HERZING UNIVERSITY

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Herzing University
Institutional Review Board Bylaws

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of individuals participating in research associated with Herzing University. This includes any study conducted by, or involving, University students, faculty, staff, or administrators.

The IRB reviews all research involving human subjects to ensure compliance with federal and state regulations, including the U.S. Department of Health and Human Services (HHS) Code of Federal Regulations under 45 CFR 46 (the 2018 Common Rule). Its primary responsibility is to safeguard participants and uphold ethical standards in all University-affiliated research.

1. The Institutional Review Board

A. IRB Membership (45 CFR 46.107)

The Institutional Review Board (IRB) shall consist of at least five members, including the IRB Chair. The Chief Academic Officer (CAO) may appoint alternate members who serve in a non-voting, advisory capacity. Alternates may be elevated to voting status when necessary, such as when voting members recuse themselves due to conflicts of interest, when additional members are needed to meet quorum requirements, or when all non-scientific members are absent.

The CAO, in consultation with graduate program leaders, is responsible for appointing the IRB Chair, voting members, and alternates. In accordance with the HHS 2018 Common Rule, IRB membership must reflect a broad range of scientific and scholarly expertise. The Board must include at least one member whose primary concerns are in a non-scientific area and at least one member who is unaffiliated with Herzing University.

Appointments are for two years and may be renewed. Terms are staggered to ensure continuity of the Board.

All IRB members, including the Chair, serve at the discretion of the CAO and may be removed for reasons such as failure to complete required IRB training and certification, lack of attendance at scheduled meetings, failure to fulfill oversight responsibilities, or by majority vote of the Board with recommendation to the CAO.

Members of the University community interested in serving on the IRB should express their interest to their Program Chair or academic leader.

B. IRB Member Responsibilities

- Attend and actively participate in all scheduled Board meetings.
- Review and evaluate assigned protocols prior to each meeting to ensure thorough preparation.
- Conduct expedited reviews when designated by the IRB Chair, following applicable guidelines.
- Serve on ad hoc taskforces as needed to address specific Board initiatives or issues.
- Complete and maintain required training (e.g., CITI or other approved programs) on human subjects research in accordance with institutional and federal requirements.

2. The IRB Chair

A. Appointment

The CAO appoints the IRB Chair for a renewable two-year term. The Chair may be removed by the CAO at any time for any of the following reasons:

- Failure to complete required IRB training and certification
- Failure to attend scheduled IRB meetings
- Failure to fulfill the oversight responsibilities of Board membership
- Recommendation for removal by a majority vote of the Board

B. IRB Chair Responsibilities

- Oversee and monitor the IRB Administrator to ensure compliance with IRB record-keeping requirements.
- Ensure at least one IRB meeting is held annually.
- Chair all regular and special IRB sessions. If unable to attend, appoint a substitute from the Board membership. If no appointment is made, the members present shall select a voting member to serve as Chair Pro-Tem.
- Vote and perform all other functions of an IRB member.
- Review all incoming applications to determine if they are exempt, eligible for expedited review, or require full IRB review.
- Evaluate applications eligible for expedited review or assign them to another voting IRB member.
- Suspend research that does not comply with IRB guidelines and report the suspension to the CAO.
- Authorize emergency protocol changes to avoid immediate hazards to subjects and report such changes to the CAO.
- Serve as the point of contact for all notices of unanticipated problems and adverse effects.

- Participate in, or designate others to participate in, sessions that inform and educate University faculty, staff, and students about IRB responsibilities and activities.
- Review the latest federal and state guidelines for research with human subjects and communicate updates to IRB members and the University community.
- Appoint and oversee any ad hoc task forces as needed.
- Authorize and report all honoraria, stipends, and other IRB-related expenses.
- Perform all other duties necessary for efficient IRB operations.

3. The IRB Administrator

A. Appointment

The CAO, in consultation with the IRB Chair, shall appoint the IRB Administrator.

The IRB Administrator serves at the discretion of the CAO and may be removed under any of the following conditions:

- Failure to complete required IRB training and certification;
- Failure to fulfill the oversight obligations of Board membership; or
- Recommendation for removal by a majority vote of the Board.

