Guidelines and Information for IRB Protocol Submission and Review

The purpose of this document is to outline the process of human subject research application submission and review, as conducted by the Midwestern University-Glendale Campus Institutional Review Board.

**INVESTIGATIONS IN HUMAN SUBJECTS MAY NOT BE INITIATED WITHOUT PRIOR REVIEW BY THE INSTITUTIONAL REVIEW BOARD.**

Please note: investigations of curricula, pedagogical methods, or other educational practices ARE CONSIDERED TO BE HUMAN SUBJECTS RESEARCH and must receive IRB approval prior to data collection.

I. Application Submission

A. Is it Research? To be determined by the IRB

The Office of Human Research Protection, Title 45CFR, Part 46.102(d), defines research as any systematic investigation designed to develop or contribute to generalizable knowledge.

B. Is it Human Subjects Research? To be determined by the IRB

The Office of Human Research Protection, Title 45CFR, Part 46.102(f) describes human subjects' research as any activity involved with obtaining information about living individuals or any activity that involves an intervention or interaction with individuals.

C. IRB Forms

All IRB forms can be found on the MWU Intranet site under the “Administrative”, “ORSP” tab. Please note, all forms will be held to the same grammatical standards as internal and external grant applications.

Form A Application: To be filed for new projects.

Form A1 Annual Report: To be filed for annual review of approved protocols

D. IRB Training Expectations
Training materials are available for all personnel involved in human subject research, including, but not limited to: principal investigators, researchers, research assistants, students, and IRB members. Various training materials can be found in the ORSP office. A list of training resources can be located on Appendix A of this document.

All personnel involved in human subject research must have a Protecting Human Research Participants training certificate on file with the ORSP, a link to this training provided by the National Institutes of Health can be found in Appendix A. NIH Protecting Human Research Participants training must be retaken every 3 years. Collaborative Institutional Training Initiative (CITI) training is not accepted by the IRB as a replacement for the NIH’s Protecting Human Research Participants training.

E. IRB Application Expectations

Forms must be prepared and submitted electronically. Upon approval of the application, they must include the signatures of all requested parties. As these documents must be available for external review and thus are a reflection of the PI’s and Midwestern University’s competency, it is requested that the PI ensures that proper formatting, composition, and grammar is maintained on all forms.

F. Submitting Application’s

Completed applications must be submitted to the ORSP in Glendale Hall 211. Electronic application submissions to the ORSP research coordinator are required (email them to: azorsp@midwestern.edu). These application’s should also be accompanied with training documentation for all personnel involved and a signed and dated curriculum vita for the principal investigator. If Protecting Human Research Participants training documentation has been provided previously for any given personnel listed on the protocol, duplicate documentation will not be necessary. Curriculum vitas will be on file with the IRB coordinator for 1 year from the date listed on the most recently received curriculum vita and will not need to be resubmitted during that year for any new applications submitted by the PI. The PI will be requested to submit a new curriculum vita for any new application’s they submit to the IRB which fall outside of the 1 year mark of their last IRB approval.

G. IRB Meeting Schedule

Scheduled monthly meeting dates can be identified by calling the ORSP research coordinator at 623-572-3728.

II. Application Review

New Applications

All new applications must be submitted by the 15th day of the month prior to the month in which the application will be reviewed (e.g., an application is due on August 15th for it to be reviewed in the September meeting). Upon submission, the application will undergo a pre-review process by the IRB coordinator and the chair to assure that the protocol has no outstanding human welfare concerns or other issues. The pre-review process must be completed and the final application must be submitted to the ORSP office no later than the 1st day of the month in which the application will be reviewed (e.g., September 1st in the example given above). Following final submission, applications will be handled by one of the following mechanisms:

Full Committee Review (FCR)
This process will be used for protocols involving more than minimal risk. In addition, a subset of applications will be randomly selected to go to FCR for IRB training purposes. Each member of the IRB will review the application to ensure compliance with the all Office of Human Research Protection policies. Based on the discussion in the convened meeting, the following actions can be taken by a simple majority of the committee quorum in reference to the application:

1) Approve
2) Require modification via Designated Member Review (DMR)
3) Require modification via FCR
4) Withhold Approval

Designated Member Review (DMR)

This review option can be used for any application’s not requiring FCR. Additionally, DMR can be used subsequent to FCR to ensure that required modifications have been made prior to approval. This process allows the IRB to review the application and approve of the DMR process prior to proceeding. The designated reviewers, chosen by the chair, will directly oversee the revision process and application approval and make the final approval decision.

Exempt Review

Exempt review is applicable to studies involving minimal risk. Exempt review means the application is exempt from full review and can be administratively approved by the chair.

Protocol Amendments

In the amendment process, the applicant should directly amend their most recently approved application. All new text written (i.e., the amendment) should be marked (underlined, highlighted, etc.) to allow reviewers easy discernment of the amendment. Additionally, the applicant should include a cover letter explaining why the amendment was made.

Upon receipt of the amended application, the chair of the IRB will determine if the amended application has undergone a significant revision or not. If not, depending upon the judgment of the chair, the amended application can be approved by the chair, via FCR, or DMR.

III. Post Approval Monitoring

A. Annual Reviews

One month prior to the anniversary of the date of the protocol’s approval, an annual review will be requested. The PI must submit a Form A1 to the ORSP research coordinator. This will be reviewed by the chair. This annual review must be submitted for each year of the application’s existence. Final reports will be reviewed and approved by the IRB chair.
APPENDIX A

Resources

All resources can be found online or in the Office of Research and Sponsored Programs, unless otherwise noted.

Books
Behind Closed Doors: IRBs and the Making of Ethical Research
   By: Laura Stark
Institutional Review Board Member Handbook (2nd Edition)
   By: Robert J. Amdur & Elizabeth A. Bankert

CDs/DVDs
Midwestern Faculty Development Series: Human Studies Research by Dr. Kaufman (55mins.)
   -This is available online at
   -This is also available in the library

Websites
Protecting Human Research Participants (Training site)  http://phrp.nihtraining.com/users/login.php

Collaborative Institutional Training Initiative (CITI)  https://www.citiprogram.org/