

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

Minutes of Meeting
Friday, 27 January 2006
[Cafeteria "Old Pub"]

Members Present:

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

Members Absent:

Anne Marie Duquette

Visitors:

Brian Hemphill & Ken Nyberg for Protocol 02-05 Renewal
Val Garcia, Dixie King, & Rosa Ventura for Protocols 03-61 & 03-63 Renewals
Kwaifa Kary Mack for Protocol 06-04 Review
Katrina Rodzon & Anne Duran for Protocol 06-06 Review
Tamara Ritter, Psychology Student

CALL TO ORDER:

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

PREVIOUS MINUTES:

McCleary moved and Abramson seconded a motion to approve the minutes for the IRB/HSR meeting of Friday, 30 September 2005. The motion was approved 7-0.

ANNOUNCEMENTS: [none]

OLD and NEW BUSINESS: Esteemed IRB member, Yeunjoo Lee, is expecting a baby.

NEW BUSINESS:

- a. **Formal Board affirmation** of protocols previously approved under standard, expedited, and exempted review since the September 2005 meeting.

Standard Review (conditionally approved at the September 2005 meeting)

1. **Protocol 05-90.** (Crystal Freeman, Marianne Abramson, & Isabel Sumaya, Psychology) "Eveningness and Morning Cognition" [Carlisle, Duquette, McCleary] on 09 October 2005.

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

Expedited Review (approved since the September 2005 meeting)

1. **Protocol 05-83.** (Roseanna McCleary, MSW) "Adult System of Care Model Development for Central California" [Carlisle, Newberry] on 29 September 2005.

2. **Protocol 05-88.** (Billie Jo Rice, Psychology) "The Effects of Stereotype Threat on Prejudice" [Lee, McCleary] on 03 October 2005.
3. **Protocol 05-89.** (Jared Chapman, Psychology) "Cognitive Load and Reading Comprehension" [Abramson, Newberry] on 11 October 2005.
4. **Protocol 05-93.** (Kelly Maurice, Psychology-AV) "Cognitive Abilities and the Speaker" [McCleary, Carlisle] on 13 November 2005.
5. **Protocol 05-104.** (John Glover, Psychology-AV) "Analysis of the Impact of the Valley Oasis Program on the Self-Esteem of Its Clients" [Meares, Newberry] on 12 December 2005.
6. **Protocol 05-106.** (Janelle Goh, MSW) "The Experience of Foster Parents in Helping Foster Youth Be Successful in High School" [Lee, Meares] on 06 December 2005.

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

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

1. **Protocol 05-80** (Laura Redic, Touro International University) "The Relationship between Two Test Accommodation Strategies and the Test-Taking Process for Limited English Proficient [LEP] Hispanic Nursing Students" on 21 November 2005.

[For **Protocol 05-80** it was explained that Touro is a private university in the Los Angeles area.]
2. **Protocol 05-86** (Linda Jeffries, Mathematics Student) "Learning for Understanding: Can Multiple Representations using Context-Based (Temperature and Direction) Manipulatives Improve Student Understanding Of the Rules For Adding and Subtracting Integers?" on 19 September 2005.
3. **Protocol 05-87** (Mi Y. Kang, Special Education) "Korean Immigrants' Knowledge of Special Education and Disability" 30 September 2005.
4. **Protocol 05-91** (LaShawn Barefield, Counseling Center) "Alcohol Needs Assessment: Utilizing the CORE Survey" on 09 October 2005.
5. **Protocol 05-92** (Terri Kurz, Department of Teacher Education) "Video Case Analysis" on 04 October 2005.
6. **Protocol 05-94** (Jianyu "Eugene" Wang, PE and Kinesiology) "Performance Patterns and Competency of Basketball Game Play Among Regular Basketball Participants" on 19 October 2005.
7. **Protocol 05-95** (Robin Shirer, Sociology Student) "Care Decisions and Social Networks Among Low-Income Parents" on 30 September 2005.
8. **Protocol 05-98** (Collete Moon, Education Student) "Research on Questioning in the Classroom for Teacher Professional Growth" on 17 October 2005.
9. **Protocol 05-99** (Michael Harville, Counseling Center) "Evaluation of Counseling Center Services" on 11 October 2005.
10. **Protocol 05-101** (Anne Duran, Psychology) "Defining Tolerance and Acceptance" on 25 October 2005.
11. **Protocol 05-102** (Debra Cook Hirai, Education) "CALLI (Content Academic Language Literacy Instruction)" 28 October 2005.
12. **Protocol 05-103** (R. Steven Daniels, Public Policy and Administration) "Transformation Interrupted: The Renewal, Decline (and Rebirth?) of the Federal Emergency Management Agency" on 28 October 2005.
13. **Protocol 05-108** (Stacy Sweeney, Education Student) "The Effects of Direct Writing Instruction Using Various Genres on Second Grade Students" on 06 December 2005.
14. **Protocol 05-109** (BreAnne Maltone, Education Student) "The Effects of an Incentive Program on Reading Attitudes of Fifth Graders" on 04 January 2006.

