

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

Minutes of Meeting
Friday, 10 June 2005
Cafeteria 101

Members Present:

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

Members Absent:

Anne Marie Duquette

Visitors:

Steve Bacon for Protocol 03-03 Renewal
Rungpet Christner & Cary Larson-McKay for Protocol 05-70 Review
Susan Rutledge & Debra Morrison-Orton for Protocol 05-73 Review

CALL TO ORDER:

Chair Paul Newberry called the meeting to order at 8:00 AM.

PREVIOUS MINUTES:

Mellon moved and Abramson seconded, a motion to approve the minutes for the IRB/HSR meeting of Friday, 28 January 2005. The motion was approved 7-0.

ANNOUNCEMENTS:

- a. Authorization dates were added for Standard Reviews 05-07 and 05-08.
- b. Renewal of 03-03 [Psychology Department Subject Pool] was added to the agenda.
- c. Discussion of an incident involving the course SW 630 was added to the agenda.
- d. Board Training on ethics of internet research was added to the agenda [later cancelled because of lack of time].

OLD BUSINESS: [none]

NEW BUSINESS:

- a. **Formal Board affirmation** of protocols previously approved under standard, expedited, and exempted review since the regular 08 October 2004 meeting.

Standard Review (conditionally approved at the January 2005 meeting)

1. **Protocol 05-07** "The Experience of Language Barriers among Limited English Proficiency Hispanics during Hospitalization" with Veronica Duran & Candace Meares, Nursing. [McCleary, Newberry, Wade-Southard] on 24 February 2005.

2. **Protocol 05-08** "Nursing as a Career Choice: Adolescents' Perceptions" with Corina Anema & Candace Meares, Nursing. [Abramson, Lee, Mello] on 31 January 2005.

[Wade-Southard moved, McCleary seconded, approved 8-0]

Expedited Review (approved since the January 2005 meeting)

1. **Protocol 05-03** (Trisha Bjerneby-Ward, Nursing Student) "Stress and Coping Mechanisms among BSN Student Nurses" [Lee, McCleary] on 15 February 2005.
2. **Protocol 05-05** (John W. Ayers, Political Science Student) "Student Attitudes on Bilingual Education in Kern County" [Abramson, Carlisle] on 28 March 2005.
3. **Protocol 05-13** (Erlinda Mulvaney, Nursing Student) "The Challenge Providing Care for the Developmentally Disabled: A Qualitative Study" [Carlisle, McCleary] on 18 February 2005.
4. **Protocol 05-17** (Flame McFerrin, Psychology Student) "Short-Term and Delayed Recall" [Meares, Newberry] on 17 February 2005.
5. **Protocol 05-18** (Sheryl Metheney, Psychology Student) "The Differential Ratings of Married Women's Competence" [Carlisle, Meares] on 10 February 2005.
6. **Protocol 05-24** (Yeunjo Lee, Special Education) "Assistive Technology Perceptions of Caregivers of School Aged Children with Disabilities" [Abramson, Newberry] on 05 April 2005.
7. **Protocol 05-26** (Barbara Minor, PPA Student) "Curbside Recycling in Bakersfield: Why is Participation in the Trash?" [Lee, McCleary] on 29 March 2005.
8. **Protocol 05-45** (Richard S. Carley, Psychology Student) "Mo' Better Velten: A Comparison of Card and Computer Versions of the VMIP" [Meares, Newberry] on 18 April 2005.
9. **Protocol 05-52** (Marianne Abramson, Department of Psychology) "Gender and Tone Effects in Implicit and Explicit Memory" [Lee, McCleary] on 29 April 2005.

[Meares moved, Mellon seconded, approved 8-0]

Exempted from Full Review (approved since the January 2005 meeting)

1. **Protocol 04-139** (Laura Moon, Education Student) "The Effectiveness of Explicit, Systematic Phonics Instruction on the Reading and Spelling Achievement of Third and Fourth Grade English Learners" on 18 January 2005.
2. **Protocol 05-04** (Debra Martin, Education Student) "Explicitly Teaching Content Area Reading to Three Spanish-Speaking Middle School Students with Learning Disabilities: Case Studies" on 25 January 2005.

There was discussion of why 05-04 was appropriate for exemption from full review. The reason offered was that the method was unobtrusive observations.

