Standard of Performance for Faculty Supervisors of Trainees Conducting Human Subject Research

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Policy Statement

This policy establishes the standards of performance expected from faculty supervisors who oversee trainees or visiting faculty PIs seeking HRPP/IRB determinations and/or conducting human subject research within our institution. The purpose of this policy is to ensure the protection and well-being of human subjects, maintain ethical research practices, and foster a conducive environment for trainee researchers to thrive.

Definitions

Faculty Supervisor: Any UIW faculty member who accepts responsibility for actively overseeing the request of determination, application, or conduct of human research where the Principal Investigator (PI) is either a trainee or visiting faculty.

Trainee: For purposes of this Policy, this term encompasses the following: student (undergraduate, graduate, professional program), resident, fellow, postdoctoral fellow, and others in training without a faculty appointment.

Visiting Faculty PI: Appointed individuals who continue their primary responsibilities outside UIW, but for a temporary period devote their efforts on a full-time or part-time (paid or non-salaried) basis to the programs of the institution. While this modifier is most often appropriate for faculty members on temporary leave from other institutions, it may exceptionally be applied to individuals who visit the institution regularly but who do not perform the delineated duties of an Adjunct faculty member.

Human Research Protection Program: The UIW Human Research Protection Program (HRPP), which includes the Institutional Review Board (IRB), is responsible for ensuring compliance with applicable laws, regulations, guidelines, and ethical principles such as those outlined in the Belmont Report and UIW's institutional policies. Its goal is to: Ensure the rights and welfare of human research participants; Promote excellence in the conduct of research; and Advance knowledge and quality research.

The HRPP assists the University in meeting its legal, regulatory, and ethical obligations and routinely collaborates with other offices across the University, as well as community partners, on various

programs and initiatives related to research that foster compliance, quality, efficiency, and the protection of human participants.

Institutional Review Board: The IRB is a federally regulated committee with the mandate to review biomedical and social behavioral research studies that take place within or under the authority of UIW. The purpose of review is to determine if the proposed research meets certain established ethical, regulatory, and policy criteria to protect the rights and welfare of the human subjects of such research.

Minor Violation*: any form of violation that is NOT persistent and does NOT: 1) adversely affect the oversight of trainee(s) or visiting faculty PI(s) conducting human subjects research. 2) affect the rights and welfare of the subjects, 3) increase risks to subjects or others or alter the risk/benefit ratio, 4) compromise the integrity or validity of the research, or 5) in a singular instance, contain numerous violations

Serious Violation*: In addition to items 1, 2, 3, 4, and/or 5, as defined in "Minor Violations," the violation results from the willful, knowing, or intentional misconduct on the part of the investigator or study staff.

Continuing Violation*: any violation that occurs in a persistent or repeated manner.

* Any violation(s) that meet the definitions outlined in UIW's HRPP/IRB policy "Investigations of General, Serious, or Continuing Noncompliance" will also be subject to and undergo investigation, evaluation, and appropriate action in accordance with the specified guidelines outlined in the policy.

Description and Procedures

A. Qualifications and Responsibilities of Faculty Supervisors

A Faculty Supervisor is any faculty member who accepts responsibility for actively overseeing the request of determination, application, or conduct of HRPP-approved human research where the PI is either a trainee or visiting faculty. The Faculty Supervisor is considered the responsible party for assisting trainees or visiting faculty PIs in making procedural, methodological, and/or ethical decisions throughout the life of the project. Responsibilities of Faculty Supervisors are the same as PI Responsibilities listed in UIW's IRB Policy, "Responsibilities of the Principal Investigator for Research in Progress," and include, but are not limited to, the additional following qualifications and responsibilities:

1. Qualifications

a. Faculty Supervisor responsibilities may only be carried out by a member of the University of the Incarnate Word faculty, or others designated as such by UIW's affiliates, who meet the qualifications to be a PI; and
b. Faculty supervisors must possess appropriate qualifications and expertise in the relevant field of research to effectively guide and mentor trainees or visiting faculty PIs conducting human subject research.

