Translational Science Toolkit

Resources to help investigators translate their basic science discoveries from bench to bedside

MICHR MICHIGAN INSTITUTE FOR CLINICAL & HEALTH RESEARCH
UNIVERSITY OF MICHIGAN

Are you looking to…

Perform research in the early translational realm? Do you want to make a difference to health research at U-M? Are you a young investigator trying to find your way through this maze?

This toolkit is for you.

This manual provides an overview of the necessary knowledge, resources and connections that will guide your exploration of the translational impact of your research findings.

This is not a textbook.

We designed this toolkit to spark action. It is not meant to be comprehensive. Read it long enough to get inspired, then put it down and get to work. Pick it back up again when you need another boost.

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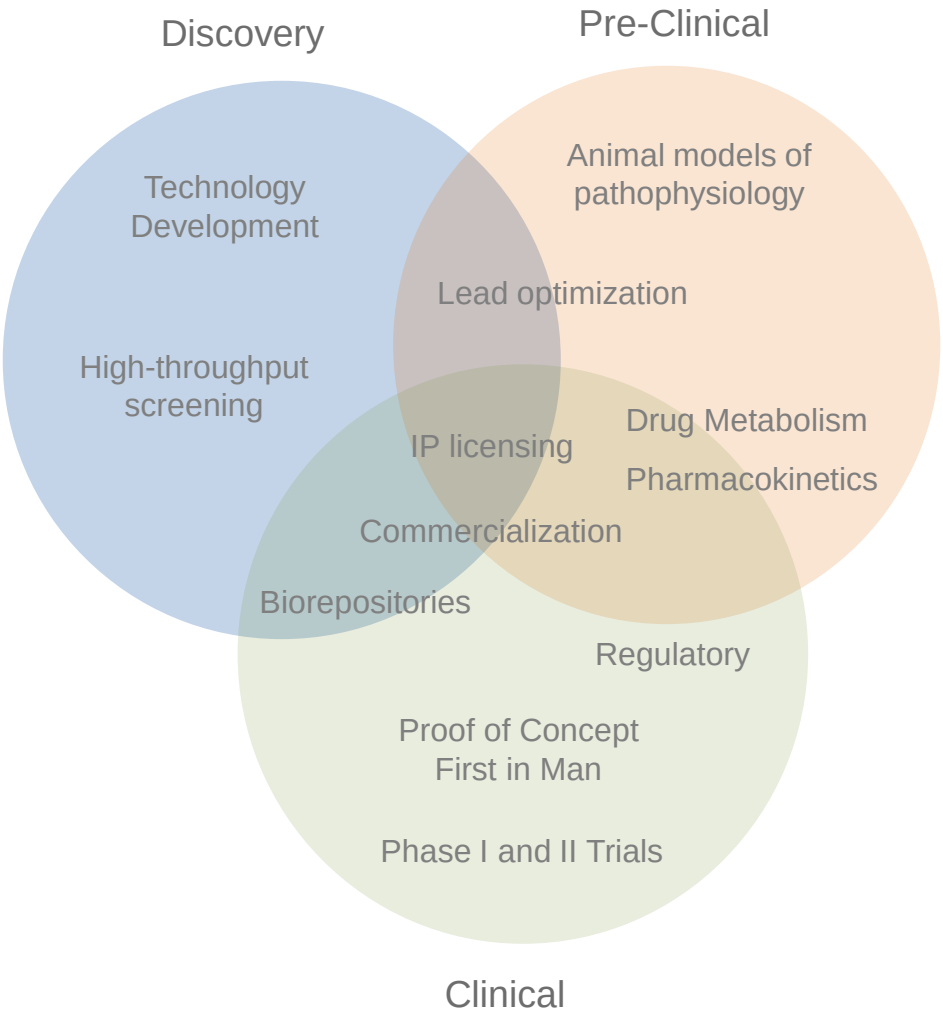
T1 Translational Research

T1 translational research can be divided into the three primary areas of discovery, preclinical, and clinical. There are numerous activities within each area, or in overlapping areas, that are necessary for successful pursuit of T1 research.



Courtesy of the Clinical & Translational Science Awards Program

Early Career Investigators

MICHR

Early Career Investigators

Are you a junior investigator thinking about a career in early translational research? In addition to understanding a potentially new line of research, it is important to find mentors who can help guide your career development.

MICHR Resources

- MICHR Postdoctoral Translational Scholars Program (PTSP): PTSP is a multidisciplinary career development award designed to prepare individuals with a PhD in a biomedical science or social science discipline for independent careers in translational research.
- Research Basics Workshop: The Research Basics workshop series is designed to present basic, introductory-level material covering concepts in clinical or health research.
- Translational Research Education Certificate: The Translational Research Education Certificate (TREC) is designed for doctoral students in basic research programs as a complement to their graduate studies.
- Summer Immersion Program: This 10-week immersion program runs from late May through early August and is designed to engage students in clinical, translational, and health disparities research and inspire them to choose a career focused on research.

Additional Resources

- NIH New and Early Stage Investigator Policies: Use these guidelines for establishing new or early stage investigator status on your NIH application.
- CTSciNet: CTSciNet, the Clinical and Translational Science Network, is an online community for people interested in or already pursuing careers in clinical and translational research. CTSciNet provides articles and information on navigating a career in clinical and translational research. Investigators can join virtual groups focused on team science, journal clubs, and ethical legal and social issues, and they can access resources from partner organizations.
- The American Society of Hematology and the European Hematology Association Translational Research Training: This year-long training and mentoring experience helps early career investigators build careers in translational research.
- Fundamentals of Clinical and Translational Research (FaCToR): FaCToR offers an overview of the concepts of clinical/translational research through dynamic and interactive online modules.

