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

MINUTES OF MEETING
Thursday, 29 September 1994
DDH-H101

Members Present

Scientific Concerns: Brenda Pulskamp, Gonzalo Santos, Steve Suter
Non-Scientific Concerns: Janet Vice, Nils Carlson, Cliona Murphy
Community Issues: Susan Christiansen, Duane Meyers, Dianne Smith

Members Absent

None

Visitors Present

T. Ken Ishida for Research Protocol #94-42.

Primary Agenda

Research Protocol #94-42, *A Comparison of Long and Short Forms of the Booklet Category Test in a Head-Injured Population*

Primary Readers: Brenda Pulskamp
Janet Vice
Dianne Smith

1. The meeting was called to order by Chairperson Janet Vice at 7:50 AM. The first order of business was to approve the minutes from the regularly scheduled meeting of 08 June 1994. Brenda Pulskamp moved acceptance of the minutes; Susan Christianson seconded the motion. There were no changes; passed unanimously.

2. There was brief discussion of adding a statement in the "Elements of Informed Consent" that a second copy of the consent form is to be given to the research subject; there was full consensus of the Board regarding this requirement. Until new copies of the IRB/HSR policies and procedures are duplicated, the Dean for Graduate Studies and Research was instructed to convey this requirement verbally to all principal investigators.

3. Since Dr. Ishida had appeared previously before the Board, there was no need for Chairperson Vice to introduce him. She asked Dr. Ishida to provide an overview of his research protocol. The primary purpose of the research was to compare the long (standard) form of the Booklet Category Test with different short forms of the same test. After a brief slide presentation of some of the stimulus items, the following issues were raised by the members of the IRB/HSR:

- Access to subject data: Who has access to the research data? And who has access to the subject data derived from Centre for Neuro Skills' records? Dr. Ishida explained that only he and his assistant, an undergraduate psychology major, would have access to the research data. It was suggested that this be made explicitly clear to the potential research subject in the informed consent form. In addition, it was strongly recommended that Dr. Ishida have each research participant sign a release so that he and his assistant have **formal authorization** for access to the subject's records at Centre for Neuro Skills.

- The Booklet Category Test needs to be explained in "simpler" terms in the informed consent form, given that the potential research subject is head-injured and may be suffering from perceptual/cognitive deficits.

- The Board became aware that Dr. Ishida plans to have two (2) sessions for test administration, and it was strongly recommended that this detail be explicitly stated in the informed consent form. Further, the subject needs to give consent prior to the second testing session.

- Both the research subject and the family/caregiver needs to receive a copy of the informed consent form. The family/ caregiver's consent form should also have contact names, addresses, and telephone numbers included.

- The brain's time course for "recuperation" from injury and the impact of these changes on the time interval between the first and second testing sessions was raised. In addition, questions were asked regarding the role of learning between the first and second testing sessions. Based upon the discussions of the above two items, it was suggested that sufficient sample size be considered in the design so that the

researchers can adequately "balance" for any performance changes due to physical/neurological changes and/or learning.

After discussing briefly the difference between head-injury and brain-damage, Dr. Ishida was excused by Chairperson Janet Vice so that the Board could vote on the protocol.

Board Action _

Nils Carlson moved that the CSUB IRB/HSR conditionally approve protocol #94-42; Cliona Murphy seconded the motion. The condition regarded changes on the subject's and/or family/caregiver's consent forms, summarized as follows:

1. Clear specification as to who has access to the research data.
2. Clarification of the identity of the research assistant.
3. Clarification of the two (2) test administrations and the fact that consent will also be obtained prior to the second testing session.
4. Category Test be explained in "simpler" terms.
5. Specification that both the subject and his/her family/ caregiver will receive a copy of the signed consent form.
6. The family/caregiver's consent form include all information of contact persons--names, addresses, and telephone numbers.

The Dean of Graduate Studies and Research was authorized to work directly with the PI and to give final approval once the above conditions were satisfied. Chairperson Janet Vice called for a vote, and **the motion was passed unanimously, with nine (9) voting "yes," zero (0) voting "no," and zero (0) abstentions.**

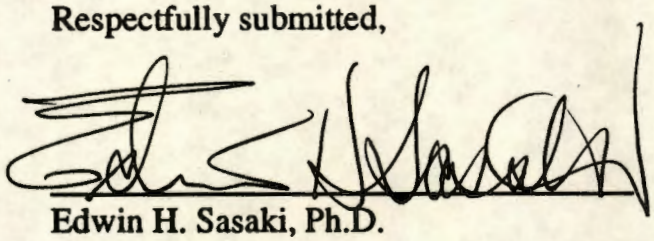
4. Two additional items for business were discussed:

a. The log of all research protocols submitted to date for review by the IRB/HSR, including those protocols reviewed for "Exemption." It was requested that an additional column be included to specify the action of the Board (including date) for "Standard" and "Expedited" reviews, since the final "Approved" column gives only the date when the protocol receives "full approval." It was suggested that the "Exempt" column be eliminated, since the Dean for Graduate Studies and Research has been authorized to review protocols for exemption so all such protocols need not have a reviewer's name identified.

b. The schedule for the remainder of the 1994-95 academic year was announced.

5. There being no further business, Chairperson Janet Vice adjourned the meeting at 9:55 AM.

Respectfully submitted,



Edwin H. Sasaki, Ph.D.
Board Secretary