

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

MINUTES OF MEETING

25 September 1998

Old Pub/Runner Cafe

Members Present

Scientific Concerns: David Cohen, Brenda Pulskamp, Gonzalo Santos
(arrives at 8:10)

Non-Scientific Concerns: Nils Carlson, Steve Carter, Merry Pawlowski

Community Issues: Nancy Car

Members Absent

Evelyn Johnson (Community Issues)

Duane Meyer (Community Issues)

Visitors

Carol Bowman, graduate student in Anthropology, and Dr. Jane Granskog,
Professor of Anthropology and faculty advisor, for Protocol 98-30.

Dr. Steven Bacon, Assistant Professor of Psychology, for Protocol 98-32.

Dr. Steven Suter, Professor of Psychology, and Dr. Jess Deegan, Associate
Professor of Psychology, for Protocol 98-33.

1. Meeting was **called to order** by Chairperson Brenda Pulskamp at 8:00 AM.
2. Merry Pawlowski announced that she would be on sabbatical leave during Winter and Spring 1999 and, therefore, would be available for IRB/HSR reviews.
3. Nils Carlson moved, and Nancy Carr seconded, a motion to **approve the minutes** for the IRB/HSR meeting of 09 January 1998, with the change in paragraph #7 that the intended protocol is 98-29 rather than 98-28. Motion was approved unanimously, with 6 "aye," 0 "nay," and 0 "abstentions."
4. David Cohen moved, and Steve Carter seconded, a motion for the **formal affirmation** of all protocol approvals made under **exempted review procedures** (Protocol 98-31) and under **expedited review procedures** (Protocol 98-27) during Summer Term 1998 (June 1998 - September 1998). The motion passed unanimously, with 6 "aye," 0 "nay," and 0 "abstentions."

[Gonzalo Santos arrived at 8:10.]

5. Nils Carlson moved, and Steve Carter seconded, a motion for the **formal closure** of all protocols previously approved one year ago (June 1997 September 1997). Protocols to be closed included 97-28 approved under **exempted review procedures** and 97-21 and 97-27 approved under **expedited review procedures**. The motion passed unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

6. Protocol 98-30, *The effect that maintaining traditional spiritual practices has on defining ethnic identity in the Native American community*, with Carol Bowman and Dr. Jane Granskog. Ms. Bowman provided an overview of her research Protocol, and she distributed a revised informed consent document. Questions from the IRB members involved:

- Objectivity of the data, given that this issue was raised in the protocol itself. Dr. Granskog replied that the research methodology is one of participant observation and that the plans are to check the interpretations made by Ms. Bowman with the actual participants.
- Limited number of subjects in the proposed protocol for comparison purposes: 12 total with 6 males and 6 females. The response was that Ms. Bowman was planning to interview Native Americans who do not participate in "traditional religious practices" to obtain comparison data.
- Issue of male subjects versus a female (Ms. Bowman) as the participant observer. The response was that Ms. Bowman would be participating in sweats involving only women or women and children. She would be interviewing male subjects who participated in sweats, but she would not be participating in their sweats.
- Correlating the experience "inside" the sweat lodge with what is said in response to the interview questions, given that Ms. Bowman would not be conducting the interview during the sweat lodge experience. Dr. Granskog responded that she herself has participated in sweat lodges and that she is comfortable that Ms. Bowman will be able to gain the trust of the participants so that she will be able to make accurate correlations of the experience with the responses to the questions.
- Changes in the revised informed consent document that was distributed during the meeting.
 - a. The "foreseeable benefits" section implies a "cause and effect" relationship between traditional spiritual practices and maintenance of ethnic boundaries. This "cause and effect" implication appears to be too strongly stated, and it was suggested that it be reworded. This same "cause and effect" implication is also contained in the title with the use of the term "effect of."
 - b. The word "require" in the last sentence of the "confidentiality of records/privacy of participants" section appears too strong, since there is no requirement that participant's names must be divulged in a public presentation of research. It was suggested that this sentence be reworded.

