

University of Wisconsin-La Crosse
Institutional Review Board for the Protection of Human Subjects

Operating Guidelines and Organizational Policies (Approved by IRB on 11/18/2024)

I. PURPOSE OF THE BOARD

- A. The UW-La Crosse Institutional Review Board for the Protection of Human Subjects (IRB) is responsible for protecting the rights and welfare of human subjects participating in research projects. The Board exercises its review and approval functions to ensure the safe, fair, and ethical treatment of persons serving as research subjects and to ensure that the University and its researchers adhere to appropriate standards of conduct in their pursuit of knowledge and understanding.

II. STATUTORY AUTHORITY OF THE BOARD

- A. Title 45 of the *Code of Federal Regulations*, Part 46 (45 CFR 46) implements amendments to the Public Health Service Act (Public Law 99-158), effective 19 August 1991, that require all institutions engaged in research involving human subjects to establish an IRB.
- B. The Chancellor, as the chief executive officer of the University, is responsible for ensuring that the UW-La Crosse IRB operates in accordance with all applicable laws. The Chancellor has designated the Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) to monitor the operation of the IRB and to appoint its membership.

III. REVIEW POLICIES AND PROCEDURES

- A. The Board shall establish policies and procedures for the review of research projects involving human subjects and shall disseminate these broadly and regularly to all appropriate faculty, staff, and students at the University. The Board shall issue (and update as needed) a substantive booklet, *A Researcher's Guide for Submission of Protocols to the IRB*, which includes required review procedures and forms. This document and other resources are available in electronic format through the UWL Office of Research and Sponsored Programs' (ORSP) IRB webpage.

IV. MEMBERSHIP OF THE BOARD

- A. Federal law requires that each IRB shall have at least five (5) members who possess sufficient expertise, experience, and breadth of knowledge to provide complete and adequate review of research activities commonly conducted at the institution. The IRB membership must have professional competence necessary to review specific research activities, as well as knowledge of institutional regulations and commitments, applicable law, and standards of professional conduct and practice.

- B. The law further requires that each IRB shall include the following types of individuals in its membership:
 - 1. At least one member of the Board must have primary professional expertise in scientific areas.
 - 2. At least one other member of the Board must have primary professional expertise in nonscientific areas.
 - 3. At least one member of the Board must not be otherwise affiliated with the institution, including having a member of the immediate family of a person who is affiliated with the institution. This member is referred to as the community representative.
- C. The law also instructs that the Board shall seek to include qualified persons of diverse personal and professional backgrounds. The Board may not consist entirely of members from a single disciplinary profession.
- D. The UW-La Crosse IRB will consist of not less than ten (10) and not more than fifteen (15) full voting members, who are appointed by the Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) with the concurrence of the Provost under the authority of the Chancellor.
- E. The Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) may appoint additional Associate IRB members in certain academic units who will have the same privileges as members of the Board except that they can only vote if the voting member from that unit is absent during the Board meeting.
- F. The membership shall include at least one (1) representative from each of the following units of the University:
 - 1. College of Science and Health
 - 2. College of Business Administration
 - 3. College of Arts, Social Sciences, & Humanities
 - 4. School of Education
- G. The committee shall include at least two, but no more than three, individuals from the community who are full voting members.
 - 1. At least one shall be from a local, non-medical organization.
 - 2. At least one shall be a licensed medical practitioner or researcher who serves on an as needed basis. Should that member be unavailable when medical expertise is required, the Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) or Coordinator shall invite individuals with appropriate medical expertise to participate in the relevant sessions as nonvoting (*ad hoc*) consultants, per Section VI.E.
- H. All members of the Board (with the exception of the community member(s) designated in Section IVB.3 and IV.G above) must be members of the faculty and/or academic staff of UW-La Crosse.

V. Term of Appointment:

- A. Each voting member of the Board will serve for a three-year term. Appointments to the IRB shall be staggered in rotation, such that no more than one-third of the Board should be appointed every year.
- B. The Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) may reappoint any member for a second term.

Ordinarily, no voting member, including the community member, may serve for more than six (6) consecutive years. However, under extenuating circumstances, the Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) may allow an extension beyond the six consecutive years. Extenuating circumstances may include an unwillingness or inability of other faculty or academic staff from the desired department to serve on the committee following the expiration of the current committee member's sixth consecutive year.

VI. Permanent and *Ex-Officio* Members and *Ad Hoc* Consultants:

- A. The Board shall elect a Chair from among its faculty and academic staff membership who will convene meetings and serve as a voting member of the full board. The Chair shall be elected at the last meeting of the IRB in the Spring Semester or immediately thereafter. The elected Chair shall begin their term on September 1st of the same year and shall serve a one-year term. This individual may be re-elected for a period commensurate with their term of appointment (see above, Section V). The Chair is still expected to review student protocols from their department. Additionally, the Chair shall review any protocols submitted by the IRB Coordinator or the Coordinator's students.
- B. The Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) shall appoint an IRB Coordinator for a period of 3 years, with an option to seek reappointment via the established search process. Ordinarily the IRB Coordinator shall be a member of faculty or academic staff at UWL who has earned a minimum of a baccalaureate degree, a minimum of three years' experience as a member of IRB or equivalent experience in conducting and/or mentoring human subjects research, and sound knowledge and understanding of the Federal Guidelines relating to the Protection of Human Subjects.
- C. The Coordinator, who reports directly to the Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO), shall serve as an *ex officio* voting member of the IRB. The Coordinator shall review all faculty and staff protocols and some protocols submitted by students who are either a) from an academic department not represented by a current member of the IRB or b) submitting during the summer unless it is determined that the protocol warrants an in-depth review at a convened meeting of the IRB. Additionally, the Coordinator will review all proposed amendments to protocols. The Coordinator may work with the elected IRB Chair in making decisions about a protocol or amendment needing in-depth review by the full board.
- D. The Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) shall serve as a permanent, nonvoting (*ex officio*) member and consultant to the Board and shall be referred to as the "IRB Administrator."
- E. The IRB Program Assistant, or another designated individual from ORSP, shall serve as a permanent, non-voting (*ex officio*) member and consultant to the IRB.

