

**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, 28 January 2005**  
**Cafeteria 101**

**Members Present:**

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

**Members Absent:**

Anne Marie Duquette

**Visitors:**

Steve Bacon for Protocol 03-03 Modification,  
Brian Hemphill & Ken Nyberg for Protocol 02-05 Renewal,  
Val Garcia, Laramie Lyda, Rosa Ventura, & Dixie Walker for Protocols 03-61 & 03-63 Renewals,  
Veronica Duran for Protocol 05-07 Review,  
Corina Anema for Protocol 05-08 Review

**CALL TO ORDER:**

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

**PREVIOUS MINUTES:**

Carlisle moved and Abramson seconded, a motion to approve the minutes for the regular IRB/HSR meeting of Friday, 08 October 2004. The motion was approved unanimously.

McCleary moved and Mellon seconded, a motion to approve the revised minutes for the special IRB/HSR meeting of Friday, 15 October 2004 including clerical revisions provided by Meares. The motion was approved unanimously.

**ANNOUNCEMENTS:** [none]

**OLD BUSINESS:** [none]

**NEW BUSINESS:**

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

**Standard Review** (conditionally approved at the regular 08 October 2004 meeting)

1. **Protocol 04-88** (Cherlyn Lirette & Debra Morrison-Orton, MSW) "How Do Teen Mothers Decide to Have Children and What Are Their Experiences" [Bragg, Carlisle, Wade-Southard on 12 November 2004.
2. **Protocol 04-94** (Debra Morrison-Orton & Bruce Hartsell, MSW) "Effectiveness of Motivational Interviewing Training with Proposition 36 Counselors" on 21 October 2004.

3. **Protocol 04-120** (Debra Morrison-Orton & Bruce Hartsell, MSW) "The Impact of Motivational Interviewing on Outcomes with Proposition 36 Clients" [Wade-Southard, Abramson, Newberry] on 21 October 2004.
4. **Protocol 04-124** (Cherie Rector & Kathleen L. Gilchrist, Nursing) "Are You INN? Outcomes of the INN Program Grant" [Duquette, Bragg, Wang] on 11 October 2004.
5. **Protocol 04-126** (Katie Fleming & Anne Duran, Psychology) "Dominance and Deception: Is the Correlation Found in the Self-Oriented Lie?" [Mellon, Leapley, Newberry] on 11 October 2004.

[Lee moved, Meares seconded, approved unanimously]

**Standard Review** (conditionally approved at the special 15 October 2004 meeting)

1. **Protocol 04-123** (Gwendolyn M. Morris & Gigi Nordquist, MSW) "Do Mentoring Programs for Children of Incarcerated Parents Benefit the Children and Their Families" [Mellon, Leapley, Case] on 25 October 2004.
2. **Protocol 04-127** (Brent Egemo & Candace Meares, Nursing) "Support Groups and Coping Behaviors in Women with Breast Cancer" on 18 November 2004.

[Mellon moved, Lee seconded, approved unanimously]

**Expedited Review** (approved since the regular 08 October 2004 meeting)

1. **Protocol 04-119** (Bruce Hartsell, MSW) "Text Analysis of Collaborative Learning Project" [Leapley, Newberry] on 01 October 2004.
2. **Protocol 04-130** (Nancy Haley, TLC) "Measuring Student Opinions: Understanding Academic Integrity and How to Avoid Academic Dishonesty" [Abramson, Wang] on 26 October 2004.
3. **Protocol 04-132** (Diana K. Najera, MSW Student) "Hispanic Fathers' Perceptions about Parenting" [Leapley, Case] on 29 November 2004.
4. **Protocol 04-134** (Zenna Beath, Psychology Student) "If I Know I Am an Imposter Will It Help Me?" [Newberry, Wang] on 19 November 2004.
5. **Protocol 04-135** (Kathy Jo Robb, Nursing Student) "Health Motivation Related to Susceptibility for Osteoporosis Among Older Women" [Bragg, Case] on 22 November 2004.
6. **Protocol 04-138** (Pattie Rhoades, Nursing Student) "Outcomes for an Asthma Education Program Directed at Asthmatic Children and Parents" [Abramson, Case] on 07 December 2004.
7. **Protocol 04-141** (Nancy Bringman, Advanced Educational Studies) "Minority Counseling Students' Experiences of Unearned Privilege" [Abramson, Case] on 10 December 2004.