Literature: Identifying the Right Mentors

The following articles emphasize the importance of mentoring for scientific career success and provide helpful tips on finding mentors that are right for you.

- Top Ten Tips to Maximize your Mentoring
- Mind Matters: Getting Yourself Mentored
- The Difference Between an Advisor and a Mentor
- Ingredients for Good Mentoring
- Reaching Gender Equity in Science: The Importance of Role Models and Mentors
- Know What to Look for When Choosing a Mentor

Additional Learning Resources

- Carving a Career in Translational Research
- Basic Scientists in the Clinic
- Perspective: The Successful Physician-Scientist of the 21st Century
- Podcast: Training Translational Scientists

"In most cases, people need more than one mentor because no one individual is capable of helping the person develop the broad range of skills that are necessary for success."

- Joe Merola, *Mind Matters: Getting Yourself Mentored*

Finding a suitable mentor is a crucial step for early career investigators. It is reasonable to expect your mentor to:

- Help you define and evaluate training goals
- Meet with you one-on-one regularly
- Listen to you and your ideas
- Provide constructive and timely feedback on your ideas
- Support training and professional development opportunities
- Help you to network
- Acknowledge your contributions through authorship

- NIH mentoring guidelines

Identifying Collaborators & Funding Opportunities

MICHR

Looking for a Collaborator?

How often do you see single author publications? Effective collaboration is essential for a successful scientific career. These tools will help you connect with collaborators at U-M and beyond.

U-M Resources

- Michigan Research Experts: A searchable, web-based database of research expertise designed for U-M and developed to foster collaboration. It goes beyond journal publications, monitoring hundreds of different channels providing the latest information from sources like books, conferences, grants, patents, and even clinical trials.
- UM Library Pivot Profiles: A database of UM faculty profiles that contain information about all aspects of a researcher's academic career, which can be used to find potential collaborators.

> "In the current state of research, there is an increasing need to build bridges between clinical and basic researchers to translate findings from bench to bedside and back again"
>
> - Heidi Kong and Julia Segre, *Bridging the Translational Research Gap*

Additional Resources

- Dimensions: Much like Michigan Research Experts, Dimensions allows users to search resource profiles that are external to the University to expose a researcher's distinctive expertise.
- ResearchGate: This is a global scientific community for presenting yourself and your work and connecting with collaborators.
- DIRECT2Experts: A pilot project facilitated by the Research Networking Working Group of the NIH-supported Clinical & Translational Science Award (CTSA) Consortium. The goal is to improve biomedical research and leverage our strengths as a community by creating a network that enables easy access to expertise and related resources across institutions.

Team Science Resources

- National Cancer Institute Team Science Toolkit: The Team Science Toolkit is a user-generated collection of information and resources that support the practice and study of team science. The Toolkit connects professionals from many disciplines, providing a forum for sharing knowledge and tools to maximize the efficiency and effectiveness of team science initiatives.
- CTSA Online Assistance for Leveraging the Science of Collaborative Effort (COALESCE): This group offers collaboration enhancement for team-based, cross-disciplinary translational biomedical research. Resources include online learning modules intended to help researchers acquire and apply a basic knowledge of team science. Additional learning modules afford an experiential learning environment where the researcher can adopt different roles and engage virtually in the challenges of team research.

Literature and Web Tutorials

- Enhancing the Effectiveness of Team Science: This 2015 study report synthesizes and integrates the available research to provide guidance on assembling the science team; leadership, education and professional development for science teams.
- Collaboration and Team Science: A Field Guide: A guide to help researchers navigate the rocky and murky territory associated with building a team on their own or at the request of someone in their organization.
- The Road We Must Take: Multidisciplinary Team Science: Translational research is complex and requires a diverse skill set. There is a critical need for understanding how to create and sustain multidisciplinary research teams.
- Bridging the Translational Gap: A Successful Partnership Involving a Physician and a Basic Scientist: Although basic and clinical scientists have long collaborated, translational research challenges investigators to move beyond the traditional training of laboratory scientist or clinician. This article discusses such a collaboration, highlighting features specific to interactions as an MD and PhD.
- Making Team Science Work: Advice from a Team: Learn how to assemble a team that is prepared to rapidly translate their clinical findings to patients.

Funding Opportunities

With the drive towards increasing the speed of translating results from bench to bedside, combined with declining resources, funding agencies are seeking proposals that foster collaboration and the translation of basic discoveries.

MICHR Pilot Grant Program

- MICHR Accelerating Synergy Award: The MICHR Accelerating Synergy Award is designed to support interdisciplinary research teams in pursuing future external large-scale grants (i.e., NIH U and P-series). In partnership with the Medical School Office of Research and the Institute for Healthcare Policy & Innovation, MICHR is offering three Accelerating Synergy Award mechanisms: (1) Basic Research, (2) Translational Research, and (3) Health Services Research.
- To view a full list of MICHR funding opportunities, click here.
- For questions about the MICHR Accelerating Synergy Award or other MICHR funding opportunities, email the MICHR Pilot Grant Program.

U-M Collaborations

- MCubed: This is a two-year seed-funding program designed to empower interdisciplinary teams of University of Michigan faculty to pursue new initiatives with major societal impact. The program minimizes the time between idea conception and successful research results by providing immediate startup funds for novel, high-risk and transformative research projects.
- View the MCubed FAQ here.

U-M Rogel Cancer Center

- Research Grants: Funding is available for investigators performing cancer-related research of for any interesting and innovative collaboration among scientists.
- Idea Grants: Funding is available for investigators who have novel and innovative ideas for cancer research.
- Innovation Grants: A principal goal of these awards is to support preliminary collaborative research studies emanating from at least two of our Research Programs that would enable and/or enhance new grant application submissions to the National Institutes of Health or other extramural, peer-reviewed funding agencies.

