BYLAWS OF THE UNIVERSITY OF WISCONSIN-WHITEWATER (UW-WHITEWATER) INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

Article I. NAME

The name of the board is the University of Wisconsin-Whitewater Institutional Review Board (hereinafter called "UWW-IRB").

Article II. OBJECT

The UWW-IRB is to ensure observance of the Federal Policy for the Protection of Human Subjects, published in the Federal Register, Vol. 56, No. 117, June 18, 1991, beginning at 28001 (the "Regulations"), and observance of policies of UW-Whitewater concerning research involving human subjects. The UWW-IRB will review all research conducted by faculty members, students, or staff that directly, or indirectly, involves human subjects.

Article III. AUTHORITY

The UWW-IRB is established under and pursuant to the letter of assurance, which expires on 24 March 2027, between UW-Whitewater and the Department of Health and Human Services (HHS), as an institutional review board (IRB) under 45 CFR §46.103 of the HHS Regulations. The UWW-IRB is empowered to:

1) Review all funded and unfunded research (as defined in the Regulations) proposed by faculty, staff, or students that involves the use of human subjects, prior to the beginning of the research.
2) Determine the type of review (exempt, expedited, or full board) that the research requires.
3) Approve, require modifications, or disapprove research protocols based upon consideration of the protection of human subjects.
4) Suspend or terminate a research project.
5) Require progress reports and perform such monitoring, as it deems necessary.

Article IV. RELATIONSHIP TO THE UNIVERSITY

The UWW-IRB shall be directly responsible to the Chief Research Administration Officer (formerly Director of the Office of Research and Sponsored Programs). The UWW-IRB shall coordinate its actions and policies with the Office of Research and Sponsored Programs.

The office of the Provost shall provide the UWW-IRB with needed clerical support, files, copying facilities, supplies, equipment and space.

Article V. MEMBERSHIP

The UWW-IRB's membership, appointed by the UWW Chief Research Administration Officer, shall consist of at least five (5) members with the following requirements:

1) Non-affiliated member(s): The non-affiliated member(s) can be either scientific or non-scientific reviewers who are willing and able to discuss research issues, but have no affiliation with the University of Wisconsin-Whitewater.*

2) Scientific members: An individual who has formal education and training as a physician or other medical professional, a Master's or Doctoral level physical, biological, or social-behavioral scientist, or significant post-baccalaureate work experiences in the physical, biological or social-behavioral disciplines. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB will use a consultant to assist in the review, as provided by 45 CFR 46.107(f) and 21 CFR 56.107(f).

3) Non-scientific member: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, non-scientific members are individuals whose education, work, or interests are not primarily in medical or scientific areas.

4) Representatives of special groups of subjects: When certain types of research are reviewed, members or consultants who are knowledgeable about the concerns of certain groups may be required. For example, if the IRB reviews research involving prisoners, an individual who can represent this group (e.g., an ex-prisoner or an individual with specialized knowledge about this group, such as a consultant) may be included in the IRB discussion.

5) Chair: The individual IRB Chair(s) must be employed by the UW-Whitewater as tenured members of the faculty and be fully capable of providing leadership to the IRB and the matters brought before it with fairness and impartiality.

6) IRB Alternate Members: All Alternates for IRB members must complete the same training as new IRB members prior to serving as an Alternate and through their expertise, training and/or affiliation are designated by the UWW Chief Research Administration Officer to serve as an Alternate for one or more IRB members.

*A *non-affiliated member* is an individual who has no affiliation with the UW-Whitewater other than as an IRB member. Non-affiliated members may include people whose only association with the institution is that of a patient, subject, or former student at the institution.

In making appointments to the Committee, the UWW Chief Research Administration Officer shall take such reasonable steps as necessary to achieve a membership with diversity in race, gender, cultural backgrounds, and professional qualifications. The members shall be appointed for a three-year term, may be reappointed, and shall be removed during their term only for stated cause or by individual resignation. Members shall hold current Collaborative Institutional Training Initiative (CITI) certification on the following: Responsible Conduct of Research (RCR), IRB Members (HSR)**,** Social, Behavioral, & Educational (SBE) Sciences - All Researchers, or any other required human subjects research training. Members may attend meetings remotely. Failure to attend two (2) consecutive meetings may constitute cause for removal and replacement by another individual designated by the UWW Chief Research Administration Officer. The UWW Chief Research Administration Officer shall appoint alternates who will be invited to attend all meetings and training sessions and who may serve in the place of absent members as necessary.

