

**INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH
CALIFORNIA STATE UNIVERSITY, BAKERSFIELD**

**MINUTES OF MEETING
11 April 1997
Academic Administration AA-101**

Members Present

Scientific Concerns: Brenda Pulskamp, Gonzalo Santos, Steve Suter

Non-Scientific Concerns: Nils Carlson, Cliona Murphy

Community Issues:

Members Absent

Merry Pawlowski (Non-Scientific Concerns), Evelyn Johnson, Duane Meyers(Community Issues)

Visitors Present

Kinny Chea, Senior Student in Nursing, and Dr. Colette York, Associate Professor of Nursing, for Protocol 97-05.

Barbara Bragg, Graduate Student in Psychology for Protocol 97-08.

Holly McQuillan, Graduate Student in Psychology for Protocol 97-11.

Amy Harbor, Senior Student in Nursing, and Dr. Colette York, Associate Professor of Nursing, for Protocol 97-12.

Nikki Kelly, Senior Student in Nursing, and Roberta Gerds, Associate Professor of Nursing, for Protocol 97-13.

Johnny Agustin, Karen Luminarias, Sheila Millan, Linhdai Nguyen, and Feliciano Tagorda, all Senior Students in Nursing, and Dr. Collete York, Associate Professor of Nursing, for Protocol 97-15.

1. Meeting was called to order by Chairperson Steve Suter at 12:50 P.M.
2. Edwin Sasaki announced that Susan Christiansen (community issues) has formally resigned from the IRB/HSR. He indicated that he is in the process of looking for a replacement person to complete Susan's term.
3. Nils Carlson moved, and Gonzalo Santos, seconded a motion to approve the minutes for the IRB/HSR meetings of 03 October 1996 and 09 October. Motion was approved unanimously, with 5 "aye," 0 "nay," and 0 "abstentions."
4. Brenda Pulskamp moved, and Nils Carlson seconded, a motion for formal affirmation of all protocol approvals made under expedited review procedures (only Protocol 96-41) for Winter (January-April) 1997. Motion was approved unanimously, with 5 "aye," 0 "nay," and 0 "abstentions."
5. Nils Carlson moved, and Gonzalo Santos seconded, a motion for formal affirmation of all protocol approvals made under exempted review(Protocols 96-42, 96-43, 97-01, 97-02, 97-04, 97-06, 97-07, 97-10, 97-14, 97-17, 97-19, and 97-20) for Winter (January-April) 1997. Motion was approved unanimously, with 5 "aye," 0 "nay," and 0 "abstentions."

6. Nils Carlson moved, and Gonzalo Santos seconded, a motion for formal closure of all protocols approved one year ago--January-March 1996 (Exempted Review: Protocols 96-01, 96-02, 96-03, 96-05, 96-06, 96-08, 96-09, 96-11, 96-14, 96-15, 96-16, 96-20, and 96-21; Expedited Review: Protocols 96-04 and 96-07; Standard Review: Protocols 96-10 and 96-12). Motion was approved unanimously with 5 "aye," 0 "nay," and 0 "abstentions."

7. **Protocol 97-05, *The RN's perception of the emotional and social support needs of the hospitalized AIDS patient,*** with Ms. Kiny Chea and Dr. Colette York. Ms Chea provided a brief overview of her protocol. The primary readers were Steve Suter, Merry Pawlowski, and Evelyn Johnson (latter two were absent; Merry Pawlowski's review form was shared with the Board). Brief discussion with questions and answers followed Ms. Chea's overview. Nils Carlson moved, and Brenda Pulskamp seconded, a motion for **conditional approval** of the protocol. The conditions that must be met prior to the granting of full approval are to revise the informed consent document and demographic form as follows:

Informed Consent Document

- Add statements detailing how confidentiality of the data are to be maintained, e.g., no identifying information is required on the questionnaire, who has access to the data, and what happens to the data (audio tapes and completed questionnaires) when the project is completed.
- Separate contact person for questions regarding the research (Dr. Colette York) from contact person for questions regarding rights as a research participant (Dr. Edwin H. Sasaki).
- Add a statement that the participant may keep a copy of the consent document for his/her own file and reference.