U-M Diabetes Research Center

- Pilot and Feasibility Study Grants aim to stimulate new research at the University of Michigan in the areas of diabetes, its complications and related endocrine and metabolic disorders.

U-M Medical School Competition Space

- U-M Competition Space is an online platform that expedites the process of finding, and applying for, funding opportunities at the Medical School.

Translating Basic Science Findings

- NIH Bench-to-Bedside Program: The Bench-to-Bedside Program funds research teams seeking to translate basic scientific findings into therapeutic interventions for patients and to increase understanding of important disease processes.

Tip

Be sure to sign up for U-M Office of Research and Sponsored Projects (ORSP) Email Alerts on the ORSP website. You will receive funding opportunities from the DoD, DoE and NASA as well as the latest policies and procedures updates from NIH and ORSP.

- NIDCD Research Grants for Translating Basic Research into Clinical Tools (R01): The NIDCD is encouraging applications that translate basic research findings into clinical tools for better human health in the NIDCD mission areas of hearing, balance, smell, taste, voice, speech and language. The intent of this FOA is to provide a new avenue for basic scientists, clinicians and clinical scientists to jointly initiate and conduct translational research projects. Multi-institutional, multi-disciplinary, and academic-industrial collaboration studies are encouraged.
- Opportunities for Collaborative Research at the NIH Clinical Center (U01): The goal of this FOA is to support collaborative translational research projects aligned with NIH efforts to enhance the translation of basic biological discoveries into clinical applications that improve health. This opportunity is specifically to promote partnerships between NIH intramural investigators (i.e., those conducting research within the labs and clinics of the NIH) and extramural investigators (i.e., those conducting research in labs outside the NIH).

Studying Complex Systems & Understanding Human Cognition

- James S. McDonnell Foundation Collaborative Activity Awards: The Foundation offers Collaborative Activity Awards to initiate interdisciplinary discussions on problems or issues, to help launch interdisciplinary research networks, or to fund communities of researchers/practitioners dedicated to developing new methods, tools, and applications of basic research to applied problems.

Tip

Writing collaborative proposals takes considerable time. Give your grant a final and thorough edit to ensure it is cohesive and reads in one voice.

International Collaborations

- Human Frontier Science Program (HFSP): The aim of the Program is to promote, through international cooperation, basic research focused on the elucidation of the sophisticated and complex mechanisms of living organisms for the benefit of all humankind. Applicants are expected to develop novel lines of research distinct from their ongoing research. HFSPO attaches the highest importance to novelty, scientific merit, internationality, and interdisciplinarity. Preliminary results are not required.
- View the HFSP Research Grants Guidelines for Award year 2020 here.

Leukemia and Lymphoma Society

- The Translational Research Program funds new and innovative research that shows high promise for translating basic biomedical knowledge to clinical application.
- Specialized Center of Research Program is intended to bring together established investigators from one or several institutions to develop a focused research program, foster new interactions and cooperation, and enhance interdisciplinary research among participants.
- To view a full list of Leukemia & Lymphoma Society funding opportunities, click here.

Diabetes

- American Diabetes Association (ADA): This program funds research studies with novel and innovative hypotheses in any area relevant to the etiology or pathophysiology of diabetes and its complications that hold significant promise for advancing the prevention, cure or treatment of diabetes.
- The ADA Innovative Clinical or Translational Science (ICTS): These awards support research with novel and innovative hypotheses, performed in human subjects, or research approaches to accelerate the transition of scientific discoveries into clinical application.

Opioid Epidemic

- NIH HEAL Initiative Funding Opportunities: The NIH launched the HEAL (Helping to End Addiction Long-term) Initiative, which is an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis.

Melanoma

- Melanoma Research Alliance Request for Proposals: Soliciting high-impact pre-clinical, translational, and early clinical research from scientists and clinicians around the world. The RFP calls for ideas that have the potential to lead to near-term clinical application in melanoma prevention, detection, diagnosis, staging, and treatment.

Travel Awards

- Burroughs Wellcome Fund Collaborative Research Travel Grants: This program provides up to $15,000 in support for relatively unrestricted travel funds to academic scientists (faculty and postdocs). Grants must be used for domestic or international travel to another lab to learn new research techniques or being or continue a collaboration to address biomedical questions.

"Running a successful collaboration, especially one with several leaders at multiple sites, means thinking like a CEO: vetting partners, delegating responsibilities and making tough management decisions."

- Chris Tachibana, *Navigating Collaborative Grant Research*

Grant Writing

Given the funding climate, it is important to submit your strongest grant on first submission. Take advantage of excellent U-M resources to receive feedback on federal and non-federal applications.

MICHR Resources

- Research Development Core (RDC): RDC offers no-cost one hour consultations designed to strengthen grant proposals. Services may include matching ideas with funding sources, developing research plans and submission strategies, identifying collaborators, and guidance on future career direction. RDC also provides grant editing assistance.

Tip

Stay informed of the research being funded in your area. NIH RePORTER and Sponsored Awards on the Web (SAW) are excellent resources.

- K Writing Workshop: MICHR's Education & Mentoring Group sponsors a K Writing Workshop each year for investigators writing Career Development (K) grants. In this three-part workshop, K writers receive peer critique and feedback from senior faculty experienced in NIH study section thinking.
- Mock Study Section: MICHR's Education & Mentoring Group hosts a mock study section, which is an opportunity to learn how NIH grant reviewers, or "study sections," think. As one of nine grant reviewers, you will discuss actual twelve-page K and R grants (already submitted in some version to the NIH). You will learn what happens behind closed doors in a real K or R grant review.
- Large-Scale Grant Support: To encourage the pursuit of large-scale grants, MICHR has developed a plan of support that is available to investigators across the university.

