

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

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**Minutes of Meeting  
Friday, 13 June 2003  
OLD PUB in the RUNNER CAFE**

**Members Present:**

Scientific Concerns: Kaye Bragg  
Nonscientific Concerns: Bob Carlisle, Paul Newberry, J.J. Wang  
Community Issues: Ann Marie Duquette, Carolyn Wade

**Members Absent:**

Marianne Abramson, Peggy Leapley

**Visitors Present:**

Cherilyn Haworth and Debra Morrison-Orton for Protocol 03-44

**CALL TO ORDER:**

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

**PREVIOUS MINUTES:**

Wang moved and Duquette seconded, a motion to approve the minutes for the IRB/HSR meeting of 31 January 2003. The motion was approved unanimously.

**ANNOUNCEMENTS:** [none]

**OLD BUSINESS:** [none]

**NEW BUSINESS:**

**Formal Board affirmation** of protocols previously approved under standard, exempted, and expedited review since the January 2003 meeting.

**Standard Review** (approved conditionally at January 2003 meeting)

1. **Protocol 03-03** [Steve Bacon, Psychology] "Establishment of a Participant Pool for the Department of Psychology" on 04 February 2003. [Bragg, Depner, Wang]

[Bragg moved, Wang seconded, unanimously approved]

**Expedited Review**

1. **Protocol 03-30** (Scott Clare, Garces High School) "Anxiety, Ocular Dominance, and Hitting the Baseball" on 02 April 2003. [Leapley, Newberry]

[Duquette moved, Bragg seconded, unanimously approved]

## Exempted Review

1. **Protocol 03-05** (Janet Zaldua, PPA Student) "An Assessment of the Current Application Process Used by Recipients to Request funding from The Kern County United Way and Recommendations for its Simplification" on 14 February 2003.
2. **Protocol 03-06** (Jarrett Fischer, PPA Student) "CSUB Career Beginnings' Effect on the Employability of Program Clients" on 07 February 2003.
3. **Protocol 03-07** (Jarrett Fischer, PPA Student) "A Study of the Management & Operational Productivity of the CSUB Career Beginnings Program" on 29 January 2003.
4. **Protocol 03-08** (Amy Zachary, Nursing Student) "Perceptions of Rural Nurse Practitioners: The Experience of Providing Primary Care" on 27 January 2003.
5. **Protocol 03-10** (Carla Tucker, PPA Student) "An Evaluation of the Intensive English Language Center's Service Delivery Options" on 28 January 2003.
6. **Protocol 03-11** (Jason R. Hade, PPA Student) "Analyzing the Benefits of Smart Growth in Metropolitan Bakersfield" on 30 January 2003.
7. **Protocol 03-12** (Ron Pimental, Management & Marketing) "Influences on Generation Y as Consumers" on 30 January 2003.
8. **Protocol 03-13** (Anthony Nuno, Modern Languages) "Recovery of Oral Histories and Traditions of Mexican-Americans/Latinos in Kern County" on 11 February 2003.
9. **Protocol 03-14** (Robert M. Snoddy, PPA Student) "Smart Growth Planning Methods of Rural Kern County" on 07 February 2003.
10. **Protocol 03-15** (Candice Banducci, Nursing Student) "The Perceptions of Newly Graduated Nurses Between Their First and Second year of Acute Care Nursing" on 07 February 2003.
11. **Protocol 03-17** (Robyne Wheelock) "A Program Evaluation of DARE: Is It Helping or Hurting America's Kids" on 18 February 2003.
12. **Protocol 03-18** (Rebecca Jamison, PPA Student) "Developing a Quality Customer Service Excellence Program in City Government" on 19 February 2003.
13. **Protocol 03-19** (Thuy D. Nguyen, PPA Student) "How To Establish a Private Practice in Today's Market" on 20 February 2003.
14. **Protocol 03-21** (Linda G. Robinson, PPA Student) "Shifting the Responsibility: Analysis of the Impact of Welfare Reform on the Non-Profit Sector in Kern County" on 10 March 2003.
15. **Protocol 03-22** (Michelle Mills, PPA Student) "A Program Evaluation of the California Children and Families First Act 1998" on 28 February 2003.
16. **Protocol 03-23** (Nancy Hairfield, Marketing Student) "Student Awareness About the Availability of Campus News/Event Information" on 03 March 2003.