15. **Protocol 05-110** (Terri Kurz, Education) "Family Math Night Rep Grids" on 03 January 2006.
16. **Protocol 05-111** (Kathy Gardner, Education Student) "Efficacy of Oral Reading Fluency Development on Reading Comprehension of Middle School Students" on 12 December 2005.
17. **Protocol 05-112** (Sandra Scott, Education Student) "The Effects of a Comprehensive Reading Program on the Reading Achievement of Struggling Seventh Grade Students" on 09 December 2005.
18. **Protocol 05-113** (Kate James, Education Student) "Using Self-Evaluation in a Kindergarten Writing Class" on 09 January 2006.

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

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 June 2005 meeting. (none)

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

1. **Protocol 03-80** (Marie Farrell, Nursing) "Exploring and Developing a Nursing Department's Community of Interest: A Replication Study" on 12 December 2005.
2. **Protocol 04-05** (Isabel Sumaya, Psychology) "Sleep Disturbances in Relation to Antipsychotic Treatment in Schizophrenic Patients" on 04 January 2006.
3. **Protocol 05-12** (Gary Mojica, Education Student) "Teaching Spanish Reading Comparing/Contrasting Instruction" on 27 December 2005.
4. **Protocol 05-23** (Penelope Swenson, Advanced Education) "A Study of Online Discussion and Course Engagement" on 06 December 2005.
5. **Protocol 05-36** (Ron Pimentel, Management and Marketing) "Maintaining Fad Products Between Fads" on 06 December 2005.
6. **Protocol 05-38** (Gail Nelson, Sociology Student) "Non-Traditional Female College Students: Great Expectations" on 02 January 2006.
7. **Protocol 05-46** (Debra Cook Hirai, Advanced Education) "Are We Closing the Gap for Reading Comprehension and Decoding for 9-12 Students?" on 25 January 2006.

[There were no modifications for any of the renewals. Wade-Southard arrived.]

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

d. Formal Board action closing protocols (unless extension granted) whose authorization will end prior to the April 2006 IRB 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," end of March 2006.
2. **Protocol 03-26** (Anne Duran, Psychology) "Central Trait Effects in Partially Versus Hierarchically Restrictive Traits" end of March 2006.
3. **Protocol 04-10** (Jaime Santos Alas, PPA Student) "Patient Satisfaction Survey" end of February 2006.
4. **Protocol 04-27** (Rose Anna McCleary, MSW) "Use of a Participatory Action Model in a Graduate Social Work Class" end of January 2006.
5. **Protocol 04-28** (Chris Mausolff, PPA) "Emotional Intelligence Training for Counseling Students" end of February 2006.

