

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

**MINUTES OF MEETING
28 MARCH 1994
DDH-H100**

Members Present -

Scientific Concerns: Brenda Pulskamp, Gonzalo Santos

Non-Scientific Concerns: Janet Vice, Nils Carlson, Cliona Murphy

Community Issues: Susan Christiansen, Dianne Smith

Members Absent -

Duane Meyer (Community Issues)

Visitors Present -

Steven Suter, Ph.D. Although Dr. Suter is a "scientific concerns" member of the CSUB IRB/HSR, he was invited to the meeting as the principal investigator for the two protocols on the agenda.

Primary Agenda -

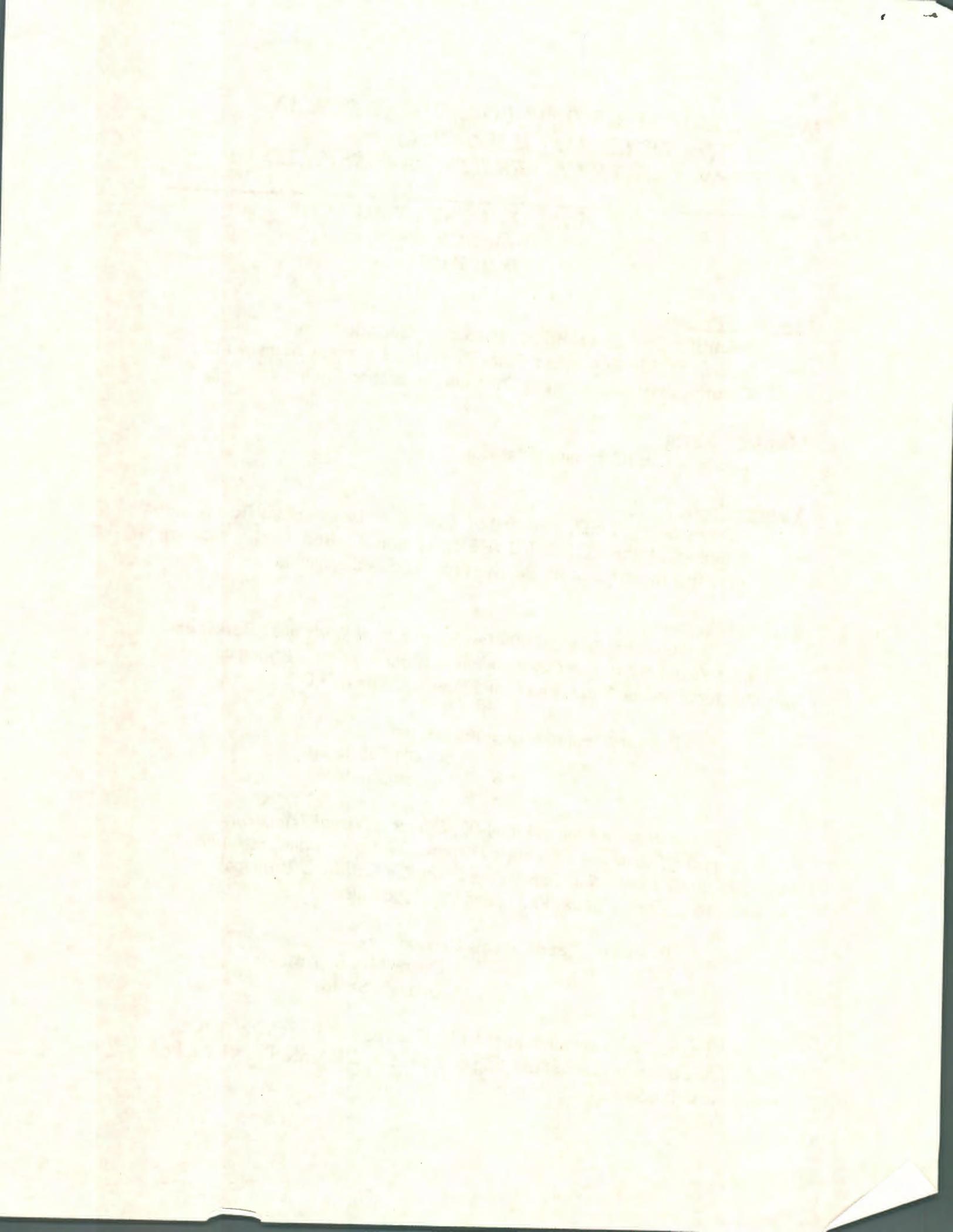
1. Research Protocol #94-04, *Longitudinal Study of Transient and Sustained Visual Subsystem Development in Human Infants*. Principal Investigators: Steven Suter, Ph.D., and Penelope Suter, O.D.

Primary Readers: Cliona Murphy
Brenda Pulskamp
Dianne Smith

2. Research Protocol # 94-02, *Effects of Visual Transient Subsystem Inefficiency and Fixation Disparity on Sensory and cognitive Visually-Evoked Potentials in Reading Disabled Children*. Principal Investigators: Steven Suter, Ph.D., and Penelope Suter, O.D.

Primary Readers: Nils Carlson
Duane Meyer (Absent)
Gonzalo Santos

1. The meeting was called to order by Chairperson Janet Vice at 10:05 AM. Since this was the first meeting of the entire IRB/HSR, Dr. Vice asked everyone to introduce themselves.