2. *Ethical Conduct and Compliance of Faculty Supervisors*

a. Acknowledge responsibility for and verify that all trainee(s) and visiting faculty PI(s) studies comply with applicable laws, regulations, ethical guidelines, institutional policies, and HRPP/IRB determinations, by being listed as the Faculty Supervisor on an HRPP/IRB application and electronically signing the study submission; Faculty Supervisors accept and acknowledge responsibility for protecting the rights and welfare of human research participants;

b. Oversee trainee(s) or visiting faculty PI(s) during the preparation of the HRPP application(s) and ensure the proposed study complies with the ethical principles outlined in the Belmont Report, human subject research regulations, institutional policies, and other applicable federal or state laws;

   i. Reviews the proposal and advises the trainee(s) or visiting faculty PI(s) on the development of a relevant study question(s);
   ii. Assists trainee(s) or visiting faculty PI(s) in determining the appropriate procedures necessary to answer study question(s);
   iii. Provides guidance and information regarding IRB review and approval;
   iv. Assists the trainee(s) or visiting faculty PI(s) in obtaining consultation with HRPP staff; and
   v. Reviews the final proposal, IRB application, and applicable documents for consistency, accuracy, and validity;

c. Ensure all activities involving human subjects have IRB approval, or HRPP determination of Not Human Subject Research, and other ancillary approval required by the institution before human subjects are involved, and implement the study activity as it was approved by the IRB;

d. Ensure all study activities are conducted in compliance with internal policies including IRB policy, applicable regulations, and state law;

e. Ensure the trainee(s) or visiting faculty PI(s) is/are in compliance with the additional responsibilities listed as investigator responsibilities;

f. Provide adequate time to consult with the trainee(s) or visiting faculty PI(s) on a regular basis to monitor study progress;

g. Assist and supervise the trainee(s) or visiting faculty PI(s) in problem-solving in the event a problem, emergent question, or concern were to arise;

h. Provide guidance and mentorship to the trainee(s) or visiting faculty PI(s) throughout the study process, including study design, data collection, analysis, interpretation, and reporting; and

i. Maintain regular communication with the trainee(s) or visiting faculty PI(s) to address any concerns, provide feedback, and monitor the progress of the project.

3. *Training and Supervision*

a. Ensure trainee(s) and visiting faculty PI(s) has/have sufficient training and experience to conduct the study in accordance with the protocol or HRPP/IRB determination;

b. Satisfy the human subject research training requirement (CITI) and understand the ethical standards and regulatory requirements governing research activities with human subjects; and

c. Ensure that the trainee(s) or visiting faculty PI(s) have a clear understanding of the study protocols, procedures, and data management practices relevant to their projects.

4. Risk Assessment and Participant Welfare

a. Conduct a thorough risk assessment for each project involving human subjects to identify and minimize potential risks to participants;
b. Monitor the well-being and safety of participants throughout the study process and promptly address any issues or concerns that may arise; and
c. Educate the trainee(s) or visiting faculty PI(s) on appropriate measures to protect the confidentiality and privacy of human subject participants, including data storage, handling, and dissemination practices.

5. Reporting and Accountability

a. Regularly review the progress of trainee(s) or visiting faculty PI(s) projects and provide timely feedback and guidance to ensure the successful completion of the study;
b. Report any real or potential conflicts of interest in compliance with the Conflict of Interest (COI) policy of the University;
c. Ensure prompt reporting by the trainee(s) or visiting faculty PI(s) of unanticipated problems and protocol deviations;
d. Ensure the IRB is notified when the research is completed. In the event that the PI is unable or unwilling to do so, the responsible Faculty Supervisor will be required to do so prior to when the PI graduates or otherwise leaves UIW; and
e. Adhere to all institutional policies, procedures, and reporting requirements related to human subject research.

B. Evaluation and Continuous Improvement

To ensure the trainee(s) or visiting faculty PI(s) receive consistent and exemplary mentorship in conducting human subjects research, it is crucial for all involved parties to remain updated on ethical considerations, responsible research conduct, and best practices. In pursuit of continuous improvement, the faculty supervisor and HRPP will undertake the following measures:

1. Faculty Supervisor

a. Enhance their own knowledge and skills in research and human subjects' protection ethics, best practices, and regulations through webinars, workshops, seminars, conferences, and other professional development activities including regular involvement in scholarly inquiry;
b. Encourage and facilitate opportunities for trainee(s) to enhance their knowledge and skills in research and human subjects' protection ethics, best practices, and regulations through webinars, workshops, seminars, conferences, and other professional development activities; and
c. Regularly assess the study performance of trainee(s) or visiting faculty PI(s) and inform the HRPP immediately if the performance is below standard.

