

**Institutional Review Board for Human Subjects Research (IRB/HSR)
California State University, Bakersfield
9001 Stockdale Highway, Bakersfield, CA 93311-1099**

**Minutes of Meeting
Friday, 25 January 2002
OLD PUB in the RUNNER CAFE**

Members Present:

Scientific Concerns: Marianne Abramson (until 9:15), Kaye Bragg, Peggy Leapley
Nonscientific Concerns: Jeanne Harrie (until 9:20), Paul Newberry, J.J. Wang
Community Issues: Nancy Carr, Devin Depner (until 10:20), Ann Marie Duquette

Members Absent:

none

Visitors Present:

Kris Grappendorf and Jeff Moffit for Protocol 02-03
Steve Bacon for Protocol 01-58
Anne Duran for Protocol 02-04
Everett Mann and Edwin Sasaki for Protocol 02-05

CALL TO ORDER AND INTRODUCTION OF NEW MEMBERS:

Chair Jeanne Harrie called the meeting to order at 8:00 AM. New members, Marianne Abramson and J. J. Wang were introduced. Members were asked to review their listing in the new IRB.HSR Roster and forward corrections to the RERC.

PREVIOUS MINUTES:

The previous minutes were corrected to accurately indicate attendees. Carr moved, and Bragg seconded, a motion to approve the corrected minutes for the IRB/HSR meeting of 28 September 2001. The motion was approved unanimously.

OLD BUSINESS:

1. The revised "Submitting Your Research for Review . ." document was discussed. The implications of inclusion of master's "projects" in IRB/HSR purview was discussed. Leapley agreed to see if this works out satisfactorily in Nursing. The Exemption section under major header "Step 3: . ." was revised to parallel the language for the Expedited section.

2. The new cover pages were discussed. The chair sign off was debated, including the depth of processing implied by the words, "I have reviewed . .". It was decided to leave the wording as is, understanding that the wording may be defined and implemented differently across departments. There was a query about the operational definition of "penalty of professional misconduct" associated with the signature of the investigator(s) and faculty sponsor on the cover sheets. Reference was made to the CSUB Handbook. The RERC was ask to distribute information on this question to the IRB/HSR members.

3. The online IRB/HSR materials were discussed. Several investigators have already used these materials to submit protocols. It was noted that colored cover pages will no longer be required. The RERC and online student assistant were commended.

NEW BUSINESS:

Formal Board affirmation of protocols previously approved under standard, exempted, and expedited review since the September 2001 meeting.

Standard Review (approved conditionally at September 2001 meeting)

1. **Protocol 01-36** (Steve Suter, Psychology) "Visual Neuroscience Lab Assignments and Research Projects for 2001-2002" on 11 October 2001.

[Depner moved, Carr seconded, unanimously approved]

Expedited Review

1. **Protocol 01-38** (Marianne Abramson, Psychology) "Vowel and Consonant Length Effects in Sentence Verification" on 12 October 2001. [Noel & Harrie]
2. **Protocol 01-40** (Jorgen Berglund, Mathematics) "Investigating the Effect of Innovative Middle School Curriculum Material on Pre-Service Elementary Teachers' Attitudes Towards, and Perceptions About, Mathematics and the Teaching of Mathematics" on 08 October 2001. [Bragg & Park]
3. **Protocol 01-47** (Kathleen Gilchrist, Nursing) "It's Really All About Chocolate...Lived Experiences of Beginning Baccalaureate Nursing Students" on 01 November 2001. [Leapley & Newberry]

[Duquette moved, Depner seconded, unanimously approved]

Exempted

1. **Protocol 01-37** (Julie Schmoll, Nursing Student) "The Relationship Between Prenatal Care Utilization and Birth Weight Among Hispanic Women with Low Risk Pregnancies" on 14 September 2001.
2. **Protocol 01-43** (Kenneth Nyberg, Applied Research Center) "California Department of Transportation Highway Maintenance Program Driver Satisfaction Survey" on 20 September 2001.
3. **Protocol 01-45** (J. Daniel McMillin, Applied Research Center) "San Joaquin Community Hospital--Diabetes Demonstration Project" on 05 October 2001.
4. **Protocol 01-46** (J. Daniel McMillin, Applied Research Center) "KC Department of Public Health--KC Tobacco Education Program (TEP) Evaluation" on 05 October 2001.
5. **Protocol 01-48** (Lorraine Tullis, Special Education Student) "Reverse Mainstreaming: A Multimedia Approach to Training Special Education Teachers" on 12 October 2001.

