

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

MINUTES OF MEETING

**09 January 1998
Old Pub/Runner Cafe**

Members Present

Scientific Concerns: David Cohen, Brenda Pulskamp

Non-Scientific Concerns: Nils Carlson, Merry Pawlowski

Community Issues: Nancy Carr, Evelyn Johnson, Duane Meyer

Members Absent

Gonzalo Santos (Scientific Concerns)

One position for non-scientific concerns open.

Visitors Present

Ms. Ann M. Livesey, graduate student in Nursing, for Protocol 97-34.

Ms. Kay McKnight, graduate student in Nursing, for Protocol 97-35.

Dr. Kaye Bragg, Associate Professor of Political Science, for Protocol 97-36.

Dr. Carol Raupp, Associate Professor of Psychology, for Protocols 97-36 and 97-37.

1. Meeting was called to order by Chairperson Brenda Pulskamp at 8:00 AM.
2. New members to the IRB, who began their respective terms on 01 January 1998, were introduced:
 - David Cohen (Psychology) who is replacing Steve Suter (former Board Chair) for "scientific concerns"
 - Nancy Carr (Community) who is replacing Susan Christiansen for "community issues"
 - Evelyn Johnson (Community) who has accepted a full 3-year appointment after replacing Diane Smith, who resigned due to job relocation

Chairperson Pulskamp indicated that the Provost and Vice President for Academic Affairs is in the process of selecting the replacement for Cliona Murphy, who completed her two terms as a member for "nonscientific concerns." The Board's recommendation for this position, which Ed Sasaki presented, was not supported by the Academic Senate.

3. Merry Pawlowski moved, and Evelyn Johnson seconded, a motion to approve the minutes for the IRB/HSR meeting of 03 October 1997. Motion was approved, with 6 "aye," 0 "nay," and 1 "abstention."
4. Chairperson Pulskamp indicated that she wished to modify the agenda to include some discussion of the following:
 - IRB "Forum" that was suggested during the meeting of 03 October 1997

- Outcome of the Board's request to have Ed Sasaki's "official" title changed from Compliance Officer
- Other issues, such as cost-benefit analysis for "research risk," research as a class activity, and orientation packets for researchers

5. Nils Carlson moved, and Evelyn Johnson seconded, a motion for **formal affirmation** of all protocol approvals made under **expedited review procedures** (Protocol 97-31). Motion was approved, with 6 "aye," 0 "nay," and 1 "abstention."

6. David Cohen moved, and Nils Carlson seconded, a motion of **formal affirmation** of all protocol approvals made under **exempted review procedures** (Protocols 97-32 and 97-33f) made during Fall (October-December) 1997. Motion was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

7. A motion for **formal closure** of all protocols approved one-year ago (October-December 1997) was deferred, due to confusion on the listing provided. The Secretary indicated that he would work with Kathy Smith, secretary for Graduate Studies and Research, in clarifying the list of protocols to be formally closed by the next IRB meeting.

8. **Protocol 97-34, *The impact of nursing intervention on cholesterol levels in an employee population***, with Ms. Ann M. Livesey. Ms. Livesey provided a brief overview of her research protocol, which was followed by questions from the members of the IRB/HSR, primarily from the three primary readers--Brenda Pulskamp, Nils Carlson, and Nancy Carr--along with David Cohen. Most of the questions, responses, and discussions revolved around the consent process and the consent document itself. Nils Carlson moved, and David Cohen seconded, a motion for **conditional approval** of the protocol, with the conditions to be that the informed consent document be modified as follows:

- Explicitly indicate that the research being performed is for Ms. Livesey's master's thesis in Nursing.
- Explicitly state that the education component will be staggered with some subjects receiving it "early" and other subjects receiving it "later"
- Carry over language regarding the handling of "adverse reactions" from the research protocol itself; include a sentence that the company physician is to be contacted.

Motion for conditional approval was passed unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

9. **Protocol 97-35, *The effects of a teaching intervention on breast self-exam on the health benefits and the confidence in their performance of women fifty years and older***, with Ms. Kay McNight. Ms. McKnight provided a brief overview of her research protocol, which was followed by questions from the members of the IRB/HSR, primarily from the two primary readers present--David Cohen and Duane Meyer--along with Nils Carlson, Brenda Pulskamp, and Evelyn Johnson. Questions and suggestions revolved around the demographic information sought, age issues (senior centers most likely to have 60+, yet research title specifies 50+), referral issues, and the "exclusionary process." Ms. McKnight accepted the suggestion that all persons who wished to attend the class component would be allowed to do

so, even if they might be excluded from the study itself, since the class component might be valuable for all the elderly women. David Cohen moved, and Nils Carlson seconded, a motion for full approval of the protocol. Motion for full approval was passed unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