6. **Protocol 04-29** (Erik Thompson, Mathematics Student) "Master's Research Project on Parental Involvement" end of March 2006.
7. **Protocol 04-39** (Emerson Case, English) "An Ethnographic Study of International Students' Participation in Group Projects/Group Presentations" end of February 2006.
8. **Protocol 04-44** (Maryam Allahyar, Psychology-AV) "Perception of Targets Using Multiple and Single High Resolution Displays" end of February 2006.
9. **Protocol 04-49** (Maryam Allahyar, Psychology-AV) "Psychological Issues Related to Virtual Environment Training" end of February 2006.
10. **Protocol 04-52** (Penelope Swenson, Advanced Education) "Response to the Constructivist Learning Environment in Foundations of American Education" end of February 2006.
11. **Protocol 04-78** (Rosa Sanchez, Education Student) "Teachers' Knowledge, Skills, and Attitudes Regarding Culturally and Linguistically Diverse Students" end of March 2006.
12. **Protocol 04-80** (Penelope Swenson, Advanced Education) "Handheld Computer Use Among K-12 Administrators and Teachers" end of March 2006.
13. **Protocol 04-93** (Cherie Rector, Nursing) "Acanthosis Nigricans Screening in High School and Elementary School" end of February 2006.
14. **Protocol 04-101** (Alejandra Perez, Biology) "Effect Size of Microbiology Manual on the C- Student in Bio 260" end of January 2006.
15. **Protocol 05-02** (Yeunjo Lee, Special Education) "Teacher Efficacy of Special Education Teachers" end of December 2005.
16. **Protocol 05-03** (Trisha Bjerneby-Ward, Nursing Student) "Stress and Coping Mechanisms among BSN Student Nurses" end of January 2006.
17. **Protocol 05-04** (Debra Martin, Education Student) "Explicitly Teaching Content Area Reading to Three Spanish-Speaking Middle School Students with Learning Disabilities: Case Studies" end of December 2005.
18. **Protocol 05-05** (John W. Ayers, Political Science Student) "Student Attitudes on Bilingual Education in Kern County" end of February 2006.
19. **Protocol 05-06** (Joan Canfield, Information Resources) "Study of Students and Information Technology" end of December 2005.
20. **Protocol 05-07** (Veronica Duran, Nursing Student) "The Experience of Language Barriers among Limited English Proficiency Hispanics during Hospitalization" end of January 2006.
21. **Protocol 05-08** (Corina Anema, Nursing Student) "Nursing as a Career Choice: Adolescents' Perceptions" end of January 2006.
22. **Protocol 05-09** (David Cherin, Grants, Research, & Sponsored Programs) "Evaluation of Kern County Aging and Adult Services Department Survey of Adult and Aging Populations 2004" end of January 2006.
23. **Protocol 05-10** (Lidia Albiar, PPA Student) "Collocated One-Stop for Non-Custodial Parents" end of January 2006.
24. **Protocol 05-11** (Diego Ocampo, PPA Student) "Teacher Efficacy of Special Education Teachers" end of January 2006.
25. **Protocol 05-13** (Erlinda Mulvaney, Nursing Student) "The Challenge Providing Care for the Developmentally Disabled: A Qualitative Study" end of January 2006.
26. **Protocol 05-14** (Anne Duran, Psychology) "Social Psychology Learning Activity" end of February 2006.
27. **Protocol 05-15** (Candace Grantham, Education Student) "Portfolio Assessment in Literacy: Meeting the Standards" end of February 2006.

