GUIDELINES FOR INVESTIGATORS IN PREPARATION

FOR COURSE-BASED AND NON-COURSE-BASED RESEARCH

All research at Missouri Baptist University must comply with U.S. federal regulations regarding protection of human subjects participating in research studies. The following website contains these regulations: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

The MBU Institutional Review Board (IRB) is responsible for ensuring that all research conducted at MBU meets the ethical standards required by these government regulations. IRB approval is needed before a researcher collects any data, including pilot data. The only categories of research that do not need IRB approval include literature reviews and hypothetical research designs that will not actually be conducted. IRB approval for course-based research projects will be obtained by the faculty member teaching the course through submission of the syllabus containing a detailed description of the required research projects. Faculty members receive face-to-face training in appropriate research protocol by the chairperson of the IRB and/or a designee from the IRB. Certificates on file are valid for two years. Faculty members may also obtain online training at the following website: http://phrp.nihtraining.com/users/login.php

Course-Based Research

Students who are required to conduct course-based research at MBU must complete the **IRB Form for Course-Based Research Projects** and submit the form to the instructor. These research activities are supervised by the instructor, an MBU faculty member who has received training in appropriate research protocol. The instructor determines the appropriateness of the research proposed by the students in the course. If the instructor is uncertain that the proposal meets the criteria for appropriate research (research that would be considered exempt by the IRB), he or she may reject the proposal as unsuitable for a course-based research project or have the student submit the IRB Form for Non-Course-Based Research. Research activities in which the only involvement of human subjects falls under one or more of the categories identified in federal regulations under 45 CFR 46.101(b) qualify as exempt. Exempt research projects do not require continued IRB monitoring, but they should be monitored by the faculty member. If the instructor approves the proposal as is, he or she signs the **IRB Form for Course-Based Research Projects**, signifying that the study is exempt. The student may begin the collection of data. Approved forms must be sent to the IRB Office for filing at Main Campus, c/o Ed.D. Office, One College Park Drive, St. Louis, MO 63141. The student must place a copy of the completed form in the appendices of the study.

Non-Course-Based Research

Doctoral students, who are required to conduct a dissertation, and other individuals who wish to conduct research intended for publication must complete the full IRB form, **IRB Form**

for Non-Course-Based Research. This research must be submitted to the IRB and approval must be obtained before any data are collected. Doctoral research is completed under the supervision of the Dissertation Committee, and all other non-course-based research is completed under the supervision of the Department Chair or Research Advisor. Supervisors of non-course-based research must have completed the online training found at the following website: http://phrp.nihtraining.com/users/login.php

The supervisor of the research must sign the **IRB Form for Non-Course-Based Research** and make a recommendation regarding exemption. The recommendation may be: (a) meets the criteria for exemption, (b) does not meet the requirement for exemption, or (c) may meet the criteria for exemption. Only the IRB can determine if the study is exempt.

An exempt study submitted by the supervisor of the research may receive an expedited review and obtain approval by the IRB chairperson or his or her IRB designee. Upon approval, correspondence is prepared and sent to the supervisor of the study. The supervisor communicates the IRB decision to the researcher, and data collection can begin. Continued monitoring of the study is not required by the IRB.

An uncertain or non-exempt study must be reviewed by the full IRB. One of three possible decisions will be made: (a) full approval, (b) contingent approval, or (c) disapproval. For full approval or disapproval, correspondence is prepared, signed by the IRB chairperson or his or her designee, and sent to the supervisor of the study. The supervisor communicates the IRB decision to the researcher. If full IRB approval has been obtained, the researcher may begin the process of data collection. Non-exempt research requires continued annual monitoring by the IRB. For contingent approval, the researcher must respond to the contingencies and resubmit to the IRB.

After IRB approval has been obtained, changes may not be made to the research protocol without permission from the IRB. Minor changes may receive expedited IRB review; however, changes that affect the risk/benefit ratio may require full review. Implementation of the change must not occur until approval from the IRB has been received.