MICHIGAN MEDICINE SITE PROFILE

JUNE 2021

CLINICAL TRIALS SUPPORT OFFICE | MEDICAL SCHOOL OFFICE OF RESEARCH

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

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Association for the Accreditation of Human Research Protection Programs, Inc.
Full AAHRPP Accreditation

ALL SPONSORED PROJECTS
Fiscal Year 2020

3,715 NUMBER OF ACTIVE AWARDS

$662M AWARDS | **$556.8M** EXPENDITURES

>3.9k Faculty FTEs (3,948 Headcount)

1,043 Average Number of Operating Beds

624,811 Diagnostic Imaging Procedures

2.4M Outpatient Clinic Visits, Treatments, Procedures

>29k Total Employees (Full Time)

1,407
ACTIVE
Clinical Trials

498
NEW
Clinical Trials

Michigan Medicine is a premier academic medical center made up of three hospitals with 60 subspecialties and more than 125 clinics throughout Michigan. In 2020-21, Michigan Medicine was named number 1 in Michigan. Michigan Medicine is a national research leader based on many measures, such as the scope and quality of its investigations and the size of its research portfolio.

Michigan Medicine Overview

In fiscal year 2020, our sponsored research reached $662 million. Michigan Medicine is committed to improving clinical care, value, and health outcomes by successfully executing a diverse portfolio of high-quality clinical trials. To that end, Michigan Medicine created an organizational structure to better support the conduct of clinical trials, including a central Clinical Trials Support Office (CTSO) with seven affiliated Clinical Trial Support Units (CTSUs) that provide robust infrastructure, training, and oversight for studies performed at U-M. The seven Clinical Trial Support Units are business units that partner with investigators and their teams to ensure the timely and efficient activation and execution of clinical trials.

Clinical Trials Support Units (CTSUs) are trans-departmental and thematically aligned based on research foci. These local units provide comprehensive support to study teams, offering high-quality and efficient service in support of a mix of clinical trials. The CTSUs provide a professional environment of expert personnel accessible to all investigators, especially early-career faculty. The central CTSO provides enterprise-wide standards, policies, and a common infrastructure that is utilized by the units and study teams.

Acute, Critical Care, Surgery & Transplant CTSU provides infrastructure to study time-sensitive, unscheduled clinical interventions in the emergency medical services system, emergency department, critical care unit, transplant, or studies conducted in an acute hospital setting.

Ambulatory & Chronic Disease CTSU is the home for all chronic, non-ICU diseases in the non-ICU adult population (excluding cancer and cardiovascular disease). These diseases constitute the majority of clinical trials in the ambulatory Internal Medicine divisions (rheumatology, endocrinology, pulmonary, geriatrics, nephrology, and gastroenterology) and the Department of Ophthalmology & Visual Sciences which account for a large number of the ambulatory trials within Michigan Medicine.

Behavior, Function, and Pain CTSU represents investigators who conduct trials that involve behavioral interventions or behavioral or biomedical trials intended to impact the following types of outcomes: health behaviors (physical activity, self-management), psychological states (e.g. mood, anxiety), maladaptive behaviors (e.g. substance use, eating disorders), physical function (e.g. recovery from stroke, rehabilitation therapies), psychosocial function, or pain.

Children's CTSU specializes in clinical trials for pediatric subjects. The unique needs of children and their families are the focus of this CTSU, and provides enhanced support to a variety of pediatric clinical trials, including but not limited to pediatric disciplines such as hematology/oncology, intensive care, nephrology, neurology, and endocrinology.

Heart, Vessel, Blood CTSU enhances performance of cardiovascular, coagulation, and nonmalignant hematologic clinical trials across the lifespan of acute and chronic disease.

Neurosciences and Sensory CTSU is a multidisciplinary, multi-departmental CTSU that aims to provide a full range of services for investigators with clinical trials related to the skin or nervous system. The CTSU is open to all faculty within the departments of Neurology, Neurosurgery and Dermatology, along with faculty outside these departments who find a natural fit with the CTSU theme.

Oncology CTSU serves as the centralized core facility of all oncology clinical research trials conducted by investigators at the University of Michigan Rogel Cancer Center and the Michigan Medicine community. As an NCI Comprehensive Center, the unit operates under the guidance of the Clinical Protocol and Data Management component of the P30 grant.

Computer & Internet

How is access to the study data controlled? External users are required to use their unique credentials, and when working remotely, access the network through the secure Virtual Private Network (VPN).