28. **Protocol 05-16** (Trina Priddy, Education Student) "Explicitly Teaching Content Area Reading to Three Spanish-Speaking Middle School Students with Learning Disabilities: Case Studies" end of January 2006.
29. **Protocol 05-17** (Flame McFerrin, Psychology Student) "Short-Term and Delayed Recall" end of January 2006.
30. **Protocol 05-18** (Sheryl Metheney, Psychology Student) "The Differential Ratings of Married Women's Competence" end of January 2006.
31. **Protocol 05-19** (Jason C. Hillis, PPA Student) "JAILink" end of January 2006.
32. **Protocol 05-21** (Deborah Maddox, Nursing Student) "Migrant Health Fair Outreach Health Fair: A Program Evaluation" end of February 2006.
33. **Protocol 05-22** (Mike Roper, Nursing Student) "A Description of the Use and Constraints for Holistic Practice by Family Nurse" end of February 2006.
34. **Protocol 05-24** (Yeunjoo Lee, Special Education) "Assistive Technology Perceptions of Caregivers of School Aged Children with Disabilities" end of March 2006.
35. **Protocol 05-26** (Barbara Minor, PPA Student) "Curbside Recycling in Bakersfield: Why is Participation in the Trash?" end of February 2006.
36. **Protocol 05-27** (Dima Mouradi, MSW Student) "What Is the Impact of 9/11 On the Arab American Community in California?" end of February 2006.
37. **Protocol 05-28** (Veronica Rethi, Advanced Education Student) "Action Research" end of February 2006.
38. **Protocol 05-29** (Anne Duran & Jordan Rude, Psychology) "Tolerance and Acceptance" end of February 2006.
39. **Protocol 05-30** (Madhavapallil Thomas & Jong Choi, MSW) "Predictive Factors of Acculturation Among Asian Immigrants" end of February 2006.
40. **Protocol 05-31** (Paula Howard, Education Student) "Vocabulary Program Review" end of February 2006.
41. **Protocol 05-32** (Michael Caniff, Advanced Education Student) "Art and Math" end of February 2006.
42. **Protocol 05-35** (Ron Pimentel, Management and Marketing) "Consumer Use of Message Boards" end of March 2006.
43. **Protocol 05-37** (Valerie M-Reyes, Nursing Student) "Experiences of Correctional Nurses: Why They Are Able to Continue Working in a Prison Setting" end of March 2006.
44. **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" end of March 2006.
45. **Protocol 05-40** (Christopher Mausolff, Public Policy & Administration) "The Impact of Learning Style on Students' Experiences with Community Service Learning" end of March 2006.
46. **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" end of March 2006.
47. **Protocol 05-42** (Chris Mausolff, Public Policy & Administration) "The Impact of Learning Styles on Students' Experiences with Experiential Exercises" end of March 2006.
48. **Protocol 05-43** (Misty Stowers, PPA Student) "Three strikes Legislation in California: An Interrupted Time-Series Analysis" end of March 2006.
49. **Protocol 05-44** (Penelope Swenson, Advanced Education) "SWOT, Delphi, and Strategic Planning" end of March 2006.

50. **Protocol 05-45** (Richard S. Carley, Psychology Student) "Mo' Better Velten: A Comparison of Card and computer Versions of the VMIP" end of March 2006.
51. **Protocol 05-47** (Roseanna McCleary, MSW Program) "Evaluation: TALK Model: Using Analogy to Communicate End of Life Concepts" end of March 2006.
52. **Protocol 05-48** (Kelly Bock, PPA Student) "Recommendations for Mutually Beneficial FMLA Procedure" end of March 2006.
53. **Protocol 05-50** (Ron Pimentel, Management and Marketing) "Enhancing Sales Education with Sales Competitions" end of March 2006.

[The IRB Chair lacked copies of closure letters for six of the above; it was verified that these had been sent closures and copies would be provided to the Chair.]

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

e. Protocol Renewals Requiring Re-Review

1. **Protocol 02-05 [Attachment B]:** "Evaluation of First 5 California" with Brian Hemphill & Ken Nyberg, CSUB Applied Research Center.

Following a round of introductions, Nyberg provided a brief summary. This protocol covers mandated evaluation of First 5 projects designed to help children, funding under Proposition 10. Their activities include data collection, analysis, and required reports. ARC works with a private company, The Corporation for Standards and Outcomes, who does some of the web-based data collection and forwards that to ARC. Hemphill pointed out that protocol originally covered multiple counties, but now it is limited to Kern County and about 50 active programs. Previously there was much variability in terms of consent procedures and confidentiality training across programs, but this has been standardized over the past year, including revision of a new consent form which is now widely adopted. Data were provided verifying that all programs are in compliance with training, which is now uniform, and consent procedures. The new consent form is sometimes used *in addition* to the unique consent forms used by the agency. Questions followed. [Q = question from IRB, C = comment from IRB, A = answer from investigator]

- Q:** What kind of data do you have? **A:** Some is aggregated with no personal identifiers, some does have personal identifiers and is collected and shared with parental consent. Personal identifiers are never reported. They are careful about security and employ someone described as a "forensic computer expert" for that purpose. The server managing the First 5 data is not connected to the CSUB network.
- Q:** What is the role of the other company? **A:** First 5 has contracted directly with them. The data that they send has personal identifiers, but these are stripped away by ARC personnel.
- Q:** How secure is the data transfer procedure? **A:** The software used enables it to be sent from the agencies in encrypted form to the company.
- Q:** Who is responsible for this? **A:** The company is responsible.
- Q:** The table you've provided indicates that no data are collected for some programs? **A:** Yes, some of these, such as providing playground equipment, don't require outcomes measures.
- Q:** Who does the training? **A:** The training used to be done by ARC personnel, but now it is done by First 5 personnel. In our periodic reports to the IRB, ARC is certifying that the programs have signed off that their personnel have been given the required training.