[Meares moved, Carlisle seconded, approved unanimously]

**Exempted from Full Review** (approved since the regular 08 October 2004 meeting)

1. **Protocol 04-48** (Rodney Radney, Financial Aid) "A Pilot Study Regarding the Kern Educational Partnership's Effect on Teacher-Participants" on 16 April 2004.
2. **Protocol 04-121** (Maryam Allahyar, Department of Psychology) "Social Cognitive Factors Influencing Political Preferences" on 01 October 2004.
3. **Protocol 04-122** (Valsamma Chandy, Nursing Student) "Factors Related to Smokers' Successful Completion of a Smoking Cessation Program" 02 October 2004.
4. **Protocol 04-125** (Tracey Sullivan, Sociology Student) "The Division of Domestic Labor among Working-Class Couples" on 07 October 2004.
5. **Protocol 04-128** (Edwin H. Sasaki, Undergraduate Studies) "Gaining Early Awareness & Readiness for Undergraduate Programs (GEAR-UP)" on 15 October 2004.

6. **Protocol 04-129** (Carolyn Wicks, Psychology Student, Loma Linda University) "Resilience: An Integrative Framework for Measurement" on 25 October 2004.
7. **Protocol 04-131** (Scott Clare, Garces High School) "Social Issues in High School Sports" on 02 November 2004.
8. **Protocol 04-133** (Emile Callahan, PPA Student) "College Education for Emancipated Youth: A Case Study of the Success and Challenges" on 12 November 2004.
9. **Protocol 04-137** (Doina Draghiciu-Apperti, Math Education Student) "Using Teacher Questioning as a Framework for Teacher Change in High School Mathematics" on 01 December 2004.
10. **Protocol 04-140** (Catherine Harvey, Bilingual/Multicultural Ed Student) "Multicultural Education In-Service Training at Taft College" on 14 January 2005.
11. **Protocol 04-142** (Leslie Raney, Education Student) "The Effects of Visualization Strategies to Improve Reading Comprehension Skills" on 28 December 2004.
12. **Protocol 04-143** (Jose Montelongo, Education Student) "An Examination of Fourth Grade English Language Learners' Attitudes Toward Their Native Language" on 09 December 2004.
13. **Protocol 04-144** (Emerson Case, Department of English) "An Ethnographic Study of Cross-Cultural Composition Students' Participation in Writing Center Tutoring" on 28 December 2004.
14. **Protocol 05-02** (Yeunjoon Lee, Department of Special Education) "Teacher Efficacy of Special Education Teachers" on 05 January 2005.
15. **Protocol 05-06** (Joan Canfield, Information Systems) "Study of Students and Information Technology" on 14 January 2005.

[McCleary moved, Abramson 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 regular 08 October 2004 meeting.

[none]

- c. Formal Board affirmation** of previously approved protocols granted renewals since the regular 08 October 2004 meeting.