17. **Protocol 03-24** (Carol Raupp, Psychology) "Replication of a Survey with Varying Wording ['Pets' vs. 'Companion Animals']" on 28 February 2003.
18. **Protocol 03-25** (Michelle Villar, PPA Student) "Genetic Discrimination in the Workplace" on 28 February 2003.
19. **Protocol 03-26** (Anne Duran, Psychology) "Central Trait Effects in Partially Versus Hierarchically Restrictive Traits" on 12 May 2003.
20. **Protocol 03-27** (Laura Soria, PPA Student) "Best Practices for Downsizing within Kern County Agencies" on 06 March 2003.
21. **Protocol 03-28** (Julie De Petro) "Exploring the Health Promotion Practices of Type II Diabetics" on 13 March 2003.
22. **Protocol 03-29** (Maurice Randall, PPA Student) "Should the City of Bakersfield Continue to Privatize or Contract Out its Water System" on 13 March 2003.
23. **Protocol 03-32** (Margarette Marie Rhamie, Nursing Student) "A Comparison of African-American Seventh-Day Adventists with African-American Church Members of Non-Seventh-Day Adventist Churches for Compliance with Hypertension Medical Regimens" on 02 April 2003.
24. **Protocol 03-33** (Tiamoyo Peterson, Psychology Student) "Social Dominance Orientation as Related to the Preference for Familiarity" on 15 April 2003.
25. **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" on 02 May 2003.
26. **Protocol 03-37** (Cynthia Alipio, Sociology Student) "Mental health Treatment: Is There a Difference Between Race, Ethnicity, and Culture?" on 02 May 2003.
27. **Protocol 03-38** (Andre L. Taylor, PPA Student) "What is the Economic Benefit of Restoring In-Stream Flow to the Kern River Parkway?" on 09 May 2003.
28. **Protocol 03-40** (Jewelle Scales, PPA Student) "The Impact of Organizational Culture On Ethical Climates Within Public Organizations" on 20 May 2003.
29. **Protocol 03-41** (Oliver J. Droppers V, PPA Student) "Kern County Environmental Health Department & Local Body Art Industry Evaluation" on 20 May 2003.
30. **Protocol 03-42** (Oliver J. Droppers V, PPA Student) "Kern County Environmental Health Department & Local Body Art Industry Evaluation" on 23 May 2003.
31. **Protocol 03-43** (Sherry Core, ARC) "NASA Dryden Flight Research Center [DFRC]--Research Grant NAG4-200" on 19 May 2003.

[Bragg moved, Carlisle 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 2003 meeting.

1. **Protocol 03-16** (Laura Hecht, ARC) "SACPA Reporting Information System [SRIS] Validation Study" on 20 May 2003.
2. **Protocol 03-31** (Edward Nelson, ARC Research Scientist) "Survey of Families Receiving Services from Proposition 10 Providers" on 14 March 2003.
3. **Protocol 03-35** (Candace Meares, Nursing) "Promise of Nursing" on 02 May 2003.
4. **Protocol 03-39** (Eun-Ja Park, Special Education) "Outcomes Assessment for Special Education Programs" on 09 May 2003.

[Wang moved, Carlisle seconded, unanimously approved]

**Formal Board affirmation** of previously approved protocols granted extensions since the January 2003 meeting.

1. **Protocol 01-50** (Marcia Tyler, Nursing) Needs Assessment of Forensic Nursing Skills in Central Valley California Region" on 06 February 2003.
2. **Protocol 02-18** (Don Diboll, Physical Education & Kinesiology) "Cardiovascular and Metabolic Responses of Endurance-Trained Cyclists to Carbohydrate Consumption During Rest and Moderate-Intensity Exercise" on 14 May 2003.
3. **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 15 April 2003.

[Duquette moved, Bragg seconded, unanimously approved]

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

1. **Protocol 02-23** (Thomas Allen, Psychology Student) "Men's Attitudes Toward Women: An Integrated Threat Theory Analysis" end of June 2003.
2. **Protocol 02-28** (Joan Digges, MSW) "Urbanishment of the Homeless" end of April 2003.
3. **Protocol 02-29** (Samasoni Aunai, PPA Student) "Program Analysis: Student Academic Performance Through Advancement Via Individual Determination (AVID)" end of April 2003.
4. **Protocol 02-30** (Phillip Patterson, Special Education) "Content and Levels of Satisfaction for Early Childhood Special Education Programs" end of April 2003.
5. **Protocol 02-31** (Hajir Nuriddin, PPA Student) "A Comprehensive Project Plan Addressing Racial Profiling" end of April 2003.
6. **Protocol 02-36** (Michael T. Brown, UC-Santa Barbara) "Differential Status Identity" end of April 2003.