- F. In accordance with 45 CFR Section 46.107(e), the Board may, at its discretion, invite individuals with specialized expertise to participate in its sessions as nonvoting (*ad hoc*) consultants.
- G. In accordance with 45 CFR Section 46.304(b), when prisoner research is involved, the IRB Administrator may appoint an *ad hoc*, voting member with specialized expertise to participate in the Board. This member may be an applicable faculty member or community member.
- H. *Ad hoc* members and consultants should be able to demonstrate close working knowledge, understanding, and appreciation of the population and/or field they have been identified to represent. This individual should have relevant experience with such populations and/or experience in the field, at least 10 years prior to the appointment to the Board.

VII. MEETINGS

The IRB Chair is responsible for convening the Board according to an established regular schedule that permits researchers to have their projects reviewed in a timely manner. The full membership of the Board shall meet at least one (1) time during the calendar year.

- A. A majority of the full appointed voting membership shall constitute a quorum for the purpose of holding an official meeting. A majority of those voting members present at an official meeting shall be sufficient to issue official verdicts, actions, and judgments.
- B. All meetings shall be conducted in accordance with the state of Wisconsin's Open Meetings Law and any other appropriate state and/or federal regulations governing the operation of this public Board.

VIII. REVIEW OF STUDENT PROTOCOLS DEEMED 'EXEMPTED'

- A. The IRB Administrator, in consultation with the IRB Chair, may designate interested academic departments to review and approve student protocols which are deemed 'exempted.'
- B. An academic department may be designated to review/approve student protocols only if at least one faculty or staff member from that department has been appointed a full member on the IRB. The department may have additional Associate members who can also review/approve student protocols in consultation with the designated IRB member.
- C. When a student protocol is being reviewed at the department level and there is any doubt about the protocol under review being non-exempt and non-expedited, the designated IRB member should immediately consult the IRB Coordinator to have that protocol reviewed under the 'full review' category. If appropriate, a 'full review' of the protocol will be conducted by the IRB at its next convened meeting.
- D. The IRB Chair, Coordinator, or Administrator, at their discretion, may ask IRB members reviewing student protocols to provide a brief summary of the reviewed protocols and/or authorize an audit of the reviewed protocols, by one or more members of the IRB, if needed.
- E. All protocols must be initially submitted and logged in the Office of Research and Sponsored Programs before being assigned for review by anyone. The departments designated to

review/approve student protocols must not review any protocols unless these are logged in ORSP.

- F. Alternative submission is accepted through the IRB Exempt Decision Tool in lieu of a complete protocol. Use of the Tool is subject to the eligibility, policy, and procedural requirements outlined on the IRB webpage at the time of submission.
- G. All protocols reviewed and approved by the IRB Coordinator, IRB Chair and/or designated IRB members must be reported in the next regularly scheduled meeting of the full Board as consent agenda. The full IRB retains the right to review, reverse, modify, or void any earlier decision or action on the protocol.

IX. CONFLICT OF INTEREST PROCEDURES

- A. Any member of the Board who has an actual or apparent conflict of interest in the initial or continuing review of a research project may not participate in the Board's deliberations or voting (except to provide general or specialized information that may be requested by the IRB).
- B. It is the responsibility of the individual Board member to identify a conflict of interest and remove themselves voluntarily by informing the IRB Chair. The specific nature of the conflict of interest need not be revealed.
- C. If someone believes that there is an actual or apparent conflict of interest in the participation of an IRB member in a particular case, and that person has not removed themselves from the proceedings, a challenge may be raised either by a member(s) of the Board or by the researcher(s) whose project is under review. A conflict-of-interest challenge must be raised prior to the Board's action on the project and takes immediate precedence as a point of order during an official meeting.
- D. The IRB minutes must clearly show that one of the members were excused from the deliberations due to the conflict of interest.

X. INSTITUTIONAL REVIEW

- A. As provided in 45 *CFR* Section 46.112, affirmative decision of the IRB may be subject to further review by University officials. The Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO), Provost/Vice Chancellor, and the Chancellor may, at their discretion, conduct additional, independent inquiry into a decision of the IRB and may, if their findings so warrant, disapprove a research project previously authorized by the IRB.
- B. In no case may the Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO), Provost/Vice Chancellor, or Chancellor approve a research project that the IRB has previously disapproved.

Operating Guidelines and Organizational Policies of the UW-La Crosse Institutional Review Board adopted 17 March 1998 and revised 31 January 2000; 1 September 2004; January 2005; 3 February 2006; 4 August 2006; 1 May 2007; 22 April 2011; 18 November 2022; 8 March 2024; 18 November 2024



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11/17/2024

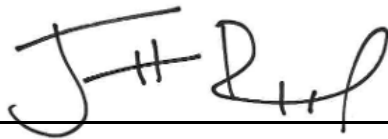
Date



Betsy Morgan
Provost & Vice Chancellor for Academic Affairs

11/18/2024

Date



James Beeby
Chancellor

11/18/2024

Date