**Michigan Institute for Clinical & Health Research (MICHR)**

The Michigan Institute for Clinical & Health Research (MICHR) strives to enable and enhance clinical and translational research by educating, funding, connecting, and supporting University of Michigan (U-M) investigators. MICHR’s ultimate goal is to accelerate the translation of scientific discoveries, resulting in improved health for local, national, and global communities. MICHR provides U-M researchers with the training, tools, and services necessary to speed discovery of new ways to diagnose, treat, and prevent disease. Specifically, MICHR develops research talent through its predoctoral and postdoctoral education programs; helps investigators launch their ideas through pilot grant funding and consultation; connects researchers with community groups, clinics, practice-based networks, and potential study volunteers; and supports research teams with clinical research management services, including biostatistical design and analysis, study management and monitoring, data management, a clinical trials office for industry partnerships, and a fully-equipped and professionally-staffed clinical research unit. U-M established MICHR as a centralized resource to transform translational research in 2006, and a NIH Clinical and Translational Science Award has supported MICHR since 2007.

**MICHR Facilities and Resources at the North Campus Research Complex:** MICHR occupies 26,000 square feet of office space in a single-story building that is part of the North Campus Research Complex. The MICHR administrative space includes six shared meeting rooms that accommodate 50 or more people, a fully equipped training room that accommodates 40 people, and multiple small meeting rooms that may be used for interviews and short video production. MICHR shares the North Campus Research Complex with the IRB, administrative offices for both U-M’s and the Medical Schools’ Offices of Research, the clinical trials office of the U-M Comprehensive Cancer Center, the U-M Office of Technology Transfer, and the U-M Business Engagement Center, creating a hub for clinical and translational research administration. Housing these resources in such close proximity fosters an unprecedented level of communication, collaboration, and sharing of best practices between these units.

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MICHR has many programs that provide research support services to U-M investigators:

**Education and Mentoring Group (EMG):** MICHR’s Education and Mentoring Group (EMG) provides multidisciplinary education, career development, and mentoring programs for members of clinical and translational research teams across U-M. Offerings include: 1) mentored research programs including (1a) the Mentored Clinical Scientists Career Development Program (MICHR K), (1b) the Postdoctoral Translational Scholars Program, (1c) the Practice-Oriented Research Training program for clinical staff and faculty, and (1d) a pre-doctoral Summer Immersion program; 2) educational and training initiatives including (2a) clinical trials training for faculty and staff, (2b) mentoring education and training, and training in (2c) scientific writing and (2d) research methods; 3) degree and certificate programs including (3a) the Master of Science in Clinical Research and (3b) the Translational Research Education Certificate; 4) research and evaluation studies to demonstrate the impact of our competency- based approach to education; and 5) consultation to other U-M units regarding educational initiatives.

*EMG Facilities and Resources*: EMG has a number of resources that facilitate educational content development and provide faculty, trainees, and mentors with an enhanced learning and teaching environment. Specifically, EMG has multimedia production software, a video camera, and audio recording equipment available for developing digital learning content. In addition, the North Campus Research Complex has a multimedia 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.

**Pilot Grant Program (PGP):** MICHR’s Pilot Grant Program (PGP) offers funding to facilitate and support innovative research across the translational spectrum. PGP encourages interdisciplinary collaborations that promote the development of transformative solutions for improving patient and community health outcomes. PGP funds three research approaches (investigator initiated, collaborative, and community-based participatory research) across the different phases of translational research (bench-to-bedside, beside-to-practice) for a variety of investigators (basic, clinical, and social scientists and community partners).

**Research Development Core (RDC):** MICHR’s Research Development Core (RDC) offers no-cost consultation and grant editing services to investigators during all stages of 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 to strengthen clarity, flow, and grammar. In the past five years, RDC has provided support for 406 grant proposals and research ideas resulting in >$51M in external funding.

**Biostatistics Group:** MICHR’s Biostatistics Group offers consultation, collaboration, and mentoring throughout the lifecycle of a study. Services include grant proposal development, protocol development, study implementation, and manuscript development. MICHR’s faculty and staff biostatisticians provide expertise in research design, randomization scheme development and implementation, data analysis planning and implementation, data quality assessment, and database review. Consultations are free of charge. Biostatisticians will serve as study co-investigators, team statisticians, or statistical analysts for a fee.

**Communities Engagement (CE) Program:** MICHR’s Communities Engagement (CE) program provides consultation, education, and funding to support research projects in community and practice-based 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 a strong, active council of community partners who work together to foster university-community research partnerships and facilitate specific community-engaged research projects.

