

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

**Minutes of Meeting
Friday, 09 June 2006
[EDUC 123]**

Members Present:

Scientific Concerns: Marianne Abramson, Roseanna McCleary
Nonscientific Concerns: Bob Carlisle , Yeunjoo Lee , Paul Newberry
Community Concerns: Patrick Mellon, Carolyn Wade-Southard
Ex-Officio: Edwin Sasaki

Members Absent:

Anne Marie Duquette, Candace Meares

Visitors:

Virginia Williams, David Chenot for Protocol 06-62

CALL TO ORDER:

Chair Paul Newberry called the meeting to order at 8:05 AM.

PREVIOUS MINUTES:

Mellon moved and Carlisle seconded a motion to approve the minutes for the IRB/HSR meeting of Friday, 21 April 2006. The motion was approved 6-0.

ANNOUNCEMENTS:

Retirement of **Edwin H. Sasaki**, author of CSUB IRB/HSR Policies and Procedures, 1st Secretary of the IRB/HSR, Interim Dean of Graduate Studies & Research, 1st Research Ethics Review Coordinator, present Ex-Officio member of the IRB/HSR. Ed was thanked for his contributions to the protection of human subjects participating in research at CSUB and presented with a wine glass: "Dr. Edwin H. Sasaki, Founder, CSUB IRB/HSR"

OLD BUSINESS:

At the previous meeting the RERC was asked to explore how data and consent form retention and storage are handled at other universities and bring a possible recommendation to the Board. The RERC reported that federal policy and policies at other universities specify retention of signed consent forms for three years, but that adopting policies for data retention may be more complex and controversial. Discussion followed mainly about data retention. It was agreed that present IRB/HSR practice of requiring destruction of audio and video tapes after data have been extracted is sound. There was not consensus about other data; RERC will explore those issues. The following recommendation of the RERC about retention of consent forms was adopted [Abramson, Mellon, 7-0]:

1. Duration. Signed consent documents must be retained for at least three years to enable research compliance monitoring and in case of concerns by research participants, consistent with federal requirements. Longer retention may be specified by the IRB/HSR for certain projects, for example involving minors or biomedical research. Consent forms may be stored longer at the discretion of the principal investigator [PI].

2. Responsibility. The PI is responsible for retaining consent forms. If the PI is a student, the faculty supervisor is responsible for the consent forms.
3. Confidentiality. The consent forms must be stored so that only the authorized investigators or representatives of the IRB have access. At the end of the retention period the consent forms must be destroyed [not re-cycled or thrown away].
4. Notification of Requirements. The above information will be communicated to investigators via IRB/HSR authorization letters and posted on the IRB/HSR website.

NEW BUSINESS:

A. Formal Board affirmation of protocols previously approved under standard review, expedited review, and exemption from full review since the April 2006 meeting.

1. Standard Review [1] (conditionally approved at April 2006 meeting)

1. **Protocol 06-37:** "Visual Neuroscience Lab Assignments and Research Projects" Steve Suter, Psychology Department [Lee, Mellon, Newberry] on 5-03-06.

[Abramson moved, Carlisle seconded, approved 7-0]

2. Expedited Review [4]

1. **Protocol 06-07.** (Jeffrey Moffit & Don Diboll, Physical Education and Kinesiology) "The Effects of Altering Ventilation Patterns on Exercise-Related Transient Abdominal Pain" [Meares, Newberry] on 4-17-06.
2. **Protocol 06-10.** (Jeffrey Moffit & Don Diboll, Physical Education and Kinesiology) "The Effects of Rotor Cranks on Cycling and Post-Cycling Running Economy in Triathletes" [Lee, McCleary] on 4-17-06.
3. **Protocol 06-11.** (Jeffrey Moffit & Don Diboll, Physical Education and Kinesiology) "The Effects of Power Cranks on Cycling and Post-Cycling Running Economy in Triathletes" [Lee, McCleary] on 4-17-06.
4. **Protocol 06-50.** (Marshall Clay Farr, PPA Student) "STAR Academy Program: Effectiveness in Reducing Student Entry into Adult System" [Carlisle, McCleary] on 5-15-06.