6. **Protocol 01-49** (Sara Castro-Olivo, Psychology Student) "The Effects of Educational Level, Ethnicity, and Religion on Attitudes Toward Infidelity" on 11 October 2001.
7. **Protocol 01-50** (Marcia Ellen Tyler-Evans, Nursing Student) "Needs Assessment for Forensic Nursing Skills in Central Valley California Region" on 11 October 2001.
8. **Protocol 01-52** (John Valdez, Sociology Student) "The Influence of Cyberspace, Society, and the Internet" on 12 October 2001.
9. **Protocol 01-53** (Emmy Darling, Psychology Student) "The Influence of Gender on University Students' Judgment of Job Seeking Behavior" on 19 October 2001.
10. **Protocol 01-55** (Thida Chea, MSW Student) "Factors Influencing Self-Esteem of Social Workers: An Empirical Analysis" on 06 November 2001.
11. **Protocol 01-56** (Josh Phelps, Psychology Student) "Teaching College Students to Differentiate between Dissociative Identity Disorder and Schizophrenia" on 09 November 2001.
12. **Protocol 01-57** (Chandrasekhar Commuri, Public Policy and Administration) "Are All Heterogeneities Alike?: A Test of Heterogeneity Thesis in the Nonprofit Sector" on 04 December 2001.
13. **Protocol 01-59** (Carrie Mosley, Nursing Student) "Nurses' Knowledge About Diabetes: A Comparison of Advanced Beginners and Expert Nurses" on 18 December 2001.

[Bragg moved, Duquette seconded, unanimously approved]

Formal Board affirmation of protocols submitted and designated as not falling within the IRB/HSR definition of human subjects research (not within IRB/HSR purview) since the September 2001 meeting.

1. **Protocol 01-41** (Ken Nyberg, Applied Research Center) "Community Learning Center Independent Assessment" on 24 September 2001.
2. **Protocol 01-42** (Ken Nyberg, Applied Research Center) "High Risk Youth Educational and Public Safety Program" on 24 September 2001.
3. **Protocol 01-44** (Laura Hecht, Applied Research Center) "KC Probation Department- Early Intervention Program, Gang Intervention and Suppression Team, and the Repeat Offender Prevention Program (ROPP)" on 24 September 2001.

[Carr moved, Bragg seconded, unanimously approved]

Formal Board affirmation of previously approved protocols granted **extensions** since the September 2001 meeting.

1. **Protocol 01-09** (Myoshi Lee, Public Policy and Administration Student) " Prevention of Primary Teen Pregnancy in the African-American Population of Bakersfield/Kern County " end of Winter Quarter 2002.

2. **Protocol 01-11** (Jess Deegan, Department of Psychology) " Sex, Sexual Orientation, and Gender Identity: Do These Impact Cognitive Task Battery Results?" end of Winter Quarter 2002.
3. **Protocol 01-16** (Dorothy Tullman, Department of Nursing) " An Intervention to Reduce Delay in Elders Responding to Early Symptoms of Myocardial Infarction " end of Winter Quarter 2002.

[Depner moved, Duquette seconded, unanimously approved]

Formal Board action **closing** protocols (unless extension requested) whose authorization will end prior to the next IRB meeting.