1) Members may receive additional compensation, as permitted by University policy, for IRB duties completed outside the scope of their primary faculty contract. The University shall provide liability coverage under its umbrella coverage.

2) The IRB Administrator/Compliance Officer will serve as a voting member of the committee if appointed by the UWW Chief Research Administration Officer.

Article VI. OFFICERS

The UWW-IRB will accept nominees and conduct a vote on the election of the Chairperson every two (2) years. The chairperson may appoint an acting chairperson to function in their absence. Other officers may be appointed to carry out activities of the committee.

The Chairperson, in collaboration with the UWW-IRB Administrator, is responsible for the following: developing an agenda for IRB meetings, conducting IRB meetings, and designating primary reviewers for full board and expedited reviews.

Article VII. MEETINGS

The IRB shall meet at least monthly throughout the year, unless a meeting is cancelled by the chairperson for good cause. Notice of time and place shall be given at least one week in advance. Meetings may be held in person or remotely. The chairperson may call a special meeting upon three (3) business days written or telephone notice. In case an IRB member needs to be absent, they will notify the Chair that an Alternate is required.

Minutes of each meeting shall be kept by the UWW-IRB Administrator. A list of the protocol actions taken since the previous meeting will be available to members.

A quorum shall consist of a simple majority, including at least one member whose primary concerns are non-scientific.

Article VIII. DECISIONS OF THE IRB

Full review by the UWW-IRB shall consist of all members or alternates who will attend meetings scheduled for consideration of protocols that require full board review.

In an emergency, the chairperson shall be empowered to circulate the protocol to members for review and conduct a telephone or web conference meeting, whereby the members can hear each other simultaneously.

The UWW-IRB shall be empowered to approve or disapprove a protocol and to give conditional approval (i.e., approval if the investigator agrees to follow the UWW-IRB requirements for protecting subjects). It may also table protocols when the review requires more information.

In the review process, the UWW-IRB shall have as its primary criteria: the degrees of physical, social, and psychological risk; the need for and degree of confidentiality; the presence, absence, or adequacy of informed consent; and the protection of particularly vulnerable subjects. The UWW-IRB shall not concern itself with the quality of the protocol or its methodology unless more than minimal risk is involved, in which case quality and methodology are appropriately considered in assessing the risk-benefit ratio.

In deciding whether a protocol shall be approved, disapproved, tabled, or conditionally approved, the UWW-IRB shall seek consensus. The action taken shall be determined by a simple majority of those attending the meeting. A member or alternate having conflicting interest in a matter before the UWW-IRB shall abstain/not vote on that matter. When a member or alternate is barred from voting because of a conflicting interest, said member or alternate shall not be counted in determining the number of votes needed for a majority, notwithstanding that the presence of said member or alternate has been counted to determine a quorum. Such members shall be absent from the deliberation and vote except for the purpose of providing information requested by the UWW-IRB.

Each UWW-IRB member shall have one vote. Voting shall proceed openly, after an opportunity for

full discussion and debate has been afforded.

Individuals whose protocols have been reviewed shall be notified of the UWW-IRB decision in writing within 5 working days.

The UWW-IRB shall retain all protocols. With regard to protocols requesting funding, notification of the UWW-IRB's decision will be given to the appropriate Grant Officer within the Office of Research and Sponsored Programs.

The UWW-IRB, upon the request of an investigator or on its own initiative, may reconsider any protocol and reverse its own determination or that of a subcommittee.

An investigator may re-submit a protocol for re-review once it has been modified in such a way as to remove the UWW-IRB's objections. There shall be no mechanism for appeal by investigators beyond the IRB.

Article IX. SUBCOMMITTEES

The chairperson shall, if necessary, appoint subcommittees from the UWW-IRB membership to execute various duties related to the objectives and policies of the IRB.