The training takes place at periodic "contractor gatherings" and we also verify during periodic site visits.

Q: Could you obtain a written agreement describing the training policy? **A:** Yes.

C: The new CSUB prefix needs to be inserted in the consent form. **A:** Will do.

The investigators were excused and deliberations followed in executive session. There was a motion for **conditional renewal** of **Protocol 02-05**. [Mellon moved, Carlisle seconded, approved 8-0]. The investigators returned and were informed of the decision of the Board. The conditions were as follows:

- a. Provide the IRB/HSR with the confidentiality training protocol for 02-05.
 - b. State in writing who is responsible for personnel confidentiality training and specifically what ARC is verifying to the IRB/HSR when training is checked off as completed for a program.
2. **Protocol 03-61:** "GEAR UP: Waiver of Written Consent" with Edwin Sasaki, CSUB, and Rosa Ventura, Transforming Local Communities. All Board Members are Primary Readers.
 3. **Protocol 03-63:** "GEAR UP: Limited Data Set" with Edwin Sasaki, CSUB, and Rosa Ventura, Transforming Local Communities. All Board Members are Primary Readers.

These interrelated protocols were discussed together. Following a round of introductions, GEAR-UP personnel outlined the program. Garcia noted that GEAR UP [Gaining Early Awareness and Readiness for Undergraduate Programs] operates via junior high schools and high schools in Lamont and Arvin, where the students are primarily Mexican-American and disadvantaged, and is designed to increase college attendance and success among this population of students. In its third year, the program provides after school tutoring, mentoring by CSUB students, parent-parent mentoring, and field trips to universities. The first generation has now reached the point of taking standardized tests, which is exciting. Ventura explained that TLC became involved last year and needed to deal with the data from the two previous years, which has been a fairly extensive process where their personnel work in the "GEAR UP Room." New staffers have taken the online CSUB Human Subjects Protection Training [HSPT] tutorial and are working on the data. Some of the data are gathered from students on the school sites and then entered. Changes have been made in how TLC will deal with federal audits and changes in consent forms have been made to alert parents that personal identifiers may be released to auditors.. Questions followed. [Q = question from IRB, C = comment from IRB, A = answer from investigator]

Q: Where do you get the data? **A:** The districts provide some of the data by gathering and compiling it for us and providing it to us. Modes of data transmission vary from file cards to electronic, across schools.

Q: Is the computer holding these data password protected? **A:** Yes, and only persons who are HSPT trained have access. The room housing the computer is locked.

Q: Is the document containing the data password protected? **A:** No, but it's on a computer that requires log in that is situated inside a locked room.

Q: Does any data go back to the schools with personal identifiers on them? **A:** No, the only data that go back are aggregate data.

Q: TLC has access to data with personal identifiers? **A:** Yes, we need to have that, but in the data sets used for analysis, only subject identification numbers are present.