U-M Resources

- Foundation Funding for Faculty: This is a collection of resources built for faculty and staff at U-M for securing funding from foundations and other organizations.
- Marisa Conte, U-M Translational Research Liaison: Marissa can help investigators identify appropriate funding opportunities for their research interests.

- Medical School Office of Research Proposal Development: This provides several resources to help researchers at every stage of the grant writing process develop successful grant proposals. If you are in need of a proposal development-related resource that is not listed, email the Office of Research to inquire.
    - Medical School Grant Proposal Sampler: This is a repository of sample proposal and proposal sections donated by Medical School faculty members. Its purpose is to offer insight into proposal development, including proposal writing (e.g., organization, detail), responding to reviewers' comments, sample sections, and tables.
    - NIH Fellowship Proposal Sampler: This is a repository of sample proposal and proposal sections donated by U-M graduate students, postdoctoral fellows and faculty members. Its purpose is to offer insight into proposal development.
    - Facility & Resource Profile Templates: Boilerplate descriptions of U-M units and resources that can be adapted for grant proposals.
    - Proposal Preparation Funding Program: The goal of the program is to provide funds to support the submission of multi-investigator grants. The funds may be utilized to offset the costs of hiring expert consultants; assembling and hosting brainstorming sessions; paying reviewers; or hiring temporary incremental secretarial, administrative, and/or expert services required to assemble and submit large proposals.

Tip

View the NIH Peer Review Process Revealed video to gain a better understanding of how your grant is evaluated. Also register for the MICHR Mock Study Section. Knowledge of the peer review process is essential to writing a strong application.

NIH Writing and Submission Resources

- NIAID Grant Submission Process Resources
- Tips for new grant applications from NIGMS
- Writing a grant: A technical checklist from NINDS
- Common mistakes in NIH applications from NINDS
- 10 Steps to a Winning R01 Application
- NIH Peer Review Process Explained
- The grant review process (NCI)
- NIH Research Career Development Awards
- NIH Application Processes and Guides
- SF424 application and electronic submission information

Tips for SBIR/STTR Grants

- SBIR/STTR policy and grantsmanship information
- Advice on SBIR/STTR applications from NIAID

Grant Writing Guides

- Focus on written communication skills: Collaborative Learning and Integrated Mentoring in the Biosciences at Northwestern University offers many resources designed to improve writing skills.

Literature

- Navigating Collaborative Grant Research

Performing Translational Research

MICHR

Drug Discovery

Drug discovery and development is a long process from target identification to clinical trials. All points along the pipeline require experts skilled in various disciplines and technologies. These resources aim to help you on your journey to discover new medicines.

Learning Resources

- Introduction to Drug Discovery Video: This video describes the basic stages of the drug discovery process, beginning with how disease targets are identified.
- From “Hit” to Pill Video: This video focuses on the later stages of the drug discovery process.

U-M Resources

- Michigan Drug Discovery: Michigan Drug Discovery is a university-spanning collaboration to find, fund and mentor drug discovery projects originating from faculty research across a sweeping range of disease areas including oncology, psychiatric disorders, cardiovascular disease and many more.
- Center for Chemical Genomics (CCG): The CCG provides high-throughput screening of extensive small molecule, natural product and siRNA libraries – along with assay development and optimization – for basic biology and drug discovery projects.
- Center for Structural Biology (CSB): A comprehensive structural biology resource for researchers at U-M and surrounding areas that houses a high-throughput protein laboratory, protein purification facilities, macromolecular crystallization and crystallography laboratories, and X-ray facilities.
- Pharmacokinetics and Mass Spectrometry Core: This core of services aim to facilitate researchers’ efforts to discover new medicines, obtain research funding, file patent applications, and publish academic research findings for both preclinical and clinical pharmacokinetic applications, including lead compound modeling, dose optimization, and clinical trials.
- Vahlteich Medicinal Chemistry Core: The VMCC is an on-campus core facility for the design and synthesis of drug-like molecules and diagnostic probes used in biomedical investigations.
- Biomedical Research Core Facilities: The Biomedical Research Core Facilities help researchers economically take advantage of our latest technology and collaborate with top experts in the field. Services include: consultation, sample preservation and archives, sample submission and analysis, and many more.

U-M Resources for Drug Discovery

- Michigan Drug Discovery Roadmap: From target discovery to clinical trials, many researchers and technology centers across the University of Michigan are involved in developing new therapeutics. Expert guidance, cutting-edge technological resources and funding are available to U-M investigators at every step along the path of innovation. This roadmap will help you find the resources and criteria for every stage of the drug discovery process.

Target Discovery | Screening | Hit-to-Lead | Lead Optimization | Preclinical Development | Clinical Trials

Additional Resources

- Assay Guidance Manual: This is a comprehensive, crucial resource for investigators optimizing assays to evaluate collections of molecules with the overall goal of developing probes that modulate the activity of biological targets, pathways or cellular phenotypes.
- National Center for Advancing Translational Sciences (NCATS) Repurposing Drugs: This initiative focuses on small molecules previously shelved from further development and on identifying new purposes for drugs that are FDA approved to treat one disease or condition.
- NCATS Tissue Chip for Drug Screening: The Tissue Chip for Drug Screening program aims to develop bioengineered devices to improve the process of predicting whether drugs will be safe or toxic in humans.
- NCATS Pharmaceutical Collection (NPC): The NPC is a comprehensive, publicly accessible collection of approved and investigational molecular entities for high-throughput screening that provides a valuable resource for both validating new models of disease and better understanding the molecular basis of disease pathology and intervention.
- SMARTCyp - Site of Metabolism prediction for Cytochrome P450s: SMARTCyp is a method for prediction of which sites in a molecule that are most liable to metabolism by Cytochrome P450.