Some academic units generate a large number of research protocols, particularly student research protocols. The UWW-IRB shall encourage the formation of departmental/academic unit screening committees, which may review protocols and identify issues likely to concern the UWW-IRB prior to forwarding those protocols to the IRB. At least one member of each such committee must be a regular member of the IRB.

Article X. EXEMPT AND EXPEDITED REVIEW

In accordance with §46.101b and §46.110 of the Regulations, the chairperson or other members of the UWW-IRB who are designated by the chairperson, shall be empowered to perform exempt and expedited reviews and approval of protocols that appear to present no more than minimal risk to human subjects. A protocol that is not otherwise exempt under the Federal regulations, and that appears to present more than minimal risk or involves research on illegal behavior, sexual behavior, or alcohol/drug use, shall not receive exempt or expedited review but shall be referred to the full UWW-IRB.

The UWW-IRB will terminate any project where the PI proceeds to collect data without IRB approval.

Article XI. PARTICIPATION OF NON-MEMBERS

With the consent of the chairperson, meetings of the UWW-IRB may be attended by persons who are not members. Such persons ordinarily would be: (1) persons with special expertise needed by the UWW-IRB, (2) persons who have submitted protocols, which in the UWW-IRB's opinion requires oral explanation and questioning, (3) persons whose research in progress requires monitoring, or (4) office staff.

Article XII. MONITORING/REPORTING

In accordance with the regulations and policies of relevant Federal Departments/Agencies and of the UW-Whitewater, the UWW-IRB shall have the authority to monitor those research projects that the UWW-IRB judges to involve more than minimal risk to the subjects. Such monitoring may include requesting periodic written or verbal reports or unannounced site visits.

The UWW-IRB will conduct continuing review of research at intervals appropriate to the degree of risk but not less than once per year. In some circumstances, a shorter review interval may be required. The IRB will require review more frequently than annually for those studies deemed "high-risk." If a study is inadvertently terminated by the investigator, it may be reactivated within 60 days without submission of an application to the UWW-IRB for a new study.

The chairperson may delegate authority to one or more experienced members of the UWW-IRB to conduct and approve uneventful continuing reviews of expedited studies and termination reports of uneventful full review studies. Full UWW-IRB studies must have the continuing review conducted by the full UWW-IRB.

In the event that the UWW-IRB (1) becomes aware of any serious or continuing non-compliance with the Regulations or the policies of the UWW-IRB, or (2) suspends or terminates a UWW-IRB approval, then written notice of such noncompliance, suspension, or termination will be given within seven (7) business days: i) to the Institution by way of the UWW-IRB Administrator and the UWW Chief Research Administration Officer, ii) to the appropriate Federal funding agency, and iii) to the Office for Human Research Protection.

Article XIII. RECORDS

The chairperson or IRB Administrator shall ensure that proper records are maintained, specifically: (1) Minutes of each meeting with the names of those present, the protocols acted upon, a general summary of the discussion of controverted issues, other UWW-IRB actions, all vote counts, and a list of exempt, expedited, and amended protocols; (2) Copies of all protocol submission documentation, documentation of review, notification of the UWW-IRB action , and any other relevant data; (3) Correspondence; and (4) Reference books and journal articles.

UWW-IRB members will be provided with the minutes of the previous meeting in advance of the next meeting. The minutes shall be kept in perpetuity. All protocols shall be kept for three years after completion of the research.

Article XIV. UWW-IRB REQUIREMENTS OF THE INVESTIGATORS

The Principal Investigator, along with any other faculty, staff or student researchers involved in the study, must complete the current IRB approved human research training program prior to review of their protocol submission.

All protocols requiring UWW-IRB review shall require the investigator to complete the online protocol submission and attach any required or pertinent documentation as outlined in the UWW-IRB Guide. If the investigator believes that their research will require review by the fully convened board, it must be submitted by the first day of the calendar month for the monthly meeting of the IRB. Additional information on protocol submission can be found in the UW-Whitewater IRB Guide.

Investigators may not collect data, acquire consent, or otherwise engage in the research process before the UWW-IRB approves the protocol.