How do Clinical Research Associates (CRA/Monitors) access secure study data? Unique user IDs are used to access the Electronic Medical Record (EMR) with an appropriate role assigned. This allows view access to a limited number of records for a limited time period.

Can the Clinical Research Associate (CRA/Monitor) connect to the internet while on-site? Yes, the Clinical Research Associates (CRA/Monitor) are permitted access to the internet through the wireless networks.

What is the preferred wireless network? MWireless is the preferred network for employees for internet access and two-factor, Duo weblogin authentication, is required.

Can the Clinical Research Associate (CRA/Monitor) access the Electronic Medical Record (EMR) to verify that source data is accurate? Yes, the Clinical Research Associates (CRA/Monitor) will be able to access the EMR through our Michigan Medicine provider portal.

Are all research personnel who are supporting the study trained on the proper handling of sensitive data? Yes, formal awareness training is required for all employees, contractors, sponsors, and other parties. There are documented disciplinary policies for violations of privacy or security of protected health information (PHI) or other sensitive data.

Are all accesses to ePHI, including view-only, logged? Yes, including who performed the access, what was accessed, and when the access occurred.

Are there CD-ROM drives available? Information on CD-ROM access can be provided by the CTSU. Only FIPS 140-2 Michigan Medicine-approved removable media can be used.

File Sharing: Michigan Medicine recommends that shared files are authorized through the use of MiShare. MiShare is a secure collaborative file transfer system that provides a method approved by the Michigan Medicine Compliance Office for Michigan Medicine personnel, non-Michigan Medicine business partners, patients, and researchers to securely transfer files, including files that contain electronic Protected Health Information (ePHI), protected research data, or other sensitive information. Files are encrypted while being uploaded or downloaded and are encrypted while they are on the MiShare server. Other approved platforms for ePHI includes Box and Dropbox.

Has the information system for the study undergone a security assessment and received authorization to operate from an appropriate authority? Yes, it is the policy of Michigan Medicine to ensure the confidentiality, integrity, and protections of all sensitive data, including ePHI. Security assessments are conducted by the office of the Chief Security Officer and research systems containing ePHI are required to have IRB approval, a risk assessment, and authorization to operate.

Do you have an EMR (Electronic Medical Record) available? Yes, we operate our Epic EMR system in line with federal, state, and local regulations, including application of the NIST 800-53 family of controls. Epic is considered 21 CFR Part 11 compliant for electronic records and signatures.

Is the information system used by the study built upon a secure baseline configuration? Yes, underlying information systems supporting clinical trials management are set up in the Michigan Medicine infrastructure to meet institutional information assurance and security requirements.

Are changes to the information system(s) tracked? Yes, underlying information systems supporting clinical trials management have change control processes in place to test, approve and document changes.

Are study users required to have secure accounts that are managed by a central authority? Yes, in order to use information systems, users are required to have a unique ID managed by an Identity and Access Management team.

How is the information system maintained? Systems are regularly maintained along their lifecycle from design, implementation, and operation to retirement.

Budgets & Contracts

The University of Michigan Office of Research and Sponsored Projects (ORSP) enables and safeguards the conduct of research and other sponsored activities for U-M. ORSP is responsible for activities such as contract negotiations of terms and conditions and facilitating the award as part of the U-M Office of Research. A second unit, the Office of Sponsored Programs, primarily oversees financial accounting to ensure compliance with applicable laws and sponsor regulations, such as allowed expenses and sponsor payment activities as part of U-M Business & Finance. The CTSUs closely partner with ORSP and Sponsored Programs on pre- and post-award activities.

Do you require that the contract and budget are finalized before submitting to the IRB for initial approval? or vice versa? No, the budget, other contract terms, and IRB can be developed and approved in parallel.

Once the protocol, budget, and contract are made available and approved through the CTSU feasibility process, the general contract terms will be sent to ORSP for review. In parallel the CTSU finance team will review the budget with the study team and lead any budget negotiations. Once the budget is finalized, it will route for internal approvals to ORSP to incorporate with the final contract language. The full contract will be processed for signatures once budget has routed internally for approvals and contract terms are negotiated. The turnaround time for final signature (once the Principal Investigator has signed) is typically less than three business days; however, any sponsor requirement of original ink signatures will likely prolong the signature process.

Payment Information

To ensure proper processing of your payment, regardless of the payment method, please notify the University of Michigan that a payment has been sent by sending an email to electronicpmts@umich.edu.