3. **Protocol 05-10** (Lidia Albiar, PPA Student) "Collocated One-Stop for Non-Custodial Parents" 03 March 2005.
4. **Protocol 05-11** (Diego Ocampo, PPA Student) "Teacher Efficacy of Special Education Teacher" on 31 January 2005.
5. **Protocol 05-12** (Gary Mojica, Education Student) "Teaching Spanish Reading Comparing/Contrasting Instruction" on 15 February 2005.
6. **Protocol 05-14** (Anne Duran, Department of Psychology) "Social Psychology Learning Activity" on 02 February 2005.
7. **Protocol 05-15** (Candace Grantham, Education Student) "Portfolio Assessment in Literacy: Meeting the Standards" on 08 March 2005.

8. **Protocol 05-16** (Trina Priddy, Education Student) "Explicitly Teaching Content Area Reading to Three Spanish-Speaking Middle School Students with Learning Disabilities: Case Studies" on 02 February 2005.
9. **Protocol 05-21** (Deborah Maddox, Nursing Student) "Migrant Health Fair Outreach Health Fair: A Program Evaluation" on 23 February 2005.
10. **Protocol 05-22** (Mike Roper, Nursing Student) "A Description of the Use and Constraints for Holistic Practice by Family Nurse" on 02 March 2005.
11. **Protocol 05-23** (Penelope Swenson, Advanced Education) "A Study of Online Discussion and Course Engagement" on 02 March 2005.
12. **Protocol 05-27** (Dima Mouradi, MSW Student) "What Is the Impact of 9/11 On the Arab American Community in California?" on 09 March 2005.
13. **Protocol 05-28** (Veronica Rethi, Advanced Education Student) "Action Research" on 17 March 2005.
14. **Protocol 05-29** (Anne Duran & Jordan Rude, Psychology) "Tolerance and Acceptance" on 16 March 2005.
15. **Protocol 05-30** (Madhavapallil Thomas & Jong Choi, MSW Program) "Predictive Factors of Acculturation Among Asian Immigrants" on 11 March 2005.
16. **Protocol 05-31** (Paula Howard, Education Student) "Vocabulary Program Review" on 09 March 2005.
17. **Protocol 05-32** (Michael Caniff, Advanced Education Student) "Art and Math" on 11 March 2005.
18. **Protocol 05-35** (Ron Pimentel, Dept of Management and Marketing) "Consumer Use of Message Boards" on 11 April 2005.
19. **Protocol 05-36** (Ron Pimentel, Dept of Management and Marketing) "Maintaining Fad Products Between Fads" on 12 April 2005.
20. **Protocol 05-37** (Valerie M-Reyes, Nursing Student) "Experiences of Correctional Nurses: Why They Are Able to Continue Working in a Prison Setting" on 11 April 2005.
21. **Protocol 05-38** (Gail R. Nelson, Sociology Student) "Non-Traditional Female College Students: Great Expectations" on 07 April 2005.
22. **Protocol 05-39** (Valerie Perez, Reading/Literacy Student) "The Effectiveness of Graphic Organizers and Written Summaries to Improve Reading Comprehension Abilities of Fourth Grade Students" on 04 April 2005.
23. **Protocol 05-40** (Christopher Mausolff, Public Policy and Administration) "The Impact of Learning Style on Students' Experiences with Community Service Learning" on 01 April 2005.
24. **Protocol 05-41** (Jennifer Dewey, Reading/Literacy Student) "The Effects of Participation in a Comprehensive Reading Program on Spelling, Comprehension, and Reading Attitude of Sixth Graders" on 01 April 2005.
25. **Protocol 05-42** (Chris Mausolff, Public Policy and Administration) "The Impact of Learning Styles on Students' Experiences with Experiential Exercises" on 13 April 2005.
26. **Protocol 05-43** (Misty Stowers, PPA Student) "Three strikes Legislation in California: An Interrupted Time-Series Analysis" on 12 April 2005.
27. **Protocol 05-44** (Penelope Swenson, Advanced Education) "SWOT, Delphi, and Strategic Planning" on 15 April 2005.
28. **Protocol 05-46** (Debra Cook Hirai, Advanced Educational Studies) "Are We Closing the Gap for Reading Comprehension and Decoding for 9-12 Students?" on 13 April 2005.
29. **Protocol 05-47** (Roseanna McCleary, MSW Program) "Evaluation: TALK Model: Using Analogy to Communicate End of Life Concepts" on 12 April 2005.
30. **Protocol 05-48** (Kelly Bock, PPA Student) "Recommendations for Mutually Beneficial FMLA Procedures" on 14 April 2005.

