Research Resources Toolkit

Training and education resources to help study teams conducting human subjects health research

Introduction

Are you part of a human subjects health research study team? Are you new to research in general, or new to research at the University of Michigan? Do you have research experience, but are looking for a refresher?

This toolkit is for you. It will give you a broad overview of the steps needed to conduct human subjects health research. It also includes information on resources and offices across the University of Michigan that you may find helpful.

While this toolkit provides a general guide to best research practices, **it is not a comprehensive list of all the processes and resources needed. It is not intended to replace or substitute for any required research training from your department or the University of Michigan.** Remember, each research study is unique. While the information included here may not be relevant to all research studies, it will give you a good place to start.

If you have questions about MICHR Training & Education, this toolkit or have additional resources to suggest please contact MICHR Education. If you have questions about any of the resources provided, please contact the sponsoring office directly. MICHR is not responsible for the content of these resources.

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Prepare for Study Management

Planning your study

The research planning phase is vital to conducting high quality research. Before you begin collecting data, there are a number of steps to think about and prepare for.

Each research study is unique, with a different set of requirements, processes, and resources needed. The information included in this toolkit may not be relevant to all research studies, but it will give you a good place to start.

Remember to check with your mentor, department, the described research offices, or if you are working with a clinical trial in Michigan Medicine, the Clinical Trial Support Office to get additional guidance on requirements for your particular study.

Determine your IRB

What is it?

There are several Institutional Review Boards that oversee research at U-M. The board that oversees your research study will depend on which department houses your study and what type of research you are conducting. You will be prompted to select an IRB when you fill out your IRB application, which is required before starting human subjects health research.

Why is it important?

Selecting the correct IRB from the start will prevent delays in your review time.

Keep in mind:

If you are unsure which board to choose check the Research Ethics & Compliance webpage for guidance.

Resources:

Institutional Review Board – Medical School (IRBMED) The five Institutional Review Boards of the University of Michigan Medical School (IRBMED) oversee human subjects research conducted at Michigan Medicine.

IRB Health Sciences and Behavioral Sciences (HSBS) IRB-HSBS oversees human subjects research conducted at University of Michigan – Ann Arbor Campus. Starting in January 2019, this IRB also oversees research at the Dearborn campus.

U-M Flint Institutional Review Board Flint IRB oversees human subjects research conducted at the University of Michigan – Flint Campus.

Submit your IRB application

What is it?

For all human subjects research, you must fill out an application on eResearch so the Institutional Review Board (IRB) can make a determination if your study meets ethical and regulatory standards. This can be a lengthy process, but you can help by filling out the eResearch application as completely as possible and promptly answering questions from the IRB. Remember, the IRB and the eResearch process are there to protect your participants, the university and you.

Why is it important?

You can't begin any human subjects research study until you have IRB approval or an exemption from the IRB.

Keep in mind:

- It is helpful to introduce yourself to your IRB contact person early on in the process.
- Before you can complete your IRB application, it's helpful to have the following information and/or documents:

  ➢ Required training for all key personnel

  ➢ Outside disclosures and conflict of interest

  ➢ Study plan

  ➢ Recruitment plan and materials

  ➢ Informed consent document

  ➢ Incentives plan

  ➢ Data collection plan

 Resources:

eResearch The system you will use to submit your IRB application.

eResearch training and resource materials While filling out your IRB application there are tips in the system to explain how to fill out each question. If that doesn't provide enough clarification, there are additional training and resource materials. When in doubt contact your IRB and ask. They are there to help you ensure your research is ethical and your participants are safe.

Complete required training: PEERRS

What is it?

Before you begin your research the first step is to identify what required training you must complete as a Principal Investigator (PI) or other study team member. Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS) training may be required for participation on a study or project team, depending on your role (e.g., Principal Investigator), the funding source (e.g., NIH, NSF), and/or the type of research (e.g., human subjects). PEERRS certification is required for anyone conducting human subjects research.

Why is it important?

Documentation of successful completion of PEERRS for all key personnel is also required for IRB applications.

Keep in mind:

- You must renew your required PEERRS training every three years. PEERRS training includes multiple modules. Check their website to see which modules are required for your role on your study.

- If you are unsure if you, or someone on your study team, has up to date PEERRS training you can enter a U-M Uniqname on the PEERRS website to check certification status.

Resources:

PEERRS homepage This page will help you determine what training is required, link you to the correct training and allow you to check your certification status.