1. **Protocol 00-41** (Donald Diboll, Physical Education and Kinesiology) "Aerobic Performance Fitness Assessments of Trained Adult Cyclists" end of Winter Quarter 2002.
2. **Protocol 01-01** (Debbie McDowell, Nursing Student) "The Effects of Continuous Epidural on Second Stage Labor?" end of Winter Quarter 2002.
3. **Protocol 01-05** (Kimberley Willis-Howe, Education Student) " Kindergarten Teachers' Perceptions of Student Success Factors " end of Winter Quarter 2002.
4. **Protocol 01-07** (Debra Morton-Orton, Department of Social Work) " Vicarious Trauma in the Child Protective Service (CPS) Worker " end of Winter Quarter 2002.
5. **Protocol 01-08** (W. Trent Butler, Public Policy and Administration Student) " Development of an After School Delinquency Prevention Program in Kern County " end of Winter Quarter 2002.
6. **Protocol 01-10** (Alberto Perez, Public Policy and Administration Student) " An Implementation Plan for Endangered Species--California State University Bakersfield Campus " end of Winter Quarter 2002.
7. **Protocol 00-14** (Jorgen Berglund, Department of Mathematics) " A Comparative Study of Student Success in Two Types of First Year Algebra Courses " end of Winter Quarter 2002.
8. **Protocol 01-15** (Stephen M. Hass, Department of Criminal Justice) "2001 Student Outcome Assessment and Technology Survey " end of Winter Quarter 2002.
9. **Protocol 00-17** (Mike Stepanovich, Public Relations Director) " Cal State Today-- Improving CSUB's Links with its Alumni " end of Winter Quarter 2002.

[Leapley moved, Duquette seconded, unanimously approved]

Protocol Reviews:

Protocol 02-03 [Attachment E]: "The Effect of Video Training on Administration of Skinfold Test" with Kris Grappendorf, Department of Physical Education & Kinesiology. Primary readers were Carr, Harrie, and Abramson

Following a round of introductions, Kris Groppendorf and Jeff Moffit summarized the proposed research.

They have developed a set of online digital video training materials for those administering a state-mandated fitness testing program. In this project, they want to assess the effectiveness of their training materials by studying the performance of adult subjects, some trained (physical education students) and some not (liberal studies students), as they administer the tests to a sample of junior high school students. They will look specifically at assessment of body composition using a skin fold test involving calipers and an impedance-based bioelectric technique (BIA) that involves placing recording electrodes on the body surface and passing a very low amperage current through the body via these electrodes. A dialogue followed.

Q: Clarify possible risks and adverse reactions using the BIA. **A:** The investigators were aware of no adverse reactions beyond possible mild irritation from the electrodes. Persons with cardiac and neural stimulation devices ought not to participate.

Q: How will confidentiality actually be maintained? **A:** Consent forms with names will be separated from the data sheets having only participant code numbers.

Q: Clarify the several consent forms involved. **A:** One (CF #A) is for parents of the junior high students. One (CF #B) is for the CSUB student testers . One (CF #C) is a release required by the school district; it is a "boiler plate" form.

Q: How will confidentiality be maintained for the junior high school students during data collection? **A:** A dividing barrier will be placed in the gym and testing will be conducted behind it.

The investigators were excused and **conditions of approval** were agreed upon. These were:

1. Add to Consent Form A only: (a) There could be brief redness or irritation due to the recording electrodes, (b) A child with any implanted electrical device, such as a pacemaker or nerve stimulator, may not participate. (c) The investigation is not studying the health of the child participant.

2. Add to Consent Forms A and B: (a) The participant can withdraw at any time without penalty. (b) Participation is strictly voluntary with no academic consequences of participating or not. (c) The participant will be videotaped as the procedures are carried out. (d) Appropriate contact information for questions about the research. (e) Appropriate contact information for questions about persons' treatment as a research participant.

3. State in the protocol and implement separation of consent forms with names from data sheets with participant numbers so that the data cannot be associated with names.

4. Insure the privacy of data collection in the gym setting.

5. The research must be conducted as specified in the protocol. Any changes must be approved in advance by the IRB/HSR.

There was a motion for **conditional approval of Protocol 02-03**.