Payment via check or money order by courier, FedEx, UPS or Express Mail
MAKE CHECK REMITTANCES PAYABLE TO:
The Regents of the University of Michigan
Box 223131
Pittsburgh, PA 15251-2131

Please include Michigan Medicine Reference ID (e.g. 1X-PAF0XXXXX or University of Michigan invoice number).

Payment via EFT/ACH:
Payable to: The Regents of the University of Michigan
Account number: 5401125777
ABA/Routing number: 071000039
Bank name: Bank of America,
2600 W. Big Beaver Road,
Troy, MI 48084

Payment Information (Continued)

Payment information: Wire/routing number:
Payable to: The Regents of the University of Michigan
Account number: 5401125777
ABA/Routing number: 026009593 (from inside USA)
Swift Code: BOFAUS3N (from outside USA)
Bank name: Bank of America,
2600 W. Big Beaver Road,
Troy, MI 48084

Payment information:
Tax ID Number 38-6006309

Who is responsible for budget negotiations?
The Clinical Trials Support Units (CTSUs) are responsible for developing a study budget and working collaboratively with the Principal Investigator and their academic department to negotiate a final budget with the sponsor. The CTSUs will submit the final budget to the University of Michigan Office of Research and Sponsored Projects to include in the study agreement along with negotiated payment terms.

Can budget negotiations begin with a draft protocol?
In special circumstances the CTSUs will assist U-M investigators in estimating the cost of conducting a trial at Michigan Medicine based on a draft protocol. However, a final protocol, draft contract, and budget template are required for feasibility review. Once approved, the contract and budget review process will begin.

What is your overhead (indirect) rate for industry sponsored clinical trials? 29%

Contact Information for budgets:
Each CTSU or program can provide the budget specialist information upon request, or for general inquiries, please contact the Clinical Trials Support Office.

Contracts

Address where grants and contracts may be sent:
Contracts are handled by the Office of Research and Sponsored Projects. Contact for a contract specialist will be provided upon request.
Wolverine Tower, First Floor
3003 South State St.
Ann Arbor, MI 48109-1274

Do you have a separate department(s) responsible for contracts? Yes, the Office of Research and Sponsored Projects (ORSP)

Will the institution accept a unilateral confidentiality disclosure agreement (CDA)? Yes, the CTSUs will assist with routing all draft CDAs to the Office of Research and Sponsored Projects for review and execution. CDAs are executed typically within two weeks.

What documents are required upon execution of the CDA? Michigan Medicine requires the following documents:

- Protocol
- Draft Contract
- Draft Budget
- Informed Consent
- Investigator brochure
- Study Manuals (Pharmacy, IVRS, etc.)
- Subject material requiring IRB approval

What does an investigator do once they receive a CDA? When the investigator receives a CDA, they should work with their Clinical Trials Support Unit to submit the CDA to the Office of Research and Sponsored Projects for negotiation and execution.

Who is authorized to sign a CDA? The Investigators are not authorized to sign CDAs. Office of Research and Sponsored Projects will review and/or negotiate and sign.

Do you have master confidential disclosure agreements (MCDAs)? Yes, we do have some MCDAs. If so, a submission to Office of Research and Sponsored Projects is required for institutional signature.

How long does a CDA take for approval? This varies. If a MCDA exists, it can be signed quickly. If not, CDAs are generally executed with 16 calendar days on average. The duration is impacted by the Sponsor and/or CRO responsiveness.

What is the average time for negotiation of clinical research contract at your site? Negotiation of Clinical Trial Agreements varies and can range from a few weeks to two months from the point a contract draft is available. University of Michigan supports and encourages the use of the Accelerated Clinical Trials Agreement (ACTA) to speed the negotiation process.

Contact Information:
Each CTSU or department administrator will provide the contract specialist information as needed upon request.

Department Specific

Is there prior site experience with use of an Electronic Data Collection (EDC) system? Yes, Michigan Medicine has three internal EDCs that are utilized by study teams. These include REDCap (Research Electronic Data Capture), OpenClinica, and Velos eResearch. Details on these systems can be obtained here. Michigan Medicine study teams also have experience with numerous sponsor-specific EDC systems. Each CTSU can provide the list of EDC systems upon request.

OnCore Clinical Trials Management System:
All clinical trials being serviced by a CTSU are managed in OnCore, an enterprise Clinical Trials Management System. OnCore allows for automated standard interfaces with MiChart (EMR), which helps reduce duplicate data entry and integrates clinical research billing for increased efficiency and accuracy. OnCore provides complete subject and financial management for all clinical trials at Michigan Medicine.

