

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

**Minutes of Meeting
Friday, 11 June 2004
Cafeteria Conference 101**

Members Present:

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

Members Absent:

Peggy Leapley

Visitors:

Cheryl Lirette for Protocol 04-88 Review,
Deyanira Gonzalez and Roseanna McCleary for Protocol 04-90 Review,
Steve Bacon for Protocol 03-03 Renewal,
Ken Nyberg for Protocol 02-05 Quarterly Report

CALL TO ORDER:

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

PREVIOUS MINUTES:

Duquette moved and Mellon seconded, a motion to approve the minutes for the IRB/HSR meeting of Friday, 13 April 2004. The motion was approved unanimously.

ANNOUNCEMENTS:

The RERC noted that the GS&R procedural manual was being revised in response to EO 890 from the CSU Chancellor's Office. The IRB section has been made more user friendly and linked to the online materials.

The Chair and RERC provided an interim report on compliance incidents. Most of the theses and projects in the School of Education have been approved. Most, but not all, of the students will graduate without incident. Still, some faculty signed off on human subject theses for which there was no IRB authorization. They were returned by the Dean. The following language was adopted by consensus:

"The IRB recommends that Masters students be allowed to register for thesis/project units only after their committee has approved a proposal. For theses/projects involving human subjects, proposal approval should be contingent on inclusion of the IRB authorization letter. There should be a line on the thesis/project tracking form indicating whether the activity is human subjects research. A copy of the IRB authorization letter should be attached to the final written product and verification that the letter is present should be a required step in the final sign-off procedure for thesis/project completion."

It was suggested that this language be forwarded with an offer from the IRB to help with adoption, dissemination, implementation, and monitoring. Lon Kellenberger [Interim Dean, School of Education] and Maria Delgado [Graduate Evaluator, School of Education] should be thanked by the IRB for their good work in dealing with this difficult situation.

OLD BUSINESS: [none]

NEW BUSINESS:

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

Standard Review (conditionally approved at April 2004 meeting)

1. **Protocol 04-50** (Judy Pedro & Candace Meares, Nursing) "Barriers and Facilitators to Seeking Healthcare: Perceptions of Hispanic Women" (Primary readers were Bragg, Duquette, Newberry) on 28 May 2004.

[Abramson moved, Duquette seconded, approved unanimously]

Expedited Review

1. **Protocol 04-44** (Maryam Allahyar, Psychology) "Perception of Targets using Multiple and Single High Resolution Displays" [Abramson, Carlisle] on 16 April 2004.
2. **Protocol 04-47** (Tanya Boone, Psychology) "Sources of Sexuality Messages: In-Depth Interviews" [Carlisle, Leapley] on 27 April 2004.
3. **Protocol 04-49** (Maryam Allahyar, Psychology) "Psychological Issues Related to Virtual Environment Training" [Bragg, Wang] on 05 May 2004.
4. **Protocol 04-54** (Joan Digges, MSW) "'Leadership Academy' for Public Residents." [Abramson, Carlisle; supplemental review at the April 2004 IRB meeting] on 28 April 2004.
5. **Protocol 04-61** (Cameron Bolles, PE & Kinesiology Student) "Effects of Muscular Fatigue Due to Resistance Training on Proprioceptive Position Sense" [Abramson, Carlisle] on 04 May 2004.

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

Exempted from Full Review

1. **Protocol 04-32** (Jewelle Scales, PPA Student) "The Effects of Ethical Climate Type On the Quality of Work Life for Employees in Public Organizations" on 24 May 2004.
2. **Protocol 04-48** (Ronald Radney, Assistant Director of Financial Aid) "Recruitment Decision Making for Military Nursing Careers" on 16 April 2004.
3. **Protocol 04-55** (Arabella Ancheta, PPA Student) "RN Internship Program: A Program Evaluation" 28 April 2004.
4. **Protocol 04-56** (Florentino Robles, Nursing Student) "Knowledge and Effectiveness of Patient Education Among Hispanic Americans with Diabetes" on 26 April 2004.
5. **Protocol 04-57** (Chanrasme K. Chea, PPA Student) "Impact Evaluation of EOP Program" on 17 April 2004.
6. **Protocol 04-58** (Janet Doucette, PPA Student) "Should Public Funds be Allocated to Faith-Based Nonprofit Organizations?" on 20 April 2004.
7. **Protocol 04-59** (Long Le, Political Science) "E-Survey of Vietnamese Student Associations' Members" on 21 April 2004.
8. **Protocol 04-63** (Gloria Duarte-Smith, Advanced Educational Studies Student) "The Effectiveness of Migrant Education on Reading Achievement" on 17 May 2004.
9. **Protocol 04-64** (Felisa Patino-Guadarrama, Bilingual/Bicultural Education Student) "An Examination of English Language Arts and Mathematics Scores of Dual Immersion Students and Mainstream Students in 5th Grade" on 05 May 2004.

