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

Minutes of Meeting
6 April 1995

Members Present _
Scientific Concerns: Brenda Pulskamp, Gonzalo Santos, Steve Suter
Non-Scientific/Humanistic Concerns: Janet Vice, Nils Carlson, Cliona Murphy
Community Issues: Susan Christiansen, Duane Meyer, Dianne Smith

Members Absent: _ None

Visitors Present:
Jess Deegan for Research Protocol #95-06
Penelope Suter for Research Protocol #95-10
Charlotte Ripley for Research Protocol #95-11
Kim George, Molly Gutierrez, Jeff Krueger, Virginia Nzekwe, Lynda Ubungen for Research Protocol #95-14

1. Meeting was called to order by Chairperson Vice at 10:40 AM.

2. **94-23 ISABEL SUMAYA-SMITH**

Ms. Suaya-Smith submitted a request for approval of a modification of her protocol, *Effects of Light Treatment on Depressed Elderly in a Skilled Nursing Facility,* in which a between-groups design be changed to a within-groups design. The justification for the change was based upon the facts that (1) fewer subjects would be eligible to participate in the research than originally considered and (2) a within-group design in a "before treatment-after treatment" comparison is statistically more powerful than a between groups design.

BOARD ACTION: Nils Carlson moved Board approval of the request; Susan Christiansen seconded the motion. The Board voted unanimously to support the motion.

3. **95-06 JESS DEEGAN**

At the request of the Board, Mr. Deegan provided a brief description of the research area represented by his protocol and a description of the procedures utilized to measure Electro-Retino-Grams (ERG).

During the discussion of the protocol, several questions and issues were raised:

1. Characteristics of the students--Specifically, why is primary recruitment from psychology classes and not "opened" to students from other disciplines? Mr. Deegan's response was that it was his experience that psychology students were most likely to be interested in participating in this research. He felt that this was particularly the case for students enrolled in the Biological Psychology class, in which this procedure is used for one of the laboratory exercises. On the other hand, he had no reservations in allowing non-psychology students to participate in this research.
2. Rationale for the exclusion criteria--Specifically, why astigmatism and allergy? The response was that these characteristics have negative consequences on the quality of data being recorded. Since astigmatism results from the non-spherical curvature of the cornea,

which is normally corrected with an appropriately oriented "barrel lens." Since a subject cannot wear corrective lens during this procedure, the astigmatism leads to a distortion of the visual stimulus, which in turn distort the electrical recording. Common symptoms of many allergies include "reddening" of the eyes and "watering" of the eyes; these symptoms complicate the ERG recording.

3. Subject reactions to the ERG electrode/fiber--Specifically, how much "watering" and "reddening?" Mr. Deegan indicated that most of the subjects with whom he had dealt in the past had experienced only "minimal discomfort" which was of short duration.

4. Procedures to be followed if a subject were to experience irration beyond a "short duration." Mr. Deegan indicated that he would refer the student of a qualified professional, such as an optometrist or ophthalmologist.

5. Cleanliness/sterility of the ERG electrode/fiber. Mr. Deegan described the procedures used to rinse the eyelid site with sterile water and indicated that the ERG electrode/fiber is used only once. He believes that the electrode/fiber is sterilzed at the "factory" so there is minimal risk of any contamination.

6. Intrusiveness of the ERG electrode--Specifically, would most people consider having an electrode placed on the inner surface of the lower eyelid "intrusive?" Mr. Deegan indicated that he did not consider the procedure intrusive since the electrode lays on the surface of the eyelid; he did not believe that the fact that the electrode was on the "inner surface" made it intrusive. He declared that intrusive in biological psychology procedures usually means that some incision/lesion has been performed on an internal organ, an injection of some drug or solution below the suface of the skin, and/or insertion of an electrode to a specific internal site/organ has been performed. The ERG procedure has none of these "intrusive" characteristics.

7. Degree of "coercion" in the proposed consent form, specifically, the term ". . . without retribution. . ." has a ring of coercion. Why not use different terminology, such as ". . . no penalty. . ." or ". . . no consequences . . .?" Mr. Deegan indicated that he had no intention of coercion during any aspect of the procedure and he would be willing to make any appropriate changes to communicate clearly that fact.

BOARD ACTION: Susan Christiansen moved for conditional approval of the protocol; Brenda Pulskamp seconded the motion. The conditions that must be met for full approval are as follows:

1. Adding additional detail specifying the "sterility" of the ERG measurement procedure.

2. Adding a statement that advises the research subject that, if there is continuing irritation of the eye beyond some "reasonable" time (T.B.D.), then the subject needs to contact you for referral to a professional for diagnosis and treatment.

3. Increase the pool of subjects to extend beyond students enrolled in the course.

4. Be more specific concerning potential benefits to the subjects and to the discipline as a result of the subject's participation in the research project.

Majority of the Board (6) voted for conditional approval of Protocol 95-06, *Contiguous Recordings of VEPs and ERGs*; 1 voted against; and 2 abstained.

4. 95-10 PENELOPE SUTER

At the request of the Board, Dr. Suter provided an overview of her research protocol, which included a description of the "fast" and "slow" subsystems of the visual system and their implication to reading disabilities, recruiting information that will be distributed, the consent form with both inclusion and exclusion criteria, and, finally, details of the two testing sessions.

