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

Minutes of Meeting Friday, 20 April 2012 [DDH A-108]

Members Present:

Scientific Concerns: Anne Duran, Roseanna McCleary Nonscientific Concerns: Paul Newberry, Steve Gamboa, Penelope Swenson Community Concerns: Lily Alvarez, Tommy Tunson

Members Absent:

Kathleen Gilchrist, Grant Herndon

Visitors:

Curt Guaglianone, Randy Schultz, & Sarah Brooks for Edvention Report
J. J. Wang for First 5 Kern Report
Alena Eshom and Edna Molina-Jackson for Protocol 12-34
Carol Raupp for Protocol 03-03
Sharon Haynes, GRaSP Administrative Support

I. CALL TO ORDER

Chair Paul Newberry called the meeting to order at 7:58 AM.

New business was conducted prior to the other meeting events in order to accommodate visitors. Alzarez departed just prior to Protocol 03-03 renewal.

II. APPROVAL OF MINUTES

A. IRB meeting of Friday, 20 January 2012.

Errors in investigator listings and type of review were detected for 6 protocols, which should be corrected.

Duran being present, there was little trouble eliciting a motion to approve the minutes as corrected.

Duran so moved, Tunson seconded, 6-0.

III. ANNOUNCEMENTS [none]

IV. OLD BUSINESS

A. Update on Culminating Project Tracking. The SSE Dean's report on tracking [4-19-2012] was reviewed. No program or department has reported an existing or new systematic procedure to ensure that human subject research projects have been reviewed and authorized by the IRB before they are carried out. There was a motion to direct the IRB Chair and RERC to meet with the SSE Dean to express the concern and displeasure of the IRB and encourage movement on this. Tunson moved, Duran 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 January 2012 meeting.

1. Standard Review [1]

Number	Author	Department	Title	Date	Faculty Sponsor	Type of	Reviewers	Final
rtambor	7 4011101	Boparanona	110	Submitted		Review		Approva
			A League of Their Own: An Exploration				D.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
	Natalie		of Gender and Ritual in the Bakersfield				Duran, Alvarez &	
12-04	Thompson	Anthropology	Diamond Divas Roller Derby Team.	1/12/2012	Brian Hemphill	Standard	McCleary	1/20/2012

Tunson moved, Gamboa seconded, 6-0

2. Expedited Review [5]

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval
11-146	Mary Storey	Social Work	Project Esperanza Program Evaluation	11/11/2011	Roseanna McCleary	Expedited	Newberry & Gilchrist	1/23/2011
12-03	Natalie Thompson	Anthropology	I am Hot! No, You're Not: An Investigation of the Complex Relationship between Self-perception of Mate Value and the Assignation of Mate Value by Others	11/12/2011	Brian Hemphill	Expedited	McCleary & Duran	2/8/2012
12-05	Matt Leon	Psychology	The Neural Basis of Human Time Perception	1/17/2012		Expedited	Gilchrist & Newberry	2/27/2012
12-07	Jade Copeland	Psychology	The Influence of Stress and Competency on Pre/Post-Test Assessment of Performance	1/20/2012	Marianne Abramson	Expedited	Swenson & McCleary	2/2/2012
12-16	Nicola Bayley	Sociology Department	Coping Mechanisms, Family Dynamics and Intervention of Suicide Survivors – Can Online Suicide Survivor Forums Shed Light on this Experience?	2/29/2012	Alem Kebede	Expedited	McCleary & Swenson	3/14/2012

Duran so moved, McCleary seconded, 6-0

3. Third-Party Access to Existing Data [1]

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval
12-31			The Effect of Instructional Group Size upon student CST scores in math	3/20/2012	Ron Hughes	3rd Party		4/21/2012