Complete required training: HIPAA

What is it?

The Health Insurance Portability and Accountability Act (HIPAA) privacy training is required for anyone with access to protected health information (PHI), whether they are an employee of Michigan Medicine or not. HIPAA training can be completed online. Check with your department for details on whether completing HIPAA training is required for your research.

Why is it important?

Not all human subjects research requires HIPAA training, but it is important to know before you start your project whether or not you will have access to PHI in your study to be in compliance with federal law.

Keep in mind:

HIPAA privacy training is required for both identifiable and de-identified data.

Resources:

[HIPAA training](#) HIPAA training for Michigan Medicine employees is available through MLearning. This site has HIPAA training for those who do not have access to MLearning.

[De-identified Data Sets](#) This page provides HIPAA-related guidance on de-identified data sets, applicable only to data based on Protected Health Information.

Complete required training: GCP

What is it?

Good Clinical Practice (GCP) from the International Council on Harmonization, is a standardized set of guidelines for clinical trials around the globe. Training on GCP is provided free to U-M employees through several avenues.

Why is it important?

U-M requires GCP training for any researcher working on an NIH sponsored clinical trial. Industry sponsors of clinical trials may also require GCP training.

Keep in mind:

- This training can be valuable for all researchers; even those not conducting clinical trials. GCP can provide important lessons for how to conduct high quality research even if some of the specific details would be implemented differently for other research contexts.

- There are many resources for GCP training and following GCP guidance. It is very important that you determine for your research what is required versus what is supplemental or can be adapted to meet your needs.

Resources:

HRPP Policy on GCP Training This is the U-M policy for who is required to have GCP training and what training meets the requirement.

Social and Behavioral Research Best Practices Training If you are conducting social or behavioral research, this course created by MICHR has tips for best practices. It will meet the GCP training requirement for social/behavioral clinical trials. It also includes downloadable job aids and resources that you can use throughout your research study.

Collaborative Institutional Training Initiative (CITI) This training is designed for biomedical clinical trials but may be of use to other types of research. To access the CITI GCP course, you must first create a CITI account (free) and affiliate with the University of Michigan within CITI. See the CITI step-by-step instructions for details

Disclosing outside interests & conflicts of interest

What is it?

Researchers need to disclose outside interests (which may include financial interests, foreign ties or volunteer positions) so they can be evaluated for potential conflicts of interest. Outside interest disclosures are a required part of an initial IRB application.

Why is it important?

If conflicts are not identified and managed properly the reliability of the research is diminished. Conflicts that are not properly disclosed have the potential to cause delays due to internal and external reviews that can keep your research suspended until the reviews close.

Keep in mind:

- There are different requirements for who needs to report, what they need to report, when they need to report and where they need to report depending on your department and type of research. Be sure to check with your department for more information.

- There is a PEERRS training on this topic that may be mandatory depending on your role. Other supplemental training is also available.

Resources:

U-M Office of Research Conflict of Interest Research Compliance Program- office that oversees all compliance related to outside interests at U-M

UMMS Conflict of Interest Board- reviews outside interests for Michigan Medicine faculty and staff

U-M Office of Research Conflict of Interest Committee- reviews outside interests for all Ann Arbor, Flint or Dearborn faculty and staff except Michigan Medicine

M-Inform Outside Interest Disclosure Instructions If you are required to disclose outside interests using the M-Inform system, this page has important information about reporting requirements and how to report within this system.

PEERRS- Depending on your role on the study team you may be required to take the PEERRS Conflict of Interest module.

Outside Interest Disclosure module- MICHR provides a supplemental module for clinical research outside of interest disclosures. This doesn't replace any mandatory training you may be required to take.

U-M Tutorial on Conflicts of Interest and Conflicts of Commitment (COI/COC) Supplemental training from the Provost's Office. This doesn't replace any mandatory training you may be required to take.

Develop your study plan (e.g. protocol)

What is it?

Do you have a protocol for your study? Maybe you have study procedure documents that you upload to eResearch? No matter what you call it, a document (or documents) that outline the processes, procedures, and guidelines for the execution and oversight of your research is necessary for every research study. Adhering to the procedures defined in your study plan is important for the success of your study.

Why is it important?

Remember that one of the key values of research is reproducibility. Someone should be able to look at your procedure documents and replicate exactly how you did your study.

