

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

**Minutes of Meeting
Friday, 23 April 2004
Cafeteria Conference 101**

Members Present:

Scientific Concerns: Kaye Bragg, Marianne Abramson, Peggy Leapley
Nonscientific Concerns: Bob Carlisle, Paul Newberry,
Community Issues: Anne Marie Duquette, Patrick Mellon, Carolyn Wade-Southard

Members Absent:

J.J. Wang

Visitors:

Judy Pedro and Candace Meares for Protocol 04-50 Review,
Joan Digges for Protocol 04-54 Clarification

CALL TO ORDER:

Chair Paul Newberry called the meeting to order at 8:01 AM.

PREVIOUS MINUTES:

Mellon moved and Wade-Southard seconded, a motion to approve the minutes for the IRB/HSR meeting of Friday, 30 January 2004. The motion was approved unanimously.

ANNOUNCEMENTS:

The Annual Report to the Provost, appended to the agenda, was noted.

The RERC noted that online materials had been revised, notably via the addition of several new documents: (a) the HIPAA guidance for CSUB researchers and (b) the materials for submitted protocols requesting third-party access to data with waiver of consent.

It was noted that a major compliance case was looming and would be taken up after the meeting.

It was announced that an additional protocol, 04-54, that is not on the agenda, would be considered later in the meeting.

OLD BUSINESS: [none]

NEW BUSINESS:

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

Standard Review (conditionally approved at January 2004 meeting)

1. **Protocol 04-05** (Luciano/Sumaya, Psychology) "Sleep Disturbances in Relation to Antipsychotic Treatment in Schizophrenic Patients": 3rd Party Access to Data [Primary readers were all IRB Members] on 11 February 2004.
2. **Protocol 02-05** (Hemphill/Nyberg, ARC) "Renewal of 'Evaluation for First 5 California' and extension to the Counties of Fresno, Inyo, and Tulare" [Primary readers were all IRB Members] on 08 February 2004.

[Wade-Southard moved, Abramson seconded, unanimously approved]

Expedited Review

1. **Protocol 04-01** (Tanya Boone, Psychology) "Sexuality Messages and Sexual Attitudes" [Bragg, Wang] on 25 January 2004.
2. **Protocol 03-83** (Dorothy Tullmann, Nursing) "Identifying Health Care Needs of Low-Income Older Adults" [Abramson, Wang] on 26 January 2004.
3. **Protocol 04-03** (Alison Burrowes, Sociology Student) "Understanding Substance Abuser Counselors in Recovery" [Abramson, Carlisle] on 03 March 2004.
4. **Protocol 04-42** (Elizabeth Alomari, Nursing Student) "What Do Parents of Obese or Overweight Children Know about Risk and Prevention of Diabetes Mellitus Type 2" [Bragg, Newberry] on 14 April 2004.

[Duquette moved, Mellon seconded, unanimously approved]

Exempted from Full Review

1. **Protocol 04-02** (Cheryl Smith, English Department) "Analytical Thinking in a College Composition Class" on 20 January 2004.
2. **Protocol 04-08** (Joshua D. Bradley, Extended University MSA Program) "Management and Evaluation of a Steam Injection Soil Remediation Pilot Project" on 26 January 2004.
3. **Protocol 03-09** (Joy Henderson, Teacher Education) "Teaching Performance Assessment Field Review" 27 January 2004.
4. **Protocol 04-06** (Lino Banuelos, MSW Student) "What Factors Have Led to the Lack of Adolescent Substance Abuse Programs in Kern County?" on 01 February 2004.
5. **Protocol 03-20** (Denise Placencia-Romero, PPA Student) "The Success Rate and Retention Level of CSU, Bakersfield EOP Students" on 02 February 2004.
6. **Protocol 04-07** (Elena Gonzalez, MSW Student) "How Does Parental Communication Influence an Adolescent's Decision to Engage in Sexual Activity?" on 04 February 2004.
7. **Protocol 04-13** (Guillermo Garcia, PPA Student) "What are the Tangible Impacts of the Public vs. Private Approach to Prison Management?" on 06 February 2004.
8. **Protocol 04-22** (Adam Alvidrez, PPA Student) "MPA--Culminating Project" on 08 February 2004.
9. **Protocol 04-23** (Lorraine Mona DeSantiago, PPA Student) "Recruiting and Retaining New Registered Nurse Graduates in Bakersfield" on 08 February 2004.
10. **Protocol 04-24** (Angela Davis, Sociology Student/CSUB-AV) "The Attributes of a Racist: A Re-Examination of Stereotypes That Have Been Attributed to the Bigot" on 08 February 2004.
11. **Protocol 04-21** (Valerie Robinson, PPA Student) "The Impact of Diversity Training--A Diversity Audit in the Public Sector" on 09 February 2004.
12. **Protocol 04-20** (Lisa E. Martin, PPA Student) "Department of Social Work Graduate Program Admissions Criteria" on 08 February 2004.
13. **Protocol 04-25** (Lidia Perez Albiar, PPA Student) "Evaluating the City of Bakersfield's Injury and Illness Prevention Program" on 09 February 2004.