McCleary moved, Tunson seconded, 6-0

4. Exemption from Full Review [6]

Number	Author	Department	lTitle	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval
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12-08	Jacquelyn Kegely	Athletics	Study on Collegiate Wagering	1/31/2012		Exemption		1/31/2012
			CSUB Graduate Center Focus Group		Curtis			
12-10	Jermey Caldwell	Doctoral Program	– Ed.D. Cohort	2/13/2012	Guaglinaone	Exemption		2/17/2012
			Assessment of Electronic Medical Record					
			Implementation in an Orthotics and					
			Prosthetics Practice Technical					
12-12	Sire Ved Khalsa	MSA Healthcare	Conference	2/13/2012	BJ Moore	Exemption		2/28/2012
			Working with Students in Math: A study					
12-13	Leslie Kelley		of Specific Interventions	2/13/2012	Randy Schultz	Exemption		2/24/2012
12-27	Judy Pedro	Nursing	Breastfeeding Survey	3/14/2012		Exemption		3/16/2012
			Windshield Survey: A Community Level					
12-30	Judy Pedro	Nursing	Documentation Study	3/16/2012		Exemption		3/20/2012

Gamboa moved, Swenson seconded, 6-0

B. Formal Board affirmation [12] of protocols submitted and designated as not falling within the IRB/HSR definition of human subjects research (**not within IRB/HSR purview**) since the January 2012 meeting.

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval
		Healthcare	An Evaluation Plan for a New Nonprofit					
12-14	Diana Delgadillo	Management	Healthcare Eye Institute	2/14/2012	BJ Moore	NRS		2/20/2012
12-17	James Wheeler	Public Policy and Administration MPA	A Policy Analysis: Is Housing First the Best Approach to Homeless Policy?	3/5/2012	Dr. Thomas Martinez	NRS		3/6/2012
12-19	Norica Ruelas	Assistant Professor of Public Administration	Comparing Healthcare Systems of Two Rural Communites	3/5/2012	BJ Moore	NRS		3/6/2012
12-20	Vivienne Sung		Methods To Prevent Kern County From Being Number One In Teen Birthrates In California	3/5/2012	BJ Moore	NRS		3/6/2012
12-21	Michelle Sophia Brown	Master of Public Administration	The Impact of the Patient Protection and Affordable Care Act on Medicaid for Special Needs Children	3/5/2012	Dr. Thomas Martinez	NRS		3/6/2012
12-22	Marilyn Jean Brown	MSA Healthcare Administration	Infant Mortality-how has the lag in healthcare impacted African American in the U.S.	3/7/2012	B.J. Moore	NRS		3/13/2012
12-23	Kristy Walker	Master of Public Administration	Strategic Management Plan for Small Business	3/13/2012	B.J. Moore	NRS		3/13/2012
12-24	Sarah Dossaji	PPA	Comparative Analysis of Healthcare Systems	3/13/2012	B.J. Moore	NRS		3/13/2012
12-25	Tania Grande	PPA	Implementation of Dual Immersion Programs	3/13/2012	R. Steven Daniels	NRS		3/13/2012
12-26	Dora Avitia Reyes	PPA	Immigration Policy Proposal: Legalization as an Instrument to Facilitate the Integration into American Society of Unauthorized Immigrants Settled in the U.S.	3/13/2012	Thomas Martinez	NRS		3/16/2012
12-28	Laura Campos- Hughes	PPA	Implementation of a paperless system in California Children's Services	3/15/2012	Thomas Martinez	NRS		3/16/2012
12-29	Jesus Tapia	Healthcare Management	Barriers to Health Care in the Hispanic Community	3/15/2012	BJ Moore	NRS		3/16/2012

Duran so moved, Tunson seconded, 6-0

C. Formal Board affirmation [8] of previously approved granted **Renewals** since the January 2012 meeting.

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval
07-91	J.J. Wang	Corp. for Standards & Outcomes (CSO)	Evaluation for Kern County Children and Families (KCCFC)	9/21/2007		Standard	All Reviewers	1/25/2008
10-56	Roseanna McCleary & Gail Davidson	Social Work & Nur	Evaluation of Knowledge and Attitude Changes in MSW and Nursing Students after Exposure to an Intergenerational Co-learning Model	3/3/2010		Exemption		3/8/2010
10-86	Anne Duran	Psychology	Changes in Tolerance and Acceptance as a Result of Gender, Race, & Ethnicity Courses	4/9/2010		Exemption		4/14/2006
10-130	Marianne Abramson & Tyson Smith	Psychology	Pain and High Heels As Sexual Attractors	8/18/2010		Expedited	McCleary & Newberry	9/2/2010
10-150	Stacy Teeters & Diana Pouge	I PSVCDOLOGV	Multicultural v. Colorblind Approach's Effect on Tolerance and Acceptance	11/8/2010	Anne Duran	Exemption		11/9/2010
11-31	Rhonda Dugan	Sociology	A Student-Led Organization for Immigrant Rights in California's Central Valley	2/24/2011		Exemption		3/2/2011
11-135	Mary Storey	Psychology	Beliefs About (Hetero)Sexua Relationships and Homophobia	10/13/2011	Anne Duran	Exemption		10/20/2011
11-143	Leslee Martinez	Psychology	Tattoos, Gender, and Perceived Pain	11/10/2011	Anne Duran	Exemption		11/16/2012