- Academic Drug Discovery Consortium (ADDC): The goal of the ADDC is to build a collaborative network among the growing number of university-led drug discovery centers and programs. Their website allows scientists to exchange technical expertise on drug discovery and development strategies and form partnerships, and it serves as a repository for drug discovery events, educational material, job postings, and partnership opportunities.
- Society for Laboratory Automation and Screening (SLAS): Provides a wide array of relevant education, information, innovation and access to the world's largest network of professionals focused on leveraging technology for scientific advancement.
- eMolecules: A search engine for chemical molecules and chemical suppliers.
- PubChem: Provides information on the biological activities of small molecules.

Literature

- Impact of High-Throughput Screening in Biomedical Research
- How Were New Medicines Discovered?
- The Influence of Lead Discovery Strategies on the Properties of Drug Candidates
- Mining for Therapeutic Gold
- Experimental and Computational Approaches to Estimate Solubility and Permeability in Drug Discovery and Development Settings

Funding Opportunities

U-M

- Michigan Drug Discovery Early-Stage Grants: Twice per year, the Michigan Drug Discovery provides grant awards of up to $50,000 each for drug discovery research in all therapeutic areas.

NIH

- Discovery of in vivo Chemical Probes for Novel Brain Targets (R01)
- Discovery of Cell-based Chemical Probes for Novel Brain Targets (R21)
- National Cooperative Drug/Device Discovery/Development Groups for the Treatment of Mental or Substance Use Disorders or Alcohol Addition (U01)
- Bench Testing Therapeutic/Indication Pairing Strategies
- NCATS New Therapeutic Uses Funding Information

"Academic drug discovery is taking on a whole new character now, with technology and new partnerships between academia and industry and disease institutes and the government."

- James Inglese, NCATS, *Drug Discovery and Development: A Complex Team Sport*

Protocol Development

Every clinical trial requires a detailed document – a clinical trial protocol – describing how the study will be conducted. It contains much more information than the methods section from your grant and is a critical part of any well-structured study.

A clinical trials protocol is a detailed action plan that outlines how your study will be conducted. The purpose of the protocol is to ensure the safety of your study participants and protect the integrity of the data you collect. Protocols need to be approved by the IRB and may be required to be uploaded to ClinicalTrials.gov.

Effectively written protocols will:

- Provide critical background information about the study
- Specify study objectives, statistical methods and outcomes
- Describe in detail the study design and organization
- Ensure that study procedures are conducted in a consistent manner

A protocol includes detailed information about your objectives, study design, methodology (including inclusion and exclusion criteria), investigational product information, statistical methods, and data safety monitoring plans. Study sponsors and IRBs will have protocol templates that you will need to follow. Check with your department or Clinical Trial Support Unit (CTSU) for the template you should use.

NIH Required Protocol Sections

Title Page (including version and dates, sponsor name, monitor name, IND/IDE and/or IRB approval numbers	Human subjects protection plan
Précis (may include a list of abbreviations)	Privacy and confidentiality plans
Table of contents	Study agents/interventions
Background	Reporting requirements for adverse events
Study Objectives (included primary and secondary objectives)	Data and safety monitoring plan
Study design and methods	Data/record management
Inclusion & Exclusion criteria	Compensation
Clinical and laboratory methods	References
Collection and storage of human specimens or data	Appendices
Statistical analysis plan	

Learning Resources

Online Training

- ClinicalTrials.gov Training Materials
- The Study Protocol Parts I and II: This two-part course is designed to guide researchers through the basic stages and concepts surrounding the creation of a protocol.
- Fundamentals of Clinical Trials: This course will provide an introduction to the scientific, statistical, and ethical aspects of clinical trials research.

Protocol Templates

- NIH Protocol Template: In 2016 the NIH released a draft protocol template developed in collaboration with the US Food and Drug Administration (FDA), which will apply to NIH-funded Phase II and III clinical trials requiring investigational new drug application (IND) or investigational device exemption (IDE). The template is available in a guided .PDF format that includes instructions as well as blank template.
- National Institute of Dental and Craniofacial Research (NIDCR) Toolkit & Educational Materials: This resource contains protocol templates and other documents needed for study start-up.
- National Cancer Institute (NCI) Protocol Templates and Guidelines: NCI maintains an online resource of protocol templates for Phase I and II clinical trials to assist in design and development.
- The National Center for Complimentary and Integrative Health Clinical Research Toolbox: This resource includes templates, sample forms, and information materials to assist clinical investigators in the development and conduct of high-quality clinical research studies.
- Common Protocol Template from TransCelerate Biopharma, INC.: Working with industry stakeholders and regulators, TransCelerate Biopharma has created a model clinical trial protocol template that contains a common structure and model language.

Clinical Trials

No matter the size or complexity, running a clinical trial can be challenging. U-M has resources that can help along the way, including infrastructure for conducting clinical research protocols and programs that assist with participant recruitment.

A **Phase I** trial tests an experimental treatment on a small group of people, to judge its safety and side effects, and to find the correct drug dosage. Sometimes, the study is in healthy people.

A **Phase II** trial uses more people than a Phase I to find out if the experimental treatment is effective and safe.

A **Phase III** trial is usually a large study with many participants. This phase compares the experimental drug or procedure to a placebo or standard treatment to make sure it is safe and works well.

A **Phase IV** trial takes place after the U.S. Food and Drug Administration approves use of a drug. A drug's effectiveness and safety are monitored in large, diverse populations.

- NIH Medline Plus

Learning Resources

Workshops

- Methods in Clinical Cancer Research Workshop: An intensive workshop in the essentials of effective clinical trial designs of therapeutic interventions in the treatment of cancer. This workshop is intended for clinical fellow and junior faculty clinical researchers in all oncology subspecialties, including radiation and surgical oncology.