- Q:** Some of the student participants are 14 or 15 years old, which is a difficult age, and they are also disadvantaged and at risk of various problems. Is there any referral system for kids who might need it, for example for mental health, physicians? **A:** We work within whatever the school system guidelines are. GEAR UP has a community counselor of our own, but we refer back to counselors in the schools. Our mentors are instructed to refer back to the schools.
- Q:** How explicit is referral policy in terms of what is within the GEAR UP purview? **A:** Referral policy is spelled out in the packets given to mentors.
- Q:** Is this in writing? **A:** Yes, it is in the packet.
- C:** There was an IRB/HSR-related problem with the audit. **A:** Yes, there are routine, yearly federal audits. The auditors asked for all of the GEAR UP data, including those having personal identifiers, so they could contact randomly selected families and students. TLC said no, because consent had not been obtained for that. Auditors were offered access within the secure room at TLC. That was not acceptable to them. Also, they were surprised that the data were not on campus -- ARC at CSUB had been doing this previously.
- Q:** Can people participate in GEAR-UP without signing off on consent? **A:** No consent is needed for the data at the schools because of FERPA regulations, but consent is needed to provide the other data that GEAR UP collects.
- C:** Some state/federal funded program participants sign an explicit consent form saying auditors can have access to their data, as a condition of funding. **A:** We have added ASSENT as part of the 03-63 protocol, so parents/guardians will agree to this.
- Q:** If the IRB/HSR were not involved in this, would it be an issue? **A:** No, The IRB/HSR element turned this into a big painful issue. TLC takes this extremely seriously in terms of protecting the rights of participants who are involved in research that they conduct. We have stated conditions specifying what data auditors can access and under what conditions.
- Q:** What if the federal auditors disagree? **A:** That would be unpleasant. The TLC and CSUB have different roles in this. Hopefully this will be coordinated through the CSUB office of Grants, Research, and Sponsored Programs in terms of informing the auditors of the conditions and letting us know about impending audits.
- Q:** Do you have any plans to give parents a "heads up" when an audit is impending? **A:** These happen with something like a week or less lead time. That would be difficult.
- Q:** Is it possible to explore or negotiate flexibility or timing in order to make this work better? **A:** Yes, flexibility of timing has to be built into an audit, so we can explore that via the CSUB office of Grants, Research, and Sponsored Programs which is contacted by the feds to initiate an audit.
- Q:** Do the auditors want access to the survey data collected by TLC? **A:** Yes, they want/have access to everything.

The investigators, including ex-officio IRB/HSR member Ed Sasaki, were excused and deliberations followed in executive session. There was a motion for **conditional renewal** of **Protocols 03-61** and **03-63** including the proposed modifications. [Meares moved, Lee

seconded, approved 8-0]. The investigators returned and were informed of the decision of the Board. The conditions were as follows:

- a. The IRB/HSR is strongly supportive of the plan to send an assent notification to parents about release of data to auditors and requires a reminder notice when an audit has been announced, including information that the audit is a routine assessment of the GEAR UP program and is unrelated to how well their child is doing.
- b. Provide a detailed, written description of the referral process, describing GEAR UP policies and instructions of personnel, in the case of mental health, illegal drug, juvenile offenses, and related problems in the GEAR UP students.

f. New Protocol Reviews:

1. **Protocol 06-04:** "Exploration of Pregnant Adolescents' Decisions in Labor Pain Management" with Kwaifa Mary Mack and Candace Meares, Department of Nursing. Primary readers were Abramson, Lee, Mellon.

Following a round of introductions, the PI outlined her proposed research. She has an RN and works with childbirth, especially adolescents, for whom, she believes, childbirth is a special problem. She works at the Family Birthing Center, where this research will be carried out. Pain is a big problem in childbirth, which can lead to several serious complications. Adolescents seem to experience more pain, but there are procedures available to control this pain. There is no research on pain management decisions by adolescents who are giving birth. This research is intended to improve the care of adolescents during childbirth. There will be confidential, taped interviews with 10 - 20 new mothers in private rooms. Questions followed. [Q = question from IRB, C = comment from IRB, A = answer from investigator]

- Q:** So, you think that care for adolescents is less good during childbirth? **A:** Adolescents are less mature.
- Q:** Data suggest that nurses underestimate the pain experienced by adolescents giving birth? **A:** Yes, but this project is intended to build on this knowledge. Kern County has the highest adolescent birthrate in California.
- Q:** Does poor adolescent communication seem to be an issue in the childbirth process for them? **A:** Yes.
- Q:** The participants you want to study seem extremely vulnerable. It's within 24 hours of childbirth, they are teenagers, they may be on pain medication . . . **A:** The pain meds wear off quickly, so they will be lucid. Most are very energized.
- Q:** There will be hospital personnel running in and out of the room, with a lot of things going on. It seems like this could be exhausting to do a one-hour interview. **A:** Could do the interview later if necessary.
- Q:** You don't include death of the child as an exclusionary factor, shouldn't that be in there? **A:** Yes, will add that.
- Q:** Most adolescent births in Kern County involve Mexican-American mothers. The mothers may speak English, but not the parents. **A:** Will develop and use a Spanish consent form.
- Q:** What if the mother is giving up the child for adoption, would that be an exclusionary factor. **A:** This almost never happens at our facility, but this would be an exclusionary factor.