McCleary moved, Swenson seconded, 6-0

D. Formal Board affirmation of protocol **closures** [9] (unless renewed) whose authorization have ended or will end prior to the June 2012 IRB meeting.

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval
03-03	Steve Bacon	Department of Psychology	Establishment of a Participant Pool for the Department of Psychology	1/17/2003		Standard Rev		6/1/2009
09-120	Cherie Rector & Kathleen Gilchrist	Nursing	Public Health Nurse (PHN) Knowledge, Attitudes & Behaviors r/t Water Quality & Safety	5/13/2009		Expedited	Blommers & Duran	6/1/2009
09-142	Jacqueline Mimms	Enrollment Management	The CSU: Summer Algebra Institute	7/2/2009		3PA		7/2/2009
11-114	Chandrasekh ar Commuri	Public Policy & Administration	A Study of the Philanthropic Practices of Second generation South Asians in California.	6/14/2011		Exemption		6/20/2011
11-116	Kathleen Gilchrist	Nursing	Reflections of RN to BSN Nursing Students	6/20/2011		Exemption		6/22/2011
11-117	Sarah Brooks	Office of the Provost	Edvention Partners-Effects of CSU Teacher preparation on K-12 Student Achievement.	6/20/2011		3РА		6/22/2011
11-118	Gokh Alshaif	Political Science	Sources of Jordanian Public Opinion of the United States of America.	6/20/2011	Michael Ault	Expedited	Duran/Newberry	7/12/2011
11-119	De Vaughen Bell, Julianna Kroeker,Andr ea Padilla	Nursing	Peer to Peer BSN Simulation Grading	7/5/2011	Deborah Boschini	Exemption		7/12/2011
11-120	Liora Gubkin/Anne Duran	Religious Studies, Psychology	Religious Imagery Pilot Study	7/15/2011		Exemption		7/20/2011

McCleary moved, Tunson seconded, 6-0.

E. New Protocol Reviews

1. Protocol 12-34. "Bipolar Disorder on Campus: Locating Adequate Resources to Foster College Success" with Alena Eshom and Edna Molina-Jackson [Sociology Department]. Primary readers are Alvarez, Gilchrist, Swenson.

Following introductions, Eshom provided a brief summary. Bipolar disorder [BPD] is a severe problem among college students, who drop out and fail to graduate at a much higher level as compared to other students. This should be investigated. She wants to find out what services exist and especially deficiencies or accessibility issues experienced by BPD students. It's about "ease of access" because difficulties here play into the troubles that BPD persons experience. In addition to phone call explorations of services at public universities in California, current and former CSUB students having BPD will be interviewed. These will be "in depth" interviews.

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

Q: You have lists of variables to be investigated, but only some of these depend upon the student interviews, yes? **A:** Yes, the project involves a review of the research literature, phone calls to universities, and student interviews. The individual data are the interview responses and the surveys.

Q: When you call a university, how do you present yourself and what will you ask? **A:** I'll say that I'm a prospective student with BPD. What sorts of services do you have?

Q: Will you keep track of the names of persons you speak with at the universities? **A:** No, just the offices interacted with. Personal identities will be guarded safely if disclosed.

Q: Why aren't you looking at private universities? **A:** BPD tends to concentrate among lower SES who wouldn't be able to afford a private university. It will be most fruitful to search for accessibility issues within public higher education in California.

Q: You don't plan to interview students who have been successful and graduated. Aren't you missing something important by excluding them? **A:** The focus of the research is on hardships experienced by persons with BPD.

