Faulkner University's IRB Policies and Procedures

Faulkner's Institutional Review Board (IRB), to the extent possible, shall be patterned after (but not directly governed by) the federal guidelines adopted by the Department of Health and Human Services (HHS) in the Office for Human Research Protections (OHRP), specifically by the 2018 final edition of the "Revised Common Rule" (45 CFR 46). These guidelines are built upon the 1974 National Research Act and the Belmont Report, which serves at the underlying principles guiding Faulkner's IRB.

Research funded by the HHS shall be specifically bound by the "Revised Common Rule" (45 CFR 46). Research in particular disciplines, or funded by various other government entities may be subject to regulations required by those agencies (APA, ASHA, FDA, NIH). In these cases, the IRB will work with researchers to assist in assuring compliance. It is the responsibility of the researcher(s) to make the IRB aware of any such additional guidelines to which the project will be amenable. In accordance with the "Revised Common Rule" (45 CFR 46) criteria, the IRB shall make the final determination as to whether a proposed study is exempt from the provisions of the "Revised Common Rule" (45 CFR 46). Further, Faulkner's IRB will seek to maintain registration of a FederalWise Assurance (FWA).

WEBSITE: Information on Faulkner's IRB forms and policies are made available via the IRB WEBSITE.

I. Definitions

- **a.** Research - "means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (§____.102)(l). Some forms of research may meet this definition, but be exempt from IRB approval requirements.
- **b.** Human Participants/Subjects - any living individual about whom information or biospecimens are collected through intervention or interaction with the individual, or about whom identifiable private information or identifiable biospecimens are obtained, used, studies, or analyzed (§____.102)(e)(1)(i,ii).
- **c.** Non-Human Animals - includes any and all animals deemed to be sentient, whether land or aquatic. It may include non-sentient animals including porifera, echinoderms, and cnidarians. Invertebrates may also be included in this definition. It does not include bacteria, archaea, protists, fungi, nor any plant (including carnivorous plants).
- **d.** Private information – "includes 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record)" (§____.102)(e)(4).
- **e.** Researcher / Investigator - includes any person directly involved in the collection, assessment, or analyzing of data or in any way directly involved in any research intervention or interaction with participants. It does not normally include research assistants limited to participation in a literature review or other indirect supportive assistance.
- **f.** Primary Investigator (PI) - refers to the individual designated as having primary oversight responsibility for the conducting of the research, disseminating of the results, and (with some limitations) oversight of the other researchers. In rare cases, more than one PI may

be designated. A designated faculty advisor serves as the PI responsible for student projects, though the student shares PI responsibility at the student level.

g. Minimal risk - "means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (§____.102)(j).

h. Greater Than Minimal Risk - means ANY degree of harm or discomfort anticipated greater than what would ordinarily be encountered in daily life or performance of routine physical or psychological examinations. Both the degree of the risk against the benefits of the research as well as the nature of the risk is to be considered.

i. Vulnerable Populations - refers to participants whose consent and decision making ability is potentially lesser than a participant with average ability, are more readily subject to coercion or undue influence, or whose status pose a higher than normal risk. This generally includes, but is not limited to, "children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons" (§____.107).

II. What is IRB?

a. IRB is the abbreviation for Institutional Review Board, required of any research facility or university conducting research.

b. The IRB at Faulkner assesses any and all applicable research and procedures using human subjects, non-human animals, and in some cases, those projects not involving living subjects.

c. The IRB's purpose is primarily to assure that research affiliated or supported by Faulkner University is conducted in an ethical manner, to include protection of human subjects, ethical treatment of non-human subjects, and to help assure validity and ethical reporting of research data and analysis. However, researchers maintain final responsibility for abiding by all laws and ethical guidelines, and liability for any breech thereof.

d. Faulkner's IRB reviews any and all research involving humans, non-human animals, hazardous materials, or any research which may pose a risk to the environment or society. Additionally, it reviews research sponsored or supported by the university to help protect the reputation of the university in conducting valid research, as well as any requests to access Faulkner students or employees, or University resources.

III. Scope of Authority

a. The IRB shall operate under the auspices of office of the Vice-President for Academic Affairs (VPAA).

b. The IRB shall have sole governing authority for approval of research involving any subject or area requiring such approval.

c. Any and all research involving human participants, non-human subjects (animals), hazardous materials or conditions, potential risk to the environment or society, or requiring accuracy of designs where the University will be represented must be submitted to the IRB for approval unless specifically exempted.

d. Approval by the IRB does in no way remove the primary responsibility and liability of the Primary Investigator (PI), nor of any other persons involved in or responsible for the collection of data or supervision thereof.

e. The IRB shall also serve as the Institutional Animal Care and Use Committee (IACUC) for the University when non-human animals are used in research unless a separate such committee shall have been established. The IACUC is commissioned to assure the use of non-human animals in research shall adhere to the applicable laws and procedures of the NIH guidelines found on the NIH-OLAW website and the Relevant Documents page, and/or the Animal Welfare Act (AWA) which can be accessed on the USDA website. (Some guidelines may be applicable only to research publically funded by government grants, and may be more restrictive than requirements for other research. However, these serve as valid and helpful guidelines for all use of non-human subjects in research, and researchers are responsible to provide appropriate care, and to abide by all applicable laws. In the event a separate IACUC is established, the IRB shall maintain all authority related to approval of research to be conducted. Approval of any research using non-human animals shall in no way minimize the responsibility of the researchers and the designated employees commissioned to care for the non-human animals. The scope of the IRB acting as the IACUC shall be limited to approval of research involving non-human animals, and shall not extend to the use and care of animals used in regular instructional capacity or other university uses. However, the IRB may serve an advisory or reporting role to assist in the use and care of animals, and to protect the interests of the University.