31. **Protocol 05-49** (Brian Bell, Mathematics Student) "Student Comprehension and Understanding of Fractions" on 26 April 2005.
32. **Protocol 05-50** (Ron Pimentel, Department of Management and Marketing) "Enhancing Sales Education with Sales Competitions" on 21 April 2005.
33. **Protocol 05-51** (Yesenia E. Galvez, Education Student) "Quality Child Care: A Case Study of Wasco Child Development Center" on 03 May 2005.
34. **Protocol 05-54** (Shelia Hall-Vailes, PPA Student) "Nurse Retention Strategies" on 06 May 2005.
35. **Protocol 05-60** (Huong Nguyen, PPA Student) "Evaluation of the Rite of Christian Initiation of Adults [RCIA] Program" on 02 May 2005.

There was discussion of why 05-60 was eligible for exemption from full review. The reason offered was that the method involved anonymous surveys and observations of individuals in group settings.

36. **Protocol 05-61** (Ana Filomia, Education Student) "Structured Improvement of Sentence Coherence" on 06 May 2005.
37. **Protocol 05-63** (Norma Nava, Early Childhood Education Student) "Attachment Disorder: A Case Study on Elementary Children" on 12 May 2005.

The title of 05-63 was incorrect in the agenda and was corrected.

38. **Protocol 05-66** (Marsha Merz, Education Student) "Involving Students in Writing Rubrics for Math Story Problems" on 26 May 2005.

[Abramson moved, Carlisle seconded, approved 8-0]

b. 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 January 2005 meeting.

It was noted that these were studies of aggregate data in agency reports, study of public documents, or library research.

1. **Protocol 05-20** (Gladys Garcia, Extended University Student) "California Work Opportunities and Responsibility for Kids [CalWORK's]" on 02 March 2005.
2. **Protocol 05-25** (Isabel Ortiz-Farmer, PPA Student) "Telecommuting: Could It Work In the Public Sector?" on 02 March 2005.
3. **Protocol 05-33** (Debora Ann Rodenhauer, PPA Student) "AIDS Research and Public Art Funding" 17 March 2005.
4. **Protocol 05-53** (Mara Schramm, Management & Marketing Student) "Image Study for CSUB" on 29 April 2005.
5. **Protocol 05-55** (Shelly Dawn Sprouse, PPA Student) "A Study to Determine the Need for an Intergenerational Facility in Bakersfield, California" on 02 May 2005.
6. **Protocol 05-56** (Brevyn Mettler, PPA Student) "Risk Assessment of the Energy and Agriculture Industries in Kern County to Terrorism" on 03 May 2005.
7. **Protocol 05-57** (Jeffery Kaya, PPA Student) "Agenda Setting in the Gay Marriage Debate" on 28 April 2005.
8. **Protocol 05-58** (Megan Mahoney, PPA Student) "Exploring the Ambiguity of Nonprofit Advocacy" on 29 April 2005.
9. **Protocol 05-59** (Alberta Marie Dougherty, PPA Student) "Keeping Pace with Community Growth, Political, Social and Economic Constraint: Patrol Organization and Personnel Allocation Management" on 29 April 2005.

10. **Protocol 05-62** (Elena Acosta, PPA Student) "An Evaluation of Self-Sufficiency Success Rates for Kern County CalWORKS Recipients from 2000 to 2004: The Effectiveness of Program Strategies for Self-Sufficiency" on 06 May 2005.
11. **Protocol 05-68** (Sheryl Chalupa, PPA Student) "The Rise of the Social Enterprise Model in Nonprofit Organizations" on 01 June 2005.

c. Formal Board affirmation of previously approved protocols granted **renewals** since the January 2005 meeting.