Keep in mind:

Having a clear study plan is especially important if you have turnover on your study team or more than one person working on an aspect of your study to ensure that all data is collected in the same way.

Resources:

eResearch Site to submit your IRB application. Reviewing the sections of eResearch can help you understand the sections that will be needed for a quality study plan

Social Behavioral Trial Protocol Template NIH template for social and behavioral clinical trials

Clinical Trial Protocol Template NIH template for phase 2 and phase 3 drug and device clinical trials

Protocol Development, Finalization, and Maintenance Standard Practice Guideline A template for creating a standard practice guideline (SPG) also sometimes referred to as a Standard Operating Procedure (SOP), for creating and maintaining a quality protocol

Develop your recruitment plan & materials

What is it?

A recruitment plan includes information about who you are planning to recruit, how you plan to recruit, where and how many times you will contact participants for your study, and all your recruitment materials such as fliers, recruitment scripts, social media posts, letters, etc.

Why is it important?

If your study includes collecting data from people, you need to submit your recruitment plan and materials to the IRB before you can start contacting or talking to participants. Having a well-defined recruitment plan helps you reach your target recruitment number so you have enough data to test your hypotheses.

Keep in mind:

MICHR can help by providing the following services:

➢ Social media recruitment

➢ Creating recruitment materials

➢ Recruitment and retention strategy planning

➢ Budgets, letters of support for grant applications

➢ Community outreach

Resources:

MICHR Participant Recruitment Program The PR team helps researchers to create a recruitment plan, make professional looking recruitment materials, assist with using the recruitment platform UMHealthResearch.org and more. You can also Request a Participant Recruitment Consultation at no charge.

Participant Recruitment Toolkit This toolkit contains a host of information and links to resources that may be helpful as you recruit participants for your study.

MICHR Community Engagement Consultation If you need assistance planning how to engage participants from the community you can request this free 1-hour consultation.

Determine informed consent requirements

What is it?

If you are recruiting participants, one very important aspect is obtaining valid informed consent. Unless you have a waiver of written consent from the IRB, you will need to provide each participant with an IRB approved informed consent document and get their signature of voluntary participation before starting any study procedures.

Why is it important?

The informed consent process is an important ethical principle of research to give participants the autonomy to make an informed decision whether or not to participate. It is also necessary in helping participants understand how you will use the data you collect from them, who to contact if they have questions or problems related to the study, and how they can stop participation if they want to.

Keep in mind:

Remember that, even if you are granted IRB waivers of informed consent documentation, informed consent is a process you should use for all human subjects studies when you are recruiting participants. This includes giving IRB approved information to the participants about your study (including risks, benefits and what they are being asked to do), answering their questions, avoiding coercion, and ensuring your participant knows that their participation is voluntary. The process of informed consent is not a one-time conversation but should continue as long as the participant is part of your study.

Resources:

IRBMED Informed Consent Templates This includes not only the approved templates from IRBMED but also guidance and tips for the informed consent process.

IRB-HSBS Informed Consent Templates and Guidance This includes not only the approved templates from IRB-HSBS but also guidance and tips for the informed consent process.

Waivers of Informed Consent Guidelines Here you can find out more about what is required to request a waiver or alteration of informed consent or a waiver of documentation of informed consent.

Conducting and Obtaining Valid Informed Consent This workshop outlines the process of obtaining valid informed consent and will give you the opportunity to demonstrate necessary language and communication skills when interacting with potential study participants and their families. MICHR typically holds this workshop in the fall and spring.

Develop participant incentives plan

What is it?

Research participants often are paid a small sum or given a token gift for their participation in research projects. You must receive IRB approval to provide incentives to study participants. Once you have this approval, make sure you work with the Human Subjects Incentive Program (HSIP) to obtain your incentives and know what record keeping is required.

All incentives for study participants must come from the HSIP. This includes not only money but also gifts or small tokens such as chocolate, study related paraphernalia, or gift cards. If you are unsure that what you are planning counts as an incentive check with HSIP before submitting your IRB application.

Why is it important?

It's important that all incentives for participating in research are both ethical and made in accordance with all federal, state and university regulations.

Keep in mind:

Study team members responsible for participant incentives may need cash-handling training prior to using the HSIP system depending on departmental policy. Be sure to plan time for this during study start up so you can start recruiting participants as soon as you have IRB approval.

Resources:

Human Subjects Incentives Program HSIP is the unit that is responsible for all participant incentives.