Calendar Review and Analysis Office assists principal investigators and study teams conducting clinical research to ensure all billable items and services align with payor and university policies. Clinical research billing analysts facilitate building the billing grid (calendar), reviewing required core documents for alignment with Medicare and university policies, resolving research participant billing issues, and auditing studies for compliance.

Contact information for a new study:
The CTSU Portfolio Managers can assist you with identifying a potential U-M investigator and navigating the U-M systm. The contact information is provided below. For general assistance, contact the central Clinical Trial Support Office.

- **Michigan CTSUs (non-oncology studies)**
  MCTSU.portfolio.managers@mich.edu
- **Oncology CTSU**
  Oncology@umich.edu

Contact Information for Potential PI: Each CTSU will provide the potential PI information, as needed.

Contact Information for Potential Study Coordinator: Each CTSU will provide the study coordinator information, as needed.

Contact Information for Finance Administrator: Each CTSU will provide the finance administrator information, as needed.

How many studies do coordinators work on at a time?
The number of studies each coordinator works on depends on the requirements and complexity of the studies. Each CTSU works closely together to provide coverage to deliver shared study support.

Site visits can be arranged by appointment in partnership with the principal investigator or study team.

Facilities

What kind of setting is your site?
Our site is an academic medical center.

Are there dedicated clinical research units? Michigan Medicine provides two dedicated locations for the conduct of clinical research: Michigan Clinical Research Unit (MCRU) and Ravitz Cancer Center Research Unit (CCRU). Both facilities provide research-supported treatment beds, chairs, and trained research staff to ensure high-quality research-focused care. Clinical trials are also conducted in other adult or pediatric inpatient and outpatient facilities throughout Michigan Medicine.

Radiology and Other Testing

Do you have a radiology facility at or near your site?
Yes.

Does your site have the capability to access imaging data (i.e. digital CT/MRI images) for a computer that has internet access? Yes.

Is your site able to obtain multiple ECG assessments using equipment provided to you and transmitting the results electronically to a central ECG service provider?
Yes.

Laboratory

Are there onsite laboratory facilities?
Yes. Multiple clinical laboratories are available. The Rogel Cancer Center, Michigan Clinical Research Unit (MCRU), and other independent program laboratories are available for research specimen processing, storage, and shipping. The Medical School Central Biorepository, a College of American Pathologists (CAP) accredited state-of-the-art facility, is also available for specimen storage, processing, and distribution services. There is also a sample processing lab at our Brighton offsite clinic.

Are your lab personnel HAZMAT or International Air Transportation Association (IATA) certified (equivalent certification is acceptable)? Yes.

College of American Pathologist (CAP): Yes.
A list of CAP accreditations can be obtained at Mlabs.

Clinical Laboratory Improvement Amendment (CLIA):
Yes, all Michigan Medicine Clinical Laboratories are CLIA certified. Clinical research laboratories do not require CLIA certification. A list of CLIA certifications can be obtained at Mlabs.

Are there qualified staff members to draw blood and prepare multiple samples for shipping? Tumor tissue? Frozen samples? Yes.

Are local normal laboratory ranges available from the university? Yes, the Local Normal Ranges (LNRs) can be found here.

Is a -70ºC/-20º C specimen storage freezer available?
Yes, through the Michigan Clinical Research Unit, Cancer Center, other independent program laboratories, offsite clinics and the Medical School Central Biorepository, there are appropriate specimen storage freezers that are temperature alarmed and monitored.

Certifications

College of American Pathologist (CAP)
Clinical Laboratory Improvement Act/Amendment (CLIA)
American Nurses Credentialing Center (Magnet)
FWA – 00004969
Laboratory International Air Transport Association for Hazardous Materials (HAZMAT & IATA)

Pharmacy

Does your site have a dedicated pharmacy and pharmacists to handle, store and dispense investigational drugs? U-M has an investigational pharmacy with a designated lead research pharmacist assigned to each study who is responsible for assuring protocol and regulatory compliance related to dispensing and management of the investigational drug.

Contact Information Pharmacy:
Michigan Medicine Research Pharmacy
UH B2D301, Box 5008
1500 East Medical Center Drive
Ann Arbor, MI 48109-5008
Phone: 734.936.7469
Fax: 734.647.9302
Questions? Email: Pharm-IDS-RPh@med.umich.edu

Are there onsite investigational pharmacies with locked storage for investigational drugs? Yes, all investigational drugs are kept in dedicated pharmacy areas with limited access to pharmacy personnel only.