C: Well, it depends upon what the research question is. If it's about the barriers persons with BPD experience in college and how they can be overcome, then you're missing out. If it's about identifying barriers, then you only need the enrolled and drop out students. **A:** It's the latter.

C: It will be critical to be objective and neutral in making the phone calls to universities. **A:** Yes, but the focus in on access issues for persons with BPD.

Q: How will you get informed consent? **A:** Initial informed consent will be done over the phone. Signed informed consent will happen in person prior to completing the survey.

C: With the snowball technique, anxiety will increase for the participant, the greater the distance between that person and yourself. **A:** Yes, recognized.

When there were no more questions, the investigators and GRaSP support person were excused and the Board deliberated in executive session. There was a motion to conditionally approve protocol 12-34 with the following conditions:

- 1. Clarify in consent form that "others" will not be able to connect participant to data.
- 2. Be self-consciously open-minded and neutral during data collection.
- 3. Add to the protocol a description of the telephone and written consent procedure.

- 4. Describe in the protocol how you plan to analyze the interview data.
- 5. Correct the several typos in the contact form.
- 6. Use the project title found on your cover page consistently in your materials.
- 7. Change tense to "having experienced . ." in Subject Selection Criteria section.
- 8. The IRB notes that your telephone calls to universities to investigate the services available to students having bipolar disorder are not within the purview of the IRB.

Duran so moved, Alvarez seconded, 7-0

The decisions and conditions were then announced to the investigators.

2. Protocol 12-39, which appeared on the agenda, was withdrawn.

F. Continuing Review and Renewal of Authorized Protocols

1. Edvention and Related. Quarterly Report with Curt Guaglianone, Sarah Brooks, Randy Schultz, & Penelope Swenson. Primary readers are all members.

Guglianone provided a general introduction. These activities are part a 5-year DOE grant, hoping to improve teacher education across the U.S. Theirs involves five universities in Central California working with a number of public schools in rural areas having poor scores on standardized tests. The four goals and 15 reform elements were summarized. Eventually information across the various elements of Edvention will be integrated into presentations and publications. The investigators provided updates on the five IRB protocols in progress thus far.

Q: How many institutions are involved? **A:** CSUB, CSU-Monterey Bay, Cal Poly-SLO, TulareCounty Office of Higher Education, Kern County Superintendent of School, plus 18 rural, high-need schools.

Protocol 10-157. Brooks summarized that baseline data and follow-ups have been collected on the 15 participating Edvention Fellows. They are being mentored, get special professional development training, iPads, and do group work. This is going well. The 2nd cohort of participants are in the program now, which is being improved based on survey feedback in the data collected.

Protocol 11-66. The "Cycle of Activity Model [CAM]" is used to organize the 15 proposed initiatives for education improvement, which have actually been narrowed down to 11, more manageable, foci. There are inter-institutional CAM groups of varying size and dynamics depending upon the participants. Thus far, data involve surveys on the CAM experience, but eventually, the focus will be how the CAM stuff ends up in the classroom and affects student performance.

Protocol 11-68. Technology is getting more important in education and more sophisticated with many teachers already savvy about use. Swenson did a recent Webinar on iPads and conference presentations.

Protocol 11-117. This deals with effects of the Edvention training activities on student educational achievement by comparing performance of students of Edvention-trained teachers with students taught by others. Several districts have dropped out. Investigators have been dealing with legal and related issues with data access. The necessary data base has already been accessed for baseline data.

Q: So, there remains some question about what data you'll be able to get? **A:** Yes, there are legal issues which seem to have been resolved, but there has been resistance when it comes to actually handing over the data. The drama in the LA district in which performance data linked to particular teachers came at a bad time.

Q: Is there any way to facilitate this? Access to these data seems critical. **A:** Providing data like these, that can be used to track individual teachers, may soon be required in order to get federal money. That would be a big help.

C: Also, when there is turnover of education administrators, which has been happening, then the rationale and necessity of accessing these data has to be re-visited and "re-fought".

Protocol 11-122. Here the focus is looking at concerns identified by principals. Some of the data were presented at a meeting last week and were well received. This project will be continued and the hope is to share information gathered with education administrators around the country.

Information about **Protocol 12-10** had been included in the electronic meeting packet. This was simply an update of a project, dealing with experiences of students in the joint Ed.D program, supervised by Guglianone, that had been completed.

