

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

**Minutes of Meeting
Friday, 11 October 2002
OLD PUB in the RUNNER CAFE**

Members Present:

Scientific Concerns: Marianne Abramson, Peggy Leapley
Nonscientific Concerns: Jeanne Harrie, Paul Newberry, J.J. Wang
Community Issues: Devin Depner, Ann Marie Duquette

Members Absent:

Nancy Carr, Kaye Bragg

Visitors Present:

Lu Royce Anne Bishop for Protocol 02-55
Carolyn Wade, Community IRB Nominee
Jake Hillman and Valerie Everett, Psychology Students

CALL TO ORDER:

Chair Jeanne Harrie called the meeting to order at 8:02 AM.

PREVIOUS MINUTES:

Depner moved and Wang seconded, a motion to approve the minutes for the IRB/HSR meeting of 14 June 2002. The motion was approved unanimously.

ANNOUNCEMENTS:

- a. Departing board members Jeanne Harrie and Nancy Carr were thanked for their service on the IRB. Carolyn Wade (Community) and Robert Carlisle (CSUB English Department) will be nominated to join the IRB. Paul Newberry has agreed to assume the duties of Chair.
- b. IRB member training will follow the meeting.

OLD BUSINESS:

- a. **Handbook Language for IRB/HSR Policies/Procedures.** A concise two-page document has been prepared by a sub-committee of Harrie, Leapley, and Newberry. The document was briefly discussed. This document will be forwarded with an appropriate cover memo for inclusion in the CSUB Handbook. There was a motion to approve [Duquette moved, Leapley seconded, approved unanimously]
- b. **Training of IRB Members and Investigators.** The RERC submitted an outline of policy, as follows:
 - (1.) Have a training certification process; GS&R does record-keeping.
 - (2.) Faculty PI's/advisors responsible for ensuring student training; IRB responsible for the process; Provost is the "responsible official"

(3.) Training should cover:

- (a.) Ethical principles that guide conduct of human research
- (b.) Use of ethical principles to protect human subjects, including vulnerable populations
- (c.) Elements of informed consent
- (d.) CSUB IRB Policy/Procedures

It was noted that this requirement would be explained at the upcoming Graduate Coordinators' Meeting, who would be expected to pass the word to their faculty, who would inform students. An announcement should be added to the CSUB IRB online materials and eventually a link to the training site. It was agreed that a convenient, online training program be adopted with a mechanism to be devised to incorporate training on CSUB IRB policies/procedures. This can be set-up with automatic e-mail notification of certification; record keeping should be in the GS&R office. There was discussion of how to link certification to protocols. It was decided that investigators would be urged to submit certification evidence with the protocol. In any case, protocol authorization will be contingent on certification. A sub-committee of Harrie, Leapley, and the RERC will work out details. There was a motion to approve the outline of policy as refined in the above discussion [Duquette moved, Abramson seconded, approved unanimously]

NEW BUSINESS:

Formal Board affirmation of protocols previously approved under standard, exempted, and expedited review since the June 2002 meeting.

Standard Review (approved conditionally at June 2002 meeting)

1. **Protocol 02-45:** (Anne Duran, Psychology) "Changes in Attitudes Toward Outgroup Members" on 20 September 2002 [Bragg, Depner, Newberry]

[Depner moved, Abramson seconded, unanimously approved]

Expedited Review

1. **Protocol 02-54:** (Don Diboll, Physical Education & Kinesiology) "Comparison of Three Body Composition Assessment Techniques in Division " on 20 August 2002. [Abramson, Bragg]

[Leapley moved, Depner seconded, unanimously approved]

Exempted

1. **Protocol 02-23** (Thomas Allen, Psychology Student) "Men's Attitudes Toward Women: An Integrated Threat Theory Analysis" on 28 June 2002.
2. **Protocol 02-26** (Judith Cecilia O'Connor, PPA Student) "A Program Plan to Streamline the Process of Barcoding a Quarter of a Million Books in Six Months" on 17 April 2002.
3. **Protocol 02-47** (Patricia Moland, PPA Student) "The Use of Educational Benefits by CSUB Employees" on 07 June 2002.