**Participant Recruitment Program:** MICHR’s Participant Recruitment Program provides an array of services for research teams needing support to recruit, enroll, and retain participants. The Recruitment Program offers consultations to faculty and other clinical research team members and can conduct recruitment analysis and strategic planning. This includes developing robust recruitment plans, creating timelines, and estimating costs. The Recruitment Program also maintains UMClinicalStudies.org, which provides research teams with a database of >25,000 individuals interested in research participation. The database recommends studies to participants on topics of interest to them and recommends participants to research teams based on participants’ responses to health profile questions.

**Clinical Research Informatics (CRI):** MICHR’s Clinical Research Informatics (CRI) team consists of staff who have specialized knowledge and experience in clinical research systems and processes. CRI develops, implements, and supports cutting-edge informatics software for clinical research investigators and currently provides researchers with three electronic data capture and clinical data management tools. The first, Research Electronic Data Capture (REDCap), is a secure web-based application that provides an intuitive interface for data entry, audit trails, automated export and import procedures, and advanced features such as branching logic and calculated fields. The second, V-OC OpenClinica® Enterprise Edition™, is a web-based application that is validated and compliant with regulatory requirements and other standards, which researchers can use by engaging MICHR data managers. V-OC is recommended for single or multi-site clinical research projects. The third, Mi-OC OpenClinica® Enterprise Edition™, is the non-validated version of OpenClinica that researchers can use to build and manage their own databases. Mi-OC is recommended for data that will not be used to support a new drug or device submitted to the FDA, federally contracted clinical trials, or industry-sponsored trials.

**MICHR IND/IDE Investigator Assistance Program (MIAP):** 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 for 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.

**MICHR Clinical Trials Office (MCTO):** The MICHR Clinical Trials Office (MCTO) supports faculty during the pre-award phase of industry-sponsored clinical trials and guides clinical research teams through the legal, financial, and regulatory phases of study start-up. Specifically, the MCTO will complete the Proposal Approval Forms (PAF), conduct recruitment feasibility assessments, draft budgets and billing calendars, negotiate budget and consent language with sponsors, complete IRB applications and consent/assessment forms, and facilitate contract approvals.

**Clinical Research Management (CRM):** MICHR’s Clinical Research Management (CRM) group provides the highest quality operational and regulatory support for single and multi-center clinical 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 assists investigators with database development, in which a team of skilled developers work with study teams to design project databases built for efficient collection, management, and analysis of research data. CRM also provides study monitoring services for clinical trials, including IND/IDE required monitoring services; site initiation, interim, and close-out visits; pre- and post-OHRCR audit reviews; and NIH/DoD preparation visits. In addition, CRM provides study teams with mentoring on data management and study management.

**Michigan Clinical Research Unit (MCRU):** The Michigan Clinical Research Unit (MCRU) provides the resources and infrastructure necessary to conduct human clinical research protocols at U-M. MCRU’s clinical core services and physical facilities provide investigators access to research nurses, medical assistants, and lab personnel. MRCU also provides MCRU2U, a mobile research service, for clinical study teams. The mobile team supports simple protocol-specific services such as blood draws and ECGs throughout UMHS, at participants’ homes, and at other locations within an hour of the U-M campus.

*MCRU Facilities and Resources*: The main performance site for MCRU is in the U-M Medical School’s Cardiovascular Center (CVC) located at the center of the U-M Medical Campus. The MCRU facility comprises approximately 7,400 square feet of space, including research-only outpatient examination rooms, research-only overnight stay beds in private rooms, and administrative offices. This location also houses a research exercise physiology area, a procedure room, a nursing workspace, a medical preparation and storage room, a patient/subject intake area, an equipment storage space, clean holding rooms, a principal investigator and study coordinator workroom, a staff locker room, a metabolic kitchen, a specimen processing laboratory, a patient waiting area, and a dining area for participants.

MCRU’s Outpatient Clinical Research Unit is located in the Domino's Farms extension approximately four miles from the medical campus in northeast Ann Arbor. This unit houses 10 exam rooms, including a research physiology room. All aspects of the unit are compliant with the Joint Commission on Accreditation of Healthcare Organizations. Shared space includes a waiting room, patient carrels, a patient intake area, an equipment room, a double secure-locked documentation room, an audit/exam room, a patient food preparation room, a staff kitchen, patient showers, and handicap accessible bathrooms. A 140 square-foot wet laboratory is contiguous with the patient facility. It contains two tabletop centrifuges, computers with internet connection for follow-up on patient laboratory values, a label printer for blood draws, and supplies for drawing blood and preparing aliquots for storage. The laboratory also contains a small specimen refrigerator, two -86° specimen freezers, and one -20° specimen freezer.