14. **Protocol 04-27** (Rose Anna McCleary, Department of Social Work) "Use of a Participatory Action Model in a Graduate Social Work Policy Class" on 09 February 2004.
15. **Protocol 04-15** (Valerie Robinson, PPA Student) "Junior Achievement Program Evaluation--PPA 502 Course" on 11 February 2004.
16. **Protocol 04-14** (Debra Speck, Literacy Education Student) "Teacher Change and the Instruction of Developmental Word Study" on 12 February 2004.
17. **Protocol 04-16** (Jennifer Lupo, PPA Student) "Measuring the Effectiveness of an Athletic Training Program" on 18 February 2004.
18. **Protocol 04-10** (Elena Acosta, PPA Student) "Patient Satisfaction Survey for Clinica Sierra Vista" on 20 February 2004.
19. **Protocol 04-35** (Frank A. Herrera, PPA Student) "Evaluating the McFarland Family Resource Center" on 01 March 2004.
20. **Protocol 04-18** (Pheap Khuth, PPA Student) "How Does the Kern County Aging and Adult Services Promote the Availability of Its Programs?" on 02 March 2004.
21. **Protocol 04-04** (Denise M. Long, PPA Student) "Patient Advocate Representation in Kern County" on 08 March 2004.
22. **Protocol 04-31** (Tom See, PPA Student) "Strategic Human Resource Management--The Impact on Organizational Effectiveness" on 10 March 2004.
23. **Protocol 04-37** (Emily Darling, Psychology Student) "Job Analysis of the Undergraduate Teaching Assistant Position" on 11 March 2004.
24. **Protocol 04-28** (Chris Mausolff, Department of Public Policy and Administration) "Emotional Intelligence Training for Counseling Students" on 11 March 2004.
25. **Protocol 04-40** (Candace Meares, Department of Nursing) "More Diversity in Generic BSN-Prepared RNs" on 18 March 2004.
26. **Protocol 04-39** (Emerson Case, English Department) "An Ethnographic Study of International Students' Participation in Group Projects/Presentations" on 24 March 2004.
27. **Protocol 04-29** (Erik Thompson, Mathematics Student) "Master's Research Project on Parental Involvement" on 29 March 2004.
28. **Protocol 04-41** (Maritza Orozco, Nursing Student) "Culturally Competent Care: Perceptions of Mexican American Patients" on 29 March 2004.
29. **Protocol 04-26** (Brad Plymire, PPA Student) "Eliminating Barriers to Effective Correctional Education at the CCI" on 04 April 2004.
30. **Protocol 04-33** (Kathleen L. Gilchrist, Department of Nursing) "Beyond Chocolate . . . Lived Experiences of Senior Baccalaureate Nursing Students" on 08 April 2004.
31. **Protocol 04-34** (Marcia Tyler-Evans, Department of Nursing) "Recruitment Decision Making for Military Nursing Careers" on 12 April 2004.
32. **Protocol 04-45** (Leonel Frias, PPA Student) "The Effectiveness of AVID" on 12 April 2004.
33. **Protocol 04-46** (Joshua Padilla, Psychology Student) "Need for Closure and Social Identity Complexity: Increasing Outgroup Tolerance" on 12 April 2004.
34. **Protocol 04-51** (Phillip Inman, PPA Student) "Local Government Accounting and Management Information Systems Offshore Outsourcing" on 12 April 2004.
35. **Protocol 04-53** (Debra Morrison-Orton, MSW Department) "Student Reaction to Impaired Social Work Students" on 12 April 2004.

