Herzing University
Institutional Review Board (IRB)
Application for Research Protocol Approval

Herzing University's Institutional Review Board (IRB) reviews all research protocol requests to determine if it is human subject research that meets definitions in The Common Rule and therefore requires review and oversight by the IRB. It is the investigator's responsibility to give complete information regarding procedures and the informed consent process. After submitting the application, the IRB will notify the applicant, in writing, of its decision or if additional information is needed.

Before submitting the application, please read the following scenarios and make a check next to the selection that you believe best applies to your project:

NOTE: Any use of research data of any type collected from or about Herzing University student, faculty, staff, or administration, however acquired, requires a full IRB Review.

PROTOCOL TYPES FOR IRB REVIEW

Research	Evidence-based practice	Quality improvement
• 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 a burning question and uses a systematic review of literature, including critical appraisal, to identify knowledge gaps • 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	• Translates the best clinical evidence, typically from research results, to make customer/patient decisions • Involves more than research use; may include expertise and knowledge gained through experience • Process begins with a burning question, 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 • Evaluation includes 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?	• QI projects are site-specific. Results <u>are not intended</u> to provide generalizable knowledge or best evidence. Usually, specific site needs determine that a study be conducted to improve either policy or practice. • Uses a system to monitor and evaluate the quality of the intervention. • Involves A systematic method for improving processes, outcomes, or both • Evolved from continuous quality improvement and total quality management organizational philosophies • Focuses on systems, processes, or functions or a combination • Because the study is driven by a specific need at a specific site, it typically doesn't require extensive review of literature or critical appraisal

EXEMPT - This site-directed **Quality Improvement Project** is designed to bring about immediate improvements at a specific site or for a specific purpose. It is not backed by standard research methods needed to validate findings so that results can be applied to other sites or settings other than in an informational sense as a unique case study (See Chart 1 Below).

EXEMPT – This **Evidence-Based Practice Project** is designed to translate prior research findings as well as other informational inputs to make patient care decisions and evaluate the effectiveness of those decisions **AND** all human information is anonymous. (See Chart 1 Below).

EXEMPT – This Project uses **publicly available information** and/**or <u>previously existing</u> aggregated or individual anonymous data where <u>no</u> risk of exposure exists** and **<u>no</u> direct contact is being made with any human subject.**

EXPEDITED REVIEW – This Research Project (1) **presents no more than minimal risk** to human subjects, and (2) **involves only procedures listed in the Federal Register**. These include:

1. The data are **NOT** from or about Herzing University students, faculty, staff or administrators.
2. The collection of blood samples using finger or heel sticks.
3. Collection of biological specimens for research purposes by non-invasive means, such as buccal swabs.
4. The collection of data through non-invasive procedures routinely employed in clinical practice, such as measures of respiration and galvanic skin response.
5. Research involving data already collected for research purposes or data collected for non-research purposes.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics employing surveys, interviews, oral history, and focus groups (if not otherwise exempt).
8. Research in which the primary risk is breach of confidentiality and the risk has been managed to no more than a minimal level.

FULL IRB REVIEW – This Project does NOT qualify under one of the options above; **OR uses data collected from Herzing University student, faculty, staff or administration.**

REQUIREMENTS: The Principal Investigator must supply the following:

_____ This completed application

_____ Research Overview that Includes:

a. *<u>The Research Question(s</u>*): Use the P.I.C.O.T. model to state the research question(s).
b. *<u>Project Abstract</u>* (A brief summary of the proposed research including the purpose, variables, value of the study, and the intended method of use and/or publication of the knowledge gained from the study)
c. *<u>Methodology</u>* (A description of your research methodology - Include the measures, where and how you plan to collect data, and over what time period. Identify all personnel who will participate in this research and outline their qualifications)

_____ A copy of all questionnaires and surveys if any

_____ Letter of Approval from Campus President and Program Director (if appropriate)

_____ A Copy of the application and approval letter from any external IRB (if available)

____ A copy of your CITI Certification (Free Certification inside of BlackBoard)

1. Project Title: _____

Principal Investigator: _____

Check One: Herzing University ____ Student ____ Faculty ____ Staff ____ Administrator

Email: _____ Cell or Daytime Contact Phone: _____

2. Location/Sponsor Information

____ Herzing University Online Campus

_____ Herzing University Ground Campus Located At: _____

Department _____

Faculty Information: (if student PI) _____ _____
Name faculty email

Faculty Phone: _____

Projected Project Start Date:

Projected Project Completion Date:

3. Participants

Are all participants members of a population who have the ability to provide informed consent?

____ Yes ____ No

Will any of the participants be younger than 18 years old? ____ Yes ____ No

Will the participants be Herzing University students, faculty or other staff? _____ Yes ____ No
(If Yes… Your Study Will Require a Full IRB Review and Approval)

If participants receive compensation for participation then please give details:

How will participants be selected or recruited?

4. Risks - Describe all known or anticipated risks to the participants (psychological or physical).

5. Benefits - Describe the anticipated benefits to the participants.

6. Informed Consent - Attach a copy of all informed consent documents that will be provided to the subjects before they participate

7. Confidentiality and Anonymity – Attach information that describe how participants' privacy will be maintained and how confidentiality will be guaranteed.

8. Responsibilities of the Principal Investigator

1. Any additions or changes must be submitted to the IRB for written approval prior to these changes being implemented.
2. Once the project has begun, any adverse effects or unanticipated problems connected with human subjects you must notify the IRB Chair immediately at irb@herzing.edu
3. Informed Consent documents must be kept by you for a period of 3 years following the completion date of the project.

9. Signatures

I certify to the best of my knowledge the information presented is an accurate reflection of the proposed research project.

A. _____ _____
Principal Investigator (PI) Date

B. _____ _____
Faculty Sponsor (Required if the PI is a student) Date
Faculty sponsor confirms the application accuracy and accepts responsibility as Co-PI.

C. _____ _____
Program Director (only for student PI) Date

FOR IRB USE ONLY:	____ Approved	_____ Disapproved	
	____ Exempt	____ Expedited Review	____ Full IRB Review
Vote:	____ For Approval	____ Against Approval	____ Recused

IRB Chair Signature_____ Date _____