

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

MINUTES OF MEETING

04 June 1999

Old Pub/Runner Cafe

Members Present

Scientific Concerns: Kaye Bragg, David Cohen, Brenda Pulskamp

Non-Scientific Concerns: Steve Carter,

Community Issues: Amanda Bevier, Evelyn Johnson

Members Absent

Nancy Carr (Community Issues)

Eun-Ja Kim Park (Non-Scientific Concerns)

Merry Pawlowski (Non-Scientific Concerns; on sabbatical leave)

Visitors

Barbara Brenner, CSUB Health and Safety Coordinator

Steve Suter, Professor of Psychology, for Protocol 97-25.

1. Meeting was called to order by Chairperson Brenda Pulskamp at 8:00 AM.
2. Steve Carter moved, and Evelyn Johnson seconded, a motion to approve the minutes for the IRB/HSR meeting of 09 April 1999. Motion was approved unanimously, with 6 "aye," 0 "nay," and 0 "abstentions."
3. Steve Carter moved, and Evelyn Johnson seconded, a motion for the formal affirmation of all protocol approvals made under exempted review procedures (Protocol 99-08, 99-09, and 99-10) and under expedited review procedures (Protocol 99-07) during the Spring Term 1999 (April 1999-June 1999). The motion passed unanimously, with 6 "aye," 0 "nay," and 0 "abstentions."
4. Steve Carter moved, and Evelyn Johnson seconded, a motion for the formal closure of all protocols previously approved one year ago (April 1998 - June 1998). Protocols to be closed included 98-12, 98-13, and 98-14 approved under expedited review procedures and 98-15 and 98-20 approved under standard review procedures. The motion passed unanimously, with 6 "aye," 0 "nay," and 0 "abstentions."
5. Protocol 99-12, *Cardiovascular and metabolic responses of endurance-trained cyclists to carbohydrate consumption during rest and moderate-intensity exercise*, by Dr. Don Diboll, Assistant Professor of Physical Education. Dr. Diboll was not available for the meeting to respond to questions from the Board. As a result, the Board did not take any action on the protocol. However, the Board requested that Edwin Sasaki convey to Dr. Diboll the following concerns/issues associated with his protocol:

- The screening tool relies entirely upon self-report and does not appear to be adequate for risk assessment, e.g., there is no question that asks specifically about a history of diabetes;
- Consent document should include a statement whereby the participant "certifies" through his/her signature on the consent document that he/she is in "good health" and is not a diabetic;
- Consent document needs to have a clearer presentation of the "steps" associated with the entire testing procedure;
- Protocol and consent document need to spell out procedures to be followed in the event of a medical emergency;
- It is not clear in the protocol if the moderate-intensity exercise is considered to be a "stress test" and whether a physician needs to be in attendance, or at least "on call," in addition to an RN;
- Protocol needs to describe clearly the procedures for drawing blood from each subject, including who performs the blood draw, sterilization, Sharp's container for used syringes, storage of blood samples, and transportation of blood samples for lab analysis;
- Protocol needs to describe procedures for sterilization of apparatus for collecting expelled air from the subject; and
- Consent document needs to reflect Edwin Sasaki's current title of "Research Ethics Assurance Coordinator."

Edwin Sasaki assured the Board that he would meet with Dr. Diboll and convey the issues/concerns raised by the Board.

6. **Request for Extension and Approval of Change in Subject Recruiting Procedures:** Protocol 97-25, *Effects of visual transient subsystem inefficiency and fixation disparity on sensory and cognitive visually-evoked potentials in reading disabled children*, with Dr. Steven Suter, Professor of Psychology. Dr. Suter explained that he and his colleague, Dr. Penelope Suter, have not yet recruited and tested sufficient subjects to complete the research as planned; hence they are requesting an extension so that they may continue with their research. In addition, Dr. Suter explained that they would like to amend their recruiting procedure by having special education teachers and/or school psychologists forward information about the research directly to parents/guardians of children who have already been identified with the type reading/learning difficulties required by the protocol. This change would not compromise any confidentiality or privacy issues related with the subjects, since the subjects have always been selected from special education classes for students with reading/learning difficulties. On the other hand, having the special education teachers and/or school psychologists make direct contact with the parents/guardians would save considerable time for Dr. Penelope Suter, who engages in an extensive screening procedure to ensure that the child has the specific characteristics defined by the protocol.