[Carr moved, Abramson seconded, unanimously approved]

Protocol 01-58 [Attachment F]: "Interrater Reliability of a Scale of Functional Ability Ratings for Mental Health" with Steven F. Bacon, Psychology Department. Primary readers were Depner, Wang, and Bragg

Following a round of introductions, Steve Bacon summarized the proposed research.

Among the many ways to assess the effectiveness of psychotherapy is to look at what the patient can do, that is, ability to function in everyday settings. At present, no such "practical" assessment tool is available. The investigator has been working for several years to develop an assessment device to accomplish this--the Scale of Functional Ability Ratings (SOFAR). The proposed research will compare scores on the SOFAR with other assessment tools.

Q: How will you address the comparability of subjects added to replace dropouts? **A:** There will be little effort to do this because all that is needed is a sample of outpatients in therapy.

Q: What sort of tests will be administered? **A:** These will include the Structured Clinical Interview to for diagnostic purposes, a symptom checklist, and the SOFAR, which requires an interview of approximately one hour asking questions about how the person is doing re self-care, personal safety, money management, at work, in school, and other practical areas of living.

Q: Who collects the data? **A:** The PI does this and students do the data coding.

Q: Do participants have a diagnosis attached when they enter the study? **A:** No, except for self-diagnoses. They do need to be in therapy.

Q: Could persons be excluded and on what criteria? **A:** Not for being not sick enough, as long as they were in therapy. They could be excluded for being too sick, for example severely psychotic or sufficiently brain-injured persons.

Q: Does the consent form adequately communicate the time commitment? **A:** It is stated in the third sentence from the top of the consent form.

Q: When do they get the consent form? **A:** First contact is typically by telephone and the elements of the consent form are communicated at that time. The actual consent form is the first activity when the participant comes in for the data collection session.

The PI was complimented on the clear wording of the consent form, in particular his handling of possible divulging of activities that would have to be reported by law. The investigator was excused.

There was a motion for **full approval of Protocol 01-58**, with the specification that the assessment instruments to be used be submitted to the RERC to added to the file prior to starting data collection.

[Leapley moved, Wang seconded, unanimously approved]

Protocol 02-04 [Attachment G]: "Measures of Attitudes Toward Outgroup Members" with Anne Duran, Psychology Department. Primary readers were Duquette, Newberry, and Bragg

Following a round of introductions, the investigator summarized the proposed research. The purpose of the research is to study the possible relationship between two measures of attitudes towards outgroup members: (a) paper and pencil tests and (b) PathFinder, a

software application generating a spatial representation of cognitive structure derived from ratings of word pairs.

Q: How and where will the subjects be obtained? **A:** They will be recruited from classes, including my own. Extra credit will be offered. [debate on the wisdom of this followed]

Q: Will summaries of the individual results for each person be provided to them? **A:** No

Q: It would be more clear to change "I" to "you" in most places on the consent form. **A:** Agreed [but debate followed in which it was decided to leave the wording as it].

Q: Perhaps the title of the research, listed at the top of the consent form, should be changed? **A:** PI was agreeable and several possibilities were discussed.

Q: Why is reading disability listed as a "rule out?" **A:** Agreed to eliminated this rule out.

Q: The testing instruments to be used are not explained well. **A:** Information could be added.

The investigators were excused and **conditions of approval** were agreed upon. These were:

1. Delete mention of extra credit in the protocol. Do not use subjects who are being awarded extra credit.
2. Add to the consent form that: (a) the signed consent forms will be locked in the PI's office and (b) individual data summaries will not be provided to subjects.
3. Delete the exclusionary use of reading disability as a rule out for participation.
4. Submit to the RERC copies of the tests to be used so they can be added to the file.
5. Revise the protocol to strengthen the presentation of the scientific merit of the research, including characteristics of the tests to be used.

