HERZING UNIVERSITY

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Herzing University
Institutional Review Board Bylaws

The Herzing University Institutional Review Board (hereinafter called "IRB") is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Herzing University (hereinafter called "University") or involving any University student, faculty, staff, or administrator as either the researcher or subject for any study in which the University is affiliated. The IRB is responsible for reviewing all research involving human subjects conducted at the university or by faculty, staff, and students affiliated with the University in order to ensure compliance with and fulfillment of: (1) the policies contained in the IRB document entitled "Guidelines for Researchers;" (2) the U.S. Department of Health and Human Services Office of Human Research Protections' *Institutional Review Board Guidebook* (hereafter, HHS OHRP *IRB Guidelines*); and (3) federal and state regulations related to research with human subjects.

1. The Board

A. Membership and Appointment: The IRB shall consist of the IRB Chair and a minimum of four (4) and a maximum of eight (8) voting members. The Provost may appoint alternates who serve in an advisory, non-voting status unless elevated to be a voting member. Such elevation may occur when voting members recuse themselves for conflict of interest when additional members are needed for a quorum or if all non-science members are absent. Responsibility for appointing the IRB Chair and IRB members and alternates rests with the Herzing University Provost in consultation with the Dean of Graduate Programs and the Division Directors/Chairs. In compliance with OHRP regulations, the membership represents the breadth of scientific and scholarly specialties at the university, and at least one member whose primary concerns are in a non-scientific area and at least one member who is otherwise currently unaffiliated with the university must make up the IRB membership. Appointments are for two years and are renewable. Appointments are staggered to assure committee continuity.

The IRB Chair and all IRB members serve at the pleasure of the Provost and may be removed from service at any time by the Provost for failure to complete required IRB training and certification, attend stated IRB meetings, otherwise fail to fulfill the oversight obligations of Board membership; or on the recommendation to the Provost by majority vote of the Board.

Any member of the university community who would like to serve on the IRB is directed to indicate his/her interest to his/her Program Chair, Division Director/Chair or Campus Academic Dean.

B. Duties of Members:

- Attend Board meetings
- Review and evaluate all assigned protocols in advance of each meeting
- If designated by the IRB Chair, review protocols eligible for expedited review
- Serve on *ad hoc* taskforces of the Board
- Complete CITI and/or other approved IRB member training for human subjects research

2. The Chair

A. Appointment: The Provost appoints the IRB Chair for a renewable one-year term. The Chair serves at the pleasure of the Provost and may be removed from service at any time by the Provost for failure to complete required IRB training and certification, attend stated IRB meetings, otherwise fail to fulfill the oversight obligations of Board membership; or on the recommendation to the Provost by majority vote of the Board.

B. Duties of the IRB Chair:

- Serves as the IRB Executive Officer and is the IRB Liaison with the Office of the Provost
- Oversees and monitors the activities of the IRB Administrator to assure IRB records compliance
- Chairs all stated and special IRB sessions. If the Chair is unable to attend any meeting, he/she shall appoint, when possible, a substitute from the Board membership. If such appointment has not been made, the IRB members present shall select a voting member of the group to serve as Chair Pro-Tem for that meeting
- Votes and performs all other functions of an IRB member
- Reviews all incoming applications and determines if the application is exempt, eligible for expedited review, or requires a full IRB review
- Either evaluates any application(s) eligible for expedited review or assigns such evaluation(s) to another voting IRB member
- Has the authority to temporarily suspend research that is not in compliance with IRB guidelines and report that suspension to the Office of the Provost
- Has the authority to authorize emergency changes to a protocol to avoid an immediate hazard to subjects and report such changes to the Office of the Provost
- Is the point of collection for all notices of "Unanticipated Problems and Adverse Effects"
- Participates in or designates others to participate in sessions designed to inform and educate University faculty, staff, and students about IRB responsibilities and activities
- Stays informed regarding the latest changes in federal and state guidelines for research with human subjects and communicates that information to other IRB members and to the University community
- Shall appoint and oversee the activities of any needed *ad hoc* Taskforce
- Authorize payment and report on all honoraria, stipends and other IRB-related expenses
- Perform all other duties necessary for efficient IRB operations

3. The IRB Administrator

A. Appointment: Under the terms of the university's current Federal wide Assurance, the Provost shall appoint the IRB Administrator in consultation with the IRB Chair. The IRB Administrator serves at the pleasure of the Provost and may be removed from service at any time by the Provost for failure to complete required IRB training and certification, otherwise fail to fulfill the oversight obligations of Board membership; or on the recommendation to the Provost by majority vote of the Board.