U-M HRPP Operations Manual Part 7 – III Payments to Research Subjects Official U-M guidance regarding payments to participants.

U-M IRBMED – Guidance Regarding Payments to Subjects Guidance from IRBMED on acceptable levels of payment.

Determine a records storage plan

What is it?

Research records need to be retained after your study is complete. Sometimes you might also want to keep study data for future projects or keep participant contact information to let them know about study results. How long your records need to be kept and what format they need to be kept in depends on the type of study you are doing and your funding sponsor.

Why is it important?

Having adequate budget, physical space, electronic storage space and other resources for storing records after your study is complete is important to think about before you start collecting data. You will be asked questions in your IRB application about plans for records storage including whether data will be identifiable or de-identified.

Keep in mind:

- De-identified data means more than just removing participant names. More information about what is required to de-identify a data set is available from the Research from A-Z Gateway from the Medical School Office of Research.

- If you plan to use data for future projects or to maintain contact information for participants for additional communication of results, this needs to be disclosed to participants during the informed consent process.

Resources:

Record Keeping Guidelines Guideline from IRBMED for how long to keep records for different types of research.

De-identified data Information about de-identified data sets including the 18 identifiers that must be removed according to HIPAA and the separate definition of de-identified data in the Common Rule.

Archiving SPG A standard practice guideline template from MICHR that you can adapt for your research to document the long-term storage of records.

Consider data dissemination goals

What is it?

A big part of research is sharing generalizable knowledge outside of your study team. Data dissemination is often thought of as publication in academic journals. However, there are many other ways to disseminate your findings including to media outlets, community members, policy makers, research participants, and at academic conferences.

Why is it important?

Where you intend to publish or share your results may impact your study design and how you collect your data. Dissemination beyond academic journals may also require different decisions regarding study design and data collection. Ultimately, you cannot disseminate what you do not collect so it is best to plan ahead.

Keep in mind:

Some journals have requirements for how data is collected or how you analyze your data. Also, some publications may require that your study is registered on ClinicalTrials.gov. If you are doing a clinical study you may want to consult the International Committee of Medical Journal Editors (ICMJE) recommendations as a large majority of clinical publications follow these guidelines.

Resources:

ICJME Recommendations Guidelines for publishing in most clinical journals

Participant Recruitment Toolkit This toolkit has a section on dissemination and follow-up that includes different ways to disseminate your findings here at U-M.

Communicating Science Series A set of archived training sessions to help you communicate your research to the general public.

Engaging Scientists in Policy and Advocacy This group provides training to engage scientists in policy and advocacy.

U-M Public Engagement and Impact Initiative This new U-M focus area is providing support and tools for researchers to disseminate research and expertise to the public.

Determine ClinicalTrial.gov responsibilities

What is it?

ClinicalTrials.gov is a registry of clinical and health research that is sponsored by the United States National Library of Medicine at the National Institutes of Health.

Why is it important?

The goal of ClinicalTrials.gov is to create more transparency in research. If you're required to register on ClinicalTrials.gov, it has implications for other parts of your study including your study plan and informed consent. The implications for your study change over time so check the resources below for offices that can help you determine your current responsibilities.

Keep in mind:

- Not every study will be required to be listed on ClinicalTrials.gov. Which studies need to register is somewhat complicated and is not always limited to clinical trials. The U-M Office of Regulatory Affairs and the Office of Research Compliance Review are good resources for determining what your responsibilities are for your research.

- Even if you're not required to register, you can use the site to explore research related to your topic of study.

Resources:

Clinical Trials Registration and Results Reporting This webpage from the U-M Office of Research gives a general overview of Clinicaltrials.gov registration requirements. For more specific guidance the below two offices are recommended.

Office of Regulatory Affairs This office provides ClinicalTrials.gov training offerings open to anyone at U-M including training on whether your study needs to register. It is also the main resource for ClinicalTrials.gov in Michigan Medicine. Note that you need to sign in with a Level 1 password to access this site.

Office of Research Compliance Review This office is the main resource for ClinicalTrials.gov for campus units.

Create a data sharing plan

What is it?

This is a description of what data you will share at the end of your study. It also includes how, when, where and for how long you will share the data. Having a plan in place before you begin your study can help you collect data in a way that makes the process of sharing more efficient.

Why is it important?