f. The IRB has the authority to suspend or terminate approval of research previously approved in the event it deems that the research is not being conducted in accord with the approval, is being conducted unethically or illegally in any part, or due to changes in applicable laws or ethical guidelines. The IRB may also suspend or terminate approval of research if the process has identified unexpected harm, breach of confidentiality, or other unexpected adverse consequences.

g. The IRB may, in some cases, seek consultation of others acting in an official capacity responsible for a specific aspect of the research, or to consult outside experts for areas beyond the expertise of the members of the IRB and which require further consideration.

IV. Comprisal and Requirements of the Board

a. The IRB shall seek to meet, at a minimum, the standards set forth by the DHHS regarding IRB membership (§____.107).

b. Membership should reflect diversity in a variety of ways as much as possible to include consideration for race, gender, cultural backgrounds, and expertise (§____.107).

c. The board must be comprised of both men and women.

d. The board should be comprised of a minimum of five members, with at least one representative from each of the respective colleges within the University represented when feasible. Where qualified or willing members cannot be obtained from a particular college, another member should be sought within or external to the University with credentials in a related discipline to the relevant college.

e. The board must include at least one member whose primary interest is in any area of science, and one member whose primary interest is in any non-scientific area.

f. When possible, at least one member whose primary interest or expertise is in an applicable area of law should be included, and/or the IRB will consult with the University's designated legal counsel as needed.

g. At least one member shall be included who is not affiliated with the University and is not a family member of anyone affiliated with the University.

h. Consultants may be recruited to offer expertise on specific projects or areas of concern as non-voting temporary members.

i. All members of the board must have completed a training course in protecting human research participants designated or approved by the Chair or the board, or must complete such within no longer than the first three months of appointment. Any member not having completed the required training will be removed from the board. Cost of the training (if applicable) will be paid by the University.

j. All members of the board are also encouraged to familiarize themselves with the laws and ethics related to the use and care of non-human animals. Projects involving research with non-human animals may require additional competency or training of board members in order to make an appropriately informed decision when the board is acting as the IACUC for the University. In addition to a number of approved conferences and seminars, free video and transcript training is available at OLAW-Educational Resources.

V. Member Selection and Tenure

a. A member shall be appointed as Chair of the board by the VPAA, and shall serve for a five year period, renewable for an indefinite number of terms. The chair may be replaced upon request of the VPAA with a vote of 2/3rds of the other members of the board at any time.

b. A Vice-chair (optional) may be selected from the members of the board by the Chair and approved by the VPAA to assist the Chair with delegate duties. The Vice-chair has the authority to act on behalf of the Chair in the absence of the appointed Chair. The Vice-chair shall serve for a three year period, renewable for an indefinite number of terms. The Vice-chair may be removed or replaced upon request of the Chair or VPAA with a vote of 2/3rds of the other members of the board at any time.

c. All other members serve for a three year period, renewable at the end of each period at the discretion of the Chair and VPAA, for an indefinite number of terms. Members may be replaced upon request of the Chair or VPAA with a vote of 2/3rds of the other members of the board at any time.

d. When possible, no more than 25% of the board shall be replaced at any one time.

VI. Other Duties and Responsibilities of the IRB

a. The IRB should seek to maintain registration and a current Federal-Wise Assurance (FWA) with the HHS and meet all other requirements necessary of the IRB necessary for researcher to obtain federal funding.

b. The IRB shall make all forms and policies readily available to members of the University who wish to conduct research. Certain policies and documents may also be available to the general public.

c. The IRB shall periodically review applicable laws and federal guidelines to assure compliance with current standards.

d. The IRB shall periodically offer training or otherwise assist in disseminating information to faculty and students of the university to promote research and inform of ethical processes in the conducting of research.

e. The IRB will work with researchers bound by an external Central or Single IRB to develop an appropriate Human Research Protection Plan (HRPP).

f. The IRB will review and approve/deny (with administrative input as required) external requests to access Faulkner's students, employees, or other stakeholders to be recruited as participants in research by external institutions, organizations or other entities.

VII. Meeting / Voting

a. The IRB will meet as a board "in person" a minimum of once per semester. This meeting will include a review of ethics, requirements, and policies, and may also include a review of current applications.

b. Submitted applications may be reviewed via an "in person" meeting, or electronically.

c. Submitted time-sensitive applications (e.g. student applications for a course; time-sensitive projects) may be reviewed between scheduled meetings in some cases as feasible.

d. All projects must be received by the 15th of the month to be considered at the meeting of the following month, or according to the schedule otherwise published by the IRB. Whenever possible, submissions will be reviewed within a maximum of 30 days.

e. Voting must be made by a quorum of at least 60% of the current board. A minimum of 60% of "approved" votes cast are required for all projects requiring full board approval in order to be approved.

f. Exempt and Expedited proposals do not require full board approval, and may be approved by the Chair, or by one or more qualified members of the board designated by the Chair. However, these proposals will be made available to the full board for review and input as needed.