INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH (IRB/HSR) CALIFORNIA STATE UNIVERSITY, BAKERSFIELD

Minutes of Meeting Wednesday, 10 June 2009 [DDH A-108]

Members Present:

Scientific Concerns: Anne Duran, Kathleen Gilchrist Nonscientific Concerns: Paul Newberry, Yeunjoo Lee, Thomas Blommers Community Concerns: Gary Bashor

Members Absent:

Lily Alvarez, Roseanna McCleary, Carolyn Wade-Southard, Robert Horton, Ex-Officio

Visitors:

Denise Dawkins & Debra Wilson for Protocol 09-125 Carol Raupp for renewal of Protocol 03-03 Andrew Crawford & Brian Hemphill for Protocol 07-91 Quarterly Report

I. CALL TO ORDER:

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

II. PREVIOUS MINUTES:

Duran soo moved and Blommers seconded a motion to approve the minutes of Friday, 17 April 2009. The motion was approved 5-0.

III. ANNOUNCEMENTS:

- A. Tom Blommers has been appointed to the IRB, finally.
- B. The Los Angeles Department of Children and Family Services [DCFS] wants all proposed projects involving their data, personnel, or clients to first go through their IRB. This will affect many potential community projects of MSW students at Antelope Valley. Bruce Friedman, MSW Chair, is attempting to coordinate and obtain a list of projects that DCFS would support.

IV. OLD BUSINESS

A. Spanish Translations. There are a few issues. Blommers noted that formal Spanish is expected for a document such as a consent form. There is an extremely wide range of Spanish reading capabilities in Kern County. The consent form is probably the most important document and a template could be devised. Could have Spanish and English on opposite sides to facilitate understanding. Blommers, McCleary, and Suter will be a summer work group on this. [Blommers moved, Bashor seconded, 6-0]

V. NEW BUSINESS

A. Formal Board affirmation of protocols previously approved under standard review, expedited review, Third-Party Access, and exemption from full review since the April 2009 meeting.





1. Standard Review [2]



Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-14	Larissa Ogden	Needs Assessment for a Comprehensive Emergency Shelter/Drop-In Center for Transition Age Youth	1/16/2009	Gilchrist, Lee, McCleary, Newberry, Duran	2/23/2009
09-84	Jonathon Leif Basilio	Atheist-Ministers and the Social Construction of Private and Public Identities	4/10/2009	Newberry, McCleary, Lee, Gilchrist, Bashor and Alvarez	6/2/2009

[Duran moved, Bashor seconded -- approved 6-0]

2. Expedited Review [5]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
08-167	Bruce Hartsell and Debra Morrison- Orton	Counselor Perceptions of Motivational Interviewing Training Results	12/10/2008	Duran and Carlisle	4/30/2009
09-82	Greg Hanel	Needs Assessment of Critical Response Teams in CPS Emergency Response	4/8/2009	Lee, Gilchrist	4/20/2009
09-95	Shelley Northrop	Promotora Role in the Enrichment of Breast Cancer Screening Beliefs and Behaviors Among Hispanic Women	4/22/2009	Duran and Blommers	5/4/2009
09-96	Heather Bosma	Are Senior Nursing Students Culturally Competent	4/20/2009	Lee and McCleary	5/4/2009
09-120	Cherie Rector and Kathleen Gilchrist	Public Health Nurse (PHN) Knowledge, Attitudes & Behaviors r/t Water Quality & Safety	5/13/2009	Blommers, Duran	6/1/2009

[Bashor moved, Lee & Duran seconded -- approved 6-0]

3. Third-Party Access to Existing Data [3]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-13	Mannette Rodriguez	Foster Children out of their School of Origin in the Antelope Valley	1/15/2009		3/5/2009
09-71	Beatriz Solano	Factors Preventing Consumer from Qualifying for Mental Health Services	3/13/2009		3/20/2009
09-92	Simon Burrowes	Aggression Replacement Training: An Evaluation of Kern County Mental Health, Children's Specialty Services, Anger Control Enrichment Group	4/17/2009		5/4/2009

