause of inefficiency or failure in research projects at any stage of translation. The goal of pilot projects is to create scientific, operational, financial, or administrative innovations that will increase the efficiency and effectiveness of translational research, ultimately improving human health.

Research Development Core: MICHR's Research Development Core (RDC) offers no-cost consultation and grant editing services to investigators during all stages of research ideation and proposal development. During consultations, the RDC team advises on hypotheses, specific aims, study design, biostatistics, future research directions, and grantsmanship; matches research ideas with funding sources; and suggests potential collaborators and mentors. RDC's grant editors review proposals and provide edits and comments to strengthen clarity, flow, and grammar.

Translational Innovation Program: Through a blend of human-centered design, meaningful experimentation, and systems thinking, MICHR's Translational Innovation Program (TIP) actively catalyzes diverse projects that bring together multiple stakeholders, including researchers, community members, technologists, and domain experts. Through services that range from one-off consultations to in-depth partnerships, TIP has helped research teams co-create human-centered service designs, patient- and community-centered health services, easy-to-use digital products for health interventions, and systems that promote connection and collaboration.