

**Report to the Faculty Senate
Institutional Review Board Activities
AY 2001-02
May 6, 2002.**

The Institutional Review Board (IRB) has held seven meetings, thus far, during academic year 2001-02. The final meeting of the academic year will be held during the week of May 20, primarily for the purpose of reviewing protocols for University funded summer student research.

IRB membership AY01-02

The Board was composed this year of the following members:

Roger Allen, Chair	Physical Therapy
Patrick Coogan	Community Representative
John Finney	Associate Dean & University Registrar
Lisa Ferrari-Comeau	Politics & Government
Judith Kay	Religion
Mary Rose Lamb	Biology
Kathy Stewart	Occupational Therapy
Tom Wells	Exercise Science
John Woodward, Secretary	Education

Review of Human Research Protocols

During AY01-02, the Board reviewed eighteen protocols received from both faculty and student researchers representing the following departments:

Education	2
Exercise Science	2
Occupational Therapy	7
Physical Therapy	4
Psychology	2
Religion	1

Following receipt of required revisions, all protocols received Board approval and all investigations are currently underway.

In addition to protocols requiring full Board review, departmental representatives reported reviewing twenty-four additional protocols which, in the designate's judgement, qualified for either exempt or expedited review.

Any and all members of the University community are welcome to review the substance of Board discussions and decisions via the minutes posted on the University web site.

Institutional Animal Care and Use Subcommittee

In addition to reviewing human subject research protocols, this year saw the implementation of the Institutional Animal Care and Use Subcommittee (IACUC). Officially, the IACUC operates under the IRB umbrella, yet has a separate membership complement. Currently chaired by Alyce DeMarais (biology), the first meeting of the IACUC will be held on May 8, 2002, to review two protocols. Alyce has expressed willingness to provide a "beginning of the year" report on initial IACUC activities to the IRB and Senate next Fall.

Noteworthy Issues Addressed

During the course of this year's reviews and discussions, two noteworthy issues were raised which established important precedents for future human subject research on campus. The first arose via a request from an outside drug manufacturer to solicit subjects from the UPS community for drug safety trials. They requested permission to post flyers on campus offering students a sum of money in exchange for their participation as drug safety test subjects. The Board gave thoughtful consideration to issues regarding the use of University facilities to recruit human subjects for external research. The Board concluded, in essence, that such requests could only be considered if the external research entity submitted their protocol for review by the UPS IRB and that solicitation of subjects on campus would not be allowed without UPS IRB review and consent.

The second important human research issue involved obtaining informed consent from brain injured patients with metacognitive disorders. Among other cognitive impairments, by their nature, metacognitive disorders result in the loss of an individual's ability to predict and judge the consequences of his/her actions. The Board did not wish to discourage research which might ultimately be of benefit to individuals affected in this way, however, the validity informed consent was certainly open to question. This concern was returned to MOT student, **Robynn Stolte**, and her faculty advisor, **Juli McGruder**, PhD, OT, to research the issue. They returned an exhaustive and well reasoned literature review along with an algorithm for determining how appropriate and valid informed consent may be obtained for such patients. Their work now stands as an excellent template should issues of this nature arise in the future.

Recommended Activities/Charges for AY02-03

In addition to the ongoing review of research proposals using human subjects and the parallel work of the IACUC, this year's Board wishes to pass on the following two recommendations for next year's IRB activity.

1) The fundamental charge of the Board is review and oversight of research involving human subjects. Review is and has been handled in a well ordered systematic fashion. However, oversight of approved research to this date has involved no more than requesting final reports from investigators at the conclusion of the study. It is recommended that next year's IRB establish a set of internal guidelines for the oversight of ongoing research. This could include, but not be limited to random site visits, checks to make sure consent and anonymity procedures are being followed, and/or standardizing the final reports from investigators. We do not make this suggestion with any intent to either increase the burden on IRB members, or throw up barriers to researchers. Rather, oversight is admittedly too thin at this time, and more thought and follow through needs to be dedicated to this component of the IRBs responsibility.

2) Recommended language for consent forms includes a section titled "No Compensation for Injury." This section typically states some variation on the following:

"In the event of physical or emotional injury resulting from participation in this study, no monetary compensation will be made. By consenting to participate, I am fully aware of the potential risks and will hold the investigators harmless for any physical or psychological harm which may result from participation in this study."

Although this is essentially boilerplate from consent forms used in human research throughout the country, it has been pointed out by current Board members that this section places the burden of monetary risk entirely on the individual subject who altruistically volunteered to participate in the study. Although the Board has no intention of recommending the establishment of a subject's compensation fund, there was significant sentiment for reviewing the language of this section with University administration and legal counsel, so that investigators are not asking subjects to waive all rights to compensation in the event they are injured or disabled as a result of their voluntary participation. It was also noted that a subject's approval of this section may also be interpreted as waiving any rights to outside disability insurance compensation, or other avenues not related to the investigators or the University. The Board recommends thoughtful consideration towards redrafting this language towards affording reasonable protection for researchers, the University, and research subjects.

Acknowledgements

The Board wishes to pass on special thanks to **Alyce DeMarais**, who has taken the lead role in the highly detailed tasks of establishing the charter Institutional Animal Care and Use Subcommittee.

Members of the Board would also like to take this opportunity to extend special thanks to our community representative, **Patrick Coogan**. Mr. Coogan is a retired Weyerhaeuser patent law specialist and long time resident of Tacoma. He has served on the IRB for the past two years without compensation of any kind, save the diverse intellectual stimulation derived from reviewing research protocols and sharing in the good company and respectfully thoughtful discussions which characterize monthly Board meetings. Entities such as the IRB cannot credibly exist without the integral involvement of conscientious individuals who are not affiliated with the institution. They serve a unique oversight role in this important process which helps protect the well being of human volunteer research subjects, faculty and student researchers, and the University as a whole. I can say, with complete confidence that all members of the Board will support this conclusion, that Pat Coogan has been an enormous asset to the Board. His careful preparations, well reasoned opinions, unique and seasoned perspectives, and articulate discourse have raised the level debate and scope of consideration during all of our deliberations since he joined the Board. I would like to request and recommend that the University send him a formal acknowledgment of thanks for the generous gift of his invaluable participation.

Finally, the members of the Board would also like to express particular thanks to Associate Dean, University Registrar, and perennial Board member, **John Finney**. Through the years, John has been the glue holding the continuity and operations of the IRB together. His office has served as the main depot for receiving all protocols and correspondence related to the IRB. His contributions to Board deliberations have always been insightful, honest, and representative of the sound hand of reasonability. He does a huge amount of the work behind the scene. We wish to give him due credit and overdue sincere thanks.

Respectfully submitted,

Roger Allen, PhD, PT
Chair, Institutional Review Board
Associate Professor, Physical Therapy