1. **Protocol 02-05** (Brian Hemphill, ARC) "Evaluation for First 5 California" on 18 April 2005.
2. **Protocol 03-20** (Denise Placencia-Romero, PPA Student) "The Success Rate and Retention Level of CSU, Bakersfield EOP Students" on 31 January 2005.
3. **Protocol 03-61** (Edwin Sasaki) "GEAR-UP: Limited Data Set" on 23 February 2005.
4. **Protocol 03-63** (Edwin Sasaki) "GEAR-UP: Waiver of Written Consent" on 23 February 2005.
5. **Protocol 04-05** (Isabel Sumaya, Department of Psychology) "Sleep Disturbances in Relation to Antipsychotic Treatment in Schizophrenic Patients" on 20 January 2005.
6. **Protocol 04-10** (Jaime Santos Alas, PPA Student) "Patient Satisfaction Survey" on 07 February 2005.
7. **Protocol 04-27** (Rose Anna McCleary) "Use of a Participatory Action Model in a Graduate School Social Work Class" on 27 January 2005.
8. **Protocol 04-39** (Emerson Case, Department of English) "An Ethnographic Study of International Students' Participation in Group Projects/Group Presentations" on 29 March 2005.
9. **Protocol 04-44** (Maryam Allahyar, Department of Psychology) "Perception of Targets Using Multiple and Single High Resolution Displays" on 29 March 2005.
10. **Protocol 04-49** (Maryam Allahyar, Department of Psychology) "Psychological Issues Related to Virtual Environment Training," on 29 March 2005.
11. **Protocol 04-52** (Penelope Swenson, Advanced Education) "Response to the Constructivist Learning Environment in Foundations of American Education" on 28 February 2005.
12. **Protocol 04-77** (Rose Foley, Advanced Educational Studies Student) "Implementing Strategies for Sight Word Acquisition for Second Language Learners" 02 May 2005.
13. **Protocol 04-78** (Rosa Sanchez, Advanced Educational Studies Student) "Teachers' Knowledge, Skills, and Attitudes Regarding Culturally and Linguistically Diverse Students" on 13 April 2005.
14. **Protocol 04-80** (Penelope Swenson, Advanced Educational Studies) "Handheld Computer Use Among K-12 Administrators and Teachers" on 15 April 2005.
15. **Protocol 04-93** (Cherie Rector, Department of Nursing) "Acanthosis Nigricans Screening in High School and Elementary School" on 18 March 2005.
16. **Protocol 04-101** (Alejandra Perez, Department of Biology) "Effect Size of Microbiology Manual on the C- Student in Bio 260" on 15 February 2005.

[Mellon moved, McCleary seconded, approved unanimously]

d. Formal Board action closing protocols (unless extension granted) whose authorization has ended or will end prior to the September 2005 IRB meeting.

It was noted that closure notices went out in April even though there was no IRB/HSR meeting, resulting in a large number of closures to affirm at this meeting.

1. **Protocol 04-30** (Billy Hull, Education Student) "Evaluation of Summer Scholars Academy [GEAR UP]," end of June 2005.