7. **Protocol 02-37** (Brad Antonioni, PPA Student) "Culminating Project for the MPA Program" end of April 2003.
8. **Protocol 02-38** (Brooke Antonioni, PPA Student) "Culminating Project for the MPA Program" end of April 2003.
9. **Protocol 02-39** (Anne Duran, Psychology) "The Cognitive Organization of Beliefs about Behaviors" end of April 2003.
11. **Protocol 02-40** (Shelly Casteneda, PPA Student) "Use of Deadly Force by the Kern County Sheriff's Department" end of May 2003.
12. **Protocol 02-41** (Amendeep Gill, PPA Student) "Maintaining Maximum Funds: A Guide for Outpatient Mental Health" end of April 2003.
13. **Protocol 02-42** (Dan Wilson, MSW Student) "Risk Factors Related to Extended Hospitalization at End of Life" end of April 2003.
14. **Protocol 02-43** (Gwendolun Hall-Ross, PPA Student) "How Has California State University, Bakersfield Implemented Section 504 of the Rehabilitation Act of 1973" end of April 2003.
15. **Protocol 02-45** (Anne Duran, Psychology) "Changes in Attitudes Toward Outgroup Members" end of August 2003.
16. **Protocol 02-47** (Patricia Moland, PPA Student) "The Use of Educational Benefits by CSUB Employees" end of April 2003.
17. **Protocol 02-50** (R. Steven Daniels, PPA) "Agency Merger and Organizational Transformation in the Department of Homeland Security" end of June 2003.
18. **Protocol 02-51** (Anne Duran, Psychology) "The Cognitive Organization of Beliefs About Behaviors II" end of July 2003.
19. **Protocol 02-52** (Mike Stepanovich, PPA Student) "MPA Culminating Project: Philanthropic Benefits to CSU and CSUB by Creation of CSU Advancement Division" end of July 2003.
20. **Protocol 02-53** (Yeunjoo Lee, Special Education) "The Use of Assistive Technology in Classrooms and Teachers' Satisfaction with Their Training Programs" end of August 2003.
21. **Protocol 02-54** (Don Diboll) "Comparison of Three Body Composition Assessment Techniques in Division I Collegiate Wrestlers" end of July 2003.
22. **Protocol 02-56** (Christopher Mausolff, PPA) "The Impact of Emotional Intelligence Training on Team Performance" end of August 2003.
23. **Protocol 02-57** (Roseanna McCleary, MSW) "Post-BSW/MSW Education Experiences of Japanese Social Workers Educated in the US" end of July 2003.

[Bragg moved, Carlisle seconded, unanimously approved]

## Protocol Reviews:

1. **Protocol 03-44 [Attachment B]:** "A Study of the Factors Related to the Family Reunification Process for Female Parolees" with Cherilyn R. Haworth, Psychology Student. Primary readers are Bragg, Carlisle, Wade. Principal Investigator interview scheduled from 8:30 - 9:15.

Following a round of introductions, Haworth summarized the proposal. As a student intern with Department of Human Services, she has noticed that it seems more difficult for female offenders to "reunify" with their children following the 1997 Adoption and Safe Families Act [ASFA]. Are there Kern County practices which help/hinder this process. What are the perceptions of mothers involved in these situations. Her research would look at all of these.