Steve Carter moved, and Evelyn Johnson seconded, a motion for approval of an extension for the protocol and for approval of an amendment in the procedures for recruiting subjects. The motion passed unanimously, with 6 "aye," 0 "nay," and 0 "abstentions."

7. **Request for Extension and Approval of Changes in the Protocol: Protocol 98-03, Evaluation of Healthy Steps for Healthy Babies Project: Year Two**, by Dr. Peggy Leapley, Professor of Nursing. Dr. Leapley was not available to meet with the Board. However, the Board decided that the written documentation submitted by Dr. Leapley was sufficient for its deliberations:

- The justification for the request of an extension is that the project has been funded for a second year.
- The justification for the proposed changes in the protocol include two major elements:
 - simplifying the data analysis because of low sample size; and
 - addition of the second-year of funding to support follow-up research on the effectiveness of the Healthy Babies Project.

Steve Carter moved, and Amanda Bevier seconded, a motion for approval of an extension for the protocol and for approval of the changes in the protocol. The motion was passed unanimously, with 6 "aye," 0 "nay," and 0 "abstentions."

8. Barbara Brenner, CSUB Health and Safety Officer, indicated that Sharon Taylor, Associate Vice President for Business Affairs, was unable to attend the meeting. She reported that CSUB had recently been audited and that the audit had found the University to be open to "risk" in some laboratory activities and student research projects associated with classroom work. She indicated that she had discussed the issue with Ed Sasaki after the January meeting of the IRB/HSR, which she and Sharon were unable to attend. She stated that she wanted to follow-up directly with the Board the issue of laboratory activities and student research projects.

After hearing Ms. Brenner's presentation, the members of the Board responded. A summary of this response included the following:

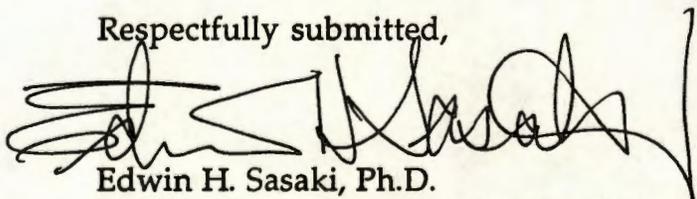
- The IRB/HSR is united in its "strong" opposition to having the Board assigned the task of reviewing and approving laboratory assignments and student research projects associated with course work. The Board believes that its role of reviewing and approving "research" conducted by faculty and students is clearly and unambiguously defined by Federal regulations and by the policy and procedures formally adopted by the University. To take on the task as presented would change dramatically the role of the IRB/HSR, which would require the consideration of course goals and departmental expectations in the assessment of laboratory assignments and student research projects completed to fulfill course requirements.
- If the "risk" associated with these course-related activities remains unacceptable for the University, then the IRB/HSR recommends that the University consider taking the following steps:
 - a specific list of the "problem" areas be constructed;

- identify the faculty member and/or department most closely associated with the "problem" areas; and
- discuss the concerns of "risk" with the faculty member and/or department and develop procedures for minimizing that risk.
- Ms. Brenner, in her role as the CSUB Safety and Health Coordinator, take a "pro-active" role in educating faculty about potential "risks" associated with laboratory activities and student projects assigned as a course requirement and serve as the primary contact for providing assistance to faculty in this area.

9. The next meeting is scheduled for Friday, 24 September 1999, 8:00 AM - 10:00 AM, with breakfast served at 7:30 AM, in the Old Pub/Runner Cafe.

11. There being no further business, Chairperson Pulskamp adjourned the meeting at 9:05 AM.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Edwin H. Sasaki', written over a horizontal line.

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