[McCleary moved, Mellon seconded, approved 7-0]

3. Exempted from Full Review [17]

1. **Protocol 06-34** (Anne Duran, Psychology Department) "Defining Tolerance and Acceptance" on 4-10-06.
2. **Protocol 06-36** (Kristine Holloway, Library-AV) "Perceptions of Instructors on Teaching with Interactive Television" on 4-13-06.
3. **Protocol 06-38** (Jeanell Guenther, Nursing Student) "Evaluation of the Diabetes Update for Nurses 2006 Program" 4-12-06.
4. **Protocol 06-39** (Angela LeBeau, Education Student) "Effectiveness of Single-Sex and Coed Cooperative Learning Groups on High School Science Achievement Scores and Attitude Toward Science for Males and Females" on 4-20-06.
5. **Protocol 06-40** (Pat Flaherty, PPA Student) "Recent Workers' Compensation Reforms in California and the Predicted Effect on the City of Sacramento" on 5-01-06.
6. **Protocol 06-41** (John Marble, History Student) "A Voice Too Long Silent: The Story of Life for the Kern County Nisei in the 20th Century" on 4-16-06.
7. **Protocol 06-42** (Wayne Clausen, PPA Student) "Should Local Governments in the San Joaquin Valley Implement Smart Growth for Air Quality Purposes?" on 4-19-06.

8. **Protocol 06-44** (James P. Jacks, Public Policy and Administration Student) "An Analysis of Communication System Interoperability among Kern County Emergency Management Agencies" on 4-24-06.
9. **Protocol 06-46** (Mark Salvaggio, Anthropology Student) "The Commodification of Backpacking" on 4-24-06.
10. **Protocol 06-47** (Aaron Hegde, Economics, Environmental, and Global Studies) "A Cost-Benefit Analysis of Brain Drain: An Empirical Investigation" on 5-12-06.
11. **Protocol 06-48** (Carey Sanders, Special Education Student) "Teacher Perceptions of Inclusion between Two Models of Special Education" 4-29-06.
12. **Protocol 06-51** (Juan Avila, Management & Marketing Student) "Recruiting Student Enrollment for the School of Education" on 4-27-06.
13. **Protocol 06-52** (Terry Kurz, College of Education) "Centennial Off-Campus Analysis" on 5-03-06.
14. **Protocol 06-53** (Elizabeth Harlin, Special Education Student) "Read With Your Child -- Reading Strategy DVD" on 5-03-06.
15. **Protocol 06-54** (Bassam Salameh, Biology Department) "Study of the Intake of Fiber, Sodium, Lipids, and cholesterol by CSUB Students" on 5-11-06.
16. **Protocol 06-55** (Kaye Bragg, TLC) "Two Questions that Promote In-Depth Course Assessment" on 5-22-06.
17. **Protocol 06-58** (Angela Fields, Special Education Student - AV) "Traumatic Brain Injury and the Impact on Instruction" on 5-23-06.

[Mellon moved, Lee seconded, approved 7-0]

4. 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 April 2006 meeting. **[3]**

1. **Protocol 06-49** (Elizandra L-McQuin, Special Education Student) "Bilingual Special Education" on 4-26-06.
2. **Protocol 06-56** (Jaclyn Brown, Health Care Management Student) "Air Pollution and the Asthma Epidemic in the San Joaquin Valley" on 5-15-06.
3. **Protocol 06-57** (Shirlena Nadsady, PPA Student) "Public Agencies and Degree Mills in Kern County, California" on 5-15-06.

[Carlisle moved, Wade-Southard seconded, approved 7-0]

5. Formal Board affirmation of previously approved protocols granted renewals since the April 2006 meeting. **[9]**

1. **Protocol 03-61** (Edwin H. Sasaki, Associate VP) "GEAR UP: Limited Data Set" 4-11-06.
2. **Protocol 03-63** (Edwin H. Sasaki, Associate VP) "GEAR UP: Waiver of Written Consent," on 4-11-06.
3. **Protocol 04-44** (Maryam Allahyar, Department of Psychology) "Perception of Targets Using Multiple and Single High Resolution Displays" 3-21-06.
4. **Protocol 04-49** (Maryam Allahyar, Department of Psychology) "Psychological Issues Related to Virtual Environment Training" on 3-21-06.
5. **Protocol 04-77*** (Rose Foley, Advanced Educational Studies Student) "Implementing Strategies for Sight Word Acquisition for Second Language Learners" 5-17-06.
6. **Protocol 04-94** (Bruce Hartsell, MSW Program) "Effectiveness of Motivational Interviewing Training with Proposition 36 Counselors" 6-05-06.

7. **Protocol 04-120** (Bruce Hartsell, MSW Program) "Effectiveness of Motivational Interviewing Training with Proposition 36 Clients" 6-05-06.
8. **Protocol 04-124** (Kathleen Gilchrist, Department of Nursing) "Are You INN? Outcomes of the INN Program Grant" 5-31-06.
9. **Protocol 05-91** (LaShawn Barefield, CSUB Counseling Center) "Alcohol Needs Assessment: Utilizing the CORE Survey" 6-07-06.

[Abramson moved, McCleary seconded, approved 7-0]

- * There was a request for additional information about Protocol 04-77 with respect to the age of the participants and what was meant by "strategies" in the title. This renewal was approved separately later in the meeting when the information had been provided.