2. **Protocol 04-32** (Jewelle Scales, Public Policy & Administration Student) "The Effects of Ethical Climate Types On the Quality of Work Life for Employees in Public Organizations" end of April 2005.
3. **Protocol 04-49** (Maryam Allahyar, Psychology Department) "Psychological Issues Related to Virtual Environment Training" end of April 2005.
4. **Protocol 04-50** (Judy Pedro, Nursing Student) "Barriers and Facilitators to Seeking Health Care: Perceptions of Hispanic Women" end of May 2005.
5. **Protocol 04-61** (Cameron Bolles, Physical Education and Kinesiology Student) "Effects of Muscular Fatigue Due to Resistance Training on Proprioceptive Position Sense" end of April 2005.
6. **Protocol 04-62** (Robert Carlisle, Department of English) "The Influence of Sonority Sequencing on the Modification of /sC/ Onsets" end of April 2005.
7. **Protocol 04-63** (Gloria Duarte-Smith, Advanced Education Studies Student) "The Effectiveness of Migrant Education on Reading Achievement." end of April 2005.
8. **Protocol 04-64** (Felisa Patiño-Guadarrama, Bilingual/Bicultural Ed Student) "An Examination of English Language Arts and Mathematics Scores of Dual Immersion Students and Mainstream Students in 5th Grade" end of April 2005.
9. **Protocol 04-65** (Lorine Vasquez, PPA Student) "The Effectiveness of an After School Program" end of April 2005.
10. **Protocol 04-66** (Jong Choi & Madhavapallil Thomas, MSW Program) "Acculturation Stress and Social Support Among Korean and Indian Immigrant" end of April 2005.
11. **Protocol 04-67** (Leah Sanchez, Advanced Educational Studies Student) "Hispanic Parent Involvement and Academic Achievement" end of April 2005.
12. **Protocol 04-68** (Daniel Velez, Bilingual Education Student) "Causal Factors of High Hispanic Dropout Rates" end of April 2005.
13. **Protocol 04-69** Ben Keller, Advanced Educational Studies Student) "The Relationship Between Achievement and Spanish Literacy Amongst High School ELL's" end of April 2005.
14. **Protocol 04-70** (Agnieszka Plate, PPA Student) "Improving Effectiveness and Efficiency of Nursing Assistants' [CNAs] Performance Evaluation Process in 'Sharing and Caring'--A Long-Term Care Public Agency" end of April 2005.
15. **Protocol 04-71** (Eric Bullard, PPA Student) "Development of an Administrative Manual: A Project with Extended University" end of April 2005.
16. **Protocol 04-72** (Rebecca A. Flores, Advanced Educational Studies Student) "CLAD Training Competency As Perceived By Teachers" end of April 2005.
17. **Protocol 04-75** (Erin George, Education Student) "The Effect of Phonological Awareness Instruction on Kindergarten and 1st Grade Achievement" end of April 2005.
18. **Protocol 04-79** (Lorenzo S. Cruz, Jr., Advanced Educational Studies Student) "The Effect of Grade Leveling" end of April 2005.
19. **Protocol 04-81** (Stephanie Kirkwood, Sociology Student) "A Study of Double Consciousness By Way of Identity Consciousness" end of April 2005.
20. **Protocol 04-82** (Connie Leal, Curriculum and Instruction Student) "Social Promotion vs. Retention in Elementary Schools" end of April 2005.
21. **Protocol 04-83** (Randy Arie, Special Education Student) "Help for South High Special Ed Students Who Struggle With Social Skills" end of April 2005.
22. **Protocol 04-84** (LeAnn Griffin, Education: Literacy Student) "An Analysis of Reading First As an Effective Teacher Preparation Program" end of April 2005.
23. **Protocol 04-85** (Shree Kelly Whittenberg, Education Student) "The Influence of Socioeconomic Status on Student Academic Achievement" end of April 2005.

24. **Protocol 04-86** (Danny Osborne, Psychology Student) "The Integrated Threat Theory and Political Affiliation: Predicting Prejudice Through Perceived Threats" end of April 2005.
25. **Protocol 04-89** (Katie Staley, MSW Student) "What Do Basque Women Believe Are the Expectations Toward Marriage Placed On Them By Their Culture and How Do These Basque Women Themselves Comply To These Expectations?" end of May 2005.
26. **Protocol 04-90** (Deyanira Gonzalez, MSW Student) "The Role of Companion Animals in the Human Dying Process" end of July 2005.
27. **Protocol 04-91** (Jeffrey Moffit, Physical Education and Kinesiology) "The Effect of Cross Country Cycling Relay Racing on Cycling Power, Heart Rate, and Cycling Muscle Electromyographic Activity" end of May 2005.
28. **Protocol 04-92** (Jodie Winningham, MSW Student) "Thesis for MSW Program" end of May 2005.
29. **Protocol 04-95** (Dan Ragle, Special Education Student) "Evaluation of Reading Programs for Learning Handicapped Students in a High School District" end of May 2005.
30. **Protocol 04-96** (Dan Durham, Special Education Student) "A Descriptive Study of After-School Programs" end of May 2005.
31. **Protocol 04-98** (S. Aaron Hegde, Department of Economics) "The Mexican Migration Decision: An Empirical Study" end of May 2005.
32. **Protocol 04-99** (Barney Simons, Sociology Student) "The Stigmatized Neighborhood" end of May 2005.
33. **Protocol 04-100** (Debra Morrison-Orton, MSW Program) "Barriers to Screening for Domestic Violence and Substance Abuse" end of July 2005.
34. **Protocol 04-102** (Laura Hecht, Department of Sociology/Anthropology) "Baker Street Area Business Survey" [Abramson, Carlisle; supplemental review at the April 2004 IRB meeting] end of July 2005.
35. **Protocol 04-103** (Valerie Sizemore, Nursing Student) "Diabetic Patient Education: Effectiveness Measured by Hemoglobin Alc Levels" end of June 2005.
36. **Protocol 04-104** (Luther Case, Education Student) "Scripted Reading Instruction for English Language Learners" end of June 2005.
37. **Protocol 04-106** (Marianne Abramson, Department of Psychology) "The Attenuation of Vowel- and Consonant-Length Effects by Concurrent Articulation" end of June 2005.
38. **Protocol 04-107** (Debra Cook Hirai & Irene Borrego, School of Education) "An Effective Professional Development Model for Educators of Second Language" end of June 2005.
39. **Protocol 04-108** (Zandree Stidham, English Student) "Socioeconomic Status and the Returning Student" end of July 2005.
40. **Protocol 04-109** (Susan Koulos, Mathematics Student) "Writing in the Mathematics Curriculum: Its Purpose, Usage, and Effects on Student Learning" end of June 2005.
41. **Protocol 04-110** (Diane Butkiewicz, Special Education Student) "Effectiveness of *Learning Strategies Curriculum* for Simple Sentence Writing" end of July 2005.
42. **Protocol 04-111** (Erica Ballesteros, Psychology Student) "Racial Profiling and Stereotyping Tendencies" end of July 2005.
43. **Protocol 04-113** (Steve Bacon, Department of Psychology) "Reliability of the Scale of Functional Ability Ratings (SOFAR) in a College Sample" end of April 2005.