Human Subjects Protection

- FDA Clinical Trials and Human Subjects Protection: FDA regulations and guidance documents regarding good clinical practices and human subject protection.
- Clinical Research and the HIPAA Privacy Rule: This fact sheet discusses the Privacy Rule and its impact on covered entities that conduct clinical research.

Literature

- The Clinical Research Team: Developing and managing a clinical research team is essential to the success of a clinical trial.
- Clinical Investigator Responsibilities: When conducting a clinical trial, it is important to meet all research expectations, including Guidelines for Good Clinical Practice.
- Learning How to Conduct Cancer Clinical Trials: Information about a training opportunity that focuses on clinical trial design.

MICHR Resources

- MICHR Clinical Research Unit (MCRU): MCRU provides the clinical staff, resources, and infrastructure necessary to conduct human clinical research protocols at the University of Michigan. MCRU hosts investigators funded by federal, state, and local agencies as well as those funded by the private sector. MCRU also serves as an institutional resource for investigators to perform pilot studies that may result in further agency funding.
- MICHR Clinical Participant Recruitment Program Services: The MICHR Recruitment Program provides expertise, tools, and resources to facilitate participant recruitment in clinical and health research studies.
- UMHealthResearch.org: UMHealthResearch.org (previously UMClinicalStudies.org) is an innovative tool that connects research study teams to interested study participants. Study teams may query the database to specific inclusion/exclusion criteria based on participants' profile responses. Potential participants may review active study postings to assess their level of interest.
- Identifying your Recruitment Audience: Before you can create your recruitment plan and materials, you need to identify who is eligible to participate in your study.
- MICHR Biostatistics Group Services: This team provides state-of-the-art knowledge, service, education, and methodology in the areas of biostatistics and outcomes measurement.
- MICHR Study Management Mentoring: Study management mentoring services empower study teams to efficiently plan, initiate, and manage their research study using standard tools and best practices.
- MICHR Clinical Research Monitoring: MICHR's Monitoring program is committed to providing services for all IND/IDE investigator-initiated clinical trials as well as support for industry clinical trials as needed.

U-M Resources

- U-M Office of Research Clinical Trials Support Units (CTSUs) are business units that partner with investigators and their teams to ensure the timely and efficient activations and execution of clinical trials at U-M. CTSUs allow investigators to focus on their research and patients, instead of administrative tasks. All U-M CTSUs offer a Finance Lead, Contract & Grant Specialist, Project Coordinator, and Study Coordinator support. The seven U-M CTSUs are:

  - Acute, Critical Care, Surgery & Transplant CTSU provides specialized services in recruitment and enrollment for clinical trials conducted through EMS, Emergency Department, Transplant Center, Intensive Care, or Acute Inpatient hospital settings.
  - Ambulatory & Chronic Disease CTSU is the home for all chronic, non-ICU diseases in the adult population, excluding cancer and cardiovascular disease.
  - Behavior, Function & Pain CTSU represents investigators who conduct trials that involve behavioral interventions, or behavioral or biomedical trials, intended to impact outcomes in health behaviors, psychological states, maladaptive behaviors, physical function, psychosocial function, or pain.
  - Children's CTSU aims to continue growing the number of pediatric industry-sponsored trials, all while remaining focused on providing the safest clinical research environment for the children enrolled as participants.
  - Heart, Vessel, Blood CTSU enhances the performance of cardiovascular, coagulation, and nonmalignant hematologic clinical trials, including specializing in device trials and drug trials across the lifespan of acute and chronic disease.
  - Neurosciences & Sensory CTSU aims to provide a full range of services for investigators with clinical trials related to the skin or nervous system.
  - Oncology CTSU provides free services to support U-M's NCI oversight obligations: single-site monitoring of investigator-initiated trials, auditing, informatics and database development, protocol editing and committee support.

- U-M Rogel Cancer Center Clinical Trials: Helpful videos provide an introduction to clinical trials and information on participating in clinical trials and the informed consent process.
- Ravitz Foundation Phase 1 / Translational Research Center: This facility offers a comprehensive array of translational research resources to Cancer Center faculty and investigators at other academic institutions and pharmaceutical and biotechnology companies. The center is open to trials for all types of cancer.

Additional Resources

- ClinicalTrials.gov: This is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.
- CenterWatch: The CenterWatch mission is to be the leading source of clinical trials information for clinical research professionals and patients.
- Researchmatch: Researchmatch is a free and secure registry aimed at both people who are trying to find research studies and researchers who are looking for people to participate in their studies.

"Developing and maintaining an exemplary research team is essential to the success of a quality clinical research program. Functions such as regulatory compliance, protocol maintenance, patient care, tissue acquisition and transmittal, data collection and submission and general administration are among the many tasks on which quality research, protection of human subjects' rights, and advancement of science depend. No single individual could expect to fulfill all of these tasks."

- Allison Baer, *The Clinical Research Team*

Regulatory Support

Investigators need to meet numerous regulatory requirements when initiating a clinical trial. These resources will help you properly adhere to regulatory obligations so you can focus on translating your findings to the clinic.

Learning Resources: IND, IDE and IRB Information

- Investigational New Drug (IND) Screencasts: From the Duke Translational Medicine Institute, this is a series of recorded segments on topics relevant to IND Best Practices for Initial Submission and Maintenance.
- Investigational Device Exemption (IDE) Preparation and Maintenance Best Practices Video: From the Duke Translational Medicine Institute, this video contains information about best practice for preparation and maintenance of an IDE.
- FDA IND Application Overview and Resources
- FDA IDE Approval Process Overview
- Office for Human Research Protections (OHRP) FAQ: These FAQs provide guidance that represents OHRP's current thinking on these topics and should be viewed as recommendations, unless specific regulatory requirements are cited.
- Regulatory Guidance for Academic Research of Drugs and Devices – IND or Biologic FAQ
- IRB FAQs: An informational sheet providing guidance for IRBs from the FDA.