During the discussion of the protocol, several questions and issues were raised:

1. Picture taking opportunity is not mentioned in the consent form. Dr. Suter agreed that the consent form would be revised to specify clearly that the picture taking was an optional opportunity.
2. Vagueness of the release of test scores, specifically, which test scores are the subjects agreeing to release for the PI's use? Dr. Suter indicated that the only scores in which they are interested are associated with a specific reading ability test, which most potential subjects would have taken to diagnose their reading disabilities. Those who have not taken this specific test would be tested as a part of the protocol. She agreed that the consent form would be revised to be more specific on which test scores were being "released."
3. Procedure for maintaining confidentiality of "IQ-like" test scores needs to be elaborated, and Dr. Suter agreed.
4. Witness verification of the oral explanation of the consent form is not provided. Dr. Suter agreed that the consent form would be easily revised to provide for witness verification.
5. Justification for subject exclusion criterion of English as first language. Dr. Suter indicated that the requirement of "English as a first language" is solely for data purposes. We have a reasonable data base and a consistent theory on the functional processes of the brain with "English as a first language" subjects, but we have a very poor data base and conflicting theories with other language situations, such as bilingualism. Therefore, this exclusion criterion is solely to allow for accurate interpretation of the data.

BOARD ACTION: Brenda Pulskamp moved for conditional approval of the protocol; Susan Christianson seconded the motion. The conditions that must be met for full approval are as follows:

1. Provide for oral explanation of the written informed consent document and for witness signature of that oral explanation on the written informed consent document.

2. In your specification for the release of test scores, provide a description of the specific tests that each subject is agreeing to "release."

3. Indicate how you are going to maintain confidentiality of any "IQ-like" test scores that are made available to you.

4. In order to minimize potential embarrassment of subjects, use special care in explaining the language requirement for participation in this research project. Specifically, the language requirement is to ensure control of variables that may affect the outcome of the research results.

5. Add to the informed consent document that each subject will have the opportunity to have their picture taken in the research setting for their own records if they so desire.

The Board voted unanimously for conditional approval of Protocol 95-10, *Effect of Visual Transient System Inefficiency and Fixation Disparity on Early and Late Visually-*

Evoked Potentials in Reading Disability. In addition, the Board offered praise to Dr. Suter in the quality of her protocol (format, organization, and clarity) and her consent document (level of language, format, and clarity).

5. 95-11 CHARLOTTE RIPLEY

At the request of the Board, Ms. Ripley provided an overview of her research protocol after which discussion of the protocol raised a few questions and issues:

1. Clarification on the procedures for monitoring glucose. Ms. Ripley explained that all subjects are already doing the procedure as part of their individual medical treatment; her research project involves the use of the data resulting from the monitoring process.
2. Potential benefit for the subject. There was agreement between the Board and Ms. Ripley that there was direct benefit to the subjects for their participation in this project. Specifically, each subject could become better educated on the necessity of complying with their prescribed diets.
3. Notification of the physician of participation of his/her patient as a research participant. Ms. Ripley agreed that such notification was easily possible and essential.

BOARD ACTION: Brenda Pulskamp moved for conditional approval of the protocol; Susan Christianson seconded the motion. The conditions that must be met for full approval are as follows:

1. Add a statement to the informed consent document that a copy of the signed consent form will be kept by the subject for his/her own records.

2. Add another statement to the informed consent document specifying that a copy of the patient's signed consent form will be forwarded to the patient's physician for his/her medical files.

The Board voted unanimously for conditional approval of Protocol 95-11, *Effects of Frequent Blood Glucose Monitoring on Dietary Compliance in Diabetic Patients.*

6. 95-14 KIM GEORGE, MOLLY GUTIERREZ, JEFF KRUEGER, VIRGINIA NZEKWE, LYNDA UBUNGEN

At the request of the Board, Ms. George provided an overview of the team's research protocol, after which discussion of the protocol raised a few questions and issues which are summarized in the conditions listed below "Board Action."

Board Action: Nils Carlson moved for conditional approval of the protocol; Susan Christiansen seconded the motion. The conditions that must be met for full approval are as follows:

1. Add "common" language in the informed consent document to explain the two different methods for measuring temperature--Axiliary (under the arm) and Tympanic (in the ear).

2. Add a description in the informed consent document of the potential benefits of this research project and a description of the potential subjects, i.e., clarify what you intend by "newborn" babies.

3. Clarify the relationship of the members of the research team with the NICU at KMC, i.e., clearly indicate in the informed consent docuement that the person(s) actually taking the temperature measurements is(are) on the nursing staff at KMC.

4. Clarify in the informed consent document that the temperature measurements will be taken only once.

5. Using the professional services at KMC, have the consent form translated in Spanish and have a person who is fluent in Spanish avalaible to explain the research protocol and to answer any questions during the consent process.

The Board voted unanimously for conditional approval of Protocol 95-14, *The Relationship Between Tympanic and Axiliary Temperature in Newborn Infants.*

7. Brenda Pulskamp requested that the Board consider changing the date of the next meeting scheduled for Thursday, 08 June, to Thursday, 01 June, because of a scheduling conflict. There were no objections, so Chairperson Vice declared that the next meeting of the IRB/HSR would be Thursday, 01 June 1995.

8. There being no further business, Chairperson Vice adjourned the meeting at 2:10 PM.

Respectfully submitted,

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