Demographic Form

- Reconsider the wording (or even the inclusion) of the questions about "pro/con on HIV/AIDS-related issues," and about "sexual orientation or preference."

The motion for **conditional approval** of the protocol was approved unanimously with 5 "aye," 0 "nay," and 0 "abstention."

8. **Protocol 97-08, *Visual evoked potential and psychophysical measures of backward masking,*** with Ms. Barbara Bragg. Ms. Bragg provided a brief overview of her protocol, and then answered questions mostly from the two primary readers in attendance--Cliona Murphy and Gonzalo Santos (Duane Meyer was absent, but his review form was shared with the Board). Brenda Pulskamp moved, and Nils Carlson seconded, a motion for **conditional approval** of the protocol. The condition that must be met prior to the granting of full approval is to add a statement(s) regarding the risks and benefits for the research participants to the informed consent document. The motion for **conditional approval** was approved unanimously with 4 "aye," 0 "nay," and 1 "abstention" by Steve Suter, who is the faculty sponsor.

9. **Protocol 97-11, *Evaluation of the efficacy of Irlen lenses in the reading disabled: Physiological measurements based on VEPs,*** with Ms. Holly McQuillan. Ms. McQuillan provided a brief overview of her protocol. The primary readers were Steve Suter, Merry Pawlowski, and Evelyn Johnson (latter two were absent; Merry Pawlowski's review form was shared with the Board). Following a brief discussion with questions, Brenda Pulskamp moved, and Gonzalo Santos seconded, a motion for **conditional approval** of the protocol. The

conditions that must be met prior to the granting of full approval are to revise the informed consent document as follows:

- Add a statement regarding the expected duration of the subject's participation.
- Add a statement regarding the subject's participation is voluntary.
- Add statements regarding the confidentiality of the data, e.g., who has access to the data and what happens to the data when the project is completed.
- Add a statement regarding the risks and benefits of participating in this research.
- Change the contact person for questions about rights of research participants to Dr. Edwin Sasaki.

The motion for conditional approval was approved unanimously with 5 "aye," 0 "nay," and 1 "abstention."

10. **Protocol 97-12, *Perceived factors related to stress in high acuity nursing,*** with Ms. Amy Harbor and Dr. Colette York. Ms Harbor provided a brief overview of her protocol. The primary readers were Brenda Pulskamp, Cliona Murphy, and Duane Meyer (Duane Meyer was absent, but his review form was shared with the Board). Brief discussion with questions and answers followed Ms. Harbor's overview. Gonzalo Santos moved, and Brenda Pulskamp seconded, a motion for conditional approval of the protocol. The conditions that must be met prior to the granting of full approval are to revise the informed consent document and demographic form as follows:

Informed Consent Document

- Add "qualifications" of the researchers, e.g., affiliation with the Department of Nursing at CSUB.
- Add the name of a contact person for any "adverse effects," including anxiety.
- Add a statement indicating the potential benefits of participating in the research.
- Provide additional details regarding who has access to the data, including the "master list" linking the fictitious name on the questionnaire with the true name on the informed consent document, and how the confidentiality of the data is to be maintained.
- Add a statement indicating that the "master" list linking the fictitious name on the questionnaire to the signed name on the informed consent document will be destroyed at the completion of the study.

Demographic Form

- Change to descriptor "race" to "race/ethnicity."
- Consider separate questions regarding "physical health" and "mental/emotional/psychological health."

The motion for conditional approval was approved unanimously, with 5 "aye," 0 "nay," and 0 "abstentions."