Q: You ask about whether this is the "first pregnancy" but it would be more sensitive to ask whether this is the "first delivery" in case of previous abortions. **A:** Yes, will revise.

Q: Is health insurance related to any of this? **A:** We have lots of Medi-CAL at FBC.

Q: If you collect data later, you might get different results. **A:** Yes, we will consider that.

Q: Do you think there might be direct benefits from your study to your participant group in having having better care and less pain in a future childbirth? **A:** No.

The investigators, including IRB/HSR member Candace Meares, were excused and deliberations followed in executive session. There was a motion for **conditional approval** of **Protocols 06-04**. [Mellon moved, Carlisle seconded, approved 8-0]. The investigators returned and were informed of the decision of the Board. The conditions were as follows:

- a. Modify the data collection timing. Establish rapport in FBC, obtain initial consent after childbirth for those willing. Either access pain scales from chart, with consent, or administer an established pain scale at this time. Interview later, after having re-established informed consent.
 - b. Translate the revised consent form into Spanish and use when appropriate.
 - c. Clarify how the knowledge obtain from this research may benefit adolescents experiencing childbirth. Will there be sharing of information within FBC, locally in some way, more broadly via presentations or publications?
2. **Protocol 06-06:** "Stereotypes of Lesbians" with Katrina Rodzon and Anne Duran, Department of Psychology. Primary readers were Meares, Newberry, Wade-Southard.

Following a round of introductions, the PI outlined her proposed research. Because of time considerations, the PI agreed to proceed directly to questions without presenting an overview of the proposed research. Questions commenced. [Q = question from IRB, C = comment from IRB, A = answer from investigator]

C: On the consent form, you refer to "lab personnel" having access to "the information." This is vague and also suggests that persons conducting the research could connect data and persons. Also, there are several typos on the consent form. It would be more effective if it included headers to organize the material **A:** Will fix.

Q: Where will the data be kept? **A:** Securely in Tanya Boone's lab area.

Q: You say there are no risks, but do you really believe that? **A:** Well, no.

Q: It appears that more than 15-20 minutes, as indicated on the consent form, will be required to provide the data. Is this realistic or do you need to pre-test? **A:** We will run some naïve pilot subjects to determine time requirements.

Q: Why is there so little space to answer? **A:** We want off the top of the head responses without deep reflection, and so don't want to encourage elaboration. Therefore, the small amount of space is intentional.

Q: How many subjects do you intend to run? **A:** Probably around 100.

Q: Will there be a self-selection problem that might limit generalization of your findings? **A:** The consent form doesn't identify the "other groups" that participants will be asked about. Also, we plan to collect data in many kinds of classes, not just psychology.

- Q:** Do you plan to fit this into the extensive existing knowledge base about stereotyping of outgroups? **A:** There is nothing on positive stereotyping of lesbians.
- Q:** Demographics would seem to be very useful such as age, gender, religion, sexual preferences. **A:** Yes, but this is a small, first step to develop a measure which then would be used in future research to look at relationships with such variables.
- C:** There seems to be a confidentiality concern with students sitting side by side filling out these surveys.

The investigators and visitor were excused and deliberations followed in executive session. There was a motion for **conditional approval of Protocols 06-06**. [Mellon moved, Carlisle seconded, approved 8-0]. The investigators returned and were informed of the decision of the Board. The conditions were as follows:

- a. Fix the wording and clerical problems in the consent form: "lab personnel," lack of headers, and several typos.
- b. Provide a concise, but comprehensive and realistic assessment of the risks or costs to the potential participants.
- c. Pre-test the instrument to estimate time requirements. Make consent form consistent with actual time required. Shorten instrument if needed to accommodate the 15-20 minute window.
- d. Ensure anonymity of responses during data collection by spacing out student respondents as needed.

OTHER CONCERNS: (none)

NEXT MEETING:

Friday, 21 April 2006 – location to be announced

ADJOURNMENT:

There being no further business, the meeting was adjourned at 11:56 AM.

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

Respectfully submitted

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