1. **Protocol 02-48** (Bonita Coyle, PPA Student) "An Examination of the Effects of the Availability of Community Health Services as a Factor in the Incidence and Treatment Expense of Inmates with Psychiatric Diagnoses" on 19 January 2005.
2. **Protocol 02-04** (Anne Duran, Psychology) "Measures of Attitudes Toward Out-group Members" on 28 September 2004.
3. **Protocol 03-26** (Anne Duran, Psychology) "Central Trait Effects in Partially Versus Hierarchically Restrictive Traits" on 31 December 2004.
4. **Protocol 03-59** (Erin C. Martinez, Nursing Student) "A Systematic Extension Replication Study: Informed Decision-Making about Hormone Replacement Therapy Among Postmenopausal Women" on 13 October 2004.
5. **Protocol 03-66** (Emily Darling, Psychology Student) "Affective Experience" on 01 October 2004.
6. **Protocol 03-68** (Corinne Preston, Nursing Student) "Caring for Organ Donation Patients in the ICU Setting—Novice to Expert Study" on 22 October 2004.
7. **Protocol 03-75** (Loida Ruane, MSW Student) "Factors Impacting the Acculturation of Filipino Americans in Kern County" on 13 October 2004.
8. **Protocol 03-80** (Marie Farrell, Department of Nursing) "Exploring and Developing a Nursing Department's Community of Interest: A Replication Study" on 24 November 2004.

9. **Protocol 04-02** (Cheryl Smith, Department of English) "Analytical Thinking in a College Composition Class" on 11 November 2004.
10. **Protocol 04-05** (Luciano/Sumaya, Psychology) "Sleep Disturbances in Relation to Antipsychotic Treatment in Schizophrenic Patients": 3<sup>rd</sup> Party Access to Data [Primary readers were all IRB Members] on 20 January 2005.
11. **Protocol 04-25** (Lidia Perez Albiar, PPA Student) "Evaluating the City of Bakersfield's Injury and Illness Prevention Program" on 28 December 2004.
12. **Protocol 04-27** (Rose Anna McCleary, Department of Social Work) "Use of a Participatory Action Model in a Graduate Social Work Policy Class" end of January 2005.
13. **Protocol 04-28** (Chris Mausolff, PPA) "Emotional Intelligence Training for Counseling Students" on 08 December 2004.
14. **Protocol 04-33** (Kathleen Gilchrist, Department of Nursing) "Beyond Chocolate. . . Lived Experiences of Senior Baccalaureate Nursing Students" on 29 November 2004.

[Mellon moved, McCleary seconded, approved unanimously]

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

1. **Protocol 03-12** (Ron Pimentel, Department of Management and Marketing) "Influences on Generation Y as Consumers," end of November 2005.
2. **Protocol 03-14** (Robert Snoddy, PPA Student) "Smart Growth Planning Methods in Rural Kern County" end of January 2005.
3. **Protocol 03-24** (Carol Raupp, Psychology) "Replication of a Survey with Varying Wording ['Pets' vs. 'Companion Animals']" end of February 2005.
4. **Protocol 03-29** (Maurice Randall, PPA Student) "Should the City of Bakersfield Continue to Privatize or Contract Out Its Water System?" end of February 2005.
5. **Protocol 03-83** (Dorothy Tullmann, Nursing) "Identifying Health Care Needs of Low-Income Older Adults" [Abramson, Wang] end of January 2005.
6. **Protocol 04-03** (Alison Burrowes, Sociology Student) "Understanding Substance Abuser Counselors in Recovery" end of February 2005.
7. **Protocol 04-04** (Denise M. Long, PPA Student) "Patient Advocate Representation in Kern County" end of February 2005.
8. **Protocol 04-06** (Lino Banuelos, MSW Student) "What Factors Have Led to the Lack of Adolescent Substance Abuse Programs in Kern County?" end of January 2005.
9. **Protocol 04-07** (Elena Gonzalez, MSW Student) "How Does Parental Communication Influence an Adolescent's Decision to Engage in Sexual Activity?" end of January 2005.
10. **Protocol 04-08** (Joshua D. Bradley, Extended University MSA Program) "Management and Evaluation of a Steam Injection Soil Remediation Pilot Project" end of January 2005.
11. **Protocol 04-10** (Elena Acosta, PPA Student) "Patient Satisfaction Survey for Clinica Sierra Vista" end of January 2005.
12. **Protocol 04-13** (Guillermo Garcia, PPA Student) "What are the Tangible Impacts of the Public vs. Private Approach to Prison Management?" end of January 2005.
13. **Protocol 04-14** (Debra Speck, Literacy Education Student) "Teacher Change and the Instruction of Developmental Word Study" end of January 2005.
14. **Protocol 04-15** (Valerie Robinson, PPA Student) "Junior Achievement Program Evaluation--PPA 502 Course" end of January 2005.