10. **Protocol 04-65** (Lorine Vasquez, PPA Student) "The Effectiveness of an After School Program" on 25 May 2004.
11. **Protocol 04-66** (Jong Choi, MSW Program) "Acculturation Stress and Social Support Among Korean and Indian Immigrant" on 11 May 2004.
12. **Protocol 04-67** (Leah Sanchez, Advanced Educational Studies Student) "Hispanic Parent Involvement and Academic Achievement" on 10 May 2004.
13. **Protocol 04-68** (Daniel Velez, Bilingual Education Student) "Causal Factors of High Hispanic Dropout Rates" on 11 May 2004.
14. **Protocol 04-69** (Ben Keller, Advanced Educational Studies Student) "The Relationship Between Achievement and Spanish Literacy Amongst High School ELL's" on 10 May 2004.
15. **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" on 10 May 2004.
16. **Protocol 04-71** (Eric Bullard, PPA Student) "Development of an Administrative Manual: A project with Extended University" on 12 May 2004.
17. **Protocol 04-72** (Rebecca Flores, Advanced Educational Studies Student) "CLAD Training Competency As Perceived By Teachers" on 17 May 2004.
18. **Protocol 04-75** (Erin George, Education Student) "The Effect of Phonological Awareness Instruction on Kindergarten and 1st Grade Achievement" on 14 May 2004.
19. **Protocol 04-77** (Rose Foley, Advanced Educational Studies Student) "Implementing Strategies for Sight Word Acquisition for Second Language Learners" on 27 May 2004.
20. **Protocol 04-78** (Rosa Sanchez, Advanced Educational Studies Student) "Teachers' Knowledge, Skills, and Attitudes Regarding Culturally and Linguistically Diverse Students" on 17 May 2004.
21. **Protocol 04-79** (Lorenzo S. Cruz, Jr., Advanced Educational Studies Student) "The Effect of Grade Levelling" on 24 May 2004.
22. **Protocol 04-80** (Penelope Swenson, Advanced Educational Studies) "Handheld Computer Use Among K-12 Administrators and Teachers" on 25 May 2004.
23. **Protocol 04-81** (Stephanie Kirkwood, Sociology Student) "A Study of Double Consciousness By Way of Identity Consciousness" on 20 May 2004.
24. **Protocol 04-82** (Curriculum and Instruction Student) "Social Promotion vs. Retention in Elementary Schools" on 24 May 2004.
25. **Protocol 04-83** (Randy Arie, Special Education Student) "Help for South High Special Ed Students Who Struggle with Social Skills" on 19 May 2004.
26. **Protocol 04-84** (LeAnn Griffin, Education: Literacy Student) "An Analysis of Reading First As an Effective Teacher Preparation Program" on 24 May 2004.
27. **Protocol 04-85** (Shiree Kelly, Education Student) "The Influence of Socioeconomic Status on Student Academic Achievement" on 24 May 2004.
28. **Protocol 04-86** (Danny Osborne, Psychology Student) "The Integrated Threat Theory and Political Affiliation" on 25 May 2004.

[Wang moved, Bragg seconded, approved unanimously]

- 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 April 2004 meeting.

1. **Protocol 04-60** (Dan Rosen, PPA Student) "Effects of Environmental Regulation on Local Economies" on 21 April 2004.
2. **Protocol 04-76** (Phillip Herriott, PPA Student) "Proposition 13: A Policy Analysis" on 14 May 2004.

[Abramson moved, Mellon seconded, approved unanimously]

c. Formal Board affirmation of previously approved protocols granted **extensions** since the April 2004 meeting.

1. **Protocol 01-52** (John Valdez, Sociology Student) "The Influence of Cyberspace, Society, and the Internet" on 01 June 2004.

[Duquette moved, Mellon seconded, approved unanimously]

d. Formal Board action closing protocols (unless extension requested) whose authorization has ended or will end prior to the September 2004 IRB meeting.