6. Formal Board affirmation of protocol closures (unless extension granted) whose authorization will end prior to the October 2006 IRB meeting. [26]

1. **Protocol 01-46** (Billie Wagner, Department of Sociology) "KC Department of Public Health - KC Tobacco Education Program (TEP) Evaluation" end of August 2006.
2. **Protocol 02-04** (Anne Duran, Department of Psychology) "Measures of Attitudes Toward Outgroup Members" end of August 2006.
3. **Protocol 03-54** (Steve Bacon, Psychology Department) "Outpatient Norms for the Scale of Functional Ability Ratings" end of August 2006.
4. **Protocol 03-55** (Steve Bacon, Psychology Department) "Inpatient Norms for the Scale of functional Ability Ratings [SOFAR]" end of August 2006.
5. **Protocol 03-70** (Tanya Boone, Department of Psychology) "Mother-Adolescent Health Communication," end of August 2006.
6. **Protocol 04-09** (Phillip Patterson, Special Education - AV) "Accessibility of Early Childhood Services for Migrant Parents of Children with Disabilities" end of June 2006.
7. **Protocol 04-117** (Tanya Boone, Department of Psychology) "Homophobia and Condom Use Among Heterosexual Men" end of August 2006.
8. **Protocol 04-126** (Katie Fleming, Psychology Student) "Dominance and Deception: Is the Correlation Found in the Self-Oriented Lie?" end of August 2006.
9. **Protocol 04-131** (Scott Clare, Garces High School) "Social Issues in High School Sports" end of August 2006.
10. **Protocol 04-144** (Emerson Case, Department of English) "An Ethnographic Study of Cross-Cultural Composition Students' Participation in Writing Center Tutoring" end of August 2006.
11. **Protocol 05-73** (Susan Rutledge, MSW Student) "Substance Abuse Recovery and the Relief of Symptoms of Depression" end of June 2006.
12. **Protocol 05-79** (Bobbi Meyer, Department of Nursing) "Recognition and Reporting of Suspected Elder Abuse and Neglect by Nurse Practitioners" end of June 2006.
13. **Protocol 05-83** (Rose Anna McCleary, MSW Program) "Adult System of Care Model Development for Central California" end of September 2006.
14. **Protocol 05-84** (Gina Walden, Sociology - AV) "Stigmatization of Mental Illness: Social Contact and Public Perception" end of August 2006.
15. **Protocol 05-85** (Lensi Goad, Department of Integrated Studies in Education, McGill University) "Multicultural Education Coursework in a CLAD Credential Program: How are Teachers of ELLs Affected?" end of August 2006.

16. **Protocol 05-86** (Linda Jeffries, MA Program in Teaching Mathematics) "Learning for Understanding: Can Multiple Representations using Context-Based (Temperature and Direction) Manipulatives Improve Student Understanding of the Rules For Adding and Subtracting Integers?" end of August 2006.
17. **Protocol 05-87** (Mi Y. Kang, Department of Special Education) "Korean Immigrants' Knowledge of Special Education and Disability," end of September 2006.
18. **Protocol 05-88** (Billie Jo Rice, Psychology Student) "The Effects of Stereotype Threat on Prejudice" end of September 2006.
19. **Protocol 05-89** (Jared Chapman, Psychology Student) "Cognitive Load and Reading Comprehension" end of September 2006.
20. **Protocol 05-90** (Crystal Freeman, Psychology Student) "Eveningness and Morning Cognition" end of September 2006.
21. **Protocol 05-92** (Terri Kurz, College of Education) "Video Case Analysis" end of September 2006.
22. **Protocol 05-94** Jianyu "Eugene" Wang, Department of PE and Kinesiology) "Performance Patterns and Competency of Basketball Game Play Among Regular Basketball Participants" end of September 2006.
23. **Protocol 05-95** (Robin Shirer, Department of Sociology) "Care Decisions and Social Networks Among Low-Income Parents" end of September 2006.
24. **Protocol 05-98** (Colette Moon, Education Student) "Research on Questioning in the Classroom for Teacher Professional Growth" end of September 2006.
25. **Protocol 05-99** (Michael Harville, CSUB Counseling Center) "Evaluation of Counseling Center Services" end of September 2006.
26. **Protocol 05-101** (Anne Duran, Department of Psychology) "Defining Tolerance and Acceptance" end of September 2006.

