

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

MINUTES OF MEETING

5 June 1998

Old Pub/Runner Cafe

Members Present

Scientific Concerns: Brenda Pulskamp, Gonzalo Santos

Non-Scientific Concerns: Nils Carlson, Steve Carter

Community Issues: Evelyn Johnson, Duane Meyer, Nancy Carr

Members Absent

David Cohen (Scientific Concerns)

Merry Pawlowski (Non-Scientific Concerns)

Edwin H. Sasaki (IRB/HSR Secretary)

Visitors Present

Selina Ganopole

Kathy Smith

Jacqueline Messinger, Sociology graduate student, for Protocol 98-28

Valerie Walker-Valenzuela, Sociology graduate student, for Protocol 98-29

1. Meeting was **called to order** by Chairperson Brenda Pulskamp at 8:00 a.m. In Dr. Sasaki's absence, Kathy Smith recorded the minutes.
2. Protocols previously approved under "exempted review" during Spring Term were presented for formal board affirmation. Upon a motion by Dr. Carter, seconded by Dr. Carlson, the exempted approvals were **unanimously affirmed** as presented, with 7 "aye," 0 "nay," and 0 "abstentions."
3. Protocols previously approved under "expedited review" during Spring Term were presented for formal board affirmation. Upon a motion by Dr. Carlson, seconded by Dr. Carter, the expedited approvals were **unanimously affirmed** as presented, with 7 "aye," 0 "nay," and 0 "abstentions."
4. Protocols previously approved one year ago (Spring Term 1997) were presented for formal board closure. Following review, upon a motion by Dr. Carter, which was seconded by Rev. Meyer, the Board was **unanimous in its vote for closure** as presented, with 7 "aye," 0 "nay," and 0 "abstentions."
5. Dr. Candace Meares' request for extension of **Protocol 96-27** ("Hispanic Women's Perceptions: Intake Cessation in the Terminally Ill" was presented for approval. Following a brief discussion, Dr. Carter moved for approval of said request, Dr. Carlson seconded the motion, and it carried unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

6. **Protocol 98-28 "Gender Perceptions of Marital Happiness"**

Jacquelyn Messinger was invited into the meeting and provided a brief biography for the Board. She stated that she was preparing a master's thesis analysis.

Ms. Messinger advised she would be establishing relationships with various pastors in the community during the summer break, developing relationships with them and their congregations. She planned loosely structured interviews in three or four churches; observing only. In the Fall, she planned to complete her instrument design and begin interviews.

There was extensive discussion with the student with regard to the informed consent, the planned data analysis, subject rights and methodology. Ms. Messinger advised that she had fundamental problems with the practice of "informed consent". Therefore, she planned to advise her subjects that it was not mandatory, although she will number the surveys accordingly. Dr. Santos explained that the questionnaire remains confidential - anonymous. Only the consent form is identifiable. Dr. Carter suggested that concrete language be added to differentiate between spirituality and religiosity.

In the discussion that followed, Ms. Messinger provided examples of the questions which she will be using in her questionnaire. She also advised that she hopes to get 50 couples into her study. Dr. Pulskamp requested further information with regard to the observation techniques Ms. Messinger will be utilizing. Ms. Messinger advised that the pastor would supply subjects for the research, and it would remain a voluntary process. She would observe behavioral patterns of the couples in the congregation and will utilize that observation data once the interviews begin.

Further discussion followed regarding the methodology of observations, extraneous information and replicability issues. Several problems were identified by the Board with an "observation only" process:

- 1.) consent/altered response
- 2.) couples that have only one attending church
- 3.) summer church attendance plummets
- 4.) replicability issues
- 5.) contingency plan for possible conflict management

At this point, Jacque exited the meeting while the Board reviewed the points previously discussed. Drs. Santos and Carlson proposed that the student be allowed to use the summer to:

- identify a subject pool and secure informed consents;
- identify four areas of ethnographic observation;
- ethnographic observation research form must be signed;
- prepare questionnaire for submission to the HSR/IRB for review and approval;

(both Dr. Carlson and Dr. Santos volunteered as reviewers [in addition to Dr. Sasaki] for an expedited review) and

- identify pastoral or counseling source for possible conflict resolution.