15. **Protocol 04-16** (Jennifer Lupo, PPA Student) "Measuring the Effectiveness of an Athletic Training Program" end of January 2005.
16. **Protocol 04-18** (Pheap Khuth, PPA Student) "How Does the Kern County Aging and Adult Services Promote the Availability of Its Programs?" end of February 2005.
17. **Protocol 04-20** (Lisa E. Martin, PPA Student) "Department of Social Work Graduate Program Admissions Criteria" end of January 2005.
19. **Protocol 04-21** (Valerie Robinson, PPA Student) "The Impact of Diversity Training--A Diversity Audit in the Public Sector" end of January 2005.
19. **Protocol 04-22** (Adam Alvidrez, PPA Student) "MPA--Culminating Project" end of January 2005.
20. **Protocol 04-23** (Lorraine Mona DeSantiago, PPA Student) "Recruiting and Retaining New Registered Nurse Graduates in Bakersfield" end of January 2005.
21. **Protocol 04-24** (Angela Davis, Sociology Student/CSUB-AVJ) "The Attributes of a Racist: A Re-Examination of Stereotypes That Have Been Attributed to the Bigot" end of January 2005.
22. **Protocol 04-26** (Brad Plymire, PPA Student) "Eliminating Barriers to Effective Correctional Education at the CCI" end of March 2005.
23. **Protocol 04-31** (Tom See, PPA Student) "Strategic Human Resource Management--The Impact on Organizational Effectiveness" end of February 2005.
24. **Protocol 04-34** (Marcia Tyler-Evans, Department of Nursing) "Recruitment Decision Making for Military Nursing Careers" end of March 2005.
25. **Protocol 04-35** (Frank A. Herrera, PPA Student) "Evaluating the McFarland Family Resource Center" end of February 2005.
26. **Protocol 04-37** (Emily Darling, Psychology Student) "Job Analysis of the Undergraduate Teaching Assistant Position" on 11 March 2004.
27. **Protocol 04-38** (Gaylene Roberts, Special Education Student) "The Extent of Fitness Goals Written in the Individualized Education Plan of Students with Mental Retardation" end of March 2005.
28. **Protocol 04-39** (Emerson Case, English Department) "An Ethnographic Study of International Students' Participation in Group Projects/Presentations" on 24 March 2004.
29. **Protocol 04-40** (Candace Meares, Department of Nursing) "More Diversity in Generic BSN-Prepared RNs" on 18 March 2004.
30. **Protocol 04-41** (Maritza Orozco, Nursing Student) "Culturally Competent Care: Perceptions of Mexican American Patients" end of March 2005.
31. **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] end of March 2005.
32. **Protocol 04-43** (Sokia Land, MSW Student) "The Role of Treatment Components in Predicting Positive Parenting Outcomes in Adult and Adolescent Fathers" end of March 2005.
33. **Protocol 04-44** (Maryam Allahyar, Psychology) "Perception of Targets using Multiple and Single High Resolution Displays" [Abramson, Carlisle] end of March 2005.
34. **Protocol 04-45** (Leonel Frias, PPA Student) "The Effectiveness of AVID" end of March 2005.
35. **Protocol 04-46** (Joshua Padilla, Psychology Student) "Need for Closure and Social Identify Complexity: Increasing Outgroup Tolerance" end of March 2005.
36. **Protocol 04-47** (Tanya Boone, Psychology) "Sources of Sexuality Messages: In-Depth Interviews" [Carlisle, Leapley] end of March 2005.