[Leapley moved, Bragg 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 January 2004 meeting.

The content of 04-12 was discussed with respect to the criteria for "not within IRB/HSR purview.

1. **Protocol 04-12** (Bruce Hartsell, MSW Department) "Department of Human Services Record Review" on 06 February 2004.

[Mellon moved, Abramson seconded, unanimously approved]

Formal Board affirmation of previously approved protocols granted extensions since the January 2004 meeting.

1. **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 01 April 2004.
2. **Protocol 03-14** (Robert Snoddy, PPA Student) "Smart Growth Planning Methods of Rural Kern County" on 06 February 2004.
3. **Protocol 03-24** (Carol Raupp, Department of Psychology) "Replication of a Survey with Varying Wording ['Pets' vs. 'Companion Animals']" on 04 February 2004.
4. **Protocol 03-26** (Anne Duran, Department of Psychology) "Central Trait Effects in Partially Versus Hierarchically Restrictive Traits" on 07 April 2004.
5. **Protocol 03-29** (Maurice Randall, PPA Student) "Should the City of Bakersfield Continue to Privatize or Contract Out its Water System" 26 February 2004.
6. **Protocol 03-48** (Steve Bacon, Psychology Department) "College Norms for the Scale of Functional Ability Ratings [SOFAR]" on 08 April 2004.

[Carlisle 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 01-52** (John Valdez, Sociology Graduate Student) "The Influence of Cyberspace, Society, and the Internet" end of May 2004.
2. **Protocol 02-18** (Don Diboll, Department of Physical Education & Kinesiology) "Cardiovascular and Metabolic Responses of Endurance-Trained Cyclists to Carbohydrate Consumption During Rest and Moderate-Intensity Exercise" end of April 2004.
3. **Protocol 02-50** (R. Steven Daniels, Dept of Public Policy and Administration) "Agency Merger and Organizational Transformation in the Department of Homeland Security" end of May 2004.
4. **Protocol 03-36** (Mehmet Serdar Ercan, PPA Student) "The Applicability of the Presidential in Turkey as an alternative to Parliamentary System in Terms of the Maintenance of Political Stability" end of April 2004.
5. **Protocol 03-37** (Cynthia Alipio, Sociology Student) , "Mental Health Treatment: Is There a Difference Between Race, Ethnicity, and Culture?" end of April 2004.
6. **Protocol 03-38** (Andre L.Taylor, PPA Student) "What is the Economic Benefit of Restoring In-Stream Flow to the Kern River Parkway" end of April 2004.
7. **Protocol 03-40** (Jewelle Scales, PPA Student) "The Impact of Organizational Culture On Ethical Climates Within Public Organizations" end of April 2004.

8. **Protocol 03-41** (Oliver J. Droppers V, PPA Student) "Kern County Environmental Health Department & Local Body Art Industry Evaluation" end of April 2004.
9. **Protocol 03-42** (Oliver J. Droppers V, PPA Student) "Kern County's Emergency Service System" end of April 2004.
10. **Protocol 03-43** (Sherry Core, ARC) "NASA Dryden Flight Research Center [DFRC]--Research Grant NAG4-200" end of April 2004.
11. **Protocol 03-45** (Janet Zaldua, Public Policy and Administration Student) "The Impact of Parent Involvement on Student Success: How Educators Can Implement Partnerships with Parents to Meet the Needs of Hispanic Students" end of May 2004.
12. **Protocol 03-46** (Ken Trone, PPA Student) "New Residential Development's Responsibility to Fund Cost of New Local Parks" end of Spring Quarter 2004.

