

**INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS
RESEARCH (IRB/HSR)
CALIFORNIA STATE UNIVERSITY, BAKERSFIELD**

**MINUTES OF MEETING
30 May 1996
STUDENT UNION 137**

Members Present

Scientific Concerns: Brenda Pulskamp, Gonzalo Santos, Steve Suter

Non-Scientific Concerns: Nils Carlson, Cliona Murphy, Merry Pawlowski (from 8:15)

Community Issues: Evelyn Johnson, Duane Meyers

Members Absent

Susan Christiansen (Community Issues)

Visitors Present

Luis Vega for Protocol 96-31, *Psychology 300: Student Research Projects*

1. Meeting was called to order by Chairperson Steve Suter at 7:55 AM.
2. Duane Meyer moved, Cliona Murphy seconded, a motion to approve the board minutes for 28 March 1996. Motion was approved unanimously with 7 "aye," 0 "nay," and 0 "abstentions."
3. Nils Carlson moved, Gonzalo Santos seconded, a motion for formal affirmation of all protocol approvals made under expedited review and exempted review procedures for Spring (March-May) 1996. Motion was approved unanimously with 7 "aye," 0 "nay," and 0 "abstentions."
4. Duane Meyer moved, Nils Carlson seconded, a motion for one-year extension of the following four (4) protocols, previously approved during Spring (March-May) 1995:
 - Protocol 95-06, *Contiguous Records of VEPs and ERGs*, with Jess Deegan, Assistant Professor of Psychology
 - Protocol 95-10, *Effect of Visual Transient System Inefficiency and Fixation Disparity on Early and Late Visually-Evoked Potentials in Reading Disparity*, with Penelope Suter, Research Associate in Psychology
 - Protocol 95-27, *College Students' Social Psychological Attitudes on Self and Others*, with Luis Vega, Assistant Professor of Psychology
 - Protocol 95-31, *Critical Thinking Skills of Baccalaureate and Graduate Nursing Students*, with Margaret "Peggy" Leapley, Professor of Nursing and Department Chair, and Bonnie Saucier, Former-Professor of Nursing and Department Chair

The PIs for these four protocols reported that there are no changes for these protocols. Motion was approved unanimously with 7 "aye," 0 "nay," and 0 "abstentions."

NOTE: Merry Pawlowski arrives 8:15.

5. Brenda Pulskamp moved, Evelyn Johnson seconded, a motion for formal closure of all protocols approved one year ago (Spring 1995), except those formally requesting extensions (see #4 above). Motion was approved unanimously with 8 "aye," 0 "nay," and 0 "abstentions."

6. **Protocol 96-27, *Caring for an Adult In-Home Hospice Patient with Cancer: Hispanic Women's Perceptions of Oral Intake***, with Candace J. Meares, Associate Professor of Nursing. Dr. Meares was unable to be present, so board member Brenda Pulskamp "volunteered" to summarize the protocol for the Board. Considerable lively discussion of the protocol and the informed consent document ensued among the primary readers--Cliona Murphy, Evelyn Johnson, and Cliona Murphy--and the rest of the board members. After 40+ minutes of discussion, Nils Carlson moved, Evelyn Johnson 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:

- Use more "common" language for the technical and sophisticated terms, so that the consent document is easily read and comprehended by the lay public.
- Clarify that ethnicity refers specifically to the caregiver, not to the patient or Hospice Nurse.
- Add a statement that specifically instructs the caregiver to "contact the Hospice Nurse," in addition to those already referenced, if the caregiver has any questions and/or concerns.
- Add the following paragraph or similar phrasing to re-affirm the necessity of maintaining "respect for the patient:"

In addition, you need not respond to any questions that might jeopardize your relationship with your patient or compromise any confidence that your patient has with you. We are not asking you to divulge any information that may harm the respect and dignity of your patient. Finally, if you feel it necessary to attend to your patient during the interview, we will stop so that you can do so.

In addition to the above conditions, the Board recommends that Dr. Meares give careful consideration to the following issues in terms of her protocol:

- Carefully explore the extent of family involvement in caregiving during the interview process. Family involvement, or the lack thereof, may be important data.
- If possible to do so without placing participants at "risk" or jeopardizing participation in the research, ascertain whether the caregiver is U.S. born or foreign-born. Origin, in terms of birthplace, may be an important independent variable that differentiates "perceptions of oral intake."
- Consider going beyond the "English only" criterion for inclusion of the caregiver as a participant in the research project. At least two members of the board feel very strongly that limiting participation to "English only" will likely bias the results. The bilingual population is very diverse in their language abilities. The expression of "feelings and emotions" may be difficult in English,

which is likely to be a "second language" for the bulk of the population being tested. Spanish, being the "first language," will provide a richer and truer expression of the feelings and emotions that the PI desires.

The motion for conditional approval of the protocol was approved with 7 "aye," 0 "nay," and 1 "abstention" (Brenda Pulskamp, because of potential conflict of interest).

7. **Protocol 96-31, Psychology 300 Research Projects**, with Luis Vega, Assistant Professor of Psychology. Dr. Vega provided a summary of the type projects being planned for his students in Psychology 300, *Research Methods in Psychology*. Ensuing questions from and discussion with the primary readers--Evelyn Johnson, Cliona Murphy, and Steve Suter--and the other members of the board followed. Dr. Vega indicated that all survey forms collected during the course would be destroyed at the end of the term and that the survey instruments developed may ask for other demographic information beyond that indicated in the sample attached to the protocol--e.g., class level, residency, income, etc. Dr. Vega agreed that he would submit for Board review brief summaries of all projects completed by his students in Psychology 300 at the end of each term. Duane Meyer moved, and Nils Carlson seconded, a motion for full approval of the protocol. The motion for full approval was approved with 6 "aye," 2 "nay," and 0 "abstention."

Before the vote was taken, considerable discussion ensued regarding the use of classtime for the completion of the survey forms. The major issue in the use of classtime for research purposes, such as completing surveys and questionnaires, is:

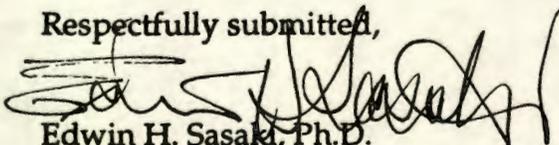
Students in a class are a "captured audience," and, as a result, they are considered a "vulnerable population" because the criteria of "autonomy" and "voluntariness" may be compromised. If the primary rationale for using students in a class is "convenience" of obtaining research subjects, then how does one justify the trade-off between "risk-and-benefit?"

There was consensus among the Board members that this issue should be discussed further during one of the meetings during the 1996-97 academic year. Faculty and students should be invited to participate in the discussions to obtain a diversity of views on this issue.

8. Next IRB/HSR meeting is scheduled for late-September or early-October 1996. The meeting schedule for the 1996-97 academic year will be distributed later.

9. There being no further business, Chairperson Suter adjourned the meeting at 10:20 AM.

Respectfully submitted,



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