

WESTERN CONNECTICUT STATE UNIVERSITY

Institutional Review Board Bylaws

1. Mandate

The Institutional Review Board (hereafter, IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. (Department of Health and Human Services Office of Human Research Protections, *Institutional Review Board Guidebook*, 2.) The Western Connecticut State University (hereafter WestConn) IRB is responsible for reviewing all research involving human subjects conducted at the university or by faculty, staff, and students affiliated with WestConn in order to ensure compliance with and fulfillment of: (1) the policies contained in the IRB document entitled “Guidelines for Researchers;” (2) the U.S. Department of Health and Human Services Office of Human Research Protections’ *Institutional Review Board Guidebook* (hereafter, HHS OHRP *IRB Guidelines*); and (3) federal and state regulations related to research with human subjects.

2. The Board

a. Membership: The IRB shall consist of at least five members. Responsibility for appointing and maintaining the IRB rests with the Provost and Vice President for Academic Affairs in consultation with the Deans of the Schools, the appropriate Department Chairs, and with the advice and consent of the Board. In compliance with OHRP regulations, the membership must represent the breadth of scientific and scholarly specialties at the university, at least one member whose primary concerns are in a non-scientific area, and at least one member who is otherwise unaffiliated with the university. Appointments are for two years and are renewable. Continuity is ensured by staggered reappointment for subsequent years whenever possible. The university’s Human Protections Administrator is a non-voting *ex officio* member of the IRB.

The IRB may have as many members as necessary in order to perform its duties effectively. A Board member can be removed from service by the Provost and Vice President for Academic Affairs on the recommendation of the Board.

Any member of the university community who would like to serve on the IRB should indicate his/her interest to his/her chair, director, advisor, and/or dean.

b. Duties of Members:

- Attend Board meetings
- Review and evaluate all assigned protocols in advance of each meeting
- If designated by the chair, act as a reviewer for protocols eligible for expedited review
- Serve on *ad hoc* subcommittees of the Board
- Complete NIH or other approved training for research with human subjects annually

- Become familiar with federal and state regulations, WestConn policies, and IRB guidelines and procedures
- Keep him/herself current on federal and state regulations, WestConn policies, and IRB guidelines and procedures

3. The Chair

a. Appointment:

The Provost and Vice President for Academic Affairs appoints the chair for a renewable one-year term with the advice and consent of the Board. The chair can be removed from service by the Provost and Vice President for Academic Affairs on the recommendation of the Board.

b. Duties:

- Chairs all regular and special sessions of the Board. If the chair is unable to attend the meeting, he/she shall appoint a substitute from the Board membership
- Performs all the functions of a Board member
- Has the authority to temporarily suspend research that is not in compliance with IRB guidelines
- Represents the Board in dealings with the uand the public when attendance of the total membership is not required
- Participates in or designates others to participate in sessions designed to inform and educate WestConn faculty, staff, and students about the responsibilities and activities of the Board
- Stays informed about the latest changes in federal and state guidelines for research with human subjects and communicates that information to other members of the Board and to the university community
- Has the authority to authorize emergency changes to a protocol to avoid an immediate hazard to subjects
- May appoint an *ad hoc* committee

4. The Office of Grant Programs/Human Protections Administrator

Under the terms of the university's current Federalwide Assurance, the Director of Grant Programs serves as the Human Protections Administrator. The Human Protections Administrator and staff have the following duties:

- Keep current on federal and state guidelines for research with human subjects and communicate that information to the Chair, the Board, and to faculty, staff, and students who do human subjects research
- Organize and participate in educational activities related to IRB policies and procedures
- Post IRB guidelines, forms, minutes, logs, and related materials electronically
- Maintain records for all protocols
- Distribute protocols appropriately
- Post meeting notices on ERes, "WestConn Report," and via all-faculty emails

- Keep on file IRB correspondence, guidelines, forms, minutes, logs, human research training certificates, and all other relevant information
- Participate in on-site reviews by federal inspectors
- Provide assurances to federal agencies of approval of protocols to be supported by federal funds
- Act as liaison between federal agencies and investigators regarding human subjects issues
- The Human Protections Administrator submits an annual report on IRB activities to the Provost and Vice President for Academic Affairs as part of his/her Annual Report

5. Special Consultants

The Board may designate a consultant with special expertise to assist in the review of a particular protocol. The consultant does not vote on protocols.

6. Meetings

a. Date and Time:

The Board meets at least three times a semester. Dates, times, meeting place, and deadlines are announced on ERes, in the “WestConn Report,” and through all-faculty emails.

b. Agenda:

The Board will discuss and act on all protocols on the agenda.

c. Voting:

A quorum, consisting of one more than one-half the IRB membership (including a nonscientist member) is required to conduct business. A majority of those voting is required for Board action. If a vote is not unanimous, a roll call vote must be taken and recorded in the formal minutes.

d. Minutes:

Minutes must be kept in accordance with OHRP guidelines. The minutes should reflect the substance of all discussions. Minutes are distributed to members via email before the meeting. After the minutes are approved, they are sent to the Office of Grant Programs to be posted on ERes.

Minutes are open to all faculty, staff, and students. Observers may comment, but may not vote at meetings.

7. Action on Research Proposals

The Board shall review research proposals that require full review and shall periodically conduct ongoing review of approved research projects.

The Chair may review and approve proposals that involve no more than minimal risk to the subject(s) or involve minor changes in previously approved proposals. Such review and approval may be conducted by the Chair or by one or more experienced members of the Board designated by the Chair.

If adverse consequences or unanticipated side effects are encountered in the course of the study, or new information becomes available that could change the perception of a favorable risk/benefit ratio, the principal investigator is responsible for informing the Board **promptly**. The WestConn IRB will make the final determination regarding protocol changes required due to adverse event reports.

Research that has been reviewed and approved by an IRB may be subject to further review and disapproval by officials of the institution. Those officials may not, however, approve research if it has been disapproved by the IRB. (HHS OHRP *IRB Guidelines*, 3)

Approved research is subject to continuing IRB review and must be reevaluated at least annually. (HHS OHRP, *IRB Guidelines*, 3)

8. Changes to the Guidelines and Bylaws

Changes to the guidelines that are mandated by the federal government will be made immediately.

Changes to local IRB regulations and changes to the bylaws must be adopted by a majority of the Board and approved by the Provost/Vice President for Academic Affairs. Prior to final approval, the Provost/Vice President for Academic Affairs will inform the university community of the proposed changes and comment will be invited.

As changes to rules, regulations, or operating procedures become necessary, they will be posted on ERes. They are also available in the *Faculty Handbook* and via electronic copy or hard copy from the Office of Grant Programs.

Last revised and approved by the IRB on 3/15/06