

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

Minutes of Meeting
Friday, 21 April 2000
Old Pub/Runner Café

*See edit
changes*

Members Present:

Scientific Concerns: Kaye Bragg, David Cohen, Peggy Leapley
Nonscientific Concerns: Jeanne Harrie, Eun-Ja Park
Community Issues: Amanda Bevier, Nancy Carr, Evelyn Johnson (at 8:20)

Member Absent: Steve Carter (Nonscientific Concerns) due to sabbatical leave for Spring 2000

Visitors Present:

Ms. DeeStephanie McGuffey, RN, graduate student in Nursing, for Protocol 00-17
Dr. Robert Fong, Department Chair for Criminal Justice, for Protocol 00-23

1. Chair Jeanne Harrie called the meeting to order at 8:05 AM.
2. David Cohen moved, and Amanda Bevier seconded, a motion to approve the minutes for the IRB/HSR meeting of 24 September 1999 with one correction. The correction was to include the final vote on the motion specified in Item #7, which was inadvertently omitted. The motion was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."

NOTE: The meeting for January 2000 had been cancelled, so there was no minutes for January 2000.

3. David Cohen moved, and Peggy Leapley seconded, a motion that the IRB/HSR formally affirm the approvals for protocols reviewed under "expedited review" and "exempted review" procedures during Winter 1999, pending clarification of dates for final approval by Heidi Lichtenberg, Administrator Support Coordinator, for Graduate Studies and Research. The motion was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."
4. Kaye Bragg moved, and Amanda Bevier seconded, a motion that the IRB/HSR formally close protocols approved during fall 1998 (October 1998-December 1998) and winter 1999 (January 1999-March 1999), pending clarification dates for final approval by Heidi Lichtenberg, Administrator Support Coordinator, for Graduate Studies and Research. The motion was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."
5. **Protocol 00-17, Caregiver's perceptions of the Hospice experience**, with DeeStephanie McGuffey, RN. Ms. McGuffey provided a brief overview of the protocol, after which she answered questions from different members of the IRB/HSR. When

there were no additional questions regarding the protocol, Ms. McGuffey was excused. Kaye Bragg moved, and David Cohen seconded, a motion to grant conditional approval for Protocol 00-17. The conditions that must be met prior to full approval are the following changes to the informed consent document:

- Add a statement regarding the procedures to be used to maintain confidentiality of the audiotapes.
- Add a statement regarding what happens to the tapes and/or information on the tapes after the completion of the research.
- Add a statement informing potential participants that their refusal to participate in the research will have no effect on the services that they have been receiving and/or will receive in the future.
- Add a statement regarding the possible use of another person to transcribe the taped conversations and that this individual will also maintain the confidentiality of the information.
- Clarify the use of pseudonyms in place of the actual names of the participants, e.g., rephrase the 4th sentence in paragraph #2 to read, "When the tapes are transcribed, pseudonyms will be used. . ."

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

NOTE: Evelyn Johnson arrived at 8:20.

6. **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). Dr. Leapley provided a brief overview of the protocol, which represented a collaborative endeavor with *The Bakersfield Californian* and KGET, Channel 17, as part of the "Fit for the Future" series examining the health and fitness of Kern County children. Many questions were raised by the members of the IRB/HSR regarding the following:

- Wording and font size of the informed consent document;
- Matching of the parent's (or legal guardian's) identity on the consent document with the respective child;
- Protecting the identity of the child with respect to certain data elements, especially body mass index measures;
- Level of detail on the "Nutrition and Activity Survey" to be completed by the child, and the memory requirements needed, e.g., many questions ask the child about events occurring in the past seven days;
- Having the teacher provide information on the child's height, weight, ethnic group, and athletic ability;
- Having the teacher administer the "Nutrition and Activity Survey," which may create a situation of "undue influence" on the voluntariness of the children's participation;
- Lack of a child's assent form;

- Signature of the principle investigator's signature on the informed consent document; and
- Use of class time for the student to complete the "Nutrition and Activity Survey."

When the members of the IRB/HSR raised no further questions, Dr. Leapley was excused. Nancy Carr moved, and David Cohen seconded, a motion to grant conditional approval of Protocol 00-22. The major condition was that a Child's Assent Document be reviewed and approved by the members of the IRB/HSR. Because of the many issues raised by the IRB/HSR regarding this protocol, the consensus was that all conditions be reviewed by the entire Board membership prior to granting full approval. Further, it was strongly suggested that Dr. Leapley arrange for a "pilot test" of the procedures and the "Nutrition and Activity Survey" prior to full implementation of the evaluation project, that appropriate adjustments be make to the procedures and survey instrument based upon the pilot test, and that the IRB/HSR be informed of these changes for its continuing review of the protocol. The motion for conditional approval passed with 5 "aye," 1 "nay," and 1 "abstention." Peggy Leapley did not vote.

NOTE: Jeanne Harrie excused herself to teach a scheduled class at 9:30; David Cohen agreed to serve as the Acting Chair in her absence.

7. **Protocol 00-23, Factors associated with academic performance: Exploring theoretical links to school success and identifying roadblocks to learning**, with Dr. Robert Fong. Dr. Fong provided an overview of the protocol, which represented a collaborative endeavor with the Kern County Sheriff's Department and the Lamont Independent School District. The project is to be funded by the Office of Community Oriented Policing Service of the U. S. Department of Justice; the award was officially made to the Kern County Sheriff's Department. Many questions were raised by the members of the IRB/HSR, including the following:

- Award of \$5.00 to the child for taking the parent's questionnaire home and bringing it back to school;
- Award of a \$5.00 gift certificate to the parent for completing the questionnaire;
- Protecting the confidentiality of the student data, since the student questionnaire includes questions regarding "illegal activities" that potentially could place the respondent "at risk";
- Status of the contents of the parent's questionnaire, since Dr. Fong reported that it was being developed;
- Status of the parent's (legal guardian's) informed consent document and child's assent form, since Dr. Fong reported that these were being modified;
- Who is actually conducting the research, since Dr. Fong's role as described appeared to be one as a "consultant" for data analysis;
- Who is "ultimately responsible" (official custodian) of the research data, since Dr. Fong intimated that the raw data would belong to the Kern County Sheriff's Department.

After this question-and-answer period, there was consensus among all members of the IRB/HSR that Dr. Fong should formally withdraw the protocol from review by the CSUB IRB/HSR because personnel from the Kern County Sheriff's Department and from the Lamont Independent School District were actually conducting the research. Dr. Fong's role appeared to be as an "independent consultant" responsible primarily for data analysis. Under these conditions, the IRB/HSR believed that the university was not formally involved in the research process that would require its oversight. Dr. Fong agreed to withdraw the protocol.

8. The next meeting will be Friday, 02 June 2000.
9. There being no further business, Acting Chair Cohen adjourned the meeting at 10:00.

Respectfully submitted

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