HERZING UNIVERSITY STATEMENT OF PRINCIPLES

Herzing University has adopted the current U.S. system of protection for human research subjects that was heavily influenced by the Belmont Report, written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report outlines the basic ethical principles in research involving human subjects. In 1981, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research recommended that a "common rule" be established for all federally-funded research involving human subjects. In 1991, Title 45 of the Code of Federal Regulations (Public Welfare) Part 46, Subpart A – better known as **"The Common Rule"** – was published.

The Common Rule essentially converted the Belmont principles into regulations for federally-funded human research. Herzing University along with many other institutions of higher learning apply The Common Rule regulations to all human subjects research (both funded and non-funded) through an Institutional Review Board (IRB) that reviews all research requests and officially determines whether it is exempt from IRB oversight or does, indeed, qualify under The Common Rule as human research that requires both IRB approval and oversight.

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

The conceptual framework upon which Herzing University has developed consists of a set of core values. Research, Research Support, and the University's commitment to human protection come from these values. **The research protocol must demonstrate:**

Professionalism
: The professional conduct of responsible research,

Respect
: Respect for the privacy and wellbeing of all human research subjects,

Integrity
: The integrity of results through the collection, treatment, and evaluation of valid data,

Caring
: The protection of the privacy and wellbeing of all human research subjects, and

Engagement
: The application of research knowledge and skills through active collaboration, including informed consent, between the researcher(s) and the research subject(s)

Herzing University's Institutional Review Board (IRB) is comprised of full-time faculty, staff members, and a member currently unaffiliated with the University who are tasked with ensuring the protection of human participants involved in research. Herzing University requires that, prior to commencing any research, **all projects** shall be reviewed and either determined to be exempt from IRB oversight or determined to be research that involves human participants or human materials and is subject to IRB oversight. Any funded or non-funded research determined to be non-exempt research involving human participants or human materials undertaken by faculty, administrators, staff, and students of Herzing University must meet the same standards of protection.

Internal Requests: The IRB will review all research requests from current staff, faculty, and students who are conducting research at Herzing University as part of their Herzing University undergraduate or graduate educational program or for their own scholarship purposes. All IRB applications shall be submitted to the Chair of the IRB committee. Further procedures and relevant information will be found on the Herzing University IRB webpage.

External Requests: The IRB will review all research requests of current staff and faculty who wish to conduct research in conjunction with an outside educational or non-educational institution. Requests will be vetted for relevance and purpose and must meet IRB guidelines for external research requests. For all such requests where an IRB approval has been or will be obtained from another institution, a copy of that IRB application and approval, if any, shall be submitted to the IRB Committee Chair along with the request. Further procedures and relevant information will be found on the Herzing University IRB webpage.

The IRB committee shall convene six times per year in the second week of each eight-week academic term. To be considered at the meeting, all IRB applications must be submitted and received by the IRB Committee Chair on or before 5p.m. Central Time on the first Monday of the eight-week academic term. All non-exempt applications received after that date will be considered at the next regular meeting in the subsequent eight-week academic term.

What is Human Subject Research?
It can be very difficult to determine what constitutes human subjects research. Unfortunately, there is no clear delineation. The Common Rule offers the following as guidance for determining human subjects research. The definitions are intentionally broad to include a wide range of research in hopes of capturing both the biomedical and humanities spectrums. These definitions are the starting point for anyone attempting to determine whether their research will require Herzing University's IRB to review and oversee the research or whether the research will be exempt from review and oversight.

The first question: Is your project actually "research" as defined by the common rule?

"Research" as defined by DHHS is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

"Research" as defined by FDA means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.102(c)]

- "Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act" means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]
- "Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act" means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]

The second question: Does your project involve human subjects?

A human subject is defined by DHHS as a living individual about whom an investigation (whether professional or student) conducting research obtains information through intervention or interaction with the individual, and uses, studies or analyzes the information; or obtains, uses, studies, analyzes, or generates identifiable private information.

- "Intervention" as defined by DHHS regulations means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. [45 CFR 46.102(f)]

- "Interaction" as defined by DHHS regulations means communication or interpersonal contact between investigator and subject. [45 CFR 46.102(f)]
- "Private information" as defined by DHHS regulations means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). [45 CFR 46.102(f)]
- "Identifiable information" as defined by DHHS means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

For more information see the Office for Human Research Protections and the Food and Drug Administration.

If the answer to both questions is "yes", then you may need IRB approval to conduct research.
You need to ask these questions:

- Does the activity involve the use of a drug (including an approved drug or an over-the-counter drug), other than the use of an approved drug in the course of medical practice?
- Does the activity involve the use of a medical device (including an approved medical device), other than the use of an approved medical device in the course of medical practice? (Note that medical devices generally include devices intended for the use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, and devices intended to affect the structure or any function of the body of humans or other animals.
- Will data be submitted to the FDA or held for their inspection?

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

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

Research
Research applies a methodology, which may be quantitative or qualitative, to generate new knowledge, or validate existing knowledge based on a theory; uses systematic, scientific inquiry and disciplined, rigorous methods to answer a research question or test a hypothesis about an intervention; begins with one or more research questions and uses a systematic review of literature, including critical appraisal, to identify knowledge gaps; and contains variables that can be measured and/or manipulated to describe, explain, predict, and/or control phenomena, or to develop meaning, discovery, or understanding about a particular phenomenon

Evidence-Based Practice [EBP]
EBP projects translate the best clinical evidence, typically from research results, to make patient care decisions. These studies often involve more than research in that these studies often include clinical expertise and knowledge gained through experience. The process begins with one or more research questions at a specific site which may arise from either problem-focused or knowledge-focused triggers;

involves a systematic review of literature, including critical appraisal, to find the best available evidence; studies whether the evidence warrants a practice change; and concludes with an evaluation that asks these questions: If practice change was made, did it produce the expected results? If not, why not? If so, how will the new practice be sustained?

Quality Improvement [QI]
QI projects are systematic, data-guided activities that monitor and evaluate the quality and appropriateness of policy or practice based on EBP data and other research to bring about immediate improvement in processes and/or policies, outcomes, or both. These projects often evolve from continuous quality improvement, and total quality management organizational philosophies; focuses on systems, processes, or functions or a combination; and, because it stems from an existing need at a specific site, typically doesn't require extensive review of literature or critical appraisal. While it is a project that applies only to a single site or a single setting and is not intended to be generalizable to other sites or settings, it may be valuable to share this information for others to consider.

Is the Project Exempt, or Qualify for Expedited Review?

Exempt:
* Research conducted in established or commonly accepted educational settings, involving normal educational practices;
* Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior;
* Research in which there are identifiable subjects in special circumstances;
* Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified;
* Research and demonstration projects that are conducted by or subject to the approval of department or agency heads for the public benefit; and
* Taste and food quality evaluation.

Expedited Review:
Research believed to contain no more than minimal risk and falls within the federal regulations that delineate expedited categories as listed below:
* Clinical studies of drugs and medical devices when research on the drugs does not require a new drug application or an investigational medical device exemption application is not required;
* Collection of blood samples by fingerstick, heel stick, ear stick, or venipuncture from healthy, non-pregnant individuals who weigh more than 110 pounds or from other adults and children considering the age, weight, and health of the subjects;
* Prospective collection of biological specimens for research purposes by noninvasive means, such as buccal swabs;
* Collection of data through noninvasive procedures;
* Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis);
* Collection of voice, video, digital, or image recordings made for research purposes; and
* Research on individual or group characteristics or behavior.