[McCleary moved, Lee seconded, approved unanimously]

e. New Protocol Reviews

Protocol 05-70 "A Calm & Attentive Mind in the Classroom" with Rungpet Christner & Cary Larson-McKay, Child, Adolescent, & Family Studies. Primary readers were Abramson, Duquette, Lee.

The investigator wants to use guided imagery to help children focus better during reading tasks, to increase their attention span, and, with relaxation training, to help children cope with stress and "calm their mind." Questions followed. [Q = question from IRB, C = comment from IRB, A = answer from investigator]

- Q: Please explain the meditation procedure to be used A: This will involve physical postures and muscle relaxation.
- C: Children don't need to close their eyes to do this. Some might get scared. A: Yes, they can just lower their eyes and look down if they prefer.
- Q: Will the text of the guided imagery be sent to the parents with the consent form? How will the parents be informed sufficiently to decide about consent? A: The focus is on the children, not the parents. The parents will be able to look at the book, "Peaceful Piggy Meditation if they like.
- Q: What are you studying? A: Focusing better and calming the mind. The faculty mentor noted that a major share of the project is curriculum development, just assembling the meditation lessons and trying them out.
- Q: How are you going to measure the variables that you refer to--stress and coping with stress, attention span, attention focusing, and so on. A: Their classroom behaviors will be observed and the journals that they will be writing about the meditation lessons will be examined.
- Q: So, are you going to actually try to measure these variables, that is focusing attention, and so on? A: [She gave a diffuse answer that did not address the question. The faculty mentor said not for this project, which is only a first step.]
- Q: Is this project just intended to organize the meditation lessons and find out if the kids are comfortable? A: Yes.
- Q: In terms of assessing effects of the meditation, you are focusing primarily on the children's journals? A: [She again referred to helping the children calm their minds and focus, but did not make clear how inferences about this could be made from the children's journals.]
- C: It's really not clear what data you will be collecting, so if the aims of this project are really much more limited than you indicated in the protocol, we need to know that, so we don't criticize your methods unfairly.
- Q: There is a lot of research on meditation with children. We need an explanation of what you believe that your project might add to existing knowledge. A: It's really primarily seeing if meditation can be used in this setting and circumstances.
- Q: Do children have to have certain characteristics to participate? What about the stigma attached if children are not selected and if the parents don't consent? A: The children will self-select. This will be the entire group of children who have picked meditation as one of their selected 4-week activities for the summer program. The whole group would participate.
- Q: How would you make sure that the parents have consented? A: It's part of the sign-up for the whole 4-week program.