[Abramson moved, Mellon seconded, unanimously approved]

Protocol Reviews:

1. **Protocol 04-50 [Attachment C]:** "Barriers and Facilitators to Seeking Healthcare: Perceptions of Hispanic Women" with Judy Pedro & Candace Meares, Nursing. Primary readers are Bragg, Duquette, Newberry. Principal Investigator interview scheduled from 8:30 - 9:00.

Following a round of introductions, Pedro, a public health nurse, summarized the proposal. She works with many low SES Hispanic women and wondered if their healthcare could be improved by finding out more about their perceptions of their own healthcare and possible barriers to good care. Useful info would then be shared with health care providers. Questions followed.

- Q: How long will the data be kept? A: Data will be collected across a three-month period and then kept for one year.
- Q: Your first contact with participants will be both oral and written? A: Correct. This is the major reason for having a translator, because the investigator does not consider her Spanish to be adequate.
- Q: Since some of the data collection is written, does this mean that non-readers would be excluded? A: Yes, but it could be possible to read the survey materials aloud to participants who could not read.
- Q: You would lose migrant workers, because many do not read A: True, some do and some don't.
- Q: Are you aware of the Greater Bakersfield Legal Assistance health information project? You could get some useful information from them.
- Q: Where will the interviews be conducted? A: At locations selected by the participants for their convenience and where they would be most comfortable.
- Q: Participants will be self-selected by responding to your posted flyers? A: Yes, and other public health nurses will be asked to mention the study during their visits at other locations.
- Q: You are using your home phone as a contact, but this is a problem re confidentiality. Do you have a cell phone that you could use? A: Yes.

- Q: It seems possibly dangerous for you to be visiting whatever locations are selected by participants? A: As a public health nurse, I visit private homes regularly and many other locations that are not necessarily desirable.
- Q: Would it be possible for you to specify the locations of the interviews to the participants? A: Probably not, because that would cause transportation problems.
- Q: You state that you will be collecting data from 10 to 20 participants. Could you state a specific number of participants? And, what do you mean by "data saturation?" A: I'll collect data from additional participants until I stop getting new information.
- Q: You'll be keeping people for three hours? A: No, the first interview is just one hour. It is possible that they could be contacted again for additional information within the call-back period stated in the protocol.
- Q: Where do you work? A: Wasco.
- Q: Are you assuming that all of the participants will have MediCal re referrals in case of adverse reactions? A: No, there will be a variety of circumstances, but there are referral resources [on a list] to cover all possibilities.
- Q: You should have two copies of each consent form and the participant will keep a copy. Also would need to alter language in the consent form to reflect that A: Yes, will do.
- Q: How will you assess the reading comprehension level of prospective participants? A: Non-readers will usually hand back materials if they cannot read it.
- Q: Could you speak to the purpose of your study with respect to the somewhat vulnerable subject population? A: Yes, they are vulnerable. The purpose of this study is to possibly improve the health care of this population.
- Q: You will be giving the information to providers. Could you elaborate? A: This should help providers give better health care by sharing information about possible barriers related to culture, beliefs, and language.
- Q: How will the information gathered in your study get to the providers. A: Via publication and distribution to health care staffers. Also could be shared with some of the many community people that she interacts with via her work.
- Q: The reading level among some lower SES Hispanics might be fairly low. You should simplify the language of the written materials, including the consent form. A: Will do.
- Q: Have you looked at existing literature on this topic? A: Yes, at published qualitative studies, as well as local information and reports.
- Q: Note the the Greater Bakersfield Legal Assistance project has a lot of information about this problem.
- Q: The data monitoring provisions are stated in the consent form, but should be added to the protocol itself. A: Will do.

Q: Will you be involving participants from beyond the Tehachapi's? A: Maybe.

The investigators were excused and more discussion followed.