4. **Protocol 02-48** (Bonita Coyle, PPA Student) "An Examination of the Effect of the Availability of Community Mental Health Services as a Factor in the Incidence and Treatment Expense of Inmates with Psychiatric Diagnoses" on 12 June 2002.
5. **Protocol 02-50** (R. Steven Daniels, PPA) "Agency Merger and Organizational Transformation in the Department of Homeland Security" on 02 July 2002.
6. **Protocol 02-51** (Anne Duran, Psychology) "The cognitive Organization of Beliefs About Behaviors II" on 23 July 2002.
7. **Protocol 02-52** (Mike Stepanovich, PPA Student) "MPA Culminating Project: Philanthropic Benefits to CSU and CSUB by Creation of CSU Advancement Division" on 30 July 2002.
8. **Protocol 02-53** (Yeunjoo Lee, Special Education) "The Use of Assistive Technology in Classrooms and Teachers' Satisfaction with Their Training Programs" on 22 August 2002.
9. **Protocol 02-56** (Christopher Mausolff, PPA) "The Impact of Emotional Intelligence Training on Team Performance" on 05 September 2002.
10. **Protocol 02-57** (Roseanna McCleary, MSW Program) "Post-BSW/MSW Educational Experiences of Japanese Social Workers Educated in the US" on 20 August 2002.

[Duquette moved, Depner 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 02-49** (Jacquelyn Kegley, Department of Philosophy/Religious Studies) "Institutionalizing Service Learning in Philosophy," on 12 June 2002.

[Newberry moved, Bragg seconded, unanimously approved]

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

1. **Protocol 01-38** (Marianne Abramson, Psychology) "Vowel and Consonant Length Effects in Sentence Verification" end of September 2002.
2. **Protocol 01-47** (Kathleen Gilchrist, Nursing) "It's Really All About Chocolate...Lived Experiences of Beginning Baccalaureate Nursing Students" end of September 2002.
3. **Protocol 01-52** (John Valdez, Sociology Student) "The Influence of Cyberspace, Society, and the Internet" end of September 2002.
4. **Protocol 02-02** (Marianne Abramson, Psychology) "Relatedness Effects and Memory for Voice Attributes in Silent Reading" end of December 2002.

[Depner moved, Wang seconded, unanimously approved]

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

1. **Protocol 01-24** (Robert Carlisle, English) "The Influence of Sonority Sequencing on the Modification of /sC/ Onsets" end of October 2002.
2. **Protocol 01-25** (Chad Peters, PPA Student) "The Placement of ACTs in the Corporate and Industrial Setting" end of December 2002.
3. **Protocol 01-36** (Steve Suter, Psychology) "Visual Neuroscience Lab Assignments and Research Projects for 2001-2002" end of September 2002.
4. **Protocol 01-37** (Julie Schmoll, Nursing Student) "The Relationship Between Prenatal Care Utilization and Birth Weight Among Hispanic Women with Low Risk Pregnancies" end of Fall Quarter 2002.
5. **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" end of September 2002.
6. **Protocol 01-43** (Kenneth Nyberg, Applied Research Center) "California Department of Transportation Highway Maintenance Program Driver Satisfaction Survey" end of August 2002.
7. **Protocol 01-45** (J. Daniel McMillin, Applied Research Center) "San Joaquin Community Hospital - Diabetes Demonstration Project Evaluation" end of September 2002.
8. **Protocol 01-46** (J Daniel McMillan, Applied Research Center) "KC Department of Public Health - KC Tobacco Education Program (TEP) Evaluation" end of September 2002.
9. **Protocol 01-48** (Lorraine Tullis, Special Education Student) "Reverse Mainstreaming: A Multimedia Approach to Training Special Education Teachers" end of September 2002.
10. **Protocol 01-49** (Sara Castro-Olivo, Psychology Student) "The Effects of Education Level, Ethnicity, and Religion on Attitudes Toward Infidelity" end of September 2002.
11. **Protocol 01-50** (Marcia Ellen Tyler-Evans, Nursing) "Needs Assessment for Forensic Nursing Skills in Central Valley California Region" end of September 2002.
12. **Protocol 01-53** (Emma Darling, Psychology Student) "The Influence of Gender on University Students" end of September 2002.
13. **Protocol 01-54** (Laurence Hill, Nursing Student) "The Use of Personal Digital Assistants by Nurse Practitioners and Physicians' Assistants" end of December 2002.
14. **Protocol 01-55** (Thida Chea, MSW Student) "Factors Influencing Self-Esteem of Social Workers: An Empirical Analysis" end of October 2002.
15. **Protocol 01-56** (Josh Phelps, Psychology Student) "Teaching College Students to Differentiate between Dissociative Identity Disorder and Schizophrenia" end of September 2002.