11. **Protocol 97-13, *Health behaviors of nursing students compared to the health behaviors of college students of other majors,*** with Ms. Nikki Kelly and Ms. Roberta Gerds. Ms. Kelly provided a brief overview of her protocol. The primary readers were Gonzalo Santos, Nils Carlson, and Evelyn Johnson (Evelyn Johnson was absent). Considerable discussion with questions and answers followed Ms. Kelly's overview; particular issues involved the

recruitment of subjects, distribution and collection of the questionnaires, and the collection of the signed informed consent documents. These issues centered on the protection of the anonymity of nursing subjects though some procedure that would ensure that members of the research team would NOT be present during the time when the nursing subjects completed the questionnaire and when they returned the completed questionnaires. Gonzalo Santos moved, and Cliona Murphy seconded, a motion for conditional approval of the protocol. The conditions that must be met prior to the granting of full approval are (1) to provide a copy of the questionnaire for the file and (2) to revise the informed consent document and the protocol regarding the recruitment of subjects, distribution and collection of the questionnaires, and the collection of the signed informed consent documents:

Informed Consent Document

- Add "qualifications" of the researchers, e.g., affiliation with the Department of Nursing at CSUB.
- Add statements that indicate how confidentiality of the data is to be maintained, i.e., who has access to the data and what happens to the "raw" questionnaires when the research is completed.
- Delete all references to a "compensation" for participation in the research.
- Consider modification of the signature block to give potential participants the option of volunteering and acknowledging that participation with a signature or volunteering but preferring not to sign the document so that the participant is not linked to the research through the consent document.

Research Protocol

- Modify the procedure of recruiting nursing subjects by getting agreement with instructors for the selected nursing classes to allow a member of the research team to make a "pitch" for participation in the research, either at the beginning of the class or the end of the class. Questionnaires may be distributed during this time.
- Modify the procedure for collecting the questionnaires and informed consent documents from the nursing subjects by providing separate "drop boxes" for each document; the questionnaire "drop box" should be secure (locked) to prevent unauthorized access.

The motion for conditional approval was approved unanimously, with 5 "aye," 0 "nay," and 0 "abstentions."

12. **Protocol 97-15, *Inner cry from Sophomore and Junior nursing students: An exploration of stress and coping in a medical-surgical clinical setting***, with Johnny Agustin, Karen Luminarias, Sheila Millan, Linhdai Nguyen, Felliciano Tagorda, and Dr. Colette York. Mr. Agustin provided a brief overview of the protocol. The primary readers were Brenda Pulskamp, Merry Pawlowski, and Duane Meyer (Merry Pawlowski and Duane Meyer was absent, but their review forms were shared with the Board). Brief discussion with questions and answers followed Mr. Agustin's overview. Brenda Pulskamp moved, and Gonzalo Santos seconded, a motion for conditional approval of the protocol. The conditions that must be met prior to the granting of full approval are to revise the informed consent document as follows:

- Add "qualifications" of the researchers, e.g., affiliation with the Department of Nursing at CSUB.

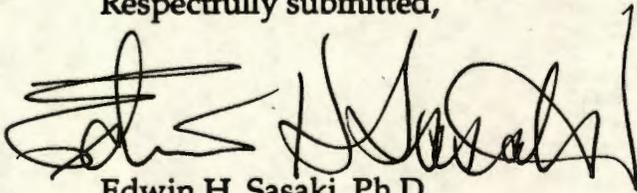
- Provide additional details regarding the purpose of the research. This may be combined with the foreseeable benefits of participation in the research.
- Add a statement regarding any foreseeable risks and provide a contact person in the event of any adverse reactions.
- Provide additional details regarding how the confidentiality of the data is to be maintained, e.g., who has access to the data (including logs and tapes) and how the data (including logs and tapes) are to be stored.
- Indicate that the logs and tapes will be destroyed (tapes erased) when the study is completed.
- Separate contact person for questions regarding the research (Dr. Colette York) from contact person for questions regarding rights as a research participant (Dr. Edwin H. Sasaki).

The motion for conditional approval was approved unanimously, with 5 "aye," 0 "nay," and 0 "abstentions."

13. Next IRB/HSR meeting is scheduled for Thursday, 06 June 1997, 12:30 - 3:30; place of meeting will be determined later.

14. There being no further business, Chairperson Suter adjourned the meeting at 3:35 PM.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'Edwin H. Sasaki', written over a horizontal line.

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