[none]

Protocol Reviews:

1. **Protocol 04-87 [withdrawn]**
2. **Protocol 04-88 [Attachment D]:** "How Do Teen Mothers Decide to Have Children and What Are Their Experiences?" with Cherlyn Raquel Lirette & Debra Morrison-Orton, MSW. Primary readers are Bragg, Carlisle, Wade-Southard. Principal Investigator interview scheduled from 8:30 - 9:00.

Following a round of introductions, Lirette summarized the proposal. She wants to do a qualitative study of teen mothers to find out why they have children. She will be working through an Adolescent Family Life Program run by Clinica Sierra Vista in downtown Bakersfield. Questions followed.

- Q: Could you describe the program? A: It's voluntary and includes teaching about parenting skills, help with gaining education [a GED], and budget skills.
- Q: All of the persons in the program are mothers? A: Yes and they are in the program voluntarily.
- Q: Are there any emancipated minors in the program, because they could sign their own consents? A: Don't know if there are. [Agreed to find out.]
- Q: Please clarify the purpose of the study. Teenage pregnancy has been studied a lot. What don't we know? A: Some previous research suggests that teens get pregnant on purpose. If so, this would lead to ideas about prevention and perhaps emotional support.
- Q: Why aren't you asking any questions about history of sexual molestation and possible incest in the pregnancy. That's fairly common? Basically, I was in a hurry and didn't have time. Also, it seemed like a touchy subject and might pose a risk.
- Q: Is this just a description study to see if they got pregnant on purpose, or are you interested in why they got pregnant on purpose? A: This is mainly just descriptive.
- Q: You have a possible role as a mandated reporter if participants start talking about molestation or incest. How will you deal with this? A: Don't know. C: You need a strategy to deal with this Be very clear about your mandated reporter requirements in relation to information about the age of the father and relationship to the mother.

- Q: Has there possibly already been screening about molestation and incest dole in connection with admission to the program? A: Don't know, but I will find out.
- Q: Could you possibly deal with some of these issues by pre-screening your participants? A: Will find out. C: Seems like special selection might seriously bias your sample; even your requirement for English speaking may do that.
- Q: You indicate that you will read the consent form to the potential participants. Some of the vocabulary is way too advanced and needs to be simplified A: I will do that.
- Q: Where is the parental consent form? A: I will create that and submit it. I was not sure that I would need to get parental consent.
- Q: What is the contact phone number that you list? A: It's my cell phone. Q: It goes only to you? A: Yes.
- Q: Were will you keep the data and how will you lock it up? A: I will figure that out and specify it in the protocol. C: Also think through how long you want to keep the data and state that.
- Q: Where will you do the interviews in order to ensure confidentiality? A: I'll interview in a private room at the clinic.
- Q: How will you get the guardian consent?: A: It was suggested that I could do that by sending the consent form home with the participant, but I will do that as a home visit.
- Q: You're not collecting any demographics? A: Yes, I will collect demographic information. I didn't have time to include that, but I will add that to the protocol.
- Q: Depending upon age, the questions might be in different directions. You need to state boundaries and range of disclosure in the consent form. A: [She agrees to this.]
- Q: Are there girls in the program who are pregnant, but not mothers? A: Yes.
- Q: However, you won't be studying them? A: Correct, only mothers.
- Q: Some of the questions don't seem very relevant. A: These are lead in questions to help establish rapport.
- Q: In the case of emotional distress or other problems you need a standard packet of referral information for mental health services. A: [She agrees to this.]

The investigator was excused and more discussion followed. There was a consensus that she had not arrived at specifics regarding many aspects of the study. There were so many areas that needed clarification that the board decided to request revision and re-submission for standard review at the Fall meeting. The RERC was directed to prepare a summary guidance document to give to the student and faculty mentor, listing specific areas of concern. The student returned to the room and was so informed.

3. **Protocol 04-90 [Attachment E]:** "The Role of Companion Animals in the Human Dying Process" with Deyanira Gonzalez & Roseanna McCleary, MSW. Primary readers are Duquette, Leapley, Wang. Principal Investigator interview scheduled from 9:00 - 9:30.

Following a round of introductions, Gonzalez summarized the proposal. She wants to carry out interviews in a hospice setting with terminally ill patients about their pets. She works in this setting and suspects there is an important patient X pet relationship from her own informal observations. Questions followed.

