Institutional Review Board (IRB)

Once you have completed your research proposal application and obtained approval from your program director you are ready to apply for IRB approval. If you are joining an ongoing project this may have already been done but it remains your responsibility to verify this. The best way to verify that IRB approval has been obtained is to request a copy of the letter from the IRB to the principal investigator (P.I.). You cannot start your study until IRB approval has been obtained or verified.

Your research proposal now needs to be expanded into a research plan/protocol. This research protocol is then submitted to the IRB for approval. Submissions to IRB’s are done by faculty (your faculty mentor signs the application and ultimately takes responsibility) but completing the necessary paperwork is likely to be your responsibility. A worksheet to help you organize your thinking and give you a step by step approach on bringing together these various components of a research protocol can be found in Appendices 6 and 7. This document should be reviewed by your faculty mentor and is an extension of the earlier proposal submitted. This research protocol should include a concise but more comprehensive overview of the relevant literature. It should contain in adequate detail the question to be addressed, the hypothesis to be tested, the study population(s) involved, the methods to be used, how data collection will occur and details about record keeping, and the analytic plan. It should contain the following elements:

- Title
- Abstract
- Specific Aims (list of main deliverables)
- Methods:
  o Subject recruitment and selection
  o Number of study subjects
  o Data collection (attach data collection forms)
  o Statistical methods:
    ▪ Data management (spreadsheet software, confidentiality procedures)
    ▪ Analysis methods to be used
    ▪ Statistical tests to be applied
    ▪ Sample size and power estimates for major study outcomes
- Expected Results
- References.
Depending on the type of research and the location where the research is being conducted there are different forms you need to complete. A list with the contact information for the IRB’s at different institutions can be found in Appendix 9 (still under development). If available, you will also find links to websites for the forms needed to be completed for the IRB application. You may need approval from the IRB at the institution where the research is being conducted, MWU’s IRB, or both (see subheading MWU/OPTI IRB Policy later in this section). Below you will find more detailed information regarding the reasons for IRB and its functions as well as the application process.

**More on MWU’s IRB and IRB’s in general:**

Each research institution (e.g. university, hospital) must have a review board to ensure compliance with federal regulation for the protection of research participants (humans as well as other animals). All research protocols need to be submitted to this Board which reviews and evaluates them. The submitted protocol can be exempt, approved, approved with revisions or denied. A first step should be to contact the individuals in charge of the IRB at the institution at which you are conducting the study. At some institutions this assistance is provided by an IRB coordinator. They can help you with determining what forms you need to complete and which type of review your study may receive (e.g. exempt, expedited or full review). Obtaining approval is a process and constitutes a dialogue between yourself and the Board. You can expect questions from the Board, as well as requests for clarifications and revisions.

[Image of Institutional Review Board (IRB)]

- **IRB functions to protect subjects in a study and to protect the organization.**
- **IRB’s are obligated to follow a code of federal regulations (45 CFR PART 46).**

The mission of the IRB is to ensure that studies are safe, ethical and purposeful. Its function is to protect the subjects in a study and to protect the organization by
ensuring that all research conducted by its faculty, researchers, students, etc adheres to all legal and ethical practices. There is a difference between your research protocol and the IRB application. Your research protocol will be part of the IRB application but this application will usually include more detail on the inclusion/exclusion of protected groups of people (i.e. underage, prisoners, pregnant women, etc), as well as detailed descriptions of the risks and the procedures used in the study to minimize risk. In your IRB application you will present a detailed study protocol including sections on the privacy of patient personal information (patient confidentiality) and (a) consent form(s) if needed written at an 8th grade reading level and using layman’s language (no medical jargon or if needed provide definitions in everyday language).

The Board is usually composed of basic scientists, clinicians, and a non-affiliated person representing patient interests. The make-up of the Board differs a bit at each institution but you certainly cannot assume that a specialist in your area sits on the Board. It thus becomes important to provide definitions and use clear and concise terms when discussing features that are important to the safety and efficacy of the study.

At MWU, the IRB has a detailed website and can be accessed at: https://www.midwestern.edu/orsp_-_home_/compliance/irbciti/iacuc/bio/rad/ire.html. All the required forms and detailed information on how to complete them can be found there as well. If you are unable to access the information on these internal webpages please contact the Office of Research and Sponsored Programs (Lindsay Goboly for AZ at AZORSP@midwestern.edu; for DG at ILORSP@midwestern.edu).

The MWU IRB homepage offers a description and outline of what a research protocol should include. There you will also find a template for the informed consent document as well as an example of a consent form for your review.

In order to receive IRB approval for your study you will first need to complete the online training in human subjects’ protection and earn the Certificate demonstrating that you have completed the appropriate training. This is part of the IRB approval process as well as necessary for approval of your research proposal by your Program Director. This online course provides an overview of: 1) events
leading up to the establishment of human subjects’ protection such as the Belmont Report, Declaration of Helsinki and The Nuremburg Code; 2) the important components of the consent form and study design which when incorporated in your proposal will address those issues the IRB is most concerned with. Details about this online training and website information can be found earlier in this manual in the section on Certificate of Protection of Human Research Participants.

MWU/OPTI IRB Policy

The MWU/OPTI does not operate its own IRB, and therefore it relies on the IRB reviews provided by Participating Partner institutions with a Federal Wide Assurance (FWA). The Participating Partner institution where specific research is performed may provide IRB review, or the MWU IRB may review MWU/OPTI research proposals to ensure that research involving human subjects meets all regulations in 45 CFR Part 46. In some circumstances, dual IRB reviews may be required to remain compliant with the appropriate IRB policies of the institutions involved. MWU will not require performance of a dual review provided that all of the following conditions are met:
The research is conducted at an institution with an Office for Protection of Research Risks (OPRR) approved Multiple Project Assurance (MPA) or Federal Wide Assurance (FWA)

The primary appointment of the principal investigator (PI) is with the Participating institution

MWU is not the primary recipient of funding

Research is conducted entirely at the other site

If any of these conditions are not met, the research proposal must be submitted to the University's IRB for review and approval.

Program Directors and Directors of Medical Education are responsible for ensuring that no research involving human subjects is initiated without the prior IRB approval appropriate for each research project.

The MWU website has everything necessary to successfully complete an application: checklist and copies of needed forms, proposal requirements, sample proposals, sample consent forms, link to the research compliance course, and the email address it gets sent to. The homepage is quite thorough and easy to navigate. Obtain access at: https://www.midwestern.edu/orsp_-__home__.html. If you do not have MWU access to this information please contact the Office of Research and Sponsored Programs, for AZ AZORSP@midwestern.edu, for DG ILORSP@midwestern.edu.
It is best to apply for IRB approval early. Be prepared for the request of revisions to your proposal, or the need to answer particular questions posed by the Board. As mentioned earlier, completion of an on-line compliance course (course in the protection of human research subjects) is a requirement.