

**INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH
CALIFORNIA STATE UNIVERSITY, BAKERSFIELD**

MINUTES OF MEETING

06 June 1997

Old Pub/Runner Cafe

Members Present

Scientific Concerns: Brenda Pulskamp, Gonzalo Santos, Steve Suter

Non-Scientific Concerns: Nils Carlson, Cliona Murphy, Merry Pawlowski

Community Issues: Duane Meyer

Members Absent

Evelyn Johnson (Community Issues)

Visitors Present

Michelle Brown, Psychology graduate student, for Protocol 97-25

Dr. Jess Deegan, Assistant Professor of Psychology, for Protocol 97-24

William Mir, Psychology undergraduate student, and Sharyn Eveland, Psychology graduate student, for Protocol 97-26

Nick Garcia, Psychology graduate student, and Dr. Ken Ishida, Assistant Professor of Psychology, for Protocol 96-19 (request for extension and approval of change)

Dr. Luis Vega, Assistant Professor of Psychology, for Protocol 95-27 (request for extension)

Margorie Leek, Anthropology graduate student, and Dr. Philip Silverman, Professor of Anthropology, for Protocol 96-05 (request for extension and approval of change)

1. Meeting was called to order by Chairperson Steve Suter at 12:57 P.M.
2. Brenda Pulskamp moved, and Nils Carlson, seconded a motion to **approve the minutes** for the IRB/HSR meetings of 11 April 1997. Motion was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."
3. Nils Carlson moved, and Duane Meyer seconded, a motion for **formal affirmation** of all protocol approvals made under **expedited review procedures** (Protocols 97-09, 97-16, 97-18, and 97-27) for Spring (April-June) 1997. Motion was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."
4. Gonzalo Santos moved, and Nils Carlson seconded, a motion for **formal affirmation** of all protocol approvals made under **exempted review procedures** (Protocols 97-22 and 97-23) for Winter (January-April) 1997. Motion was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."
5. Brenda Pulskamp moved, and Merry Pawlowski seconded, a motion for **formal closure** of all protocols approved one year ago--April-June 1996 (Exempted Review: Protocols 96-06, 96-08, 96-09, 96-11, 96-15, 96-16, 96-20, 96-21, 96-22, 96-25, 96-28, and 96-32); Expedited Review: Protocols 96-07, 96-23, and 96-26; Standard Review: Protocols 96-13, 96-17, and 96-18). Motion was approved unanimously with 7 "aye," 0 "nay," and 0 "abstentions."

6. **Protocol 97-25, *Effects of visual transient subsystem inefficiency and fixation disparity on sensory and cognitive visually-evoked potentials in reading disabled children,*** with Ms. Michelle Brown (other listed co-investigators are Dr. Penelope Suter and Dr. Steven Suter). Ms. Brown provided a brief overview of her protocol. The primary readers were Gonzalo Santos, Cliona Murphy, and Evelyn Johnson (absent). Brief discussion with questions and answers followed Ms. Brown's overview. Brenda Pulskamp moved, and Merry Pawlowski seconded, a motion for **conditional approval** of the protocol. The conditions that must be met prior to the granting of full approval are to make the following revisions and additions:

- **Research Protocol:** Amend procedure, page 5, to indicate that the information handout for recruiting subjects will be distributed to all students directly, rather than relying upon the teachers to select "appropriate" students as potential subjects.
- Add a separate **child's assent form**, in which the language parallels that in the child's information handout, to accompany the parent's informed consent document.

The motion for **conditional approval** of the protocol was approved by a vote of 6 "aye," 0 "nay," and 1 "abstention" (Steve Suter for "conflict of interest").

7. **Protocol 97-24, *Visual neuroscience lab assignments and research projects,*** with Dr. Jess Deegan (other listed co-investigators are Dr. Penelope Suter and Dr. Steven Suter). Dr. Deegan provided a brief overview of his protocol. The primary readers were Brenda Pulskamp, Nils Carlson, and Duane Meyer. Lengthy, often heated, discussion lasted for 68 minutes. The basic issue of discussion revolved around the question of what the IRB/HSR was actually being asked to approve--(1) a protocol for "research" involving evoked potentials (EP) and electroretinograms (ERG) that are also laboratory assignments for three psychology courses, OR (2) a protocol for the use of data obtained from laboratory assignments involving EPs and ERGs as "research data." If the first item is the correct one, then it was argued that the ERG procedure, in particular, is "sufficiently invasive" and "potentially risky" that additional protections are warranted, especially since students enrolled in any of the three classes are the primary subjects, and students enrolled in a class are considered a "vulnerable population."

Brenda Pulskamp moved, and Gonzalo Santos seconded, a motion for **conditional approval** of the protocol. The conditions that must be met prior to the granting of full approval are to remove the brackets, [], from the section describing the procedures for the ERG measurement (first page of the informed consent document) and to add the sentence, "My participation in the ERG research is completely voluntary, and I may decline participation and/or terminate my participation at any time, without any penalty or loss of privileges as a student enrolled in the course." The motion for **conditional approval** was defeated by a vote of 1 "aye," 4 "nay," and 2 "abstention" (including Steve Suter for "conflict of interest").