10. **Protocol 97-36, *Reactions to possible California ballot initiatives about rivers and water usage: A class activity***, with Drs. Kaye Bragg and Carol Raupp. Drs. Bragg and Raupp provided a brief overview of their research protocol, with was followed by questions from the members of the IRB/HSR, primarily from the three primary readers--David Cohen, Merry Pawlowski, and Evelyn Johnson--along with Brenda Pulskamp. David Cohen indicated that it was his reading that there was an "implied" request for a waiver of signed consent, and both Drs. Bragg and Raupp indicated that they would appreciate receiving a waiver of signed consent from the Board. Their justification was that much of the survey will be conducted via telephone and it would be extremely burdensome to get signed consent documents from every participant. Further, they indicated that some individuals likely would choose not to participate if their identity were known, even if it was only through the consent document. There were additional questions regarding the type of questions being asked (no questionnaire was included) and the time required to complete the questionnaire. David Cohen moved, and Nils Carlson seconded, a motion that the Board approve the **waiver of signed consent**. The motion was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions." David Cohen moved, and Nils Carlson seconded, a motion for **conditional approval** of the protocol, with the conditions as follows:

- A transcript for the informed consent that will be verbally given to each participant be developed and reviewed by Ed Sasaki on the behalf of the Board;
- The questions to be asked be developed and reviewed by Ed Sasaki on the behalf of the Board; and
- Ed Sasaki, based upon his review of the above documents, be authorized to give full approval on the behalf of the Board.

The motion for conditional approval was passed unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

11. **Protocol 97-37, *Do attitudes about animals change during a Psychology course about animals?--An extension***, with Dr. Carol Raupp. Dr. Raupp provided an overview of the protocol, which she indicated was basically the same as the previous protocol that the Board had approved for Spring 1997. The request is to allow her to use the same protocol, with some modifications to the questions, for Spring 1998, which would include students in Psychology 301, Principles of Learning, and Psychology 301L, Learning Laboratory. Dr. Raupp indicated that this course is being offered for the first time in many years with live rats being used for the laboratory assignments. Dr. Raupp indicated that she felt it important for her research to get comparable data from students who actually handled live laboratory animals. There were only a few questions from the Board. Nils Carlson moved, and Duane Meyer seconded, a motion for **full approval** of the protocol. The motion was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

12. Issue of the IRB open forum was raised. During the meeting of 03 October 1997, the Board voted unanimously to have an "open forum" during Winter 1998, if at all possible. Ed

Sasaki reported that he had discussed the idea of an IRB open forum with the Faculty Teaching and Learning Center, the Academic Senate, and the Associated Students, and they all supported the idea and agreed to co-sponsor the open forum. It was decided that Spring 1998 would be better than Winter 1998, so Ed Sasaki indicated that he would work with Chairperson Pulskamp in scheduling the IRB open forum during Spring 1998.

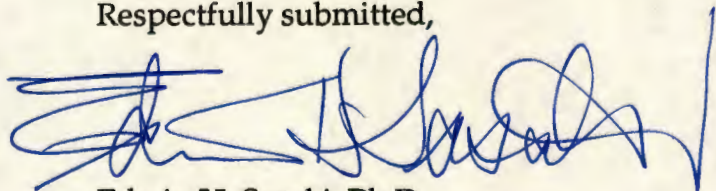
13. Ed Sasaki reported that Dean Ganipole had received a memorandum from Steve Suter regarding the Board's wishes to have his (Ed Sasaki's) title changed from University Compliance Officer to a "more appropriate" title. Dean Ganipole indicated that she had no problems with the request, and we agreed that Ed Sasaki's "official title" will become **University Research Ethics Review Coordinator**.

14. It was decided that the issues of cost-benefit analysis for "risk" and research as a class activity should be addressed after the IRB open forum, where these issues would likely be discussed. Ed Sasaki reported that an orientation packet already exists for all researchers; it is available from Graduate Studies and Research. The packet includes a "flow diagram" of the three different review processes (exempted, expedited, and standard), contents for the research protocol, contents for the informed consent document, research "areas" that are covered under "exempted review," and research "areas" that are covered under "expedited review," and the CSUB policy and procedures. It was suggested that we try to modify the wording so that these documents are more "user friendly" and contain suggestions as to specific wording and/or reference to specific "problem areas" that the Board had found from its previous reviews. It was also suggested that "check-off" lists be developed for the review process and for each of the major documents that were required--research protocol and informed consent document. Finally, it was suggested that researchers be notified that they could receive "pre-review" assistance from IRB members if they submitted their protocols early. Ed Sasaki indicated that these suggestions were all appropriate and would improve the research review process and that he would work to get these suggestions implemented.

15. It was learned that several members of the Board would not be able to attend a meeting on Friday, 03 April, and several members indicated that the following Friday, 10 April, was not a "good" date since it was Good Friday and that entire week was Easter vacation for most of the local schools. Therefore, it was decided that the next IRB/HSR meeting be **tentatively scheduled for Friday, 17 April (8:00 AM-11:00 AM), with breakfast being served starting 7:30 AM**. Place of meeting will be the Old Pub, Runner Cafe.

16. There being no further business, Chairperson Pulskamp adjourned the meeting at 10:35 AM.

Respectfully submitted,



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