[Duquette moved, Depner seconded, unanimously approved]

Protocol 02-05 [Attachment H]: "Evaluation for Kern County Children and Families Commission (KCCFC)" with Everett Mann, Applied Research Center. Primary readers are Carr, Wang, and Leapley

Following a round of introductions, Sasaki summarized the research. Everett Mann is responsible for data security, including training others who collect and handle the data. This is Phase 2 of a study first presented to and approved by the IRB/HSR last year (Protocol 01-22). This research is program evaluation of contracted services being delivered to children (0-5 years) and their families by local agencies via contracts with the Kern County Children and Families Commission (KCCFC). This project is a joint effort by the CSUB Applied Research Center (ARC), KCCFC, and the Corporation for Standards and Outcomes (CS&O). The proposed research will involve: (a) analysis of data collected by agencies in the course of providing care, (b) analysis of a survey being developed by CS&O, and (c) collect and analysis of follow-up data to be obtained by ARC, the nature of which will be determined by findings that emerge from the other data. A dialog followed.

Q: How will the children be contacted for the new data collection? **A:** Via their parents through agency contacts.

Q: How is confidentiality handled? **A:** Data handling and confidentiality among the agencies and KCCFC is specified in various appendices included in the protocol. A new consent form has been developed for the children/parents (which was submitted to the IRB/HSR) at this time (see Protocol 02-05 file). At ARC names will be separated from the data, although the list associating names and participant codes will be available at ARC. Names will be destroyed at some later point, following completion of the contract research. At the participating agencies names will still be associated with the data.

Q: What is the status of the CS&O survey?" **A:** The survey is still a draft and has not been approved by their board.

Q: How will possible termination of services be dealt with that could follow from results of the research? **A:** If an agency is judged to be not effective, then it might be a possible outcome for those services to be terminated. **Q:** But it could be ineffective in general, but effective for that particular family. **A:** Perhaps referrals could be made to other agencies.

When there were no more questions, the investigators were excused and discussion followed. There are three discrete types of information about the children/families that will be involved in this research. These were handled separately by the IRB/HSR in responding to this protocol.

Conditional approval was granted for access to existing agency records and the OC&S survey data to be collected. The conditions were:

1. A new consent form must be created and approved by the IRB/HSR that is specific to access to existing agency records and the OC&S survey.
2. The OC&S survey must be submitted to the IRB/HSR and access to it approved.
3. The consent form must be provided in a language that can be read by the participants.

[Duquette moved, Wang seconded, approved with 5 affirmative and one abstention due to possible perception of conflict of interest.]

A second action, by consensus of the board, was that collection of new data from the children/families by ARC should be handled in a new protocol that should be submitted when the nature of the data to be collected could be specified more clearly. It is anticipated that this submission would be handled under Expedited Review procedures.

OTHER CONCERNS:

1. The RERC noted that he had submitted an annual report to the Academic Provost, Jim George, covering July 2000 to June 2001. It is not clear that this is required and has not been done in the past. It was planned to continue this practice.
2. The RERC noted that the federal regulations for Expedited Review in 45 CFR 46 have been revised. The new version has been posted in the online CSUB IRB/HSR materials. There seem to be no changes in practices that would follow from the revision.
3. The RERC wondered whether it might be time to review the CSUB Handbook language governing the IRB/HSR to see if changes should be proposed (such as the new Expedited Review language). Leapley noted that the Senate was presently revising language in this document and that it would be a good time to consider substantive changes. The RERC and Leapley agreed to organize a subcommittee to undertake this task. Other IRB/HSR members would be solicited as well.

NEXT MEETING:

The next meeting will be Friday, 19 April 2002 - Stockdale Room ("Old Pub")
7:30 breakfast, 8:00 meeting

ADJOURNMENT:

There being no further business, the meeting was adjourned at 11:45 AM.

[Carr moved, Duquette seconded, unanimously approved]

Respectfully submitted

Steve Suter, Ph.D.
Professor of Psychology
and IRB/HSR Secretary