**MARIAN UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD**

**POLICIES AND PROCEDURES**

**Effective 2013-14**

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**MARIAN UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD**

**GENERAL POLICIES AND PROCEDURES**

**I. Overview**

The Institutional Review Board (IRB) ensures that research involving human subjects complies with ethical standards set by the federal Office for Human Research Protections (OHRP), which operates within the Department of Health and Human Services (DHHS). All research involving human subjects to be conducted at or supported by Marian University are subject to review by the IRB and such research may not be conducted without IRB approval. In the event that a specific issue arises that has not been addressed in the policies and procedures document, or the policies and procedures document of the reviewing subcommittee, then the reviewing IRB will follow the guidelines found in The Belmont Report (1979) or Title 45, Code of Federal Regulations, Part 46 (2009, or the most up to date revision).

**II. Rationale for a University Policy**

The IRB reflects Marian University’s commitment to basic ethical principles, as well as the specific Franciscan values that inform the university’s mission—especially, the “dignity of the individual”— in the treatment of all persons and provides a consistent application of those principles across disciplines involved in behavioral or biomedical research.

**III. Creation of the Review Board**

The Marian University Institutional Review Board is an administrative committee under the auspices of the Provost, who derives his/her authority from the Board of Trustees. The chair of the IRB reports to the Provost, but the Provost is not a voting member of the IRB.

**IV. Composition and Tenure of the Review Board**

The Marian University IRB is composed of a Chair, who has had formal training in ethics, and at least five members per each standing subcommittee. Subcommittees will comprise Marian University faculty members as well as an external community member not officially affiliated with Marian University. Care shall be taken to ensure scientific and non-scientific members populate each subcommittee. Faculty members shall be recommended to serve on the IRB by their respective Deans. However, the Provost has final appointment capacity. Community members shall be chosen by the Provost for their capacity to serve as community liaisons on matters concerning human subjects research. Excessive absenteeism shall be grounds for dismissal and reappointment. Every effort will be made to be sensitive to issues of diversity in populating the IRB, including gender, ethnicity, cultural identification, and academic discipline.

The community IRB member(s) will be appointed for a 2-year term. IRB members affiliated with Marian University will be appointed for staggered 4-year terms, with each cohort consisting of two IRB members. All members may serve consecutive terms, with the approval of the Provost. The Chair and subcommittee chairs of the IRB, selected by the Provost in consultation with the current IRB members and the proposed new Chair and subcommittee chairs’ respective Deans, will serve a 2-year term, renewable with the approval of the Provost.

**V. Conflict of interests:**

No member of the IRB may participate in the review of a study in which the member has a conflict of interest, except to provide information to the IRB. Members who recuse themselves for a specific review will not be replaced; the review will be carried out by the remaining members. If the recused member is the subcommittee chair, a temporary chair will be appointed for that specific review. In addition, the IRB may invite individuals with competence in special areas to assist in the review process.

**VI. Subcommittees:**

**A.** There shall be at least two standing subcommittees, including a Biomedical Research Subcommittee and a Social and Behavioral Research Subcommittee. The Chair may form additional subcommittees as needed.

**B.** Standing subcommittees shall be composed of a chair, at least four Board members, and a community member. At least one member of each subcommittee shall represent a non-scientific background. Alternates and consultants may be added as needed.

**C.** Subcommittees shall act as completely separate IRBs and the respective chairs shall report their activities and decisions to the IRB Chair at least once a year.

**D.** Subcommittees must adopt and adhere to policies and procedures that are in compliance with Title 45 Code of Federal Regulations Part 46 and approved by the IRB Chair and Provost.

**VII. Duty of the IRB**

**A.** The IRB shall review and have the authority to approve, require modifications (to secure approval), or disapprove all research activities involving human subjects that fall under its authority, including research that qualifies for “exempt” status under the provisions of 45 CFR 46. Furthermore, the IRB shall have the ability to review any activity involving human subjects and the faculty, staff, or students of Marian University to determine if that activity constitutes research. If the IRB determines the activity constitutes research by Marian University faculty, staff, or students, then the IRB has full authority over such research.

**B.** The IRB shall determine if a project submitted by an investigator meets the regulatory definition of human subject research under 45 CFR 46.102(f) and 21 CFR 56.102(f).

**C.** The IRB shall have the authority to conduct continuing reviews of approved human subject research studies at intervals appropriate to the degree of risk. Research studies qualifying for “exempt” status in accordance with 45 CFR 46.101(b) will not be subject to continuing review.

**D.** The IRB shall have the authority to review prospectively all modifications to previously approved research protocols and/or informed consent documents, the only exception being a protocol deviation that may be necessary to eliminate an apparent immediate hazard to a given research subject. All such emergency deviations shall be documented in detail and presented to the IRB within 3 business days.

**E.** The IRB shall have the authority to observe or have a third party observe the conduct of approved human subject research studies, including the informed consent process.

**F.** The IRB shall have the authority to suspend and/or terminate the approval of human subject research activities that are not being conducted in accordance with the IRB’s requirements or have been associated with unexpected serious harm to subjects.

**G.** Stating that which is implicit in the above authorities, the IRB shall have the authority to review and place restrictions on any human subject research activities under its purview in order to protect the rights and welfare of the subjects.

**H.** The IRB shall have the authority to require a final report upon completion or closure of each approved human subject research study.

**VIII. Duties of the Chair**

1. The Chair shall be responsible for maintaining registration of the IRB with the federal Office for Human Research Protections in the Department of Health and Human Services.
2. The Chair shall monitor IRB membership and ensure IRB members have access to and have completed appropriate training.
3. If either of the subcommittee chairs is temporarily unable to perform their respective duties, these duties will be taken on by the IRB Chair until either (a) the subcommittee chair is able to resume these duties, or (b) the subcommittee chair is terminated and a new subcommittee chair is appointed.
4. The Chair shall receive all preliminary proposal forms (IRB Form 1)
	1. The Chair shall first determine whether the proposed activity involves *human subjects*. The Chair shall be liberal in their definition to allow the appropriate subcommittees the ability to fully discuss close cases.
		1. **Human subjects** are defined by the regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."
	2. If the proposed activity involves human subjects, the Chair shall then determine, also in a liberal fashion, if the proposed activity involves *research*.
		1. **Research** is defined by the regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
	3. If the proposed activity is determined to involve human subjects and is considered research, the Chair shall then determine which subcommittee is appropriate to review the proposal and forward IRB Form 1 to the subcommittee chair, who shall then direct the researcher to submit a complete application for further review consistent with the policies and procedures of that subcommittee. The Chair shall complete this initial determination no later than 14 days from the receipt of IRB Form 1.

**IX. Compensation of the IRB**

The IRB Chair, chairs of each subcommittee, IRB members, and any consultants may be compensated for their IRB duties and responsibilities if deemed appropriate by the Provost in consultation with the IRB Chair and subcommittee chairs. The rate of compensation shall be at the discretion of Marian University Department of Human Resources and shall take into account the professional background of the individual and the expected time commitment of the appointed position to IRB activities.

**X. Indemnification**

Marian University shall have a policy that provides legal defense for faculty and staff acting within the scope of their IRB duties. Indemnification shall be afforded to the IRB Chair, chairs of each subcommittee, IRB members, consultants, and staff.