

**INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH
CALIFORNIA STATE UNIVERSITY, BAKERSFIELD
9001 Stockdale Highway, Bakersfield, CA 93311-1099**

MINUTES OF MEETING

24 September 1999

Old Pub/Runner Café

Members Present:

Scientific Concerns: Kaye Bragg, David Cohen, Brenda Pulskamp

Nonscientific Concerns: Steve Carter, Merry Pawlowski, Eun Ja Park

Community Issues: Nancy Carr

Members Absent:

Amanda Bevier and Evelyn Johnson (both Community Issues)

Visitors Present:

Dr. Don Diboll, Assistant Professor of Physical Education, for Protocol 99-14

Dr. Steve Bacon, Assistant Professor of Psychology, and Ms. Celestina Horn, undergraduate student in Psychology, for Protocol 99-13

1. Meeting was called to order by Chairperson Brenda Pulskamp at 7:57 AM.
2. Steve Carter moved, and David Cohen seconded, a motion to approve the minutes for the IRB/HSR meeting of 04 June 1999. Motion was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."
3. Since Don Diboll was available for Protocol 99-14 at 8:00, Chairperson Pulskamp requested that the Board postpone action regarding (a) formal affirmation of protocol approvals made under exempted review procedures and expedited review procedures, and (b) formal closure of protocols approved one year ago. The Board consented to this change in agenda.
4. **Protocol 99-14, *Cardiovascular and metabolic responses of endurance-trained cyclists to carbohydrate consumption during rest and moderate-intensity exercise***, with Dr. Don Diboll. This protocol was initially referred to the Board for its meeting on 04 June 1999, but no specific action was taken regarding the protocol because Dr. Diboll was unable to attend the meeting. Dr. Diboll indicated that he had revised the protocol to include the suggestions made by the Board and to clarify the issues raised by the Board at its June 1999 meeting. He then provided a brief overview of his proposed research in exercise physiology. Several members, especially David Cohen, Nancy Carr, Steve Carter, and Brenda Pulskamp, asked Dr. Diboll questions about his protocol. These questions concerned the following issues:
 - Sterilization procedures for the equipment after each participant. Dr. Diboll responded that the equipment would be dismantled after testing each participant and sterilized in accord with the manufacturer's recommendations. He agreed that he

would include within his informed consent document statements describing the sterilization procedures.

- Confidentiality of the data. Dr. Diboll responded that an individual's data would not be shared with others, although he planned to allow an individual to see his/her own data if requested to do so. He indicated that his research participants were very "competitive" and that they would, most likely, like to know about their own performance.
- Safety of the requirement for 8-hours of fasting prior to testing. Dr. Diboll stated that he plans to do all of his testing in the mornings so that the participants' "8-hour" fasting would include their sleep time and that they would not be deprived of food for an excessive amount of time. Dr. Diboll further stated that this requirement for 8-hours fasting prior to testing is "standard protocol" for this type research.
- Having a physician "on call" during the maximum aerobic exercise component of the testing in case of any medical emergencies. Dr. Diboll indicated that he plans to contact the CSUB Health Center and enlist the cooperation of the physician to be "on call" during his testing. He also reported that a RN, who would be available "on-site" during all of his testing, would perform the three blood draws for each participant. Dr. Diboll further reported that a Sharps container would be used for collecting the syringes and that he has arranged with the CSUB Health Center for disposal of all biohazard wastes.
- Using a 12-lead ECG system for monitoring heart activity during the initial "stress test." Dr. Diboll responded that this procedure was also standard protocol for this type testing. He agreed that he would clearly communicate to participants in his informed consent document that their heart activity would be monitored during testing with a 12-lead ECG system and that there would be no danger of electrical shock from the leads.

David Cohen moved, and Steve Carter seconded, a motion to grant full approval for Protocol 99-14 with the understanding that Dr. Diboll would add statements in his informed consent document regarding the sterilization procedures for the equipment and the use of a 12-lead ECG system for monitoring heart activity. The motion was passed unanimously with 7 "aye," 0 "nay," and 0 "abstentions."

5. **Protocol 99-13, Interrater reliability of the Scale of Functional Ability Ratings (SOFAR) in an inpatient psychiatric setting**, with Dr. Steven Bacon and Ms. Celestina Horn. Dr. Bacon provided an overview of the protocol and described the SOFAR as an instrument that he is developing to measure psychiatric patients' abilities to perform daily activities. He stated that he would be conducting the clinical interviews with the psychiatric patients, who would be recorded, and that he and Ms. Horn would both score the interviews using the SOFAR. The primary purpose of the research protocol is to establish a measure of the interrater reliability for the SOFAR. Questions from several Board members covered the following issues:

- Length and apparent complexity of the informed consent document, especially for psychiatric patients. Dr. Bacon indicated that the informed consent process is to have him read one paragraph at a time to the patient and to ask the patient after each paragraph if he/she had any questions regarding the information in the paragraph. In

addition, Dr. Bacon indicated that the protocol excludes patients who are highly psychotic, intoxicated, and/or brain-damaged so that only patients who are lucid and functioning at a level sufficient to understand would be approached for participation. Dr. Bacon further indicated that he would do some "pre-screening" of potential participants through posted announcements and consultation with clinic staff.

