HERZING UNIVERSITY

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Herzing University Institutional Review Board Statement of Principles

Herzing University follows the U.S. system for protecting human research subjects, which is rooted in the ethical principles outlined in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979). This report, developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, established the foundation for ethical research practices.

In 1981, the President's Commission recommended creating a unified standard for federally funded research. This led to the publication of the Common Rule in 1991, codified in Title 45 of the Code of Federal Regulations, Part 46, Subpart A. The United States Department of Health and Human Services' (HHS) Office for Human Research Protections (OHRP) and these regulations guide our commitment to safeguarding the rights and welfare of research participants.

The Common Rule translates the ethical principles of the Belmont Report into federal regulations for research involving human subjects. At Herzing University, these regulations apply to all human subjects research, whether funded or not, through our Institutional Review Board (IRB). The IRB reviews all research proposals to determine whether they are exempt or require full IRB approval and oversight under the Common Rule.

The Common Rule was revised in 2018, and the updated provisions, known as the 2018 Common Rule, took effect in January 2019.

1. Research, Human Protection and the P.R.I.C.E. of Success Model

Herzing University's approach to research is grounded in its core values, expressed through the P.R.I.C.E. of Success Model. These values shape our commitment to ethical research practices and the protection of human subjects.

A. P.R.I.C.E. of Success Model

Every research protocol must demonstrate alignment with these principles by:

Professionalism

Conducting research with competence, accountability, and adherence to established ethical and regulatory standards throughout the research process.

Respect

Recognizing and honoring the autonomy, dignity, and rights of all research participants, including informed consent and confidentiality.

Integrity
Ensuring honesty, transparency, and accuracy in all aspects of research, from data collection to reporting, without fabrication, falsification, or misrepresentation.

Caring
Prioritizing the safety, well-being, and emotional needs of participants by minimizing risks and providing appropriate support when necessary.

Engagement
Actively involving stakeholders, such as participants, communities, and institutional partners, in the research process to promote trust, collaboration, and mutual benefit.

2. IRB Membership, Research Review Process, and Meeting Schedule

Herzing University's IRB includes full-time faculty, staff, and an unaffiliated member. The IRB is responsible for ensuring the protection of human participants in research. Before any research begins, all projects must be reviewed to determine whether they are exempt from IRB oversight or require full review. Any research involving human participants or human materials, whether funded or not, conducted by Herzing University faculty, staff, administrators, or students must meet the same standards of protection.

A. Internal Requests
The IRB reviews research proposals from current Herzing University faculty, staff, and students conducting research as part of their academic programs or for scholarly purposes. All IRB applications must be submitted to the IRB Chair. Additional procedures and resources are available on the Herzing University IRB webpage.

B. External Requests
The IRB reviews research proposals from current Herzing University faculty and staff who plan to conduct research in collaboration with an external institution. All requests must meet IRB guidelines for external research. If IRB approval has been obtained from another institution, a copy of the application and approval must be submitted to the IRB Chair along with the request. Additional procedures and resources are available on the Herzing University IRB webpage.

C. Meeting Schedule
The IRB meets six times per year. To be considered at a meeting, applications must be submitted to the IRB Chair by 5:00 p.m. Central Time on the first Monday of each eight-week academic term. Non-exempt applications received after this deadline will be reviewed at the next scheduled meeting.

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3. What is Human Subjects Research?

Determining whether a project qualifies as human subjects research can be complex, as there is no single, universally accepted definition. To provide clarity, the Common Rule establishes broad definitions intended to encompass a wide range of research activities, including biomedical, social science, and humanities studies.

These definitions serve as an essential starting point for determining whether the project requires review and oversight by Herzing University's IRB or if it may qualify for an exemption.

If, after reviewing these definitions and questions, it remains uncertain, consult the IRB for guidance before initiating research. This ensures compliance with federal regulations and institutional policies.

1. **Is the project considered "research"?**
   Before beginning a project, determine whether it meets the federal definition of research under the Common Rule. This is the first step in deciding if IRB review is required. According to the Common Rule (45 CFR 46.102(l)):

   "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." *(Code of Federal Regulations, https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46)*

   If the project involves a structured process to collect and analyze data with the goal of producing findings that apply beyond the specific setting (for example, publishing results or informing policy), it likely qualifies as research.

   The Food and Drug Administration (FDA) does not use the term "research" in the same way as the HHS OHRP. Instead, the FDA uses the term "clinical investigation", which is considered synonymous with research in its regulations. According to 21 CFR 50.3(c), a clinical investigation is:

   "Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit." (*Code of Federal Regulations, https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50/subpart-A/section-50.3)*

To be considered "clinical investigation" by the FDA, the study:

- Must involve a test article (e.g., drug, device, biologic, food additive)
- Must involve one or more human subjects
- Requires prior FDA submission or Its results will be submitted to or inspected by the FDA for a research or marketing application

Nonclinical laboratory studies (e.g., animal studies under Part 58) are not included.