Is the drug storage facility temperature-controlled?
Yes, the storage areas are maintained according to USP standards for drug storage, and the environment is monitored using an automated electronic system, Temp Track.

Is your pharmacy or site staff willing to collect batch numbers of drug? Yes, for investigational drugs that the Research Pharmacy manages.

Does someone from your pharmacy attend the Site Initiation Visit (SIV)? Yes.

Does someone from your pharmacy attend the pre-site qualification visit? Yes.

Does your pharmacy have additional information to provide upon request? Yes — copies of all policies and SOPs are available upon request.

Are Research Pharmacy services available at other sites?
Yes. Study Teams can access research pharmacy services at offsite facilities such as Brighton, Northville, and Dominos Farms.

Do you ship drugs to patients? Yes. Investigational drugs being studied under an Investigational New Drug (IND) is eligible for interstate shipment without restriction. If a drug is not being studied under IND, but is shipped within Michigan, the drug may be eligible for shipment. Drugs not studied under IND cannot be shipped out of state.

IRB/Regulatory

Contact Information:
IRBMED
Plymouth Road, Bldg 520, Room 3214
Ann Arbor, MI 48109-2800
(734) 763-4768
irbmed@umich.edu

Does your site follow ICH-GCP guidelines? Yes, studies are conducted per sponsor requirements.

Can regulatory documents be collected simultaneously with the contract/budget and IRB review/approval process? Yes.

Is the use of a commercial IRB permitted?
Yes, when U-M agrees to cede regulatory oversight to a commercial IRB. U-M currently has master agreements with several commercial IRBs. Ancillary committee review and approvals, and IRBMED acknowledgement to cede letter are required prior to commercial IRB review of site.

How often does the local IRB meet?
IRBMED consists collectively of 6 Boards and hosts 3 Board meetings per week. The A1 and A2 Boards meet simultaneously every other Thursday, and the B1 and B2 Boards meet simultaneously on the alternating Thursdays. The C1 and C2 Oncology Boards meet on alternating Fridays.

Certification, AAHRPP:
Yes. U-M was reaccredited with Full Accreditation in 2021 for five years. U-M has held Full Accreditation since 2008.

Certification, FWA:
FWA 00004969

What is the submission time prior to an IRB meeting?
To be considered for an upcoming Board agenda, all identified changes for an application must be addressed and resubmitted to IRBMED 8 business days in advance of the convened meeting. Resubmission by this date does not guarantee that the application will be reviewed at the next convened meeting.

What is the turnaround time for notification of an IRB Board decision? Time from review of a study at a full board meeting and notification of the outcome is typically within 2 business days.

Are there interpreter services available to translate informed consent documents into other languages?
Yes, if a need exists, access to the interpreter services is available upon request and appointment.

Do you agree to have monitoring visits, possible sponsor audits, and possible IEC/IRB and regulatory inspections conducted during the course of the clinical trials? Yes.

Are there any other committees that need to approve the protocol? Yes, all new clinical trials in a CTSU will initially go through a feasibility review or a Cancer Center Protocol Review Committee (PRC) review. The reviews are conducted in partnership between the PI and CTSU. The PRC meets on the 2nd and 4th Tuesday of each month with submissions due 1 week prior. For non-oncology studies, there are no deadlines for feasibility submission. Approval is typically received within 5 business days.

For regulatory review, the protocol is submitted through an electronic application system. The study will proceed to the applicable ancillary committees before the application reaches the IRB for review. U-M has several ancillary research review committees, including: Clinical Research Calendar Review and Analysis Office, Conflict of Interest, Research Pharmacy, Radioactive Drug Research Committee, Subcommittee on Human Use of Radioisotopes, Institutional Biosafety Committee, and Tissue Procurement Core.

Studies are reviewed only by those review units that are applicable. Ancillary committee review and approval must be completed before final IRB approval is released.

What is the submission time prior to a meeting for these other approval committees? Upon submission of the regulatory application, U-M's electronic management system sends the IRB application to all applicable ancillary committees based on information provided in the application.

How often do these other approval committees meet?
Meetings occur to meet the demands of the submitted studies.

What is the total turnaround time for IRB approval?
Total time to approval will vary with an individual application's review needs, including other committee reviews, application completeness and clarity at submission, and IRB reviewer schedules.

UMHealthResearch.org
is provided by the Michigan Institute for Clinical & Health Research (MICHR), the home to U-M's NIH Clinical & Translational Science Award (CTSA).