There are many new regulations and guidelines requiring data sharing or a data sharing plan, including in ClinicalTrials.gov, as part of an increased focus on transparency and reproducibility in the scientific community.

Keep in mind:

Figuring out the best data sharing plan and the necessary rules and regulations can be complicated. The U-M Library has experts who can help.

Resources:

Data Sharing Resources and Policies This overview of data sharing is provided by the U-M Office of Research.

Library Research Data Services The library system, including the Taubman Health Sciences Library, has a suite of services to help with data sharing

IMPACT Series This series of training from MICHR about clinical trials includes a session on ClinicalTrials.gov and the latest information on data sharing plan requirements.

Consult relevant analysts

What is it?

In order to analyze your data, your study team may need an analyst. This could be someone already on your team or you may need to add someone who specializes in analysis. Depending on your type of research this role could be called a biostatistician, program evaluator, epidemiologist, etc.

Why is it important?

Analysts are not magicians. If you haven't collected the right data in the right way, they won't be able to fix it for you after the fact. If you are not an expert in statistics and you're planning to get help with analysis, talk with someone early in the grant planning process so that you can set up your data collection in the right way from the start.

Keep in mind:

Analysts can help determine what data needs to be collected and what format(s) to collect it in. They can also help determine how many participants you need for your study and how to address data issues related to participant withdrawal or missing data.

Resources:

CSCAR Consulting for Statistics, Computing and Analytics Research (CSCAR) provides consulting services and training opportunities in statistics, data science, and advanced research computation for all U-M researchers.

MIDAS The Michigan Institute for Data Science (MIDAS) partners with multiple U-M departments, schools and colleges to offer a wide range of data science education options.

MICHR Biostatistics Support The MICHR Biostatistics team is available for consultation and other biostatistical services throughout your research but recommend being contacted early in the process.

Create a data management plan

What is it?

A data management plan is a document, or collection of documents, that outlines the processes for managing data, the roles and responsibilities related to collecting and maintaining quality data and a description of the intended deliverables.

Why is it important?

In order to answer your study questions and complete required reporting during your study, you need to have reliable and timely data available throughout your study. Creating a data management plan early helps all members of your study team understand their role related to the data and how each piece works together to obtain the necessary data and maintain it with high quality.

Keep in mind:

The data management plan is a living document that should be updated as your study progresses especially if roles on your team change. You can learn more about data management plans and other data management tools in the MICHR online training Research Basics: Fundamentals of Data Management.

Resources:

Research Basics: Fundamentals of Data Management This online training is targeted for clinical research but provides information relevant to anyone collecting data from human subjects.

Data Management Planning The library can assist you with developing a data management plan specific to your research

MICHR Data Management Mentoring Data management mentors empower study teams to more efficiently collect and manage their research data by sharing data management tools and best practices. This service is free but fees may apply if you need additional assistance with creating databases or managing your data.

Finalize your data collection instruments

What is it?

Data collection instruments are called different things depending on the type of research you are doing (e.g. case report form, survey, etc.). In general, a data collection instrument is not only a place to gather your data, but also includes information about what data needs to be collected and how it should be collected.

Why is it important?

Whether you have one person or multiple people collecting data, it is important for data throughout your study to be collected in the same way. Having consistent data collection instruments and consistent implementation of those instruments is an important step in collecting reliable data that can be used to answer your study questions. It is also is important for reproducibility of the study findings.

Keep in mind:

Sometimes you will be using already established data collection instruments, previously validated scales or new measures that are created for your study. No matter where your instrument comes from it is important to test it with those who will be collecting the data and, if possible, with those who will be analyzing the data before taking it to your study participants. This allows you to either change the instrument or create additional guidance if the instrument isn't clear on how each data point should be interpreted and collected.

Resources:

Finding Test and Measurement Instruments This is a research guide from the U-M libraries about finding tests or measurements in the health or behavioral sciences.

Data Management Mentoring MICHR data management mentors can assist with design of case report forms

Determine electronic data capture & storage plan

What is it?

Before you begin collecting data you will need to decide where and how you will store it in a way that is secure and fits the parameters of your study.

Some options for data storage include: REDCap, Qualtrics, SPSS, Access and Nvivo Excel is also an option, but these files can easily become corrupted and may not be secure.

Why is it important?

If research data isn't stored properly and accurately you may encounter problems in answering your research question. Losing data or storing it improperly is not only bad for the study team, but is also unfair to the participants who gave their time and effort to the study.