2. **Does the project involve human subjects?**
   According to HHS in 45 CFR 46.102(e), a human subject is defined as:

   "A living individual about whom an investigator (whether professional or student) conducting research:

   - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
   - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

   (Code of Federal Regulations, https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102)

   Other relevant definitions include:

   - Intervention: Physical procedures for gathering information or biospecimens (e.g., venipuncture) or manipulations of the subject or their environment for research purposes.
   - Interaction: Communication or interpersonal contact between investigator and subject.
   - Private information: Information about behavior in contexts where privacy is expected, or information provided for specific purposes that the individual expects will remain confidential (e.g., medical records).
   - Identifiable: Information or biospecimens where the subject's identity is or may readily be ascertained by the investigator.

   (Code of Federal Regulations, https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102)

If the answer to both questions is "yes", then the project may need IRB approval to conduct research.

Additionally, to determine regulatory considerations, ask these questions:

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- Does the activity involve the use of a drug (including an approved or over-the-counter drug), other than when used in the normal course of medical practice?
- Does the activity involve the use of a medical device (including an approved device), other than when used in the normal course of medical practice?
  Note: Medical devices generally include items intended for diagnosing, curing, mitigating, treating, or preventing disease in humans or animals, or those intended to affect the structure or function of the body.
- Will any data be submitted to the FDA or retained for FDA inspection?

If the answer to any one of the above questions is "yes," then the project will need IRB approval to proceed.

4. Is it Research, Evidenced-Based Practice, or a Quality Improvement Project?

Research

- Purpose: Generate new knowledge or validate existing knowledge.
- Method: Uses systematic, scientific inquiry (quantitative or qualitative).
- Key Features:
  - Begins with research questions or hypotheses.
  - Requires a comprehensive literature review and critical appraisal.
  - Involves measurable and/or manipulable variables.
  - Aims to describe, explain, predict, or control phenomena.

Evidence-Based Practice (EBP)

- Purpose: Apply the best available evidence to improve patient care.
- Method: Combines research evidence, clinical expertise, and patient preferences.
- Key Features:
  - Triggered by a clinical problem or knowledge gap.
  - Involves systematic literature review and critical appraisal.
  - Evaluates whether practice changes improve outcomes.
  - Focuses on sustainability of changes.

Quality Improvement (QI)

- Purpose: Improve processes, policies, or outcomes within a specific setting.
- Method: Data-driven, iterative improvement cycles (e.g., PDSA).
- Key Features:
  - Focuses on systems and processes.
  - Usually does not require extensive literature review.
  - Not intended to be generalizable beyond the site.
  - Often shares findings for others to consider.

Aspect	Research	EBP	QI
Goal	Generate new knowledge	Apply best evidence	Improve local process
Literature Review	Extensive	Yes	Minimal
Generalizable?	Yes	Sometimes	No
Methods	Scientific, rigorous	Evidence translation	Data-driven cycles

5. Does the Project Qualify for Exemption, Expedited Review, or Full Board Review?

Exempt Research

Projects may be exempt under 45 CFR 46.104 if they involve minimal risk and fall into one of these categories:

- Conducted in established educational settings using normal educational practices (§46.104(d)(1)).
- Use of educational tests, surveys, interviews, or observation of public behavior (§46.104(d)(2)).
- Collection or study of existing data, documents, or specimens that are:
    - Publicly available, or
    - Recorded so subjects cannot be identified (§46.104(d)(4)).
- Public benefit projects approved by a government department or agency (§46.104(d)(5)).
- Taste and food quality evaluations (§46.104(d)(6)).

Expedited Review

Projects may qualify for expedited review under 45 CFR 46.110 if they involve no more than minimal risk and fit federal expedited categories, such as:

- Clinical studies of drugs or devices that do not require FDA approval.
- Blood sample collection by fingerstick, heel stick, ear stick, or venipuncture:
    - From healthy, non-pregnant adults weighing over 110 lbs, or
    - From others based on age, weight, and health.
- Noninvasive collection of biological specimens (e.g., buccal swabs).
- Noninvasive data collection procedures.
- Use of existing materials (data, documents, records, specimens) collected for non-research purposes.
- Voice, video, or image recordings for research purposes.
- Studies on individual or group characteristics or behavior.

Full Board Review

Projects require Full Board Review under 45 CFR 46.108(b) if they:

- Do not qualify for exempt or expedited review.
- Involve more than minimal risk, such as:
    - Personally intrusive, stressful, or potentially traumatic procedures.
    - Risks that are physical, psychological, social, financial, or legal.
- Include vulnerable populations, such as:
    - Children, prisoners, or individuals with cognitive impairments (§46.111(b)).
- Use intentional deception where participants are misled or given false information.
- Present sensitive topics that could cause harm or distress to participants.

Full Board Reviews are conducted at convened IRB meetings and require additional time for review and approval.

IRB Approval Criteria

When reviewing research, the IRB must determine according to (45 CFR 46.111) that:

1. Risks to subjects are minimized (§46.111(a)(1)).
2. Risks are reasonable in relation to anticipated benefits (§46.111(a)(2)).
3. Selection of subjects is equitable (§46.111(a)(3)).
4. Informed consent will be sought and documented unless waived (§46.111(a)(4)-(5)).
5. There are adequate provisions for data monitoring (§46.111(a)(6)).
6. There are adequate provisions to protect privacy and maintain confidentiality (§46.111(a)(7)).
7. Additional safeguards are included for vulnerable populations (§46.111(b)).

(Code of Federal Regulations, https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46)