MICHR Resources

- MICHR IND/IDE Investigator Assistance Program (MIAP) Regulatory Services: The MIAP program was established to provide comprehensive regulatory support, guidance, and education services to faculty investigators involved in FDA-regulated clinical research at U-M. MIAP's primary focus is regulatory assistance to sponsor-investigators of a drugs, biologics, or medical devices.
    - Responsibilities of IND/IDE Sponsor Investigators
    - IND Decision Worksheet
    - IDE Decision Worksheet
    - Study Management Templates and Guidance
- Guidance for Investigators: Determining whether Human Research Studies can be Conducted without an IND

U-M Resources

- Institutional Review Boards of the University of Michigan Medical School (IRBMED): IRBMED is charged with protecting the rights and welfare of participants in clinical trials and other human subjects research studies. IRBMED is responsible for monitoring compliance with federal and state laws, university policies, and ethical principles (particularly those articulated in the Belmont Report).
- U-M IRB Collaborative (U-MIC) Human Subjects and IRB Procedures Resources: U-MIC provides both in-person and online resources to help guide investigators through various human subjects and IRB-related procedures.
- University of Michigan Office of Regulatory Affairs: The UMMS Office of Regulatory Affairs works to build and maintain a strong foundation of regulatory good-standing upon which the Medical School's missions can flourish. Their mission is to lead or facilitate the prevention or resolution of concerns, disputes, and compliance issues related to laws, regulations, institutional policies, accreditation/certification requirements, and other professionally accepted standards that impact the activities and reputation of the Medical School.

Tip

You may feel intimidated by the thought of meeting with the FDA to discuss the regulatory strategy for your drug or device. These meetings require careful planning and implementation. The MICHR MIAP team has extensive experience guiding meetings with the FDA and assists with all preparation and follow-up.

Clinical Data Management

The data you generate during a clinical trial needs to be reliable and statistically sound. Adhering to quality standards and practices as you collect, clean and manage your data will help ensure confidence in your conclusions.

Learning Resources

- Colorado Clinical & Translational Sciences Institute's Translational Informatics Seminar & Learning Tools
- Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule
- FDA 21 CFR Part 11: FDA guidelines on electronic records and signatures.
- Guidelines for Good Clinical Practice: International Conference on Harmonisation

Tip

Include a clinical data manager on your multidisciplinary clinical trial team. This person will provide expertise in all phases of your trial, including setup, conduct, and closeout.

MICHR Resources

- MICHR Research Management - Database Development: Skilled study developers and data management mentors work in partnership with study data managers and other clinical research professionals to design project databases built for efficient collection, management, and analysis of research data.
- MICHR Clinical Research Informatics Services: This team develops, enhances, and supports multiple clinical research IT applications. They are responsible for several initiatives that have the potential to transform U-M's clinical and translational research mission, including REDCap, OpenClinica Enterprise, and the Treatment Assignment Tool – University of Michigan (TATUM).
- REDCap training opportunities.

Entrepreneurship & Commercialization

MICHR

Entrepreneurship & Commercialization

It’s never too early to start thinking about the steps involved in translating your research findings to a commercial product. We highlight resources at U-M and in the state of Michigan that can offer you guidance.

Learning Resources

Clinical and Translational Science Institute of Southeast Wisconsin

The path from discovery to commercialization can be long. These training modules provide an introduction to the technology transfer process

- When is something of commercial value?
- How do I document discoveries?
- What is the patenting process?

Tip

In the United States, the patent applicant must be the inventor of the patent. Be sure to carefully document your invention from inception to patent to prove ownership.

U-M Resources

- U-M Drug Discovery partners with University of Michigan researchers to accelerate drug discovery by identifying, funding, and mentoring the most promising projects across the university.
- Business Engagement Center provides resources, counsel and connections for faculty and staff that facilitate industry partnerships and research funding.
- Center for Venture Capital & Private Equity offers research, teaching and practitioner programs to encourage the channeling of equity capital to build companies and to harvest and recycle capital in emerging fields.
- Fast Forward Medical Innovation (FFMI): FFMI offers resources and support to world-class biomedical researchers at U-M and across the state. FFMI's funding programs, dynamic educational offerings, and deep industry connections help researchers navigate the road to successful innovation and commercialization.
    - Idea Consultation: Meet with an FFMI commercialization expert to discuss your path to successful commercialization.
- Tech Transfer: Tech Transfer is responsible for the commercialization of inventions based on U-M intellectual property and is part of a campus-wide collaboration to create an environment that encourages exploration, discovery, innovation and risk-taking. Read Tech Transfer's FAQ or view of full list of their resources here.
- Innovate Blue: As U-M's hub for entrepreneurship and innovation, Innovate Blue helps turn ideas into action by supporting, connecting, and expanding the Michigan entrepreneurial network and community.

U-M Resources

- College of Engineering Center for Entrepreneurship (CFE): The CFE is an innovation hub where the ideas, people, resources, and technology meet and create the future. The CFE provides active learning experiences to all students and faculty at The University through classes and programs that are designed to teach the skills needed to successfully translate high-potential projects and ideas into the world.
    - Michigan I-Corps: Michigan I-Corps, offered by CFE, is a statewide program designed to foster, grow, and nurture a statewide innovation ecosystem.
    - TechArb Student Venture Accelerator: A joint program between CFE and Zell Lurie Institute for Entrepreneurial Studies, the TechArb Venture Accelerator program empowers U-M students to bring their ideas to life and build viable ventures in an intensive hands-on entrepreneurial education experience.