2. *HRPP*

a. The HRPP will provide opportunities for faculty supervisors to engage in professional development webinars through the CITI Training Program to enhance their knowledge and skills in research supervision and ethics.

C. Violation(s) and Appeals

Failure to adhere to these requirements may constitute a policy violation. Policy violation may occur at any point of the HRPP/IRB process (e.g., from HRPP/IRB application submission to protocol closure). Minor, non-continuous violation(s) may be managed by the HRPP in consultation with the IRB Chair. Serious or Continuing violation(s), as identified by any member of the HRPP, will be referred to the convened IRB for review. Serious noncompliance and continuing violation(s) are determined by the convened IRB and subject to corrective action.

Any violation(s) that meet the definitions outlined in UIW's IRB policy, "Investigations of General, Serious, or Continuing Noncompliance," will also be subject to and undergo investigation, evaluation, and appropriate action in accordance with the specified guidelines outlined in the policy.

1. *Minor Violation*

a. Determination
   i. Minor violations of this policy, as determined by the HRPP, are any form of violation that is NOT persistent and does NOT: 1) adversely affect the oversight of trainee(s) or visiting faculty PI(s) conducting human subjects research. 2) adversely affect the rights and welfare of the subjects, 3) increase risks to subjects or others or alter the risk/benefit ratio, 4) compromise the integrity or validity of the research, or 5) in a singular instance, contain five (5) or more violations

b. Corrective Action
   i. If a Minor Violation is determined by the HRPP, the program may impose the following corrective actions:
      1. Informal Warning;
      2. Formal Letter Warning; or
      3. Formal Letter of Reprimand to include Faculty Supervisor's Department Chair and/or Dean.

2. *Serious or Continuous Violation(s)*

a. Determination
   i. Serious violation of this policy, as determined by the IRB, is any violation that: 1) adversely affects the oversight of trainee(s) or visiting faculty PI(s) conducting human subjects research, 2) adversely affects the rights and welfare of the subjects, 3) increases risks to subjects or others or alters the risk/benefit ratio, 4) compromises the integrity or validity of the research, 5) results from the willful, knowing, or intentional misconduct on the part of the faculty supervisor, and/or 6) in a singular instance, contains five (5) or more violations.
   ii. Continuous Violations of this policy, as determined by the IRB, is any violation that occurs in a persistent or repeated manner.

b. Corrective Action
    i. If a Serious and/or Continuous violation(s) is determined by the HRPP, the program may impose, but is not limited to, the following actions:
        1. A Formal letter of reprimand to include the Faculty Supervisor's School/College Dean;
        2. A requirement to complete additional training, (e.g., in human subjects' protections, in the field of the supervised protocol and/or protocol application, and/or in research supervision);
        3. Additional continuing reviews (e.g., every 3 months or every 6 months);
        4. Requiring the faculty member to submit regular reports on their supervision of trainee(s) or visiting faculty PI(s) research;
        5. A requirement to co-supervise all future trainee(s) or visiting faculty PI(s) research projects;
        6. A limit on unsuccessful trainee(s) or visiting faculty PI(s) submissions with the same Faculty Supervisor;
        7. Disapproval, Suspension, or Termination of an HRPP/IRB application or protocol; and/or
        8. A restriction or prohibition on the faculty member's ability to supervise trainee(s) or visiting faculty PI(s) human subject research (*cases of egregious noncompliance or abandonment of supervisory responsibilities)*.

3. Appeals

For Serious and/or Continuous Violations, Faculty, with support from their Dean, may appeal Faculty Supervision corrective actions imposed by the IRB, provided they demonstrate: 1) sufficient evidence for non-violation, or 2) after due time, substantial change in the ability to supervise human subject research.

a. Appeals must be submitted in writing and sent to the institution's Research Officer or Institutional Official for Research. Where appropriate, the Research Officer or Institutional Official for Research may consult with the applicable dean, director, HRPP, IRB Chairs, and/or the IRB.
b. The decision of the Research Officer or Institutional Official for Research shall be final in all respects.

Effective Date

July 5, 2023

Revision History

June 30, 2023