Participant Population

How do you identify patients for participation in research studies? DataDirect: The Medical School Office of Research has developed a self-serve tool, Data-Direct, for CTSUs and study teams to use to facilitate cohort discovery. DataDirect enables access to robust, up-to-date data on more than 2 million unique patients from across the health system to inform study design and determine availability of eligible patients for study recruitment.

UMHealthResearch.org is an engaged participant registry with over 60,000 users that enables the public to view active clinical and health research studies at U-M. The portal allows potential volunteers to search studies or be auto-matched based on self-reported health history and/or interests. Study teams can communicate with volunteers and send batched messages using editable templates. UMHR posts can be linked to social media ads to connect with thousands of MM patients using the Paid, Targeted Social Media Ad Service.

MiChart (EMR): The Best Practice Alerts (BPAs) can be developed in our EMR as recruitment or screening tools using potential participant identifiers associated with study eligibility, diagnosis codes, problem lists, appointment dates, attending physicians, and other variables.

EMERSE: The Electronic Medical Records Search Engine (EMERSE) works with free text clinical documents in the EMR to support rapid data retrieval.

How do you support participant recruitment? The MICHR Participant Recruitment (PR) Program offers consultations to study teams across U-M and can assist with recruitment analysis and strategic planning that meet the needs of the study. The team works with investigators on recruitment plans that include retention strategies, development of effective recruitment materials, timelines, and community outreach.

The team offers assistance with the creation of Michigan Medicine and U-M branded recruitment materials such as brochures, posters, fliers and postcards to be distributed to potential volunteers. The PR Team can also meet with study teams to develop a robust social media campaign that includes demographic targeted social media advertising to meet the enrollment goals set by the Principal Investigator.

What are the patient demographics and geographic statistics of those that visit the institution? 75% of patients reside within 50 miles of Michigan Medicine.

Patient Demographics: Adult - 80% Caucasian, 9% Black or African American, 5% Asian, 6% Other. **Pediatric** - 76% Caucasian, 10% Black or African American, 5% Asian, 9% Other. 4% of Adults and 6% of Pediatrics patients identified as Hispanic/Latino.

Do you have patients whose first language is not English? Yes; 97% of patients speak English as their first language. A small percentage speak Spanish, Japanese, Chinese, or Arabic. Interpreter services are available.

Study Teams

Tell us about your clinical trial center and office. More information related to the Clinical Trials Support Office (CTSO) and the seven affiliated Clinical Trials Support Units (CTSUs) is available at: CTSOgroup@umich.edu.

Is additional investigator background available on request? Yes, more information can be obtained once an investigator has been identified, including the investigator's CV and the population that the investigator has access to.

Do you have the personnel to meet the study requirements? U-M is well positioned with highly trained study personnel, including principal investigators, co-investigators, radiologists, pathologists, pharmacists, biostatisticians, project managers, study coordinators, registered nurses, LPNs, medical assistants specialists, research assistants, multisite coordinators, laboratory technicians, database developers, data managers, regulatory coordinators, study monitors, and recruitment consultants. Each department or program personnel may vary slightly.

Are investigator profiles available? Yes, more information can be obtained once an investigator has been identified. This information will be provided by the CTSU.

How many studies do coordinators work on at a time? The number of studies each coordinator works on depends on the requirements and complexity of the studies. Each CTSU works closely together to provide coverage to deliver shared study support.

Do you use long-term off-site storage? Yes.

General

Is the institution part of a Site Managed Organization (SMO)? No.

Is clinical research conducted on adult and pediatric populations? Both.

Cancer Care Centers:
University of Michigan's Rogel Cancer Center – All cancers represented

Children's Hospital:
C.S. Mott Children's Hospital

Magnet Certification: Yes.

Other Institutional Certifications:
An extensive list of accreditations/certifications is available at the provided link.

Phases of studies conducted at the institution?
Phase I thru Phase IV and post marketing approval.

Specialty and Treatment Centers:
Michigan Medicine has several specialty and treatment centers, including: Rogel Cancer Center, Rehabilitation Center, Kellogg Eye Center, Frankel Cardiovascular Center, and Geriatrics and Rehabilitation Centers. A complete list is available at: http://www.uofmhealth.org/our-locations/specialty-care-centers.

NIH Clinical and Translational Science Award (CTSA):
Yes. U-M's CTSA is housed in the Michigan Institute for Clinical & Health Research (MICHR)

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