After additional discussion (22 minutes), it was finally agreed that the IRB/HSR was being requested to consider approval for the second item listed above, i.e., a protocol for the use of data obtained from laboratory assignments involving EPs and ERGs as "research data." Therefore, Nils Carlson moved, and Cliona Murphy seconded, another motion for **conditional approval** of the protocol. The condition that must be met prior to the granting of full approval is to revise the entire informed consent document so that it clearly indicates that the student is voluntarily agreeing to allow the investigators to use his/her data obtained for the EP and/or

ERG laboratory assignments in Psychology 302, 303, and/or 304 (as appropriate) for "research purposes." This second motion for conditional approval was approved by a vote of 4 "aye," 1 "nay," and 2 "abstention" (including Steve Suter for "conflict of interest").

8. **Protocol 97-26, *Potential performance differences on a cognitive task battery for women of different sexual orientations***, with Mr. William Mir and Ms. Sharyn Eveland. Mr. Mir provided a brief overview of her protocol. The primary readers were Steve Suter, Merry Pawlowski, and Duane Meyer. Following a brief discussion with questions, Nils Carlson moved, and Cliona Murphy seconded, a motion for conditional approval of the protocol. The conditions that must be met prior to the granting of full approval are to revise the informed consent document as follows:

- Provide additional information regarding the identity of the researchers, e.g., that the research is for Mr. Mir's senior thesis in his psychology major.
- Revise the sentence in the second paragraph that includes "so that . . . so that".
- Revise the grammar and general "style" by working in cooperation with Dr. Merry Pawlowski.

The motion for conditional approval was approved unanimously with 7 "aye," 0 "nay," and 1 "abstention."

9. **Protocol 96-19, *The influence of intensified stimuli on visual attention tasks in ADHD children***, with Mr. Nick Garcia and Dr. Ken Ishida. Since this was a request for an extension of a protocol approved by the IRB/HSR at its meeting of 28 March 1996 and a request for approval of some changes in the research procedures, Mr. Garcia provided a brief overview of his protocol to reacquaint the Board and reviewed the changes to the original protocol. Most of the changes were minor and/or had been requested previously by the Board; the primary change was that all subjects were being asked to refrain from taking any medication 48 hours prior to their participation in the research. Since most of the potential subjects are not on medication continuously, there appeared to be minimal risk associated with this change. Nils Carlson moved, and Duane Meyer seconded, a motion for approval of a one-year extension, with changes. The motion for approval of a one-year extension, with changes, was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

10. **Protocol 95-27, *College students' social psychological attitudes on self and others***, with Dr. Luis Vega. This is a second request for an extension of a protocol originally approved under expedited review procedures in May 1995; the first request for extension was granted by the IRB/HSR at its meeting on 30 May 1996. Dr. Vega provided a brief overview of his protocol to reacquaint the Board. After a few questions and brief discussion, Nils Carlson moved, and Cliona Murphy seconded, a motion for approval of a second one-year extension. The motion for approval of a second one-year extension was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

11. **Protocol 96-05, *Life histories of older men and women***, with Ms. Marjorie Leek and Dr. Philip Silverman. Dr. Sasaki explained to the Board that he had approved this protocol originally under "exempted review procedures" because of a time constraint, when Ms. Leek discovered at the last minute that she had an opportunity to interview elderly men and women during her trip to Peru. Dr. Sasaki indicated that, because the subject population are elderly, he believed that the "standard review procedures" were appropriate, but he also knew

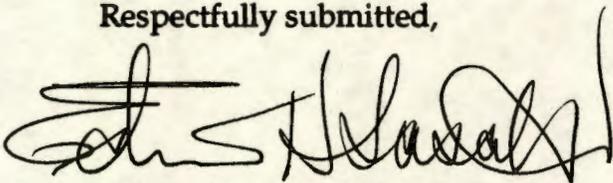
that Ms. Leek did not have time for a "standard review," since she was leaving for Peru when she learned of the opportunity. Dr. Sasaki did review the protocol and the informed consent document and requested some changes to the informed consent document; the final version was approved via international mail.

Given the situation, Dr. Sasaki requested that Ms. Leek now come before the IRB/HSR for approval of her request for an extension and of changes to her protocol. Ms. Leek provided a brief overview of her original protocol and the requested change, which involved a change of "setting" from Peru to Shafter, CA. After a few questions and brief discussion, Nils Carlson moved, and Gonzalo Santos seconded, a motion for approval of a one-year extension and a change in "setting" to Shafter, CA. The motion for approval of a one-year extension and a change in "setting" to Shafter, CA, was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

12. Next IRB/HSR meeting is tentatively scheduled for Friday, 03 October 1997, 8:00 AM-11:00 AM, with breakfast beginning 7:30 AM; place of meeting will be determined later.

13. There being no further business, Chairperson Suter adjourned the meeting at 3:30 PM.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Edwin H. Sasaki', written in a cursive style.

Edwin H. Sasaki, Ph.D.
IRB/HSR Secretary