37. **Protocol 04-48** (Ronald Radney, Assistant Director of Financial Aid) "Recruitment Decision Making for Military Nursing Careers" end of March 2005.
38. **Protocol 04-51** (Phillip Inman, PPA Student) "Local Government Accounting and Management Information Systems Offshore Outsourcing" end of March 2005.
39. **Protocol 04-53** (Debra Morrison-Orton, MSW Department) "Student Reaction to Impaired Social Work Students" end of March 2005.
40. **Protocol 04-54** (Joan Digges, MSW) "'Leadership Academy' for Public Residents." [Abramson, Carlisle; supplemental review at the April 2004 IRB meeting] end of March 2005.
41. **Protocol 04-55** (Arabella Ancheta, PPA Student) "RN Internship Program: A Program Evaluation" end of March 2005.
42. **Protocol 04-56** (Florentino Robles, Nursing Student) "Knowledge and Effectiveness of Patient Education Among Hispanic Americans with Diabetes" end of March 2005.
43. **Protocol 04-57** (Chanrasme K. Chea, PPA Student) "Impact Evaluation of EOP Program" end of March 2005.
44. **Protocol 04-58** (Janet Doucette, PPA Student) "Should Public Funds be Allocated to Faith-Based Nonprofit Organizations?" end of March 2005.
45. **Protocol 04-59** (Long Le, Political Science) "E-Survey of Vietnamese Student Associations' Members" end of March 2005.

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

#### e. Protocol Modifications

**Request to Modify Protocol 03-03** "Establishment of a Participant Pool for the Department of Psychology" (originally approved on 19 June 2003 and renewed on 15 June 2004) with Steve Bacon, Department of Psychology.

Bacon summarized the history and nature of the Psychology Department subject pool associated with the introductory psychology course. He wishes to modify the present restriction that the instructor of the course may not use the subject pool in support of his/her own research projects. This was originally incorporated in order to minimize risks to student participants whose grade might be influenced by a decision to participate or not or by his/her performance in the research. This concern is real, but it is a big handicap for graduate students depending on the subject pool whose research is being supervised by an instructor teaching the introductory psychology course. The proposal is to allow such students to use the pool, but with additional safeguards in place. Questions followed.

Q: Why are you requiring that the instructor's name not be indicated in association with the project? A: This is to make sure that student's don't feel more compelled to volunteer if the instructor's name is attached.

Q: Wouldn't it be a clue if the faculty supervisor's name was missing only on those listings? A: We could uniformly list only the graduate student and make that a blanket format.

Q: But, the instructor would still be listed as one of the contact persons on the consent form. Is there a way we can get around that? A: We could set up a designated contact person who would either have clinical competency or consult with another faculty.

The investigators were excused and deliberations followed in executive session.

There was a motion for conditional approval of the modifications to **Protocol 03-03**. [Carlisle moved, Wade-Southard seconded, unanimously approved]. The investigators returned and were informed of the decision of the Board. The condition was as follows:

1. Remove the name of faculty mentors from consent forms and set up a system of designated contacts.

## f. Protocol Renewals

**Renewal of Protocol 02-05** "Evaluation for First 5 California" with Brian Hemphill & Ken Nyberg.

There have been a number of changes in First 5 activities since 02-05 was last renewed. At that time there were some programs that were out of compliance, but all 52 Kern County programs are in compliance now in terms of data security, confidentiality, and informed consent. Several counties have been dropped from the ARC contract. There are 17 new programs added in the Healthy Families/Healthy Kids phase, which involves an insurance program designed to fill gaps in the present system--families of undocumented parents and persons within certain income ranges. This is administered via HealthNet. ARC is tracking enrollment demographics, which services are accessed, and the impact of the services obtained. Questions followed.