When there were no more questions, the investigators, GRaSP support person, and IRB member Swenson, were excused and the Board deliberated in executive session. There was a motion to approve the Edvention report.

Duran so moved, Alvarez seconded, 6-0 [Swenson recusing]

The decisions and conditions were then announced to the investigators, who were complimented on their good work on an important project.

2. Protocol 07-91. Quarterly Report with J. J. Wang. Primary readers are all members.

The investigator announced that the only change is that the Turning Point Mother-Infant project has closed related to state budget drama.

- **Q:** During the site visits, what are the "adverse events" that are check for? **A:** Personnel at each agency have done the confidentiality training, but there could be slip ups, so sites are visited to make sure everything is OK.
- **Q**: Are there particular questions asked during the site visit? **A**: Yes.
- C: It seems amazing that there are never any adverse events whatsoever.
- C: Perhaps we should worry whether agency personnel are fearful to disclose potential problems.

When there were no more questions, the investigator and GRaSP support person were excused and the Board deliberated in executive session. There was a motion to approve the Protocol 07-91 report with a recommendation that the IRB Chair and RERC meet with Wang to review adverse event monitoring procedures via site visits.

Swenson moved, McCleary seconded, 7-0

The decisions and conditions were then announced to the investigator, who was thanked to his cooperative efforts with the IRB.

3. Renewal of Protocol 03-03 with Carol Raupp, Psychology Department. Primary Readers are all members.

The investigator summarized that Protocol 03-03 has been active since 2003. Students in introductory psychology get 5% of their course grade from participation as subjects in psychological research or from an alternative activity. Thus participation is voluntary and non-coercive. Several studies have been added to the available opportunities since the present report was filed. Several instructors have made the research participation option greater than 5%, but have agreed to return to the 5% authorized by

the IRB. There have been no complaints to the psychology chair, Raupp, or to introductory psychology instructors.

- **Q:** How is the opportunity to complain presented to students? **A:** All the steps of potential participation are listed in the syllabus. The complaint procedure is posted in large print on a bulletin board devoted to the subject pool.
- **C:** A student experimenter did not show up for a session last week and has been dismissed as a student assistant. A operating procedure has been developed on what to do in case of a researcher no show. In that case, the student will get credit.
- **C**: Researcher no shows happen periodically, but infrequently.

When there were no more questions, the investigator was excused and the Board deliberated in executive session. There was a motion to approve the renewal of Protocol 03-03.

Gamboa moved, McCleary seconded, 5-0 [Duran recusing]

The decision was announced to the investigator, who was thanked for her presentation.

VI. OTHER CONCERNS: [none]

VII. MEETING DATES FOR 2011-2012:

Fall 2011: October 7th, 2011 Winter 2012: January 20th, 2012 Spring 2012: April 20th, 2012 Summer 2012: June 13th, 2012

VIII. ADJOURNMENT:

At 10:33 AM Swenson moved, McCleary seconded, 6-0.

IX. BOARD TRAINING:

- **A.** Spot check of protocols authorized since last meeting:
 - 1. Protocol 12-30 [Judy Pedro, Nursing Department] "Windshield Survey: A Community Level Documentation Study" Submitted 3-16-11; authorized 3-16-11; following exemption from full review.
 - RERC summarized, explaining the "windshield survey" approach and the Omaha data recording tool. The only tricky IRB element dealt with consent, which is a data release for research purposes actually doing the survey is a required class project. Because students will work in groups, if one student doesn't agree to have his/her data released for research purposes, then the data collected by that group will not be entered into Survey Monkey for research use.
 - 2. Protocol 12-31 [Janet Yakoub & Ron Hughes, Advanced Educational Studies] "The Effect of Instructional Group Size upon Student CST Scores in Math" Submitted 3-20-12; authorized 4-02-12, following exemption from full review. [Attachment G: original protocol, final re-submitted protocol, e-mail correspondence latest to earliest]
 - RERC summarized that this involves comparing math scores following whole class vs. small group instruction in certain math lessons. The only hitch was that this needed to be re-submitted as a "Third-party Access to Existing Data" protocol, since the whole class data had been collected previously in the student-teacher's classroom.