The RERC noted that there are no reviewers because he processes protocols for data not having identifiers and those routinely accessing test scores in the educational testing. [Gilchirist moved, Blommers seconded -- approved 6-0]

4. Exempted from Full Review [24]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
08-114	Racquel Dominguez	The Assessment of Houghton Mifflin Curriculum	9/25/2008		5/15/2009
09-17	Chuck Tate	Attitudes about Informal Mentoring	1/16/2009		4/27/2009
09-18	Chuck Tate	Attitudes about Bisexuality	1/16/2009		4/27/2009
09-19	Chuck Tate	Cognitive Representations of Sexual Orientation	1/16/2009		4/27/2009

09-20	Chuck Tate	Prediction Processes	1/16/2009	4/27/2009
09-21	Chuck Tate	Racial Jokes and Prejudice	1/16/2009	4/27/2009
09-29	Jasmine Reed	An Analysis of Blending Cluster Onsets and Cluster Rimes: Is One More Difficult Than the Other	1/21/2009	4/20/2009
09-70	Michael Butler	Is it Service-Learning? A Theoretical Assessment Model for Quantitative Classification of Experiential Education Programs	3/16/2009	5/12/2009
09-79	Charles Brown	Affects of Stricter Admission Standards on BC Paramedic School of Attrition Rates	4/9/2009	4/16/2009
09-86	Sonia Diaz	Meaningful Performance Measurements	4/14/2009	4/20/2009
09-87	Cindy Goodmon	Research Related to Balancing Budgets in California State University Athletic Program	4/14/2009	4/16/2009
09-93	Jinping Sun	Budget Strategy: A Survey of California County Governments	4/21/2009	4/29/2009
09-94	Kristina Stricker	Evidence for how the preschool experience impacts early literacy in Kindergarten	4/20/2009	5/15/2009
09-97	Angelica McKay	Children Creating PowePoint Presentation	4/20/2009	4/30/2009
09-98	Alicia Dowd	Pathways to STEM Bachelor's and Graduate Degrees for Hispanic Students and the Role of Hispanic-Serving Institutions (Case Studies)	4/27/2009	4/28/2009
09-101	Sandra Crumlish	Communication and Leadershiop Competency is Relational to Job/Career Advancement	4/29/2009	5/4/2009
09-105	Elma Gatus	A classroom Web Page: A Link between School and Home	5/4/2009	5/5/2009
09-106	Chuck Tate	Judging Personality	5/5/2009	5/15/2009
09-107	Chuck Tate	Attitudes about trans-persons	5/5/2009	5/15/2009
09-112	Kim Kotrla	Is there a True Continuum of Care for Individuals with Multiple Sclerosis in Kern County?	5/8/2009	5/14/2009
09-113	Debra Wilson	Student Perceptions about an Alternate Senior Practicum Experience	5/8/2009	5/12/2009
09-114	Christie Marie Caldwell	The Introduction of a Discipline Based Art Education Program through the use of California's History and the California Missions	5/8/2009	5/28/2009
09-119	Lisa Van Boeing	The Effects of Turnover in a Highly Stressful Healthcare Setting	5/11/2009	5/27/200
09-129	Randy Schultz	Technology Relevance: Differences in perception betwee pre-teachers and credentialed teachers	5/20/2009	5/22/200

Duran wondered if it would be ethical to contact Tate about his research listed here, because she shares research interests. RERC thought this was dandy since protocols are publicly available. [Duran moved, Lee seconded -- approved 6-0]

B. Formal Board affirmation [24] 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 2009 meeting.

Number	Author	Title	Date Submitted	Reviewers	Final Approval
08-116	Josephine Alamillo	Los Angeles County Department of Children and Family - What Permanecey Means to Youth in Long-Term Foster Care: A Focus Group Approach.	9/26/2008		2/20/2009
09-61	Evette Rodriguez	Title 19 Drawdown Social Work Services	3/3/2009		4/23/2009
09-77	Martina Cisneros	LGBTQ Sensitivity Training for Foster Parents: A Model Program	4/6/2009		4/8/2009