Keep in mind:

- If you have PHI as part of your data you will need to check that your data storage plan is HIPAA compliant.

- REDcap is a highly secure option for data capture and storage with individual login capability to audit any changes made to the data. REDCap was designed primarily for clinical research studies, but it can be modified for use with other types of studies. Because of its focus on clinical studies, some of the features may not be useful for other types of studies.

Resources:

REDCap Database Environment This is the link to get access to REDCap at U-M.

REDCap Training Online training is available to help you learn how to use REDCap.

Qualtrics- Campus This is the campus Qualtrics Wiki page that gives you information and access to the campus version of Qualtrics.

Qualtrics- Michigan Medicine This is the Michigan Medicine Qualtrics Wiki page that gives you information and access to the Michigan Medicine version of Qualtrics.

HITS   If you need additional data storage or analysis software added to your computer this is the unit responsible in Michigan Medicine.

ITS If you need additional data storage or analysis software added to your computer this is the unit responsible on campus.

Training the study team

What is it?

The type of training study team members need will depend on their role(s) and might include:

➢ Participant recruitment and consent	➢ Data collection, maintenance, and storage
➢ Regulatory reporting	➢ Study-specific procedures and/or interactions
➢ Management and reporting of Adverse Events (AE), Serious Adverse Events (SAE), Unanticipated Adverse Device Effects (UADE), Unanticipated Problems (UaP), and other reportable occurrences	

Updated training may be needed to accommodate changes in the study plan, work process, use of new equipment or technology, or changes to who is on the study team.

Why is it important?

It is the principal investigator's (PI's) responsibility to oversee the activities of the study team, ensure all members are qualified for their roles, and provide training on the study protocol and related procedures. Regardless of your role, it is your responsibility to identify the training you need and seek out training resources.

Keep in mind:

▪ While training is vitally important to quality research, it is important to balance training with your other responsibilities. Get advice and/or permission from your mentor or supervisor before you begin training.

▪ In drug and device clinical trials, a training log is an essential document. However, keeping a record training record for is a best practice for all types of studies to ensure that responsibilities are being done by qualified study team members.

Resources:

Study Team Highlights Newsletter A monthly MICHR newsletter featuring training and resources across campus on research implementation and day to day study management.

IT4U webinars IT4U is a regular series of 30 to 45-minute interactive webinars and an archive of past webinars on topics like Google, Box, U-M Data Warehouse, accessibility tips, safe computing, videoconferencing, and more.

U-Mic The U-M IRBs have collaborated to provide online training. This training can be used regardless of what IRB you submit to.

Library Research Guides The U-M libraries offer guides on a wide range of topics including research resources.

Organizational Learning Provides access to online and in-person professional development training. While not specifically created for research training, many of the offerings teach skills useful for successful research.

Utilize MICHR training resources

What is it?

The Michigan Institute for Clinical & Health Research (MICHR) has a number of in-person and online training classes and resources to supplement your mandatory training.

Current topics include:

➢ PI Responsibilities (online)

➢ Research Basics (online)

➢ Conducting and Obtaining Valid Informed Consent (In-person)

➢ Statistics from 32,000 Feet (Parachute Included): A Gentle Introduction to Data Analyses (In-person)

➢ IMPACT (In-person)

Why is it important?

MICHR is here to support you in your research. MICHR provides training on key research implementation skills as well as pointing you to other resources across campus.

Keep in mind:

▪ If you want to stay informed about upcoming learning opportunities from MICHR and across campus, sign up for the Study Team Highlights Newsletter.

▪ MICHR services and resources are available to anyone across campus. Many, but not all, of these trainings are designed for clinical research but still provide information useful to anyone doing human subjects research.

Resources:

MICHR Education and Training Resources Online training classes and other online resources

MICHR Recurring Events In-person training classes that occur on a regular basis. Note that how often classes occur varies and you can always check the MICHR Events page for current offerings

Find training on the DIAMOND portal

What is it?

The DIAMOND portal is an online discovery learning space collection of clinical and translational training and assessment resources for clinical research professionals.

Why is it important?

The DIAMOND portal brings together training resources from all over the United States. Many of the resources are available online and are free of charge. This resource may help fill additional training needs for you and your study team.