2. The first agenda item was Research Protocol #94-04. Dr. Suter was asked to provide a general summary of the protocol. In his summary, he provided a brief overview of the *parvo subsystem* and the *magno subsystem* of the human visual system. He then described the basic procedures for obtaining recordings of the electrical activity of the visual system and circulated some gold-cup electrodes that would be attached to the surface of the scalp along with a tube of the electrode paste needed to keep the electrodes in place and to ensure a "good contact" with the scalp surface. He also circulated some pictures of infants with their parents taken during previous projects to illustrate the physical setting of the testing rooms, the equipment being used to present the visual stimuli and to record the electrical activity, and the way in which infants were held by their parents while being tested.

Chairperson Vice then asked the primary readers to lead the discussion of the protocol by asking their questions of Dr. Suter. The questions and ensuing discussion included the following issues:

- the nature of the consent process
- the advisability of getting signatures from both parents rather than just the attending parent, who is most likely to be the mother
- sample size of three (3) infants, i.e., is this sufficient to achieve meaningful results, and would the research be at risk if the data from one of the subjects was substantially different from the other two
- selection criteria for the three subjects, i.e., what is a "normal" baby
- benefits to the infants directly, i.e., what specifically results from the visual screening conducted by Dr. Penelope Suter at her optometry office
- level of risk, i.e., are there special extra-protection requirements for infants in terms of electroshock
- implications from previous research with older infants
- provisions for follow-up to determine consistency of the data
- meaning of "longitudinal", i.e., shouldn't provisions be made now to allow for "long-term" follow-up
- follow-up may be considered as an additional benefit to the subject

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The second part of the document focuses on the importance of maintaining accurate records of all transactions. It emphasizes that proper record-keeping is essential for the success of any business or organization. The text outlines various methods for recording transactions, including the use of journals, ledgers, and spreadsheets. It also discusses the importance of regular audits and reconciliations to ensure the accuracy of the records.

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There being no further questions regarding this protocol, Chairperson Vice recommended that the Board take a 10-minute break and, upon returning, consider the second protocol.

2. The second agenda item was Research Protocol #94-02. Again, Dr Suter was asked to present an overview of the proposed research. He presented the purpose of the project, and he spent considerable time presenting the controversies around the definition of "reading disabled," specifically the varied practices of the local school districts in diagnosing such students and the "operational definition" which the project is taking for defining its potential subject population. The "bottom line" is that "reading disabled" can involve "breakdowns" at every level of the human information processing system and that it is not a unitary disorder like "measles." One goal of the proposed project is to gather information about the different "levels" at which apparent "breakdowns" occur. Dr. Suter again referred to the roles that the parvo system, the magno system, and other "higher order systems" might play in "reading disorders" and to the basic rationale of using the evoked potential measurement as a means of obtaining valuable information regarding this disorder.

As with the first protocol, Chairperson Vice then asked the primary readers to lead the discussion of the protocol by asking their questions of Dr. Suter. The questions and ensuing discussion included the following issues:

- benefits; specifically help, diagnosis, and remediation of "reading problems" for the subjects versus general information about the problem.
- school contact issues, especially what schools will be contacted, what is (are) the proposed role(s) of school counselors and/or teachers in helping to recruit potential subjects, and what feedback is planned for the administration.
- subject selection issues, especially why right-handedness, why the specific age criterion, how is reading ability going to be assessed, and how is the criterion of "English as the primary language" going to be operationalized.
- subject identification issues, especially how is the "privacy" of the student who is selected to participate to be protected (given the "public" nature of the school environment and the "peer social networks") especially for the student who is in the group identified as having "reading problems."

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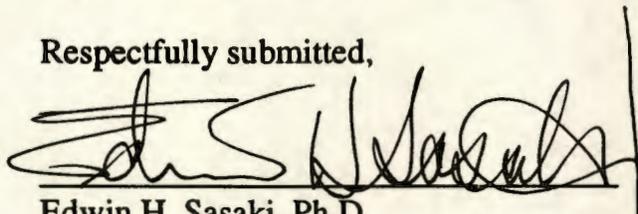
Specific to this issue, considerable discussion ensued regarding the desirability of making every effort to ensure that students for both "treatment" groups are drawn from each classroom, so that the students in the "reading problem" group, in particular, are not all selected from a single classroom or single school. The Board felt strongly that such assurance would minimize stigmatization by other students and minimize any self-perceptions of "being a failure." Dr. Suter agreed to attempt to implement such efforts to the degree possible during the subject selection process.

Finally, the Board conveyed special commendation to the two PIs, Dr. Steve Suter and Dr. Penelope Suter, for their sensitivity in the "level of language" used in developing their informed consent forms and subject assent forms. There was unanimous expression from the Board that the PIs had done a "superb" job in describing a highly technical procedure of the research protocol into easily understandable language for the consenting parent(s) and the assenting child. The Board excused Dr. Suter so that they could vote on the two protocols.

Board Action —

Nils Carlson moved that the CSUB IRB/HSR approve both protocols, #94-02 and #94-04; Brenda Pulskamp seconded the motion. Some discussion ensued, primarily (1) the issue of the Board establishing a policy that consent forms for longitudinal studies should be required to include a statement of potential follow-up, and (2) the need to ensure that the subject selection process minimizes any potential stigmatization of any "problem" that characterizes a subject. For the first item, there was no sentiment to establish such a policy at this time to apply to Research Protocol #94-04. For the second item, the Board members felt that the PIs were sufficiently aware of the Board's concerns and that they would act in good faith during the subject selection process for Research Protocol #94-02. Chairperson Janet Vice called for a vote, and **the motion was passed unanimously, with seven (7) voting "yes," zero (0) voting "no," and zero (0) abstentions.** Chairperson Vice adjourned the meeting at 1:45 PM.

Respectfully submitted,



Edwin H. Sasaki, Ph.D.
Board Secretary

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