- Q: This is quite a vulnerable population. How are they judged to be terminally ill? A: They have to be medically diagnosed as such to be in hospice.
- Q: Once accepted into hospice is death imminent? A: It really varies and can go as long as six months, but the average length of stay in the hospice program is two weeks.
- Q: What kinds of hospice patients would be eligible? A: The patients would need to be able to participate and to give consent. Patients who are actively dying would not participate.
- Q: Also, they couldn't be on too much medication, right? A: Yes, they would need to be clear enough to participate.
- Q: Are these patients involved in some kind of special pet therapy program? A: No, these are just their own pets.
- Q: How will you deal with distress that arises in the patient with respect to what will happen to their pet when they die? A: They typically have already dealt with that. That is a specific part of the social work assessment plan at admission.
- Q: Is there any research on longevity and pets? A: Not aware of anything, but there is lots of research dealing with well-being.
- Q: Will you be doing your own transcriptions of the audio recordings? A: Yes, faculty mentor requires that.
- Q: Where will the locked cabinet be for data storage? A: It will be at home.
- C: Some of the language needs to be simplified on the consent form, particularly in describing the questions. A: [She agrees.]
- Q: Will you be collecting demographic information? A: Yes, I will add that to the protocol.
- Q: Why will you only interview English-speaking patients? A: Actually I can do interviews in either English or Spanish.
- C: You will need a consent form in Spanish. A: I will provide that.
- Q: Why will you be doing two or three data collection sessions? That seems like a lot. A: It's to get all of the information collected. The sessions have to be fairly brief because the patients tire easily.
- Q: What findings are you actually looking for? Do you have a guess? A: Not really. [The faculty advisor hopes this is true, consistent with the rationale of qualitative research.]

The investigators were excused and more discussion followed.

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

1. Simply the language of the consent form.
2. Specify the demographic data to be collected.
3. Supply a consent form in Spanish.
4. Specify in the protocol that the data will be stored at home under lock and key.

Request for Renewal

1. **Protocol 03-03 [Attachment F]:** First Year Report: "Psychology Department Subject Pool" with Steve Bacon, Psychology. Principal Investigator interview scheduled from 10:00 – 10:15.

Bacon indicated that the subject pool is working smoothly for both the faculty researchers and the student participants. Initially 8 units of participation were required, but this was revised to 6 and this appears to be working fine. The non-participation level for this 5% of the grade was low in comparison to other comparably weighted components of other courses. There have been no complaints. There were questions:

Q: How do you deal with complaints/concerns? A: Each study using the subject pool has been through the IRB, so there is contact info in the consent form. Also, the subject pool bulletin board has contact info for complaints about the workings of the subject pool itself.

Q: Is there always enough participation available for the students to end up with full credit?
A: Yes, sometimes students combine subject participation with alternative activities to get all of the credit.

The investigator left the room and the renewal was approved.

[Duquette moved, Carlisle seconded, approved unanimously]

2. **Protocol 02-05 [Attachment G]:** Quarterly Report: "First 5 California Program Evaluations" with Brian Hemphill, Applied Research Center. Principal Investigator interview scheduled from 10:15 – 10:30.

Nyberg explained that the quarterly report summarizes the status of data collection, consents, and confidentiality training in the several counties at the various agencies. There were several questions:

Q: For Inyo county agencies, you show data collection, but no consents. Can you explain? A: There are personnel limitations in Inyo. ARC has been going to Inyo to enter the data itself on a laptop. Although ARC sees the identifiers, they are not entered into the database.

Q: The process is to go directly from the paper files to the database in the laptop at the site? A: Yes.

OTHER CONCERNS: IRB policy for "Third Party Access" in data sets without identifiers

Protocol 04-93 ["Acanthosis Nigricans Screening in High School and Elementary School"] was discussed. Some school nurses have collected screening data with parental consent, but not with consent to use the data for research purposes. A Nursing faculty person wishes to report the data in a article, which would be co-authored by the school nurses. What are the principles involved here and how does the IRB wish to proceed? The IRB would not approve use of the data, unless the person seeking IRB authorization really were a "third party." That seems true in this case. Also, the risk needs to be minimal, which generally means lack of personal identifiers, which is the case with this data set. The IRB will generally authorize third party access to existing data without personal identifiers, but would want to go on a case by

case basis with respect to the "third partyness" and the "minimalness" of risk. There was a consensus that this protocol should be approved without further review.

NEXT MEETING:

Friday, 08 October, 2004 – meeting room to be announced

ADJOURNMENT:

There being no further business, the meeting was adjourned at 10:55 AM.

[Carlisle moved, Duquette seconded, approved unanimously]

Following the meeting there was an IRB/HSR training session dealing with compliance monitoring.

Respectfully submitted

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