B. Duties of the IRB Administrator:

- Keep current on federal and state guidelines for research with human subjects and communicate that information to the IRB Chair, the IRB members, and to faculty, staff, and students who do human subjects research
- Complete IRB Administrator training
- Organize and participate in educational activities related to IRB policies and procedures

- Post IRB guidelines, forms, minutes, logs, and related materials electronically
- Maintain records for all protocols
- Distribute protocols appropriately to IRB members
- Post meeting notices to the University community
- Archive IRB correspondence, guidelines, forms, minutes, logs, human research training certificates, and all other relevant information
- Participate in on-site reviews by federal inspectors
- Provide assurances to federal agencies of approval of protocols to be supported by federal funds
- Assist the Chair in processing honoraria, stipends and other IRB-related expenses
- Act as liaison between federal agencies and investigators regarding human subjects issues
- Submit an annual report on IRB activities to the IRB Chair and Provost

4. Special Consultants:

A. Appointment: The IRB Chair may designate a consultant with special expertise to assist in the review of a particular protocol and authorize payment for such consultation services. The consultant does not vote on protocols. The contract ends when the protocol review has been completed.

5. Meetings

A. Stated Meetings: The IRB Stated Meetings shall be held in the second week of every 8-week term. Dates, times, meeting place, call-in numbers and deadlines will be announced university-wide by the IRB Administrator.

B. Special Meetings: The IRB Chair may call a special meeting if needed. The same quorum and attendance requirements shall be maintained as in any Stated Meeting. All business of the IRB may be conducted at a Special Meeting.

C. Agenda: The Board will discuss and act on all protocols as well as conduct other business on the agenda.

D. Voting: A quorum, consisting of one more than one-half the IRB membership (including a nonscientist member) is required to conduct business. A majority of those voting is required for Board action. If a vote is not unanimous, a roll call vote must be taken and recorded in the formal minutes, listing the name of each member and how they voted.

E. Minutes: Minutes shall be kept in accordance with OHRP guidelines. The minutes shall reflect the substance of all discussions. Minutes are distributed to members via email before the meeting for additions and corrections. The minutes will be archived for audit by the IRB Administrator and notice of actions will be posted to the university community.

6. Action on Research Proposals

A. Full Review: The IRB shall review research proposals that require full Board review and shall periodically conduct ongoing review of approved research projects.

B. Expedited Review: The Chair may review and approve proposals that involve no more than minimal risk to the subject(s) or involve minor changes in previously approved proposals. Also, such review and approval may be conducted by one or more experienced members of the board designated by the Chair.

C. Exempt Research: Researchers may submit protocols that they believe may be exempt from either expedited review by the IRB Chair/designee or a full IRB review. That determination will be made by the IRB Chair/designee. The research may not go forward until the approved, in writing, by the IRB Chair.

D. Adverse Consequences/Unanticipated Effects: If adverse consequences or unanticipated side effects are encountered in the course of the study, or new information becomes available that could change the perception of a favorable risk/benefit ratio, the principal investigator is responsible for informing the IRB Chair **promptly**. The IRB will make the final determination regarding any protocol changes that may be required due to such a report.

E. Administrative Restrictions and/or Disapproval: Research that has been reviewed and approved by an IRB may be subject to further review and administrative restrictions. Upon further review, the research protocol may be disapproved by Herzing University officials. Herzing University officials may not, however, approve research if it has been disapproved by the IRB. (HHS OHRP *IRB Guideline,* 3)

F. Continuing Review: Approved research is subject to continuing IRB review and must be reevaluated at least annually. (HHS OHRP, *IRB Guidelines,* 3)

7. Changes to the Guidelines and Bylaws

Changes to the guidelines that are mandated by the federal government or other regulatory agency or accreditor will be made, effectively immediately upon passage.

Changes to local IRB regulations and changes to the bylaws must be adopted by a majority of the Board and approved by the Provost. Prior to final approval, the Provost will inform the university community of the proposed changes and a ten (10) day period of comment will be invited. Notice will be given to any research underway that may be impacted by such change.

As changes to rules, regulations, or operating procedures become necessary, they will be posted by the IRB Administrator on the IRB Website and also made available in the *Faculty Handbook*.