After all questions had been answered and discussed, Ms. Carol Bowman and Dr. Jane Granskog were excused. David Cohen moved, and Steve Carter seconded, a

motion for full approval of the protocol, with the provision that the informed consent document be revised with the suggested changes specified above and filed with Graduate Studies and Research. The motion passed unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

7. **Protocol 98-32, Interrater reliability of a scale of functional ability ratings for mental health with Dr. Steve Bacon.** Dr. Bacon provided a brief overview of his protocol. Gonzalo Santos commented that Dr. Bacon had submitted an excellent protocol in terms of format and level of detail. Nils Carlson made a similar comment, indicating that he felt that Dr. Bacon's protocol was one of the best, if not the best, protocol he has seen in the five years he has been a member of the IRB/HSR. A few questions were raised:

- Why the diagnostic information from the participant's therapist was necessary. Dr. Bacon responded this information was necessary to measure the accuracy and sensitivity of the rating scales that are the subject of his protocol.
- "Mechanical issues" regarding the participants, e.g., place of the interviews and, if at CSUB, parking "problems." Dr. Bacon indicated that he would follow up on these issues.
- Potential problems with privacy and confidentiality if any of the participants are CSUB students, given that students will be trained as raters. Dr. Bacon indicated that he would look into this problem and develop appropriate procedures to ensure that the privacy and confidentiality of the participants are protected.

After all questions had been answered and discussed, Dr. Bacon was excused. Nils Carlson moved, and Steve Carter seconded, a motion for full approval of the protocol. The motion passed unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

8. **Protocol 98-33, Visual neuroscience lab assignments and research projects: 1998-99, with Drs. Steve Suter and Jess Deegan.** Dr. Deegan provided a brief overview of the protocol, indicating that this protocol was similar to the one reviewed and approved by the IRB/HSR one year ago. Specifically, the protocol was requesting a "blanket approval" for the use of data gathered during laboratory assignments in Psychology 302L and 303L for research purposes. All students would participate in the laboratory exercises as part of the laboratory courses. However, students would volunteer to have their data used for research purposes; they would sign an informed consent document as they would for any research project. Care would be taken to ensure that the instructors have awarded final grades for the laboratory courses before they would know whether students had volunteered to have their data be used for research purposes. Gonzalo Santos requested that students be given an option in participating in different laboratory activities, especially for the ERG (electoretinogram) lab, where a small electrode is placed between the eye ball and the lower eye lid to record the electrical potential of the eye

ball. Dr. Deegan indicated that he did not believe that this activity was harmful or caused any risk for students; he also stated that the procedure is not "invasive" since it involves only a surface electrode. The ERG is a "standard" measurement technique in visual neuropsychology, and students have much to gain by participating in the use of this measurement procedure. Gonzalo Santos also requested that the informed consent document have specific language that made it clear that students did not have to allow their data to be used for research purposes and that refusal to do so would have no effect on their course grade. Both Drs. Deegan and Suter indicated that they believed that the proposed informed consent documents enclosed with the protocol did exactly what Dr. Santos was requesting.

There being no further questions, Drs. Deegan and Suter were excused. David Cohen moved, and Merry Pawlowski seconded, a motion for full approval of the protocol as submitted. During discussion of the motion, Gonzalo Santos stated that he "profoundly disagreed" with the motion and the procedure being used by Drs. Deegan and Suter for the Psychology laboratory courses. He stated that he wanted the minutes to reflect clearly his position. Dr. Santos indicated that, after six years on the IRB/HSR, he has concluded that the Psychology laboratory activities covered under this protocol are being driven by the research agendas of the instructors rather than consideration of the educational value. He also indicated that the refusal of the faculty to consider offering students an optional laboratory activity to those involving "invasive" procedures, especially an option to the ERG lab, convinces him that the Psychology faculty are using students as "guinea pigs" for their personal research interests. Question was called, and the motion was passed with 4 "Yes," 1 "No," and 2 "Abstentions."

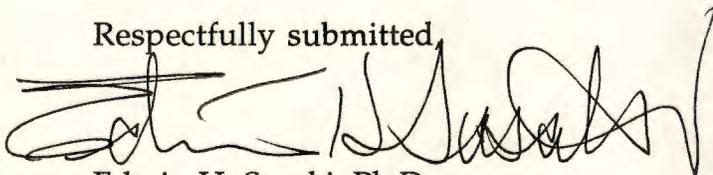
[Steve Carter leaves to teach class at 9:30.]

9. Chairperson Pulskamp inquired again about the status of the IRB/HSR Forum that was rescheduled for Fall 1998. Dr. Sasaki indicated that he was unable to get the Forum organized and scheduled for Fall 1998, but, given the discussion with Protocol 98-33, it is clear that we need the Forum. He promised that it would be organized for January 1999.

10. The next meeting is scheduled for **Friday, 08 January 1999, Time TBA**, in the Old Pub/Runner Cafe.

11. There being no further business, Chairperson Pulskamp adjourned the meeting at 9:45 AM.

Respectfully submitted



Edwin H. Sasaki, Ph.D.
Research Ethics Assurance Coordinator
and IRB/HSR Secretary