09-81	Aba Aikins-Adjaye	Respective Health and HIV/AIDS of the James Town Youth in Ghana: Development of Grant Components	4/7/2009	4/13/2009
09-83	Kathleen A. Sweeney	Eating and Playing for Good Health on a Budget: An After School/After Work Family Program	4/8/2009	4/13/2009
09-89	Lourdes Vargas- Nilon	Does Charitable Choice Violate the First Amendment	4/14/2009	4/17/2009
09-90	Bonita F. Eighmey Steele	The Impact of Community Mental Health Funding Levels on the Percent of Prison Population with Mental Health Diagnoses	4/15/2009	4/17/2009
09-99	Geoffrey Hill	An Analysis of Function Performance Measures and Performance Measurement for County	4/24/2009	4/30/2009
09-100	Heather Moulton	Standards-Based, Reflective Portfolios in the Middle School Classroom	4/28/2009	4/30/2009
09-102	Andreas Gebauer	CSUB Robert Noyce Teacher Scholarship Program-Phase	4/29/2009	5/4/2009
09-104	Reginald L. Gridiron	Program Proposal: It Takes Change: Transforming Bakersfield City School Supplemental Educational Services in wake of African American Students	5/4/2009	5/5/2009
09-108	Maritza Cardenas	An Analysis of the Problem and Alternatives to Increase Farmworkers Utilization of Health	5/5/2009	5/11/2009
09-111	Mike Case, Rajinder Dhillon, Jami Ekstrom, Sally Rodriguez and Anastasia Throsell	Bridging the Gap: Advocacy for Increased Affordable Childcare for College Students	5/7/2009	5/7/2009
09-115	Sarah Sewell	Evaluation of the Juvenile Waiver	5/8/2009	5/12/2009
09-116	Holly Gonzales	The Effectiveness of Dual Immersion	5/11/2009	5/19/2009
09-118	Dirk Baron	Planning for a Math and Science Partnership for the San Joaquin Valley of California	5/13/2009	5/12/2009
09-126	Erin Mooney	Resources for Teachers Website	5/18/2009	5/19/09
09-127	Aaron Miller	A Project Plan for Breaking the Glass Ceiling Within the California Department of Corrections and Rehabilitation (CDCR)	5/19/2009	6/1/200
09-128	Greg Rico	Improving Access to Health Care for Member of the Deaf Community	5/19/2009	5/21/200
09-130	Staci Loewy	San Joaquin Valley Rocks!!:Inspiring Future Geoscientists	5/21/2009	5/21/200
09-131	Eva Felix	The Challenges of Health Care Delivery System to the Homeless Population	5/21/2009	5/22/200
09-132	Kathy lves	Demographic Distribution of Foundation Funding within California	5/22/2009	5/22/200
09-133	Cari Long	The Effect of Inspection Frequency & Fines in Air Quality Compliance Rates	5/22/2009	5/26/200
09-134	Mansor M. Jaber	The Impact of Proposition 21 on Juvenile Crime Rates in California	5/28/2009	6/1/200

There are many of these because MSW and PPA students must provide documentation of having interacted with the IRB for their theses and culminating projects. Students doing this at the last minute tend to do literature review projects. If students began their projects sooner, more of them would choose to carry out empirical research. [Duran moved, Blommers seconded -- approved 6-0]

C. Formal Board affirmation [5] of previously approved protocols granted <u>renewals</u> since the April 2009 meeting.

|--|

08-92	Laura Elton	An Exploration of Strengths and Resilience of the Tubatulabal People as It Relates to Current Tribal Identity	5/21/2008	Meares, Newberry,	6/23/2008
04-124	Cherie Rector and Kathleen Gilchrist	Are You INN? Outcomes of the INN Program Grant	9/23/2004	Newberry,Lee,Bragg, Meares, Leapley Abramson	10/11/04
06-77	Kathleen L. Gilchrist	CSUB Nursing Program Evaluation Project	8/16/2006		8/22/2006
08-101	Roseanna McCleary, Bruce Friedman	Evaluation of the Practicum Partnership Program Adoption Initiative	8/13/2008		9/10/2008
08-102	Roseanna McCleary, Bruce Friedman	Hartford Partnership Program for Aging Education Career Tracking Survey	8/13/2008		9/10/2008

