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

MINUTES OF "SPECIAL" MEETING
07 APRIL 1994
DDH-H100

Members Present

Scientific Concerns: Brenda Pulskamp, Gonzalo Santos, Steve Suter
Non-Scientific Concerns: Janet Vice, Nils Carlson
Community Issues: Susan Christiansen, Duane Meyer

Members Absent

Cliona Murphy (non-scientific concerns), Dianne Smith (community issues)

Visitors Present

Steve Bader, Keri Chew, Rod Martens, Dawn Smith, and Laurie Mitchell (Nursing faculty)

Primary Agenda

1. Research Protocol #94-05, *The Relationship of Axillary, Oral, and Tympanic Temperatures to Pulmonary Artery Temperatures in Adult ICU Patients*. Principal Investigators: Keri Chew, Rod Martens, and Dawn Smith.

Primary Readers: Nils Carlson
Susan Christiansen
Steve Suter

2. Research Protocol # 94-06, *An Investigation into Whether the Use of EMLA Cream among Pediatric Patients Ages 5-15 Reduces the Pain of Intravenous Cannula Insertion.* Principal Investigators: Nancy Ayers, Steve Bader, Jennie Goodrich, Valerie Raines, and Heather Welch.

Primary Readers: Susan Christiansen
Steve Suter
Janet Vice

1. The meeting was called to order by Chairperson Janet Vice at 10:37 AM. She noted that this was a "special" Board meeting convened because both protocols were initially reviewed under "Expedited Procedures" and

were subsequently referred for "Standard Review." The visiting students and faculty member introduced themselves to the Board, and the Board members reciprocated.

2. The first agenda item was Research Protocol #94-05. Chairperson Vice asked the three (3) students to provide an overview of the research protocol. The primary purpose of the research was to determine the accuracy of axillary, oral, and typmanic temperatures relative to pulmonary artery temperatures. The former three temperatures represent standard techniques used by nurses in hospitals for obtaining "external" body temperature, while the pulmonary artery temperature is the accurate indicator of the internal temperature of the body.

Chairperson Vice then asked the primary readers to lead the discussion of the protocol by asking their questions of the three students--Keri Chew, Rod Martens, and Dawn Smith. The questions and ensuing discussion included the following issues:

- Type of patient who would be potential subjects--It was clarified that coronary by-pass patients were specifically selected since they would already have in-place the pulmonary artery catheter as part of their surgery. It was further determined that data would be obtained only from "ambulatory, conscious, and alert" patients.

- Consent process--It was clarified that potential subjects would be approached by one of the three PI's at the time of the scheduled Pre-Op Education session prior to surgery to gain consent for participation.

- Consent form--It was requested that the consent form be changed to include reference to the patient or the patient's representative being given a copy of the signed consent form.

When discussion was completed, Chairperson Vice excused the students from the meeting room so that the Board could vote on the protocol.

Board Action

Susan Christensen moved that the CSUB IRB/HSR conditionlly approve protocol #94-05; Steve Suter seconded the motion. The condition regarded the change on the consent form to include reference to the patient or the patient's representative being given a

signed copy of the consent form. The Dean of Graduate Studies and Research was authorized to work directly with the PI's and to give final approval once the above condition was satisfied. Additional discussion regarded the unfortunate additional time needed to have a "special" meeting of the entire Board to address issues, which could have been clarified with a separate research protocol being filed in accord with the new procedures; the Dean of Graduate Studies and Research was requested to ensure that this procedure be rigorously enforced in the future. 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.**

3. The second agenda item was Research Protocol #94-06. Chairperson Vice asked Steve Bader to provide an overview of the proposed research. Mr. Bader described that the existing medical protocol of the pediatricians in the outpatient clinic was to prescribe EMLA cream prior to the insertion of an intravenous cannula, while the pediatricians in the inpatient clinic did not normally prescribe EMLA cream for intravenous cannula insertion. One of the major reasons for this difference in practice in the prescription of EMLA cream is that the time-frame in the inpatient clinic is normally "compressed" so that there is rarely time to wait for the beneficial effects of the EMLA cream to take effect. The purpose of the proposed project is simply to take advantage of these differential practices to compare any differences on the perceived level of pain by patients, aged 5-15, undergoing the insertion of intravenous cannula.

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

- Need to develop an assent form, composed in "children's language," for each child to sign.

- Need to simplify the language used in the informed consent form so that it is more easily understandable by a "lay" person.

- Need to have only one version of the informed consent form, not three, as was submitted (one for the non-EMLA group and two variations for the EMAL group--one with general description of side-effects and the second with explicit, detailed descriptions).

Considerable discussion ensued regarding the level of detail needed to describe the potential "side-effects" of the EMLA cream to be used for one group. It was finally resolved that the use of EMLA cream was part of the medical protocol and that the research protocol was simply taking advantage of a prescribed medical procedure. Therefore, the obligation of describing in detail the potential "side-effects" of EMLA cream fell to the prescribing physician and not to the research team. In addition, the level of detail concerning side-effects appeared to create potential "bias" in the subject's responses regarding their perceptions about the level of pain experienced during the intravenous cannula insertion procedure, which in turn could comprise the purpose of the proposed research.

- Potential stress effects from the "Oucher Scale," which is being used to obtain measurements on the perceived level of experienced pain--Appears to be minimal.

- Timing of obtaining consent--For out-patient subjects, between 5:00A-7:30A prior to insertion procedure and, for in-patient subjects, during pre-admission.

- Basis on which English speaking is to be determined--very "subjective" to be determined by PI's judgment during interview with the prospective subject in obtaining informed consent.

When discussion was completed, Chairperson Vice excused Mr. Bader from the meeting room so that the Board could vote on the protocol.

Board Action

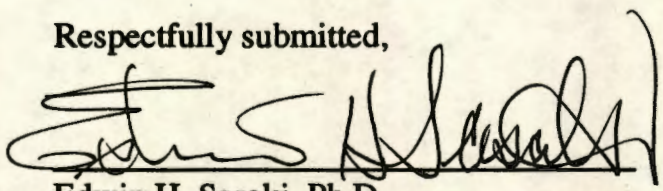
Brenda Pulskamp moved that the CSUB IRB/HSR conditionlly approve protocol #94-06; Susan Christianson seconded the motion. The conditions regarded the implementation of the following changes:

(1) a child assent form written in "children's language" be developed to be signed by each child;
(2) the informed consent form be rewritten to simplify the language; and
(3) the informed consent form not refer to the use of EMLA cream or to any potential side-effects resulting from the cream so that a single consent form can be used for both groups of subjects.

As with Research Protocol #94-05, the Dean of Graduate Studies and Research was authorized to work directly with the PI's 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 seven (7) voting "yes," zero (0) voting "no," and zero (0) abstentions.**

There being no further business, Chairperson Vice adjourned the meeting at 12:50 PM.

Respectfully submitted,



Edwin H. Sasaki, Ph.D.
Board Secretary