- Q: You will be starting with a larger group, because there will likely be attrition from children who get bored and drop out. A: Yes.
- C: The children's consent form contains some age inappropriate language. Please make sure that all of the language is age appropriate. A: Will do.
- Q: How could a parent withdraw a child from the study? A: A child would withdraw by simply approaching me. Parents are able to contact me.
- C: Please specify the procedures used to keep the data confidential and if and when they will be destroyed. A: OK.
- Q: Do you have training in instructing meditation or a license? A: She has studied meditation, but is not a certified instructor.
- Q: Do you have approval of your project from the program? A: Yes. C: You should submit a letter showing this to the IRB.

The investigators were excused and deliberations followed in executive session.

It was decided that there were too many weaknesses for a conditional approval and that the project should be resubmitted with much more limited aims and a better explanation of the planned activities. There was a motion for disapproval of **Protocol 05-70**. [Abramson moved, Wade-Southard seconded, approved 8-0]. The investigators returned and were informed of the decision of the Board. The following guidance was to be provided in written form to the investigators to assist in resubmission.

1. Limit the aims of the project to development and pilot testing of the meditation curriculum and determining the acceptance of the children and parents.
2. Provide a review of the literature indicating what is known about meditation in children and specifying what is project is intended to add.
3. Describe the meditation procedures by providing an appropriate lesson plan.
4. Create a children's "assent form" with age-appropriate language.
5. Create sufficiently descriptive parental consent materials.
6. Correct the contact information of the consent materials guided by the CSUB online examples.
7. Clarify the subject selection criteria, including any exclusions?
8. Specify how the data will be held confidential, separated from names, and possibly destroyed.
9. Specify how you will deal with cases of distress among children, providing appropriate referrals.

Protocol 05-73 "Substance Abuse Recovery and the Relief of Symptoms of Depression" with Susan Rutledge & Debra Morrison-Orton, MSW. Primary readers were Carlisle, Meares, Wade-Southard.

The investigator summarized her project. This is an attempt to see if an exercise program will diminish depression among women in a substance abuse treatment program. There is high incidence of depression and this interferes with the recovery process. One group will get the standard treatment and the other the standard treatment plus exercise. A depression scale will be administered to all participants pre- and post-. These are vulnerable person, many having just come from prison, and elected the treatment option; some have lost child custody. Participants will be screened with the "PAR-Q" instrument used at CSUB for adult exercise programs, and interpreted by Dr. Moffit of the PE/Kinesiology Department. Questions followed.

- Q: What will you do with bi-polar individuals? A: Not sure whether they would be left in or excluded, probably retained.
- Q: What is the source of the depression diagnosis? A: This would either come with the person from the prison setting or take place at admission. If diagnosed, sometimes persons are then referred to KCMH for medication.
- C: I noticed that you said that the participants will not be given physicals by a physician. KCMH would do physicals for potential participants referred over.
- Q: Will medication be changed as part of the exercise program? A: No, any medications prescribed would continue.
- C: The PAR-Q may not be adequate as a screener; a physical would be better.
- Q: Do persons sometimes come to the center already prescribed medication for depression? A: Yes.
- Q: Weight gain in women recovering from stimulant dependence is a prominent risk factor in relapse. A: Yes, and the exercise program might help with that.
- Q: How will participants be assigned to groups? A: Persons already there will be assigned randomly, then new admits will be assigned alternately to exercise and control.
- Q: Who goes out with the participants on their exercise walks? A: She will go with them at first and then use a treadmill that she will provide to the center. On other walks, there will be a staff person accompanying them.
- Q: Compliance with the exercise program will be self-report? A: Yes, some of it.
- Q: Participants will differ in how long they have been off their drugs of abuse? A: Yes, this would vary, but there has always been a minimum of a 10-day "black out" period from drugs.
- Q: They will be just walking, not engaging in a more elaborate exercise program, as might be suggested by the letter from San Luis Sports Therapy? A: Yes, just walking, although the participating physical therapist will advise about the initial level of walking for each participant.
- C: You should add a confidentiality statement for anyone who will have access to data containing personal identifiers? A: OK.
- C: We also need to know when the data will be destroyed. A: OK.
- Q: What is the phone number that you are providing as contact? A: It's my home phone.
- C: We would suggest using a temporal cell phone number as contact.
- Q: Are you interested in using information about whether or not the person is taking antidepressants or other drugs in your analysis? A: Probably should look at this. The center has information and participants could self-report as well. I could access data on when they start/stop.
- Q: Who does the blood pressures? A: I will. It's an automated cuff.