- Q: So, this is for kids, not adults? A: Kids and pregnant mothers.
- Q: Do they take undocumented families? A: Yes.
- Q: How is consent obtained? A: our consent document is administered as they sign up. However, it is a separate document from the paperwork for signing up for the HealthNet insurance. The data are then delivered to us with all of the personal identifiers already stripped.
- Q: Do the personnel signing up these families sign a confidentiality statement? A: They are not ARC people and work for the agencies, so we don't know.
- Q: Is confidentiality training provided to personnel? A: CSO does confidentiality training for persons who do interviews.
- Q: Is staff retrained every year? A: Don't know; that would be determined by the policies of Clinica Sierra Vista and the other providers of services.
- Q: The consent form is in Spanish? A: Yes
- Q: What does the designation "unk" mean in Table 1? A: At that time full compliance could not be verified for two programs. The current spreadsheet shows all in compliance.
- Q: Won't undocumented persons be less likely to sign up for this insurance? A: There is concern about that, but enrollments seem to be going well in other counties. This is something that we can track in our data. We note that there have been no breaches of confidentiality in the First 5 program and Immigration Services claims not to be interested in databases like this.
- Q: Is it possible that presentations or publications may follow from these data? That's not in the consent form. A: Yes and we will add that to the consent form.
- Q: The reading level seems high in places. A: It is difficult balancing the necessity to provide the information needed, yet having it easily understandable. The consent is done face to face so there is the ability to ask questions and have them answered.
- Q: Are the persons getting consent trained to prompt for questions? A: Yes.
- Q: What if a program would be terminated based on the data provided by participants? Shouldn't they be warned about that in the consent document? A: That is extremely

unlikely in this situation. It is more likely that a program might be shifted to a new/better provider, which ought to be a good thing.

Q: Will you be specifically tracking those who access mental health benefits? A: Yes, we will be tracking by different types of services by locations, also. Some places have a shortage of certain kinds of health care providers.

Q: Will you be tracking school enrollment? A: No.

Q: On the consent form contact info, the two contacts need to be separated out. A: Will do.

The investigators were excused and deliberations followed in executive session.

There was a motion for conditional approval of renewal of **Protocol 02-05**. [Meares moved, Carlisle seconded, unanimously approved]. The investigators returned and were informed of the decision of the Board. The conditions were as follows:

1. Add to the consent form that the data may be used for research purposes.
2. Separate the contact information appropriately on the consent form.
3. Systematically edit the consent form for simplicity of reading and then submit both the English and Spanish versions.

**Renewal of Protocol 03-61** "GEAR-UP: Limited Data Set" & **Protocol 03-63** "GEAR-UP: Waiver of Written Consent" with Val Garcia, Laramie Lyda, Rosa Ventura, & Dixie Walker.

GEAR-UP has been operating since December 2002 under a 5-year grant directed toward children in Arvin and Lamont. This presently involves 8<sup>th</sup> and 9<sup>th</sup> graders, with about 1100-1200 at each grade level. GEAR-UP provides academic support in the form of tutoring, mentoring, and parental involvement, and includes educational programs about career and educational choices. There are tutors, mentors, and English "pull-out" services in place in the schools that are involved. Outcomes assessment involves looking at student performance to see whether they are improving. Protocol 03-61 covers access to data already collected by the schools in the normal course of things. These data then reside in a locked office with an alarm at TLC [Transforming Local Communities]. Protocol 03-63 is about TLC access as third parties to data to which they already have access via FERPA regulations. There is a single parental information/student information document that will go home. Questions followed.

Q: Every participating school has the tutors and mentors in place? A: Yes.

Q: Do these persons have access to the data? A: No, the data reside at the TLC office.

Q: How are the files kept? Are paper files kept? A: We are working on getting direct electronic transfer. We do need to have personal identification information for the children and contact information for the parents. The computer holding the data has a security code, so the electronic copy is not accessible.

Q: How is the consent process being modified? A: We are simply informing parents about our accessing the data. They will keep that information.

Q: Do they get any choice in this? A: They can choose whether or not to return the survey. We already have access to the data under FERPA regulations.