16. **Protocol 01-57** (Chandrasekhar Commuri, PPA) "Are All Heterogeneities Alike?: A Test of the Heterogeneity Thesis in the Nonprofit Sector" end of September 2002.
17. **Protocol 01-59** (Carrie Mosley, Nursing Student) "Nurses' Knowledge About Diabetes: A Comparison of Advanced Beginners and Expert Nurses" end of December 2002.
18. **Protocol 02-01** (Deborah Boschini, Nursing Student) "Family Presence During Resuscitation Efforts: An Exploration of ER Nurses' Attitudes" end of December 2002.

[Duquette moved, Abramson seconded, unanimously approved]

Policy On Exemption Of Protocols Involving Children. The RERC noted that Title 45 policy on protocols involving children is actually more permissive than it has been interpreted at CSUB. Specifically, protocols qualifying for exemption by virtue of involving standard educational activities are exempt for children as well. However, exemption by virtue of use of survey, etc. does not apply to children. It was agreed that CSUB would follow the federal policy.

Protocol Reviews:

1. **Protocol 02-63:** " Visual Neuroscience Lab Assignments and Research Projects for 2002-2003" with Steve Suter, Penelope Suter, & Jess Deegan, Department of Psychology. Primary readers are Carr, Harrie, Leapley. Principal Investigator interview scheduled from 8:45 - 9:30.

Steve Suter summarized the proposal. It was explained that their visual neuroscience research always involves recordings of brain activity from surface electrodes while the participants look at visual stimuli on a video monitor. The IRB was reminded that one of the proposed consent mechanisms, consent to release data from required lab assignments for research purposes, had been rejected by the IRB one year ago. This time it was accepted, noting that it preserves anonymity of consenting/not consenting. Members of the IRB commented that the procedure was better explained this time. There was a motion for **approval of Protocol 02-63.**

[Leapley moved, Depner seconded, unanimously approved]

2. **Protocol 02-55:** "Art Therapy May Lessen Verbal/Physical Aggressiveness of 'At Risk' Students" with Lu Royce Anne Bishop, Education Student. Primary readers are Abramson, Duquette, Newberry. Principal Investigator interview scheduled from 9:30 - 10:15.

After a round of introductions the investigator summarized the proposal. Following student assent and parental consent, the BASC will be administered, which involves responses from the student, the parent, and another adult who knows the child. "Art therapy" in the context of the art class will follow. The BASC will be re-administered following the class. The investigator wishes to obtain evidence that the "bonding" that she perceives subjectively actually occurs as a function of this class. The BASC assesses how stress is handled, outlook on life, and other aspects of functioning of the individual. The course includes discussion of the lives of artists, personal essays, production of art, and group discussion of art products; the investigator noted that the course includes certain qualities of group therapy. A discussion followed.

Q: Is there some mechanism to achieve confidentiality of the artwork? A: Products will not be identified by artists in her written works, but they are not anonymous in the course. Students are encouraged to talk about their art that is posted in the classroom. Students can choose not to have their work posted or discuss it.

Q: So it is up to the student whether confidentiality is broken? A: Yes.

Q: You mentioned about previous students having become very emotional in this course. How will you handle serious problems that might happen? A: Referrals are carried out.