- Q: The regular center treatment includes strolls. Those will continue? A: Yes, I'm interesting in the aerobic part.
- C: There is a lot of published research on exercise in connection with drug rehabilitation.
- Q: All participants will take the depression inventory? A: Yes. Pre- and post-.
- Q: Participants will be walking 30 minutes, four times per week. Is that enough for an effect? A: That appears to be the minimum acceptable in the existing literature.
- C: The consent form should include something about possible risks, e.g., twisting an ankle.
A: OK.

The investigators were excused and deliberations followed in executive session.

There was a motion for conditional approval of **Protocol 05-73**. [Meares moved, Mellon seconded, approved 8-0]. The investigators returned and were informed of the decision of the Board. The conditions were as follows:

1. Clarify the investigator's responsibility for reportable offenses in the protocol and consent form.
2. Train the staff person supervising the walks in the protocol, and individual levels of walking specified, and add a confidentiality sign-off.
3. Indicate, if the data will be destroyed, when that would be.
4. Add a statement to the consent form describing possible risks.
5. Add an affirmation statement to the consent form, that "I have completed the 'PAR-Q' exercise screening questionnaire.

f. Protocol Renewals

Renewal of Protocol 03-03 "Department of Psychology Participant Pool" with Steve Bacon.

This completes the second year of operation since IRB/HSR approved the pool in June 2003. Each student in Psyc 100 is required to earn six units of participation, equal to 1.5 hours, which accounts for 5% of the course grade. This can be via being a research participant, an alternative activity, or a combination of the two. The process is running smoothly with no complaints. This application is to request a renewal for one year. Questions followed.

- Q: This seems to be working fine? A: Yes and six faculty contributed research projects this year, or about ½ of the department faculty.
- Q: Do all students who want to get to participate? A: Yes. There is a set of projects available at the beginning of the term and more become available during the term.
- Q: Students can look for what appeals to them? A: Yes, although choices may be reduced at the very end of the term. Also, a student can always choose the alternative activity.
- Q: Can you give an example of an alternative assignment? A: The student would find an article in the popular press on a psychology-related topic and critique the article using knowledge from the course.

Q: If they don't earn any units, then they get 0% credit? A: Yes. but about 75% choose to complete the assignment, which is better than other, small percentage assignments, from his experience.

Q: So students who don't earn the credit have *chosen* not to do so? A: Correct.

The investigator was excused and deliberations followed in executive session.

There was a motion for approval of renewal of **Protocol 03-03**. [Mellon moved, Carlisle seconded, unanimously approved]. The investigator returned and was informed of the decision of the Board.

OTHER CONCERNS:

Incident in MSW Course. The IRB Chair and RERC presented a memo [09 June 2005] summarizing a recent incident in which protocols were submitted to the IRB that described [in future tense] activities that had already taken place. It should be noted that data collection involving human subjects does not require IRB authorization if use is limited to satisfying a course assignment. The students were all enrolled in SW 630 [Advanced Research Methods in Social Work] taught by Dr. Debra Morrison-Orton. The instructor argued that this had occurred because of confusion on the students' part, who were to submit the protocols to her, although the submitted protocols had been signed by her. The RERC visited the class to explore further and conduct an IRB orientation. The instructor was unable to attend that class meeting; the SW Chair filled in. The students reported that they were not confused and had been instructed to submit protocols to the IRB and carry out focus groups without regard to the disposition of the IRB submissions. The IRB Chair and RERC met with the instructor and SW Chair. The instructor reiterated her position and presented the course syllabus. The syllabus did not clearly support either the students' or instructor's position. It was concluded that this incident did not constitute an attempt to circumvent the IRB and that it would not be investigated further, although the incident will be reported in the annual report to the Provost on IRB activities.

NEXT MEETING:

Friday, 30 September 2005 – location to be announced

ADJOURNMENT:

There being no further business, the meeting was adjourned at 11:15 AM.

[Mellon moved, McCleary seconded, approved 8-0]

BOARD TRAINING: Cancelled because of length of the meeting. **Protection of Human Subjects in Online Research** will be conducted after the September 2005 IRB meeting.

Respectfully submitted

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