Q: Your data will be partly limited by parental involvement. A: Yes, but we can track this.

Q: Where is the Spanish consent form? A: It wasn't included.

The investigators were excused and deliberations followed in executive session.

There was a motion for conditional approval of renewals of **Protocols 03-61 & 03-63**. [Abramson moved, Wade-Southard seconded, unanimously approved]. The investigators returned and were informed of the decision of the Board. The conditions were as follows:

1. Refer to the letter as an informational letter and submit the final version in both English and Spanish.
2. Add a telephone contact number to the student information sheet to get assistance if needed for parents who don't read well enough.
3. Specify the security arrangements for any data disks, including when they will be destroyed.

**g. New Protocol Reviews:**

**Protocol 05-07** "The Experience of Language Barriers among Limited English Proficiency Hispanics during Hospitalization" with Veronica Duran & Candace Meares, Nursing. Primary readers were McCleary, Newberry, Wade-Southard.

Research shows that language limitations have negative effects on health care, but there is not much research looking at the role of patient perceptions in this. The focus will be on what the patients feel about what happened during their hospitalization experience. She will recruit via posted flyers listing a telephone contact number. Informed consent will then be obtained and then an approximately one-hour, tape-recorded interview will take place, with a second follow-up interview later. These will be in person or by telephone. The interview will be in the language [English/Spanish] of preference. The data will be kept in locked storage and coded only by identification number in the computer data file. The tapes will be destroyed after one year. Questions followed.

Q: How will you be using code numbers? A: All of the materials will get a single code number, beginning with the audio tapes, and will be kept separate from any personal identification information, such as the consent forms.

Q: What is the telephone contact that you list on the flyer? A: This is her personal cell phone number.

[Member Comments: Concern is expressed about her providing her telephone contact and address on the flyers. The recruitment process will tend to limit the sample studies to literate persons. There are many errors in the Spanish versions of the materials, which need to be corrected.

Q: What is meant by "hospital experience" as used in this protocol? A: It means having been admitted, so an emergency room experience would not qualify.

Q: You state that you will exclude persons over 70. Why is that? A: There is concern about cognitive impairments in older persons. [Member Comment: You would miss out on the potentially valuable perspectives of older persons. A cognitive limitation might be better.]

Q: Have you done the English-Spanish-English back translation of your materials. A: Yes.

Q: How will you do the Spanish-English translation of the interview recordings. A: [Answer is not clear insofar as she says at different times that it would be done by her alone, by two persons independently, and by two persons working together.]

- Q: Shouldn't you put something about the \$10 payment in the flyer and consent form? A: She should rather keep it separate so as not to get people signing up for the money. The \$10 will be a nice reward at the end.
- Q: There is lots of research on this topic. How will your research potentially add to what is known? A: It will focus on persons' reflections about their own experiences.
- Q: There actually seems to be quite a lot on that as well. A: She hasn't seen the qualitative research on Spanish speakers' hospital experiences.
- Q: Is it possible to state what your research might add in terms of the "gaps" that you mention, that is, specifically what is missing? A: There is little research on health outcomes. She will focus on how the former patients "feel." There is particular interest in the local situation and how the findings in the general literature may or may not apply to the local situation. This might be a first step toward developing something to help correct limitations.

[Member Comment: The demographic scales need improvement in terms of getting rid of the Yes/No dichotomous responses in favor of scaled answers and separating out literacy questions about reading and writing Spanish.]

- Q: You're really just interested in getting Spanish-speakers with limited English proficiency, and not so much ethnicity or genetics, correct? A: Yes.
- Q: There could be dramatic emotional distress in connection with providing information about awful experiences in the hospital. It's not clear how you are prepared to deal with these. A: In some cases there is contact information on insurance cards... [Comment: But the undocumented persons won't have insurance cards. This needs to be explicit in the consent form and in the protocol. Note the Mental health 1-800 number. Also, there should be a place to fill in contact information on the consent form that is appropriate for each person.]