Additional Resources

- Ann Arbor SPARK: The mission of the Ann Arbor SPARK is to create a dynamic environment of entrepreneur-driven innovation within the Ann Arbor region by facilitating the commercialization of technology-based products and services. MichBio: As the association for Michigan's biosciences community, MichBio promotes cooperation between Michigan's bioscience-related businesses, forges stronger relationships, develops business-to-business opportunities, and serves as a united industry voice to promote a science-friendly environment.
- Michigan Venture Capital Association (MVCA): The MVCA consists of firms and professionals dedicated to the development, growth, and sustainability of Michigan's venture capital industry.
- BBC Entrepreneurial Training and Consulting: BBC assists clients with technology assessment, commercialization planning, pre- and post-award SBIR/STTR grant assistance, entrepreneurial training, grants/contracts management, and tech-based economic development programs.

Additional Resources

- Michigan Economic Development Corporation (MEDC): MEDC is a public-private partnership serving as the state's marketing arm and lead agency for business, talent and jobs, tourism, film and digital incentives, arts and cultural grants, and overall economic growth. MEDC offers a number of business assistance services and capital programs for business attraction and acceleration, economic gardening, entrepreneurship, strategic partnerships, talent enhancement, and urban and community development.
- National Center for Manufacturing Sciences (NCMS): In partnership with the MEDC, the NCMS is a cross-industry technology development consortium, dedicated to improving the competitiveness and strength of the U.S. industrial base. Members of NCMS benefit from an accelerated progression of idea creation through execution.

Funding Opportunities

- U-M Fast Forward Medical Innovation offers researchers a number of funding opportunities to help advance biomedical research projects.
- The Michigan Translational Research and Commercialization (MTRAC) Innovation Hub for Advanced Transportation: A statewide program that funds translational research applications in advanced transportation materials, robotics and autonomy, sensors, and advanced manufacturing processes. This innovation hub is jointly run by the U-M Center for Entrepreneurship and the U-M Office of Tech Transfer, in partnership with Michigan Economic Development Corporation.
- Michigan Emerging Technology Fund (ETF): Designed to expand funding opportunities for Michigan technology based companies, the ETF provides commercialization funding to match federal Small Business Innovation Research and Small Business Technology Transfer awards for technology-based Michigan companies.
- Accelerate Michigan Innovation Competition: This is an international business competition designed to bring together later stage entrepreneurial companies with local, national, and international investors.
- NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Funding Opportunities: These programs fund small business early stage R & D. The PI of the SBIR must have greater than 50% employment with the small business.

Additional Research Support

MICHR

Resource Sharing

The sharing of scientific resources is essential in an environment where investigators are challenged to do more with less. These resources will help you find many tools, from chemical probes to plasmids.

- Eagle-i: A free web-based resource discovery tool built to facilitate translational science research. Eagle-i users can
- NCI Clinical Center Collaborations & Assets: This site illustrates the special resources at the NIH Clinical Center and provides information about potential opportunities for collaboration.
- NCATS Pharmaceutical Collection: The NCATS Pharmaceutical Collection (NPC), also known as the NIH Chemical Genomics Center (NCGC) Pharmaceutical Collection, is a comprehensive, publicly accessible collection of approved and investigational molecular entities for high-throughput screening that provides a valuable resource for both validating new models of disease and better understanding the molecular basis of disease pathology and intervention.
- Bridging Interventional Development Gaps: Led by the NCATS Division of Pre-Clinical Innovation, BrIDGs makes available, on a competitive basis, certain critical resources needed for the development of new therapeutic agents. Successful applicants receive access to NIH contractors who conduct preclinical studies at no cost to the investigator. In general, synthesis, formulation, pharmacokinetic, and toxicology services in support of investigator-held investigational new drug (IND) applications to the FDA are available.
- NIH Molecular Libraries: The Molecular Libraries Screening Centers Network (MLSCN) is a national high-throughput biological screening resource that was launched on June 15, 2005. The goals of the MLSCN are to expand the availability and use of chemical probes to explore the function of genes, cells, and pathways in health and disease and to provide annotated information on the biological activities of compounds contained in the central Molecular Libraries Small Molecule Repository in a public database (PubChem).
- Addgene: A non-profit plasmid repository dedicated to helping scientists around the world share high-quality plasmids.
- CTSA Tool Shop Webinars: This webinar series focuses on a single tool each session, highlighting its features and benefits and how it can be transported and installed at another site.

U-M Core Services

It is impossible to be an expert in everything. U-M has numerous core services that provide the equipment and the know how for achieving your scientific goals.

U-M Core Services

- Core Facilities: The U-M Office of Research provides a comprehensive table of the U-M cores available to investigators.

Tip

The MICHR Pilot Grant Program has a Translational Technology Seed Grant that provides vouchers for core service support. Visit the MICHR Pilot Grant Program website for eligibility information.

U-M Seminars

Attending seminars is a great way to network and stay apprised of the latest research. Although not a comprehensive list, we highlight several standing U-M clinical research seminars.

U-M Clinical Seminars

- Frontiers in Cardiovascular Medicine
- Department of Internal Medicine Medical Grand Rounds
- Department of Psychiatry Grand Rounds
- OBGYN Grand Rounds
- Department of Radiology Grand Rounds
- Pediatrics & Communicable Diseases Grand Rounds
- Comprehensive Cancer Center Grand Rounds
- Kellogg Eye Center Grand Rounds

Attending seminars may not always be a priority, but their benefits can be far-ranging and include:

- Guidance for solving your own scientific challenges
- Learning about new techniques and procedures
- Opportunities for networking
- Exposure for you and your research
- Improving communication skills through asking questions and participating in discussions

- NIH Office of Intramural Training and Education

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While MICHR takes full responsibility for any shortcomings with the toolkit, we cannot take responsibility for any of its successes. Those successes are yours.

This is a working prototype.
To give feedback for the next edition of this toolkit and to let us know what you found useful, please email michr-rdc@umich.edu.