[Gilchrist moved as corrected, Duran seconded -- approved 6-0]

D. Formal Board affirmation of protocol <u>closures</u> [25] (unless extension granted) whose authorization have ended or will end prior to the October 2009 IRB meeting.

Number	Author	Title	Date Submitted	Reviewers	Final Approval
05-99	Michael Harville, Beth Rienzi	Evaluation of Counseling Center Services	10/7/2005		10/11/2005
07-81	Suzann Henrikson & Rebecca Ofila	Sheepherding History Around Craters of the Moon National Monument for the BLM, Idaho	7/18/2007	McCleary, Newberry	7/31/2007
07-83	Donna Simmons & Judith Pratt	Ethical Minefields for Journalists and Public Relations Professionals in the Public Debate Over Spreading Biosolids (Sludge) from Los Angeles and other Areas in Southern California on Kern County Lands	7/25/2007		8/1/2007
07-90	Emerson Case	Connecting High School and College Through a Common Reader Program	9/20/2007		9/24/2007
07-92	Jeffrey Moffit, Tim Anderson, Jacobo Morales	Normative Data for Standing Long Jump, Vertical Jump, and Genu Varum/Valgus	9/21/2007	Meares, Lee	10/9/2007
07-94	Ron Pimentel & Marketing Students (BPA)	Establishing a Front Door for a University: Make the University Experience More Easily Accessible	9/24/2007		9/24/2007
07-107	Luis Vega	Qualitative/Quantitative Measurement Issues in Social Psychology	10/19/2007		10/24/200
08-87	Suzanne De- Armond-Rodriguez	Lesson Study-High School Math	5/15/2008		10/3/2008
08-93	Lincy Maliyekkal	Self-Management Knowledge of Patients' in a Rehabilitation Hospital: A Needs Assessment	5/22/2008	Meares, Alvarez, Carlisle	10/15/200
08-98	Chandra Commuri	The Dimensions of Diversity: How Nonprofit Governors Make Sense of the Board Diversity Issue	6/20/2008	McCleary & Carlisle	8/18/2008
08-100	P. Michael Lutz & Carl Lager (UCSB)	Todos Secondary Mathematics Projects	8/6/2008		9/2/2008
08-103	Jean-Claude Tubajika	Program Evaluation of the Student Health Center	8/18/2008		8/28/2008
08-105	David Stricker	Should the National Recreation and Park Association's Aquatic Branch develop a certification for individuals in the field of Aquatic Management	8/28/2008		9/22/2008
08-107	Donna Simmons, Judith Pratt & Christine Cruz- Boone	Big West Refinery Expansion Communication Efforts: Media Campaign & Risk Communication	9/10/2008		9/23/2008

	1	1	
1			
1	J		J
	((

08-108	Blanca Luz Anderson	Program Planning Study-Clinica Sierra Vista's Behaviorial Health Program	9/19/2008		9/22/2008
08-110	Steve Suter	CSUB Vision Lab Visual Neuroscience Research Projects	9/23/2008	Gilchrist & Bashor	10/20/2008
08-111	Guadalupe Tapia	Is Clinica Sierra Vista's AF:P/Cal-Learn Program Effective at Preventing Repeat Pregnancies?	9/23/2008		9/25/2008
08-113	Natalie Tran & Jacqueline Hughes	Design and Implementation of Teaching Performance Assessments	9/24/2008		10/1/2008
08-115	Christina Contreras	Reading Comprehension in the After School Program: A Pilot Study	9/25/2008		9/26/2008
08-119	Yamileth Fisher	Perceptions of Cultural Issues	10/13/2008		10/21/200
08-120	Luis Vega	Students' Knowledge and Attitudes about Intergroup Relations	10/13/2008		10/30/200
08-123	Michael Way	Using Video Feedback to Improve Performance and Retention in an Online course	10/15/2008		10/24/200
08-132	Cathy <mark>Flores-</mark> Mendiola	The Impact of Computer Use at Home on Sixth Grade Students' Academic Achievement	10/24/2008		10/30/2008
08-147	Kristianna Serrano	Virtual Technology's Effect on the Literacy Rates of At- Risk Adolescents	10/24/2008		10/30/2008
08-149	Nicole Van Dyke	Master's in Education, Curriculum, & Instruction Purview	10/27/2008		10/28/200