The Board expressed **unanimous agreement** to this plan of action, so Ms. Messinger was called back into the meeting and advised that her proposal had received a **conditional approval**, pending the following:

- Change sequence of informed consent before observation (identify and secure subject pool);
- Change informed consent to allow observation only;
- Obtain signatures on informed consent;
- Identify a pastoral or counseling source for possible conflict resolution;
- Completed questionnaire and format for replicating to be submitted to the HSR/IRB for expedited review; and
- The Board strongly suggested fine tuning of the methodology.

7. Protocol 98-28 "Understanding and Explaining Sexual Behavior: The Ongoing Nature vs. Nurture Debate"

Valerie Walker-Valenzuela was invited into the meeting and provided a brief biography for the Board, stating that she worked at Houchin Blood Bank as an RN, and was a master's candidate at CSUB. Following synopsis of her protocol, Ms. Walker-Valenzuela advised that she was hoping to involve 75 couples in her study, the interview portion of which would entail approximately 2 - 3 hours each.

There was extensive discussion regarding concerns over diary disclosure between couples and the verbiage contained therein. Valerie noted that she would be focusing on pre-menopausal women, and would be strongly suggesting to the subjects that the diaries be considered private -- not to be shared. Dr. Carlson expressed the need for a contingency plan for conflict resolution, especially in light of the sensitive disclosures that would be solicited from each subject. In response to Dr. Carlson's inquiry, Ms. Walker-Valenzuela advised that each subject will see the diary before signing the informed consent.

Ms. Walker-Valenzuela advised that the subject pool will be identified through a "snowball" effect.

Following extensive discussion of existing data from The Kinsey Report, etc.; data disclosure/confidentiality; hypothesis; hormonal influences; possibility of on-line or e-mail responses (password protected); the need for self reporting only; data contamination via cosmetics; replication issues; testing for validity; length of survey (40 days); survey identifiers; complexity of survey (will couples realistically participate long-term?); how attrition will effect results; and statistical integrity, Ms. Walker-Valenzuela was excused from the meeting.

The Board commenced a lengthy discussion regarding the validity of the project, with Dean Ganopole noting that the risk factor was a significant concern. How to best protect the subjects? Although Dr. Cohen wasn't able to attend the meeting, he had asked Dr. Ganopole to voice his opinion that the subject matter was intrusive enough to justify a look at the data analysis. He also questioned the student's ability to follow-up effectively. Dr. Pulskamp agreed with Dr. Cohen's concern regarding the risk vs. benefit factor. Dr. Ganopole also raised ethical issues, with Drs. Carlson and Carter expressing their belief that it was the Board's responsibility to protect the rights of the subjects.

There was consensus that the informed consent was not sufficient, in that the risks were not stated clearly enough, and there was no provision made for the possibility of conflict resolution.

Steve Carter and Nils Carlson recommended **conditional approval**, pending the following:

- 1.) **Risks clearly identified;**
- 2.) **Confidentiality between participants ensured;**
- 3.) **Confidentiality of data storage ensured;**
- 4.) **Options identified for conflict resolution;**
- 5.) **Expedited review of revised informed consent (to include Drs. Cohen and Sasaki)**

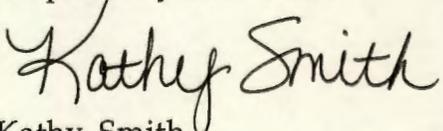
The Board expressed **unanimous agreement** with this plan of action. Ms. Walker-Valenzuela was called back to the meeting and advised of the conditions necessary to secure final approval.

8. **Protocol 98-30 "The Effect that Maintaining Traditional Spiritual Practices has on Defining Ethnic Identity in the Native American Community"**

Ms. Bowman did not present for her protocol review.

9. There being no further business, Chairperson Pulskamp adjourned the meeting at 10:20 a.m.

Respectfully submitted,



Kathy Smith
Graduate Studies and Research