Renewal requests for protocols 04-94, 04-120, 04-124, and 05-91 were received after the agenda had been created and were transferred from the closure list to the renewal list. [Mellon moved, Wade-Southard seconded, approved 7-0]

e. Protocol Renewals Requiring Re-Review [none]

f. New Protocol Reviews: [1]

1. **Protocol 06-62:** "Interactions Among Anger, Substance Abuse, and Female-Initiated Domestic Violence" with Virginia Williams, Roseanna McCleary, and David Chenot, MSW Program [Carlisle, Duquette, Meares]

Williams outlined the protocol. She wants to look at the relationship among drug abuse [primarily alcohol and methamphetamine], anger [as measured by a standard clinical scale], and female-initiated domestic violence [DV]. There is not much research in which all of these variables are studied together. The primary subject population will be clients at Capistrano Community for Women in Bakersfield. Potential participants will self-refer after she attends group meetings to introduce herself and the research project. Active drug users and mentally ill who are judged unable to exercise proper consent will be excluded. This research could improve intake evaluations and strengthen individualization of treatment plans. Questions followed.

Q: Will the women be in-patients and will they be court-mandated?. **A:** Yes, this is a residential program and most are court-mandated.

Q: How long are the residents there? **A:** The minimum is 45 days, but normally it is a six-month program.

- Q:** Is it possible that the women might say something incriminating? **A:** Yes. She is a mandated reporter and this is specifically pointed out in the consent form. However, participants will not include their names on the survey instruments.
- Q:** It mentions an "interview." If you do that in person, won't you potentially be able to identify individuals. **A:** Actually, there will be no in-person questioning, just having the women fill out the written survey instruments individually or in groups.
- Q:** How would you do your mandated reporting, if you cannot identify individual women. **A:** She would go to the program director and seek identifying information.
- Q:** Describe your face-to-face activities with the women. **A:** She would be present at the beginning of group meetings so they could become familiar with her and with her project. Questions will be answered in those meetings. At that point participants will self-select to participate.
- Q:** Would you attend staff meeting? **A:** No, she would attend counseling sessions, before the counseling actually gets underway.
- Q:** "In-patient" is a bad term to use to refer to such persons -- they are not confined, for example. **A:** Our definition is simply that persons in residential programs are "in-patients."
- Q:** Are you studying the experience of anger or the expression of anger -- that wasn't clear to me. **A:** We are interested in both. The clinical anger scale assesses the experience of anger and the survey about domestic violence history gets at the expression of anger.
- Q:** Only females who have perpetrated DV will be invited to participate? **A:** No, we will be studying women in drug treatment, many of whom, we think, will have initiated DV. We need to have a varied group with respect to DV in order to see the relationships we are looking for.
- Q:** How will you ensure that participants are not using drugs. **A:** There are random drug tests at the facility which we will require to be negative. These aren't done every day so it would come down to a behavior judgment about whether a person were sufficiently impaired so that informed consent is not possible.
- Q:** You will be studying only the residential women? **A:** They wouldn't need to be residential.
- Q:** Your DV survey seems to be somewhat crude in terms of limiting report to a single instance of domestic violence. What if there are repeated instances of DV? What if some participant sometimes initiated the DV and other times it was her partner? Does the time scale on this make a difference? **A:** We will revise the survey to make it more precise, including adding a time scale.
- Q:** How do you know that local programs are not already doing what you argue is lacking in drug treatment programs? **A:** We don't know whether what is alleged to be true in the overall research literature is true locally. One thing we could do is add items to the survey asking clients about the elements of their treatment.

When there were no more questions the investigators were excused and the IRB/HSR deliberated in executive session. There was a motion to conditionally approve Protocol 06-62 [Mellon moved, Lee seconded, 7 -0]. The conditions were:

1. Refine the domestic violence section of the survey to incorporate multiple instances of domestic violence and information about time periods of these events.
2. Provide a step-by-step description of subject recruitment/selection, beginning with your contact with program administrators and ending with obtaining written informed consent.
3. Explain specifically how, and the extent to which, confidentiality will be protected.
4. Submit to the IRB/HSR written authorizations from the treatment programs from which you will obtain participants for your research.

OTHER CONCERNS: There was a consensus that the next report to the Provost should mention that non-English speakers and/or readers are routinely excluded in protocols brought to the IRB/HSR.

NEXT MEETING:

Friday, 06 October 2006 – location to be announced

ADJOURNMENT:

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

[Duquette moved, Mellon seconded, approved 7-0]

Respectfully submitted

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

TRAINING: There was a review of protections for children as research participants structured around two documents: (a) Title 45 CFR Part 46: Subpart D: "Additional Protections for Children Involved as Subjects in Research" <http://www.nihtraining.com/ohrsite/guidelines/45cfr46.html> and (b) IRB Guidebook, Chapter VI -- "Special Classes of Subjects, Section C -- Children and Minors" http://www.hhs.gov/ohrp/irb/irb_chapter6.htm#g4. It was clear that two elements of how the CSUB IRB/HSR deals with research involving children needs to be modified: (a) assent of the child participant is *required*, not just encouraged, with the parent/guardian providing "permission" for the child to participate and (b) all research using interviews or written surveys involving child participants must be handled at the expedited or standard review levels. It was suggested that this information be added to our online guidance for investigators submitting protocols.