

WESTERN CONNECTICUT STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Annual Report for Academic Year 2008-2009

Submitted to
Dr. Linda Rinker
Provost/Vice President for Academic Affairs

The Western Connecticut State University (WestConn) Institutional Review Board, an independent administrative committee, is charged with the responsibility for review and approval of research involving employees or students of the University. In accordance with the university's Federalwide Assurance, the requirement for review applies whether the research is funded or unfunded, regardless of the source of funding or the site at which the research is conducted.

The WestConn IRB operates in compliance with the U.S. Code of Federal Regulations, Department of Health and Human Services (HHS) Title 45 Part 46, "Protection of Human Subjects and the HHS Office of Human Research Protections (OHRP) *Institutional Review Board Guidebook*. WestConn's IRB is registered with the OHRP.

I.
IRB Committee Members, 2008-2009

Gene Buccini
Sue Cizek
Karen Daley
Marcy Delcourt
Ron Drozdenko
Robin Flanagan
Jack S.C. Fong (non-WCSU member)
Jenny Innes
Shane Murphy (Chair)
Oluwole Owoye
Bill Petkanas
Wynn Gadkar-Wilcox

II.
Meetings of the IRB

August 27, 2008
3 Proposals Full Reviewed

September 17, 2008
1 Proposal Full Reviewed

October 15, 2008
5 Proposals Full Reviewed

November 19, 2008
3 Proposals Full Reviewed (1 tabled from October 15)

December 10, 2008
4 Proposals Full Reviewed

February 04, 2009 (meeting postponed from January)
8 Proposals Full Reviewed

February 18, 2009
5 Proposals Full Reviewed (2 tabled from Feb 4)

March 18, 2009
7 Proposals Full Reviewed

April 15, 2009
6 Proposals Full Reviewed (1 tabled from March 18)

May 20, 2009
3 Proposals Full Reviewed

All meetings were attended by guests, often students in research methods/thesis courses, as well as some researchers.

III.

Proposals Reviewed in 2008-2009

During Academic Year 2008-2009 (information as of May 19, 2009), the IRB received 197 protocols, all of which were logged in by Martha Palanzo and forwarded to the IRB chair or his designee (Applications for Exempt Review and protocols eligible for expedited review) or to the full committee. The log is posted on ERes, the library's electronic reserve system.

A total of 41 unique proposals were fully reviewed by the IRB during this academic year. 36 of these approvals were approved or approved pending minor modifications. Another 3 proposals were approved after more extensive modifications. Two proposals were not approved.

Another 156 proposals were given either expedited or exempt reviews. Most of the expedited proposals were student research proposals for University research/methods/thesis courses and most were reviewed and a decision returned within a week of submission. The vast majority (over 95%) were approved, although a few were

sent to full review, and several were withdrawn after IRB feedback. A very few were deemed to not be human subjects research.

IV.

Notable Achievements

1. The new WCSU IRB website - <http://www.wcsu.edu/irb/> - went “live” in Fall, 2008. The completely redesigned website is now the “one-stop shopping” address for all IRB issues. Prospective researchers can download all necessary forms from the website and links are provided to a variety of helpful sites. The full schedule of meetings is posted on the site and guidelines are available for those wishing to submit a Human Subjects Application. In conjunction with the operation of the website, all existing forms and documents were removed from the old ERes site. The ERes site is now used only for logging proposals and for maintaining past reports, etc.
2. The IRB approved the CITI (Collaborative Institutional Training Initiative) program for human subjects research training. The CITI training requirements were modified to simplify the training process, especially for students. The CITI training proved to be a very popular way for prospective researchers to fulfill their federally mandated human subjects training requirements.
3. IRB Workshop for new faculty was held on October 2, 2008. Conducted by Shane Murphy and William Petkanas, it was well attended and well received.

V.

Case Studies

I thought it would be instructive this year to select three proposals that were not approved by the IRB and briefly discuss them. This might be instructive for both the IRB, to learn from these experiences, and for prospective applicants, to help identify potential problem areas.

- A. **Medical research proposal, outside researchers.** This proposal from a researcher at a nearby institution concerned the application of a psychoactive drug for treatment or possible prevention of PTSD in trauma sufferers. This use of the drug is “off-label” (not FDA approved). Although the potential benefit (prevention of PTSD) from the research is high, the IRB was concerned that they did not have the expertise to fully evaluate the possible risks of using the medication, which included significant effects on blood pressure. Given the sensitivity of the subject pool (veterans on campus), and the lack of potential support on campus for any negative reactions to the drug use, the IRB was especially cautious. Modifying a non-WCSU, grant-funded research program is very difficult, and the IRB did not approve this research.
- B. **Medical research proposal, WCSU.** This proposal from a graduate student at WestConn concerned the application of an existing medical procedure with a novel subject pool. Both the benefits (better care for dialysis patients) and risks (blood clotting) of this intervention were high. The IRB has 2 physicians and a member of the nursing faculty as members and they took an active role

in helping the committee evaluate this proposal carefully. The initial proposal as submitted was not approved, but the student and her faculty supervisor worked intensively with the Chair and with another IRB member from that department to modify the proposal in order to meet IRB concerns. The modified proposal was resubmitted and subsequently approved by the IRB. The IRB is mindful of encouraging worthwhile research while doing everything possible to protect the rights of human subjects.

- C. **Undergraduate student proposal.** This proposal from an undergraduate student as part of an upper-level research methods course concerned face-to-face interviews with returning Iraq War veterans concerning their evaluation of experiences while serving in a combat environment. The stated risk of the research was asking about memories that might trigger PTSD-type symptoms (flashbacks, strong negative emotions) during or after the interview. In this case the perceived benefit (completing an undergraduate course requirement) was not seen by the IRB as outweighing the potential risk. Several potential modifications were considered, but none being satisfactory, the proposal was not approved. Due to course time constraints, the proposal was not resubmitted.

This study was representative of a few undergraduate student proposals that were not approved. In all cases, the risks of the study were deemed unacceptably high (in another case, a student wanted to interview fellow workers at her workplace about attitudes towards extramarital affairs), especially in terms of triggering strong negative emotions in subjects. The IRB is especially cautious in reviewing undergraduate proposals, as these are inexperienced researchers, with little long-term commitment to the research project, and the studies often lack a strong theoretical foundation to be able to evaluate potential benefits accurately.