[Blommers moved as corrected, Bashor seconded -- approved 6-0]

E. New Protocol Reviews

 Protocol 09-125: "Promoting Reflective Learning of Students Using Human Patient Simulators -- A Replication Study" with Denise Dawkins and Debra Wilson [Nursing]. Primary readers were Duran, Newberry, & Wade-Southard.

Dawkins summarized. This project involves use of realistic robotic simulated patients for clinical training of Nursing students. Project is to find out if feedback based on videotapes of training would facilitate learning.

Questions followed [Q = question, A = answer, C = comment]

- Q: Protocol mentions "cues". What does this mean? A: These are basically clues or prompts offered by the instructor to nudge the student in the right direction.
- Q: About how many students will be in a class? A: Given budget constraints, this could be around 45 students.
- Q: So, everyone does the patient stimulator training, but only some get videotaped? A: Correct.
- Q: What are the data? A: These will be the various check-offs done by the instructor and included in the protocol.
- Q: Do you think that the videotaping might lead to better learning? A: Yes, possibly.
- C: You ought to include that as a potential benefit.
- Q: You plan to destroy the videotapes at some point? A: Yes, the tapes are destroyed or recorded over right after they have been used. We will add this to the protocol.
- Q: Will students be trained individually or in groups? A: They will be trained in groups, probably groups of 5, but this might go up depending upon reactions to the budget.

- Q: Since you are also dropping out your previous practice of having other students watching the students being trained, do you think this might influence performance? A: Students will still be getting feedback from each other as they are being trained.
- Q: But will you be able to tell if the students are actually doing better than previously? A: We'll do a mock "code" as we have been doing in previous quarters and compare performance to the data obtained previously.
- Q: Your survey includes a lot of demographics, including ethnicity. What is the purpose? A: This might be needed later to describe the sample if we were to publish.
- C: You should explain in the consent form that you won't be doing comparisons using the demographics. A: OK
- C: You should add "other" to the choices for ethnicity. A: OK
- C: You should move the demographics to the end so as not to trigger "saliency" effects, for example related to ethnicity. A: OK
- C: Change the applicable demographic stems to "How do you self-identify?" A: OK
- C: The investigators were commended for presenting an interesting and well-done protocol.
- Q: Is there existing research on effectiveness of robotic patient simulators in nursing training? A: Very little.
- Q: What if the video feedback training students get better grades? A: That can't happen because grades are not based on performance, just participation.
- Q: Could the students in the control condition see the videotapes afterwards to also experience the possible benefits? A: No, we never show the video of one set of students to different students.
- Q: Could you videotape everyone, to control for the effects of being on camera, but only use the video as feedback for the experimental group? A: Yes, we could do that.
- Q: How will you keep track of students so that the various data elements can be associated the correct student? A: We will use participant codes that are stored securely and known only to the investigators.

When there were no more questions, the PIs were excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 09-125**.