Keep in mind:

- Click here to view a quick video about DIAMOND. Utilize the search features to narrow down to specific training topics or browse all trainings by competency domain for a bigger picture view.
- Resources on the DIAMOND portal can be used to supplement training available at U-M. The learning objectives and descriptions of items on DIAMOND are determined by the contributing institutions, not U-M.

Resources:

Diamond Portal An online training resource for clinical research professionals.

Develop standard practice guidelines

What is it?

Standard Practice Guidelines (SPGs), sometimes called Standard Operating Procedures (SOPs), are descriptions of the processes and procedures used to implement a research study that applies across multiple studies. These types of documents allow study teams to familiarize themselves with a defined way of doing a procedure or task. It's important that all study team members are trained on the relevant SPGs for their role.

Why is it important?

It is important to document the way procedures are implemented during a research study for consistency and reproducibility. Standard Practice Guidelines (SPGs) can promote adherence to your study plan and consistency in how study team members implement study procedures.

Keep in mind:

You should also document study specific procedures. A collection of procedure documents for a specific study is called a Manual of Procedures (MOP). Creating a MOP can help your study team stay organized and know exactly where to go to look for a procedure document when they need it.

Resources:

[Standard Practice Guideline Templates](#) While these templates are designed for drug and device trials, they also provide starting places for developing SPGs for any type of human subjects research.

[IMPACT Series](#) This series of training about clinical trials includes a session on procedures documentation that specifically focuses on manuals of procedure.

Document staff roles & responsibilities

What is it?

Principal Investigators (PIs) are responsible for ensuring that staff are adequately trained for their role. As part of this responsibility, it is important to document the roles and responsibilities of research study team members to know who is qualified to conduct study-specific tasks and who is currently responsible for each part of a research study. Study team roles and responsibilities may change throughout the course of your research. Documentation of these roles and responsibilities should be kept up to date accordingly.

Why is it important?

Documenting who is responsible, qualified and trained in each role and responsibility helps maintain safe and appropriate conduct for a research study, not only for drug and device clinical trials where this documentation is required, but for all types of research studies. It also helps with team communication and functioning if everyone is on the same page with roles and responsibilities.

Keep in mind:

Drug and device clinical trials use an essential document called a Delegation of Authority log. This template may be a helpful starting point even if you ultimately develop something different for other types of research.

Resources:

Delegation of Authority Log Template this template for drug and device clinical trials can be a starting point for adapting what will work for other types of research.

Organize your study documents

What is it?

Important study documents need to be kept secure and confidential. However, you should also make sure that the people who need them have access.

Common documents include:

➢ Most current version of study plan/protocol

➢ IRB correspondence including amendments, approval letters, initial application, etc.

➢ Procedures documents

➢ Staff roles and responsibilities

➢ Documentation of training

➢ Study contact list

Why is it important?

It's important to maintain an organized set of records so that anyone can find documents at a moment's notice. This prepares you for any study team changes or study reviews, such as an audit. Setting up a plan to organize documents before you start collecting data will help you keep up with study documents and changes to your study in real time.

Keep in mind:

The organization of study documents is often called a regulatory binder or study binder. However, your document organization can be done electronically, on paper, or both, as long as you can easily find what you're looking for and you are meeting any requirements for your type of research and/or from your funding sponsor.

Resources:

Study Management Templates and Guidance These templates are based on essential documents for drug and device clinical trials but many can be adapted for other types of research. The Regulatory Binder Templates can be a good starting place for organizing the study documents that are important for your study.

Dropbox This is U-Ms online storage and collaboration tool. This link provides access to Dropbox but also provides important information if you need to store sensitive data.

Utilize MICHR services & resources

What is it?

There are a number of services and resources MICHR provides that may be of use to you or your study team.

Some of the services include:

- ➢ Participant Recruitment Consultations and Toolkit
- ➢ Study Team Training
- ➢ Biostatistics
- ➢ Database Development
- ➢ Community Engagement Consultations
- ➢ Research Development Core Consultations

Why is it important?

Your study team does not need to be experts in every aspect of research. MICHR has a wide array of expertise that you can tap into.

Keep in mind:

Many MICHR services are free but some are fee for service. Be sure to plan for what services you need before you finalize your study budget.

Resources:

MICHR Services With some exceptions, this is where you will find ways that MICHR can help you with your research that require you to interact with someone at MICHR.

MICHR Resources With some exceptions, this is where you will find ways that MICHR can help you with your research that are self-service and can be used at your convenience.