There was a motion for conditional approval of the protocol. [Wade-Southard moved, Duquette seconded, unanimously approved]. The investigators returned and were informed of the decision of the Board. The conditions were as follows:

1. Change the phone contact info to your cell phone in consent form and flyer.
2. Simplify the language in all materials to be read by participants.
3. Read the consent form and survey aloud to participants.
4. Use a bilingual and biliterate interpreter.
5. On consent form, change wording to "keep a copy" of the form and state that only the investigator and assistant can associate data with personal identifiers.
6. In the protocol itself, state the data monitoring procedures to be used.
7. Revise protocol to eliminate reading literacy as a condition of participation.
8. Correct several clerical errors on the flyer.

2. **Protocol 04-54** "Leadership Academy' for Public Residents" with Joan Digges. [Protocol under expedited review brought to the IRB meeting for supplemental review.]

Following a round of introductions, Digges summarized the proposal. The Leadership Academy Project is already underway and is a training program local public residents designed to enhance their ability to communicate and negotiate with local community elements. Meetings are being videotaped, as suggested by officers of the Bakersfield Homeless Task Force at a retreat. These tapes are being used, with permission of the persons taped, as teaching aides in Social Work classes. This proposal is to be able to use the videotapes for research purposes by possibly presenting some of the content at professional meetings. Questions followed.

Q: This is about using the videotapes in scholarship? A: Yes, the purpose is to reach a wider audience and national conferences.

Q: Once the tapes have been edited are there any protections in place for the participants? A: Wishes of the participants will be respected throughout. Will ask each individual the next day and do any requested editing/deleting of material. Also members from the group would be included in any presentations.

Q: How many people are involved? A: There are six officers of the organization. The idea is that they, in turn, will train others.

Q: Won't there be possible peer pressure if someone decides not to consent for use of the videotape? A: The consent results will be kept confidential.

Q: There could be some risk involved in showing the videotapes broadly? How will you deal with the long range risks? A: She will obtain consent in whatever fashion is required by the IRB, including additional, later consents for future uses.

- Q: Would it lessen the effectiveness of the videotapes if faces were blurred out? A: Probably would. She would only do that at the request of the participants.
- Q: Is there a stable membership of this organization? A: Yes, it is fairly fixed and involves a tight social network.
- Q: Some persons don't like to acknowledge earlier problems in their lives, for example alcoholism. How would you deal with this re later uses of the videotapes? A: Will only show the material with consent of all; would get future consent for each future use if the IRB required this.
- Q: Will these be individual or group videotapes? A: They will be all in the group setting at meetings.
- Q: They will experience no pressure about losing services with respect to the consent process? A: No.
- Q: The protocol also mentions other photos, interviews, and videotapes. What are we approving? A: There are really two projects included here--the taping of meetings and then also material from street interviews/images to round out the context.
- Q: The meeting tapes are presently being used? A: Yes, by participants who make classroom visits in CSUB courses.
- Q: Please explain about the Leadership Skills Assessment Inventory [LSAI]. This isn't clear in the protocol. A: It has been administered already. The proposal is to gain access to these results and to administer it post-training for a pre/post comparison.
- Q: Was consent obtained for the earlier administration of the LSAI? A: No.

The investigators were excused and more discussion followed.

There was a motion for conditional approval of the protocol. [Mellon moved, Leapley seconded, unanimously approved]. The investigators returned and were informed of the decision of the Board. The conditions were as follows:

1. Authorization is limited to the Leadership Academy meetings.
2. In the first overall consent form: explain the use of the LSAI, that there are no direct benefits of the videotaping itself, and provide a mechanism for participants to reserve the right to view videotapes or waive their right to do so.
3. Add a confidential, post-session consent form, to be administered the day after each taped session. Include consent to have the tape edited, a notice that the participant can revoke his consent at any time afterward, and do not disclose the outcome of the consent process to participants.
4. Have participants place each set of post-session consent forms in a sealed envelope with the results to be viewed by a faculty colleague and announced to you without divulging identities of persons who do and do not consent.

OTHER CONCERNS:

None

NEXT MEETING:

Friday, 11 June 2004, 8 AM – meeting room to be announced

ADJOURNMENT:

There being no further business, the meeting was adjourned at 10:30 AM.

Following the meeting there was a one-hour IRB/HSR training session dealing with noncompliance issues.

Respectfully submitted

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