B. IRB Administrator Responsibilities

Compliance and Communication

- Stay current on federal and state guidelines for human subjects research and communicate updates to the IRB Chair, members, and the university community.
- Serve as the primary liaison between federal agencies and investigators regarding human subjects issues.
- Provide required assurances to federal agencies for protocols supported by federal funds.

Training and Education

- Complete and maintain IRB Administrator certification and training.
- Organize and participate in educational activities related to IRB policies and procedures.

Recordkeeping and Documentation

- Maintain accurate and complete records for all research protocols.
- Post and update IRB guidelines, forms, meeting minutes, and related materials electronically.
- Archive IRB correspondence, training certificates, and all other relevant documentation in compliance with retention policies.

Operations and Reporting

- Distribute protocols to IRB members for review.
- Post meeting notices to the university community.
- Assist the Chair with processing honoraria, stipends, and other IRB-related expenses.
- Participate in on-site reviews by federal inspectors.
- Submit an annual report on IRB activities to the IRB Chair and the CAO.

4. Special Consultants

Appointment and Role

The IRB Chair may appoint a consultant with specialized expertise when additional knowledge is needed to review a specific protocol. The consultant provides expert input but does not participate in voting on the protocol. The IRB Chair may also authorize payment for these services. The consultant's engagement ends upon completion of the protocol review.

5. IRB Meetings

A. A. Stated Meetings

The IRB holds Stated Meetings during the second week of each 8-week term. The IRB Administrator will announce dates, times, virtual meeting details, and submission deadlines to the University community.

B. Special Meetings

The IRB Chair may call a Special Meeting when necessary. These meetings follow the same quorum and attendance requirements as Stated Meetings. All IRB business may be conducted during a Special Meeting.

C. Agenda

The Board reviews and acts on all submitted protocols and addresses additional items listed on the agenda.

D. Voting

A quorum, defined as a majority of IRB members plus one, including at least one nonscientist, is required to conduct business. Board actions require a majority vote of members present. If a vote is not unanimous, a roll call vote will be recorded in the minutes, listing each member's name and vote.

E. Minutes

The IRB Administrator records minutes in compliance with OHRP guidelines, capturing the substance of all discussions. Draft minutes are distributed via email before the next meeting for review and corrections. Final minutes are archived for audit, and a summary of actions is posted to the University community.

6. Action on Research Proposals

A. Full Review

The IRB conducts a full review for research proposals that require comprehensive evaluation. The IRB also performs periodic reviews of approved projects to ensure ongoing compliance.

B. Expedited Review

The IRB Chair (or a designated experienced member) may review and approve proposals that meet the following criteria:

- The research involves no more than minimal risk to participants, or
- The research includes only minor changes to previously approved protocols.

C. Exempt Research

Researchers may submit protocols they believe qualify for exemption from full or expedited review. The IRB Chair (or designee) will make the final determination.
Important: Research may not begin until written approval is granted by the IRB Chair.

D. Adverse Events and Unanticipated Effects

If any of the following occur during the study, the Principal Investigator must promptly notify the IRB Chair:

- Adverse consequences or unanticipated side effects, or
- New information that could alter the risk/benefit assessment.

The IRB will determine whether protocol modifications or additional actions are required.

E. Administrative Review and Disapproval

Research approved by the IRB may be subject to additional administrative review by Herzing University officials. These officials may impose further restrictions or disapprove a protocol.
However: University officials **cannot approve** research that has been disapproved by the IRB. *(HHS OHRP IRB Guidelines, Section 3)*

F. Continuing Review

All approved research is subject to continuing IRB oversight and must be re-evaluated at least annually. (*HHS OHRP IRB Guidelines, Section 3)*

7. Changes to Rules and Operating Procedures

A. Federally Mandated Changes

Any changes required by federal law, regulatory agencies, or accreditors will take effect immediately upon adoption.

B. Local IRB Regulations and Bylaws

- Proposed changes must be approved by a majority of the Board and the CAO.
- Before final approval, the CAO will notify the University community and allow a 10-day comment period.
- Any ongoing research affected by these changes will receive direct notice.

C. Communication of Changes

All approved changes will be posted on the IRB website and included in the Faculty Handbook.