Q: What if an episode of major anger would occur? A: A referral would be carried out and request for assistance in the classroom.

Q: Are numbers assigned to the BASC paper forms after completion? A: Yes; plus they will be kept in a locked file.

Q: How will you administer the BASC confidentially? A: Parents will be telephoned and completion arranged. Students will be contacted on an individual "pull out" basis for completion of their part of the BASC.

Q: You want to study only "at risk" students. How will they be identified. A: By counselors.

Q: Do you have legal access to "at risk" student designations? A: Yes.

Q: Are you going to be recruiting "at risk" students for your class? A: No, all of the students have already been assigned to the class. All of the students in the class do the same assignments.

Q: Will you be comparing the data of the "at risk" students to the data of other students? A: No.

Q: What are the criteria for "at risk" status? A: This is based on having low grades; behavior problems can also lead to this, particularly anger management.

Q: Does the school have specific criteria for "at risk" designation? A: I am not aware of specific criteria--relying on the school counselor to deal with this. The focus in this research is on behaviorally "at risk." The art therapy is seen as providing an "outlet" for such students.

Q: How will the BASC be administered? A: At home. [This answer apparently referred only to the parents, because students are supposed to do this on a "pull-out" basis in school--see above.]

Q: With regard to your emphasis on in the rationale and comments re anger/violence, what if there is an incident in class? A: There is no security on campus; one relies on other teachers.

Q: The student BASC results will be available to parents? A: Yes.

Member Comment: The student's BASC data should be kept confidential from the parent.

Q: What if the parent consents, but the child does not assent? A: The child would not participate.

Q: What is the BASC like? A: It is a behavioral assessment battery.

Q: How will you hand out the BASC to students? A: Individually via conferences.

Q: Who gives consent in broken homes? A: The custodial parent.

The investigator was excused and a discussion followed. It was decided that if only “at risk” students are studied, the rights of those participants could not be adequately protected. **A motion to not approve the protocol passed unanimously.**

This major problem was explained to the investigator along with a possible solution by studying either a *random sample of students*, or *all of the students* in a class. The investigator was invited to re-submit her protocol addressing this major problem and, in addition, the following:

1. Specify how adverse reactions (emotional and behavioral crises) will be handled.
2. Specify how the BASC will be administered confidentially to each type of respondent [student, parent, other adult].
3. The IRB is concerned about portrayal of the proposed art activities to participants as “art therapy” in the absence of necessary licensing of the investigator. Justify the use of the concept of “art therapy” or re-focus appropriately.
4. Explain how “at risk” is defined at this school by the personnel involved. Will all of these students be in the class or a subset of so-designated students? If a subset, how will they be selected?
5. Re-state appropriately the rationale and purpose for the research, given the revisions in the proposed methods and possible revisions re “art therapy.”
6. Attach the BASC to the new protocol.
7. Specify that student assent will be obtained prior to parent assent and that solicitation of parent consent will be “low key.”
8. On the consent/assent forms:
 - a. Simplify the language of the student assent form to facilitate understanding.
 - b. Eliminate mention of “consent” in the student assent form.
 - c. Either specify that the students’ BASC data will be kept confidential from the parents or explain that the BASC data will be available to parents in the consent/assent forms.
 - d. Describe the BASC more fully in the consent/assent forms in order for potential participants to be adequately “informed.”
 - e. Delete the project title from the consent/assent forms so that participants are not labelled as “at risk” and the activity is not portrayed as “therapy.”
 - f. State the possible psychological risks in the consent/assent forms.

OTHER CONCERNS: none

[A quorum ceased at this point.]

NEXT MEETING:

The next meeting will be Friday, 31 January 2003 - Stockdale Room ("Old Pub")
7:30 breakfast, 8:00 meeting

ADJOURNMENT:

There being no further business, the meeting was adjourned at 10:45 AM.

Following adjournment there was a training session for IRB members reviewing The Belmont Report principles and their application in the work of the IRB.

Respectfully submitted

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