

Institutional Review Board for Human Subjects Research (IRB/HSR)
California State University, Bakersfield
9001 Stockdale Highway, Bakersfield, CA 93311-1099

Minutes of Meeting
Friday, 02 June 2000
Old Pub/Runner Café

Members Present:

Scientific Concerns: Kaye Bragg, David Cohen, Peggy Leapley
Nonscientific Concerns: Jeanne Harrie, Eun-Ja Park
Community Issues: Evelyn Johnson

Members Absent: Steve Carter (Nonscientific Concerns) due to sabbatical leave for Spring 2000; Amanda Bevier and Nancy Carr (both Community Issues)

Visitor Present:

Dr. Candace Mears, Department Chair for Nursing, for Protocol 00-18 (formerly 96-27)
Heidi Lichtenberg, Administrative Support Coordinator, Graduate Studies and Research

1. Chair Jeanne Harrie called the meeting to order at 8:05 AM.
2. Ms. Heidi Lichtenberg, Administrative Support Coordinator, Graduate Studies and Research was introduced to the Board. Ms. Lichtenberg provides all the clerical support for the IRB/HSR, and she makes all arrangements for the quarterly meetings of the IRB/HSR.
3. David Cohen moved, and Eun-Ja Park seconded, a motion to approve the minutes for the IRB/HSR meeting of 21 April 2000 with several corrections:
 - On page 1, paragraph #2, under “NOTE,” change “was” to read “there were no minutes. . .”
 - On page 3, paragraph #6, first bullet of the page, correct spelling to read “principal investigator’s signature. . .”
 - On page 3, paragraph #6, first major paragraph of the page, change “make” to read “adjustments be made. . .”
 - On page 3, paragraph #7, next to last bullet of the page, remove “one” to read “appeared to be as a consultant. . .”

The motion to approve the minutes for 21 April 2000 with corrections as noted above was approved unanimously, with 6 “aye,” 0 “nay,” and 0 “abstentions.”

4. Board actions for formal affirmation of protocols previously approved under exempted and expedited review procedures during Spring 2000 (11 April to 02 June) was deferred until the next meeting because the listing of protocols was inadvertently omitted from everyone’s meeting packet.

5. Board action for formal closure of protocols previously approved one year ago (April 1999 to June 1999) was deferred until the next meeting because the listing of protocols was inadvertently omitted from everyone's meeting packet.
6. **Protocol 00-18, Hispanic women's perceptions: Intake cessation in the terminally ill**, with Dr. Candace Mears, Department Chair for Nursing. Dr. Mears indicated that this protocol was the same as Protocol 96-27, which the IRB/HSR approved in 1996 and granted an extension in 1997. Dr. Mears explained that the research has taken considerable longer than originally planned because of the difficulty in recruiting participants with the original hospice agency. Therefore, the only change in the new Protocol is that a different hospice agency is now involved; otherwise the procedures as specified in Protocol 96-27 remain the same. To reacquaint the members of the Board, Dr. Mears provided a brief overview of the protocol, after which she answered questions from different members of the IRB/HSR. These questions regarded the following:
 - Number of interviews for each participant. Dr. Mears indicated that only one interview would be scheduled; there would not be multiple interviews over time.
 - Place where interviews would take place. Dr. Mears indicated that the protocol specifies the caregiver's home or another location specified by the caregiver. The reason for allowing the caregiver to specify where the interview would take place is so that the caregiver would feel comfortable talking about the hospice experience.
 - Title for Dr. Edwin H. Sasaki as "Secretary, Institutional Review Board." Dr. Mears agreed that she would change the title to "Research Ethics Assurance Coordinator" for the final version of the informed consent document.

When there were no additional questions regarding the protocol, Dr. Mears was excused. Kaye Bragg moved, and Evelyn Johnson seconded, a motion to grant full approval for Protocol 00-18. The motion was passed unanimously with 6 "aye," 0 "nay," and 0 "abstentions."

7. **Protocol 00-22, Nutrition, activity and body mass index of 5th grade children in Kern County**, with Dr. Peggy Leapley (other co-investigators are graduate students in Nursing at CSUB: Idalia Ablin, Janine Bourelle, Michelle Pearl-Krizo, and Catherine Salyers). This protocol was reviewed previously by the IRB/HSSR at its meeting on 21 April 2000, and the Board requested that it be informed of the progress of the research for its continuing review of the protocol. Dr. Leapley provided an update of the pilot-testing for the procedures and the instrument, "Nutrition and Activity Survey," which was suggested by the Board:
 - A "Child's Assent Form" was developed, using as a model one used by Drs. Steven and Penelope Suter in their visual evoked potential research with children having reading disabilities. This Assent Form was reviewed and approved by the 5th grade teachers involved with the research. The Assent Form was pilot tested with several 5th grade students, and there were no problems with the students being able to read and understand the document.
 - The "Nutrition and Activity Survey" was also pilot-tested with several 5th grade students, and there were no problems with the students being able to read and respond appropriately to the questions. The concern expressed by some of the members of the

Board regarding the length, level of detail, and/or the memory load requirements of the instrument did not surface during the pilot testing.

- Spanish translations of the Parent’s Informed Consent Document and the Child’s Assent Form were developed and pilot tested. Copies of each document were distributed to the IRB/HSR.

Two suggestions were made by members of the IRB/HSR regarding the Child Assent Form:

- In the second paragraph, change “effect” to “affect” so that the sentence reads “will not affect my grade. . .”
- In the fourth paragraph, add the title “Professor” to Peggy Leapley so that it reads “contact Professor Peggy Leapley . . .”

Dr. Leapley agreed with both suggestions, and she stated that these changes would be made to the Child Assent Form.

There were no further questions or comments from the Board, so Dr. Leapley was excused. David Cohen moved, and Eun-Ja Park seconded, a motion to approve the Child Assent Form with the “minor” changes specified above. The motion passed with 5 “aye,” 0 “nay,” and 0 “abstentions.” NOTE: Dr. Leapley was not present for the voting.

8. The next meeting will be Friday, 22 September 2000.
9. There being no further business, Chair Jeanne Harrie adjourned the meeting at 8:40 AM.

Respectfully submitted

Edwin H. Sasaki, Ph.D.
Professor of Psychology
and IRB/HSR Secretary