

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

MINUTES OF MEETING

8 January 1999

Old Pub/Runner Cafe

Members Present

Scientific Concerns: David Cohen, Brenda Pulskamp

Non-Scientific Concerns: Steve Carter

Community Issues: Nancy Carr, Evelyn Johnson

Members Absent

Merry Pawlowski (Non-Scientific Concerns)

Visitors

Candace Meares, Professor of Nursing / Department Chair, for Protocol 98-46

Kathy Smith, Graduate Studies and Research

1. Meeting was **called to order** by Chairperson Brenda Pulskamp at 8:08 a.m.
2. Steve Carter moved, and Nancy Carr seconded, a motion to **approve the minutes** for the IRB/HSR meeting of 25 September 1998 as presented. Motion was approved unanimously, with 5 "aye", 0 "nay", and 0 "abstentions".
3. David Cohen moved, and Steve Carter seconded, a motion for the **formal affirmation** of all protocol approvals made under **exempted review procedures** (Protocols 98-35, 98-36, 98-37, 98-38, 98-41, and 98-43), and under **expedited review procedures** (Protocols 98-39, 98-40, and 98-42) during Fall Term 1998 (September - December, 1998). The motion passed unanimously, with 5 "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 (September - December, 1997). Protocols to be closed included 97-29, 97-32 and 97-33 under **exempted review procedures**, 97-31 under **expedited review procedures**, and 97-30 under **standard review procedures**. The motion passed unanimously, with 5 "aye", 0 "nay", and 0 "abstentions".
5. **Protocol 98-45, Secondary Screen for the Evaluation of the Employment Readiness Demonstration Project (ERDP)**, with Edwin H. Sasaki (Kathy Smith took minutes during this interview). Dr. Sasaki provided an overview of his research Protocol. Questions from the IRB members involved:

- Is there any benefit to the ERDP participants vs. regular Cal Works? The response was that, aside from more personalized case management, there was no benefit to those participating in ERDP as opposed to those participating in the Cal Works program.
- How will confidentiality be maintained at the county level? Dr. Sasaki responded that each county will assign one person to administer the secondary screening. The data will then be forwarded to CSUB. Only one individual on the CSUB campus (Laura Hecht) will see the actual data, as she will be responsible for inputting the data into the computer. Nobody else on the ERDP will have access to the initial data received from the respective counties.
- Can someone from the ERDP team sign the informed consents and send them to the counties? This would provide a fully executed signed consent to the participants. Dr. Sasaki indicated he thought this could be accomplished.
- Is there an appearance of a conflict of interest, as Dr. Sasaki is listed as both the Principle Investigator and the IRB/HSR contact for ethics concerns. Dr. Sasaki understood this concern and suggested Dr. Pulskamp, as Chair of the IRB/HSR, be listed as the IRB/HSR contact instead. This was acceptable to the Committee.

After all questions had been answered to the Committee's satisfaction, David Cohen moved, and Steve Carter seconded, a motion for **full approval** of the protocol, with the provision that the informed consent document be revised to list Brenda Pulskamp as the IRB/HSR ethics contact, and Dr. Sasaki to provide each county with signed consent forms for their use in administering the secondary screening tool. These changes must be made and a revised informed consent form filed with Graduate Studies and Research. The motion passed unanimously, with 5 "aye", 0 "nay", and 0 "abstentions".

6. **Protocol 98-46, *Perceptions of Issues and Needs Related to End-of-Life Care***, with Dr. Candace Meares. Dr. Meares provided a brief overview of the protocol, indicating that this was the third study on end-of-life issues she has conducted. The goal of this project is to assess the needs in the local community so that end-of-life care can be improved. Because the patients involved in this study are the most vulnerable, they will be looking for patients who are not in the active phase of dying. A few questions were raised:

- Why is the study limited to English speaking subjects only? Dr. Meares admitted that this was a limitation, but due to a need to access information as soon as possible by the End of Life Project, the decision had been made to limit the study

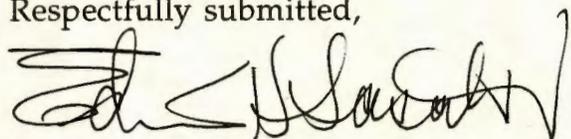
to English speaking subjects at this time. Dr. Meares indicated she would like to expand the study at some future date to include Spanish speaking subjects.

- Is the wording at the bottom of the page on Appendix C too vague regarding withdrawal from the study? Will the subjects understand that the absence of a "negative impact" refers to any services or benefits they're receiving? Perhaps it should be reworded to assure that if a subject chooses not to participate, or terminates participation at any time, it will not affect the services they are currently receiving. Dr. Meares felt this was a valid point, but pointed out that this form would also be signed by parties not receiving benefits or services (clergy, social workers).
- How will the patient subjects be assessed for mental competency? Dr. Meares noted that, as a nurse with extensive hospice experience, she is able to judge when a patient is mentally alert and aware of their actions. She advised that, should she arrive for an interview to discover that a patient has recently received medication that could temporarily alter their competency, she would voluntarily reschedule the interview.

After all questions had been answered to the satisfaction of the Committee, Dr. Meares was excused. Evelyn Johnson moved, and Steve Carter seconded, a motion for **full approval** of the protocol. The motion passed unanimously, with 5 "aye", 0 "nay", and 0 "abstentions".

7. The next meeting is scheduled for **Friday, 9 April, 1999**, 7:30 Breakfast, 8:00 Meeting, in the Old Pub/Runner Cafe.
8. There being no further business, Chairperson Pulskamp adjourned the meeting at 9:07 a.m.

Respectfully submitted,



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