[Duran moved, Lee seconded -- approved 6-0]

The following conditions were announced to the PIs when they returned:

- 1. Add increased learning to the consent form as a possible benefit.
- 2. In the consent form, state that the videotapes will be destroyed after use.
- 3. Explain in the consent form that demographics will be used to describe the sample, not as a basis to look at the data.
- 4. On the survey: [a] change the applicable demographics stems to "How do you self-identify?" [b] add "other" as a choice in ethnicity, and [c] add "domestic partnership" as a choice where marital status is queried.
- Change the research design so that everyone is videotaped, but that it will be used for feedback in only one condition. Change the protocol and consent form accordingly.
- 6. Describe the steps taken to ensure the security and confidentiality of the data.
- 7. Correct the "IRB/HSK" typo at the end of the consent form.
- 8. Move the demographic data to the end of the participant survey.





F. Continuing Review and Renewal of Authorized Protocols

1. Protocol 03-03: "Department of Psychology Participant Pool" with Carol Raupp [Psychology]. Primary Readers were all Board Members.

Raupp summarized. Many psychology departments have such participant pools, designed to create a supply of research participants, while allowing students to find out something firsthand about psychological research. Ours was set up in 2003 and the authorization is reviewed yearly. Protocols offered to the students must be already IRB-approved and the students select among the menu offered. There is an alternative assignment. Events proceeded as planned, except there was a shortage of research opportunities one quarter which necessitated reducing the hours of assigned participation. There were no complaints registered. One proposed modification is to allow for a student to not be allowed to sign up additional times for a specific study if he/she has no-showed twice.

Questions followed [Q = question, A = answer, C = comment]

- Q: A protocol is listed as available for a while? A: Yes. Time slots are shown and students come by a bulletin board to sign up.
- Q: Might it not be a problem if a student were to participate multiple times in a study? A: Students are instructed not to do that, although sometimes it happens by accident and they are turned away.

When there were no more questions, the PI was excused and the Board deliberated in executive session. There was a motion to renew **Protocol 03-03** as modified.

[Blommers moved, Bashor seconded -- approved 6-0]

 Protocol 07-91: CS&O Quarterly Report for activities conducted assessing performance and outcomes of First 5 agencies in Kern County with Andrew Crawford and Brian Hemphill. Primary Readers were all Board Members.

Crawford summarized. Defeat of Proposition 1 was good, unless all of the First 5 funding is diverted. First 5 agencies are basically in a holding pattern due to budget uncertainty. Only aggregate data will be collected from The Nurse Family Partnership Program until the process for consent from parents who are minors is approved. Crawford is leaving CS&O and taking a statistician position at UC-SF. IRB members are sad and commended him for helping establish a strong IRB tradition for First 5 locally. Nominees for a replacement are being solicited. There is an application for CS&O interns up in RunnerLinks.

Crawford requested standards and procedures for Spanish translations from the IRB. A sub-committee of Blommers, McCleary, and the RERC was assigned the task. The IRB decided not to authorize any pending First 5 Spanish translations until standards and procedures are recommended by the sub-committee and hopefully adopted at the next [10-02-09] IRB meeting.

The CS&O quarterly report was accepted by the IRB.

VI. OTHER CONCERNS:

A. De-Briefing. There was a brief discussion of risk minimization and harm removal related to debriefing, which arose from ambiguity in the Protocol Review Form. This should at least be clarified in the form and possibly a requirement for de-briefing should be added to protocols. The RERC will investigate and report back.

VII. NEXT MEETING:

Friday, October 2nd, 2009 [please mark your calendars!]

VIII. ADJOURNMENT:

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

[Lee moved, Gilchrist seconded, approved 6-0]

A. Update on IRB non-compliance investigations

Newberry and the RERC summarized the three non-compliance investigations and reports that have happened since the previous meeting. It was noted that something useful has been learned from every investigation. For example, GRaSP now sends an acknowledgement e-mail to IRB submitters specifically stating that research cannot commence until an authorization letter is received. There has been no response to the three non-compliance letters from chairs, deans, or Provosts involved. There is no CSUB policy on IRB non-compliance. There was a consensus among members that there should be. Non-compliance will be featured prominently in the impending [Summer 09] report to the Provost. Newberry and the RERC will seek to discuss the issue with the Provost to lobby for action on developing a CSUB policy on IRB non-compliance.

Respectfully submitted

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



. . 1