The investigators were excused and deliberations followed in executive session.

There was a motion for conditional approval of **Protocol 05-07**. [Wade-Southard moved, McCleary seconded, unanimously approved]. The investigators returned and were informed of the decision of the Board. The conditions were as follows:

1. Edit the Spanish materials, including doing back translations and submit these to the IRB.
2. Revise the demographic survey so that interval scales are used and there are separate questions about reading and writing Spanish proficiency.
3. Make clear in the protocol that you are interested in "native Spanish-speakers with limited English proficiency."
4. Specify how the transcription will be done.
5. Drop the age limitation.
6. Specify how the contact information for possible distress will be handled, identifying phone numbers for mental health services, the mental health hotline, and other significant support people when appropriate.
7. Clarify the focus of the proposed research, expressing the potential value in terms of possible contributions to existing knowledge. This may be primarily in looking at possible local differences with respect to current understanding of this problem.

**Protocol 05-08** "Nursing as a Career Choice: Adolescents' Perceptions" with Corina Anema & Candace Meares, Nursing. Primary readers were Abramson, Lee, Mellon.

There is currently a shortage of nurses. There apparently needs to be more interest in careers in nursing among youths. The purpose is to interview high school students to determine their perceptions of nursing. Parental consent and student assent will be obtained. Interviews will be tape-recorded using participant codes with no personal identifiers. Questions Followed.

Q: Why are you getting personal identifiers at all? A: Names and addresses are needed for the consent process. The audio tapes will only have participant codes on them.

Q: Where and how long will you keep the consent forms? A: They will be locked up at home, then shredded after the information collection is finished.

Q: How will you advertise at the schools? A: I'll just set up a table with a banner. There might be flyers and/or announcements in student publications.

Q: How many students will you be interviewing? A: Probably 12 – 20 to reach saturation, that is, until the information obtained starts being redundant.

Q: The tapes will be erased after transcribing? A: Yes.

Q: You see this as a recruiting tool? A: Not really. The aim is to just describe perceptions, including to see if there are misperceptions.

Q: Why not use focus groups? A: Peer pressure might be a problem and distort the data.

The investigators were excused and deliberations followed in executive session.

There was a motion for approval of **Protocol 05-08**. [Mellon moved, Wade-Southard seconded, unanimously approved]. The investigators returned and were informed of the decision of the Board.

#### **OTHER CONCERNS:**

The following actions were approved with respect to the issue of eliciting better information about the potential benefits of proposed research:

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

1. The IRB Protocol Review Forms should be posted with the online materials to clarify that IRB approval comes down to a cost/benefit analysis.
2. Each cover page should be revised to contain a specific space in which the investigator is asked to make the case for potential benefits of the proposed research.
3. A document stating IRB concerns and pointing out the cost/benefit process in IRB authorization should be prepared and distributed in a way that it will reach faculty mentors and student researchers.
4. The RERC should prepared drafts of the above and distribute them to IRB members for comments.
5. The links to the online IRB materials should be easier to find.

#### **NEXT MEETING:**

Friday, 22 April 2005 – Old Pub

**ADJOURNMENT:**

There being no further business, the meeting was adjourned at 11:05 AM.

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

**BOARD TRAINING:** “Making the Case for Possible Benefits of Proposed Research”

The IRB must conclude that potential benefits outweigh costs/risks to participants to authorize proposed research. Sometimes the investigator does not make a convincing case. Sometimes investigators simply claim there is “little research” on a topic, suggesting that practically anything would be valuable, when there is actually a vast body of existing research. It is often not clear what the investigator thinks he/she might be adding to existing knowledge. How can we address this problem without extending undue IRB influence into structure the content of faculty/student research? With respect to student research how does the IRB purview and the faculty mentoring process interface? These issues were discussed, and the IRB decided upon several actions. The meeting was reconvened and these steps were approved. These are listed under “OTHER CONCERNS” [above].

Respectfully submitted

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