

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

MINUTES OF MEETING
28 SEPTEMBER 1995
STUDENT UNION 137

Members Present

Scientific Concerns: Gonzalo Santos, Steve Suter
Non-Scientific Concerns: Nils Carlson, Merry Pawlowski
Community Issues: Duane Meyers

Members Absent

Brenda Pulskamp (Scientific Concerns)
Cliona Murphy (Non-Scientific Concerns)
Susan Christiansen (Community Concerns)
Diane Smith (Community Issues)

Visitors Present

Dr. Beth Rienzi, Associate Professor of Psychology
Kevin McNeill, Graduate Student in Psychology

Primary Agenda

1. Meeting was called to order by new Chair Steve Suter at 8:00 AM.
2. New Board member, Merry Pawlowski, Associate Professor of English, was introduced. She is replacing former Chair Janet Vice for the area of "non-scientific/ humanistic concerns."
3. The first order of business was to discuss an issue raised by Dr. Beth Rienzi and Mr. Kevin McNeill. Specifically, the issue was one in which they wanted to include a "research component" within a long-standing class project involving a visit to the Holocaust Museum in Los Angeles and Allensworth State Historical Site. The "research component" involved the assessment of changes in the students' attitudes and beliefs after their experiences with these two visitations. After considerable discussion, the Board concluded that ". . . when a person becomes *conscious* of the potential for research in any class activity, then the mechanisms for informed consent should be activated." These

mechanisms include precautions from coercion to participate, precautions to preserve the confidentiality of the data, and all the other "normal" precautions associated with research involving human subjects.

4. The second order of business was to discuss the issue of conducting research with students during class time and with employees during work hours. It was unanimous that a faculty member should NOT conduct his/her own research with students in his/her own class due to the "implied power" of a faculty member relative to his/her students. Further, a faculty member should NOT conduct research using as subjects clerical/technical staff in the same department/unit for the same "implied power" reason. This "implied power" negates one of the basic principles of ethical conduct of research, i.e., that human subjects must be treated as autonomous individuals. In terms of getting students in another faculty member's class to participate in a research project during class time, the Board concluded that it was the responsibility of the faculty to (1) consider fully the cost/benefit of using instructional time for research purposes and (2) consider fully the issues of coercion, voluntariness, and trust in making the transition of student in the classroom to human subject in research. The Board unanimously voted to include both students in the classroom and employees in the workplace in the listing of "vulnerable populations." Such listing would require protocols using these subjects to be reviewed under "standard review procedures" involving the entire Board. (NOTE: These changes have already been made in the "IRB/HSR policies and procedures" document.)
5. The third and final order of business involved research using existing data, especially medical records. The major issue is that medical records are maintained primarily for medical purposes and consent is normally obtained only for use by the physician. In other words, it is not standard practice to obtain "informed consent" from patients for the use of data from their medical records for potential research. After considerable discussion, the Board concluded that it was the responsibility of the principle investigator (PI) to (1) consider fully the cost/benefit of extracting data from medical records which were compiled for medical purposes and not research purposes, (2) identify fully the specific data elements required for research, and (3) specify clearly how confidentiality of the extracted data AND the other information in the medical records themselves are to be maintained. Dr. Sasaki, who is a member of the IRB for Kern Medical Center (KMC), indicated that KMC has a special "simplified" form for requesting review

of research involving data from existing medical records. He indicated that our conclusions are fully in line with the requirements of KMC.

6. Next IRB/HSR meeting is scheduled for Thursday, 04 January 1996.
7. There being no further business, Chair Steve Suter adjourned the meeting at 10:25 AM.

Respectfully submitted,

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

