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

MINUTES OF MEETING
4 JANUARY 1996
DDH A108

Members Present

Scientific Concerns: Brenda Pulskamp, Gonzalo Santos, Steve Suter
Non-Scientific Concerns: Nils Carlson, Cliona Murphy, Merry Pawlowski,
Community Issues: Susan Christiansen, Duane Meyers
Board Secretary: Edwin H. Sasaki

Members Absent

Visitors Present

Dr. Kenneth L. Nyberg, Professor of Sociology
Dr. Peggy Leapley, Professor of Nursing
Dr. T. Ken Ishida, Assistant Professor of Psychology
Mr. Robert B. Hefner, Graduate Student in Psychology

Primary Agenda

1. Meeting was called to order by Chairperson Steve Suter at 1:25 PM.

2. Secretary Edwin Sasaki announced that Dianne Smith has resigned as a community representative on the IRB/HSR due to moving out-of-state to accept a new position. Secretary Sasaki indicated that he was working to find a replacement for the remainder of Diane Smith's term.

3. Minutes for the meeting of 28 September 1995 were briefly discussed, but they were not approved. There was some concern expressed in the wording of paragraph #4 regarding the issue of conducting research with students during class time and with employees during working hours. It was decided that Secretary Sasaki should meet with Chairperson Suter to revise the wording so that the minutes could be reviewed and approved at the next meeting of the IRB/HSR, 28 March 1996.

4. There was no OLD BUSINESS.

5. NEW BUSINESS

a. There was unanimous affirmation by the IRB/HSR for the approval of all the protocols reviewed under exempted procedures during Fall (Oct-Dec) 1995.

b. There was unanimous affirmation by the IRB/HSR for the approval of all the protocols reviewed under expedited procedures during Fall (Oct-Dec) 1995.

c. There was unanimous approval by the IRB/HSR for the formal closure of all the protocols approved one-year ago, Fall (Oct-Dec) 1994. The Board requested that the Office of the Dean, Graduate Studies and Research, take the responsibility to notify all principal investigators prior to Board action for formal closure.

d. Protocol 95-59, *Comprehensive Public Health Survey and Valley Fever Epidemiology*, with Drs. Kenneth L. Nyberg (Professor of Sociology, Department Chair,

and Director of Applied Research Center) and Peggy Leapley (Professor of Nursing and Department Chair). Both Drs. Nyberg and Leapley took turns providing an overview of the research protocol, including the comprehensive survey to be implemented and the blood drawing from a subsample. After considerable exchange of questions and answers regarding several aspects of the protocol, Drs. Nyberg and Leapley were excused. Duane Meyer moved that the Board give "conditional approval" to Protocol 95-59; motion was seconded by Susan Christiansen. After a clear listing of the conditions was prepared, Chairperson Suter called for a vote. The motion was passed unanimously with 8 in favor, 0 opposed, and 0 abstensions. The Board authorized the Dean for Graduate Studies and Research to work directly with the PI's to ensure that the following conditions were met to receive full approval:

1) Include statement(s) in the informed consent document that the blood to be taken will be tested only for Valley Fever antigens and for no other purpose, such as HIV/AIDS, drug use, etc. Include also a statement that the blood samples will be destroyed at the end of the study.

2) Include statement in the informed consent document that the survey responses will be entered into computer data bank and that the actual survey forms will be subsequently destroyed.

3) Spell out in greater detail in the informed consent document the other potential uses of the computer data bank, i.e., Valley Fever, as well as other medical, social, cultural, educational, political, and economic issues important to the County of Kern. Emphasize "benefits" of helping to provide this valuable information through participation in this survey. Also, indicate that this information will be invaluable to future researchers in aiding policy makers in answering significant issues confronting citizens of the County of Kern.

4) Reformat the type and font size, simplify the language, use headings/subheadings, use "same person" throughout the informed consent document, or produce an additional simple summary version as a supplement.

5) Include a statement in the informed consent document that a copy of the report summary will be available when the study is completed.

6) Throughout the informed consent document, enlarge references to identifiers. i.e., use "Latino/Hispanic, Mexican-American, or Mexican" instead of a single identifier to ensure that all cultural backgrounds will be correctly identified.

7) Include a clear concise statement in the informed consent document that the participant is free to decline answering any specific question without penalty.

8) Finally, Dean Sasaki and the PI's need to check further regarding the liability of researchers, ARC, and CSUB in case of any complications resulting directly from participation in the study. Any liability for any of the parties should be clearly stated in the informed consent document.

e. Protocol 95-60 (formerly 94-25), *Confrontational Naming in Alzheimer's with Regards to Visual Pathway Impairment*, with Robert B. Hefner, Graduate Student in Psychology, and Dr. T. Ken Ishida, Assistant Professor of Psychology. Mr. Hefner indicated that he has just recently completed the revision of the informed consent document that had previously been awarded "conditional approval" at the IRB/HSR meeting of 08 June 1994. Since that approval was more than one-year ago and, therefore, has now lapsed, Mr. Hefner was requesting that the Board review the protocol for approval. According to Mr. Hefner the protocol procedures have remained unchanged for the initial review; the only changes made have been in the informed consent document as requested by the Board. Gonzalo Santos moved that the Board delegate to the Dean for Graduate Studies and Research the responsibility of reviewing the revised informed consent document to confirm that the requested conditions have been met; motion seconded by Duane Meyer. Chairperson Suter called for the vote; motion was unanimously passed with 8 in favor, 0 against, and 0 abstensions. The conditions to be met prior to full approval are:

1) Eliminate "technical" terms, such as "confrontational naming;"

2) change pronouns to refer to the Alzheimer patient as being the participant in the research;

3) be clear as to the type of feedback, if any, that will be provided to the caregiver;

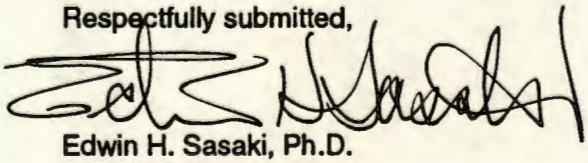
4) be specific as to how subjects will be recruited and how their assent will be obtained, and

5) indicate that a copy of the signed consent form will be provided to the person signing the consent form.

6) The assent form should ensure that the basic information is congruent with the caregiver's consent form and specify that the testing may take more than one session, especially if the subject chooses to terminate a session before the testing is completed.

5. There being no further business, Chairperson Suter adjourned the meeting at 3:30 PM.

Respectfully submitted,



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