- Potential benefits for participants. Dr. Bacon responded that the primary benefit for participation by the psychiatric patients would be one of "diversion" from their everyday activities.
- Why focus on psychiatric patients rather than family and caregivers? Dr. Bacon reported that it would be too expensive, in terms of time and money, to include family and caregivers. He indicated that the protocol represents an early phase of the entire process for testing the SOFAR. He reported that he strongly believes that it is most important to focus on the patients themselves at this initial phase in the development of the SOFAR.
- Preferences for any specific hospital in recruiting participants. Dr. Bacon stated that his goal was to recruit participants with diverse psychiatric "disorders" so he did not have any preference for a specific hospital or clinic.
- Issue of getting consent from the hospital or clinic to approach their patients who are receiving treatment. Dr. Bacon reported that he will get consent from the hospital, and he agreed to include a statement in his informed consent document that he has the consent of the hospital or clinic to approach the patient for participation in his study.
- Issue of potential stress on the psychiatric patients for volunteering to participate. Dr. Bacon responded that the interview should be "low stress" for the research participant because the questions focus on daily functioning and not on psychiatric symptoms.

Nancy Carr moved, and Steve Carter seconded, a motion to grant full approval for Protocol 99-13 with the understanding that Dr. Bacon would add statements in his informed consent document regarding the consent of the hospital or clinic for him to approach the patients as potential research participants. The motion was passed unanimously with 7 "aye," 0 "nay," and 0 "abstentions."

6. Requests for Extension

- a. **Protocol 98-33, *Visual neuroscience lab assignments and research projects***, with Drs. Steve Suter and Jess Deegan.
- b. **Protocol 97-34, *The impact of nursing intervention on cholesterol levels in an employee population***, with Ms. Ann M. Livesey.
- c. **Protocol 96-27, *Caring for an adult in-home hospice patient with cancer: Hispanic women's perceptions of oral intake***, with Dr. Candace Meares.

There were no changes to the protocols as originally approved by the IRB/HSR. Merry Pawlowski moved, and David Cohen seconded, a motion to grant approval for one-year extensions for Protocols 98-13, 97-34, and 96-27. The motion passed unanimously with 7 "aye," 0 "nay," and 0 "abstentions."

7. Formal Board affirmation for protocols previously approved under "expedited review" and "exempted review" procedures: Steve Carter moved, and Nancy Carr seconded, a motion that the IRB/HSR formally affirm the approvals for the following protocols:
- Protocol 99-15, *Beliefs and practices of breast self-examination among Vietnamese-American women*, approved under "exempted review" procedures on 14 September 1999.
 - Protocol 99-16, *Beliefs and practices about menopause among Vietnamese-American women: A micro-ethnography*, approved under "exempted review" procedures on 14 September 1999.
 - Protocol 99-17, *Ethnicity and sexual orientation as factors in assessing attitudes towards victims of hate crimes*, approved under "exempted review" procedures on 16 September 1999.

8. Formal Board closures of protocols previously approved during June 1998-September 1998. Steve Carter moved, and Eun-Ja Kim Park seconded, a motion that the IRB/HSR formally close the following protocols:

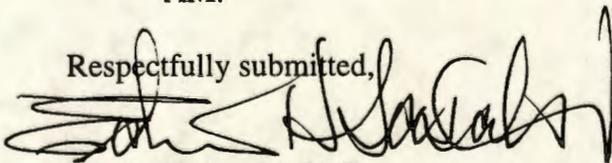
- Protocol 98-27, *Teachers attitudes towards children of lesbian parents*, approved under "expedited review" procedures on 25 September 1998.
- Protocol 98-28, *Gender perceptions of marital happiness*, approved under "standard review" procedures on 03 August 1998.
- Protocol 98-31, *Survey of mental health stakeholders' views on functional impairment*, approved under "exempted review" procedures on 25 September 1998.

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

David Cohen moved, and Steve Carter seconded, a motion that the Office for Graduate Studies and Research notify, via letter, the principal investigator(s) for each protocol that the Board has formally closed the protocol. The motion was passed unanimously with 7 "aye," 0 "nay," and 0 "abstentions."

9. The next meeting is scheduled for Friday, 14 January 2000, 8:00 AM – 10:00 AM, with breakfast served at 7:30 AM, in the Old Pub/Runner Café.
10. 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