Institutional Review Board Minutes April 23, 1999

Present: Wilson (Chair), Finney, Holland, Moore, Preiss, Wadsworth, Wells

Wilson opened the meeting at 9:04. Members were referred to the web-based minutes of the February 23, 1999, meeting. The minutes were to be approved by email.

Wilson asked that the IRB consider protocols. Because two protocols used the same participants, 9899-012 and 9899-017 were considered together. With regard to 9899-012, Wells noted that the protocol did not include a letter of support from the faculty sponsor and that sections of the protocol required clarification. Wilson inquired about the specific steps used to mitigate risks. Holland requested that the Informed Consent Form be shortened and phrased in lay language. Wells remarked that the Informed Consent Form must be on University letterhead. Approved: Vote, 7 Yes, 0 No (pending modifications)

Regarding 9899-017, a discussion ensued of the differences between this protocol and protocol 9899-012. Moore suggested striking the term "mental health." Wilson asked for more information on devices used for measurement. Wells suggested combining the Informed Consent Form for protocols 9899-012 and 9899-017.

Approved: Vote, 7 Yes, 0 No (pending modifications).

Protocol 9899-013 elicited considerable discussion. Members agreed that an extensive revision of prose, style, and exclusion criteria was required. Members provided a detailed critique of these changes, suggested modified exclusion criteria, and asked that the Informed Consent Form be phrased in lay language.

Approved: Vote, 7 Yes, 0 No (pending modifications)

Members noted that protocol 9899-014 shared participants with protocol 9899-013. Wells asked for additional information on the equipment used to monitor participants and a clear statement of costs and payments. Holland pointed to areas requiring changes in style and prose. It was noted that the Informed Consent Form needed to be phrased in lay language and appear on University of Puget Sound letterhead.

Approved: Vote, 7 Yes, 0 No (pending modifications)

In the discussion of protocol 9899-015, members noted that the Informed Consent Form needed to be phrased in lay language, that the sign up sheet and procedures needed to be included with the protocol, and that a section on blood-born pathogen control needed to appear in the protocol. Approved: Vote, 7 Yes, 0 No (pending modifications)

Protocol 9899-016 required minor modifications. Wilson asked that two Informed Consent Forms be used.

The form for the experimental group was to be phrased in lay language. The control group Informed Consent Form did not need to detail the potential risks encountered by participants in the experimental group.

Approved: Vote, 7 Yes, 0 No (pending modifications)

Protocol 9899-118 used high school students as participants. It was noted that formal high school approval was required. Members were assured that written permission had been obtained and would be included in the protocol. The author was asked to phrase the Informed Consent Form in second person.

Approved: Vote, 7 Yes, 0 No (pending modifications)

Protocols 9899-019 and 9899-20 were not submitted prior to the deadline for protocols and required extensive revision. After discussion, members decided the authors and their instructor

had not allowed the IRB enough time to thoughtfully consider the projects. The IRB elected not to consider the protocols and notified the authors not to initiate the projects.

Wilson thanked members for their work during the 1998-1999 academic year and dismissed the meeting at 10:17.

Respectfully submitted,

Ray Preiss