- Q: How will you recruit your subjects? A: They will be given info via parole officers and agencies and the subjects would initiate contact by phone.
- Q: Are there any facilities in which mothers would have their children with them? A: Thought not. [An IRB member pointed out at least one in the Bakersfield area.]
- Q: How many subjects will you have? A: The goal is 10 pre-ASFA and 10 post-ASFA. [IRB members commented that this was probably not enough subjects to answer the many questions posed in the rationale for this research.]
- Q: Please explain a little about the ASFA. A: Mothers having problems used to get extensions of time for successful reunification. Now, the period is strictly 6 months total up to 3 years of age for the children.
- Q: What would stop reunification? A: Failing a drug test, not having a job or place to live.
- Q: These weren't factors previously? A: Yes, but extensions would be given.
- Q: What factors will you look at that might influence reunification? A: Things such as types of programs, services provided, parole services, community reintegration.
- Q: Is there a general profile of the women who will be involved? A: They will be diverse, but tend toward less educated.
- Q: Will subjects be English only? A: Yes, or bilingual. Their language needs to be such that we can interact successfully.
- Q: Is there anything on ethnicity X reunification? A: Not aware of any research, although African-Americans are over-represented in this subject population.
- Q: This appears to be a vulnerable population. How will you deal with this so it is not unduly threatening or coercive? A: Subjects will initiate contact and will understand that their responses will not influence their parole status or the reunification process. A waiver of reporting requirement for suspected parole violation is being sought.
- Q: How will you deal with diminished capacity associated with possible mental illness or substance use? A: Subjects will be excused from participation if their state makes them too vulnerable.

- Q: How the the revised consent form differ from the consent form that IRB members read? A: [A revised consent form was now distributed to IRB members.] The language is simpler, there are clearer statements on non-participation and confidentiality procedures.
- Q: How will you obtain consent? The consent form seems extremely lengthy. A: Will go over the entire consent form with subjects and discuss/explain it.
- Q: What if you cannot get the parole violation reporting waiver? A: Will have to modify the consent form.
- Q: How long with the records be kept? A: [A general discussion followed involving possible agency requirements and ethical/legal conflicts.] A: A memo of understanding will be created so that any intermediaries will not attempt to learn which clients participate in this research.
- Q: What if participants get upset by certain questions? A: Would stop prior to asking the more sensitive questions which are located near the end of the session.
- Q: In what setting will the interviews take place? A: In an informal setting, such as a park, or possibly in a visitation room. The subject will be able to choose. [It was suggested that indoor interviews be conducted behind closed doors.]
- Q: Are the numbers really adequate for looking at pre-/post- ASFA and successful/unsuccesful reunification effects? A: Shooting for 20, could adjust [the implication was *downward*, however].
- Q: Would you include as subjects, mothers who are in the process of reunification?  
A: Yes.
- Q: Now you have at least 5 groupings of subjects. Do you have enough? A: It is a preliminary study.
- Q: What if you decide that your sample really is too small or prospective participants don't call you? A: Would revise procedures and re-submit to the IRB.

The investigator was excused and more discussion followed. There was a consensus that there was little chance that the research could actually answer the stated questions of interest due to the small number of subjects, but the risks to subjects was also minimal, if implemented according to the conditions stated below. It was decided to conditionally approve the protocol.

[Bragg moved, Carlisle seconded, unanimously approved]

The conditions were explained to the investigator:

1. The language in the revised consent form needs to be simplified further, to about 8th grade reading level.
2. The interview must be conducted in a confidential setting.
3. The waiver of parole violation reporting requirement must be obtained.
4. A prominent statement must be added to the consent form stated the requirement of the interviewer to report certain offenses.

5. IRB approval of the content of the interview must be obtained. The file copy of the written survey must be provided.

It was explained to the investigator that the research could go forth when the conditions have been satisfied.

**CSUB Draft HIPAA Documents [Attachment C]:**

The RERC provided an overview of HIPAA, the role of HIPAA in research, and the role of the IRB with respect to HIPAA requirements. Situations were discussed in which HIPAA would and would not apply, and how the requirements would be implemented. Two documents were approved: [a] "Use the Personal Health Information and the Health Insurance Portability and Accountability Act [HIPAA]: Guidance for CSUB Researchers" and [b] "Requests to the CSUB IRB/HSR for Waiver of Authorization for Use/Disclosure of Information for Research Purposes: 'Third-Party Access to Data.'" Approval of procedures as on a "trial basis."

[Duquette moved, Wade seconded, unanimously approved]

**OTHER CONCERNS:** [none]

**NEXT MEETING:**

Friday, 03 October 2003 - Stockdale Room ("Old Pub"), 7:30 a.m. - Breakfast  
8:00 a.m. - Meeting

**ADJOURNMENT:**

There being no further business, the meeting was adjourned at 10:13 AM.

[xxx moved, xxx seconded, approved unanimously]

IRB member training for this meeting was HIPAA orientation associated with the New Business item, "CSUB Draft HIPAA Documents."

Respectfully submitted

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