

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

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**Minutes of Meeting  
Friday, 04 October 2013 [DDH A-108]**

**Members Present:**

Scientific Concerns: Anne Duran, Roseanna McCleary  
Nonscientific Concerns: Steve Gamboa, Paul Newberry, Randy Schultz  
Community Concerns: Lily Alvarez, Grant Herndon

**Members Absent:**

Mike Butler, Lily Alvarez

**Visitors:**

J. J. Wang for **First 5 Kern Report**,  
Gwen Parnell, **GRaSP Administrative Coordinator**  
Sarah Brooks-Arriola for **Edvention Report**  
Mike Smith for **Protocol 13-96**  
Melissa Lett & Shirelle Perez for **Protocol 13-97**

**I. CALL TO ORDER**

Chair Paul Newberry called the meeting to order at 8:02 AM.

**II. APPROVAL OF MINUTES**

The minutes of the previous meeting on Wednesday, 12 June 2013 were approved. Duran so moved, Schultz seconded, 7-0.

**III. ANNOUNCEMENTS**

- A. IRB Orientation.** There is an IRB orientation set for January 2014 for graduate students. It is not quite clear who the target group will be. Board members wished to encourage good publicity and attendance. Newberry provided an overview of the content of the presentation. Persons who teach graduate methodology courses should be contacted for possible presentations in their courses. Schultz brought up the possibility of a “canned” presentation that could be available online.

**IV. OLD BUSINESS**

- A. IRB Tracking.** The Sociology Department has added a line for IRB authorization to the forms used to track graduate student culminating activities.
- B. Dedicated IRB Software.** A proposal was submitted to the Provost over the summer. She is seeking advice from computer personnel. Kallya Shenoy is setting up a meeting and product demonstration for Parnell and Suter of a document management software product that CSUB is already using, for example in Enrollment Management.

## 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 June 2013 meeting.

### 1. Standard Review [0]

### 2. Expedited Review [3] McCleary moved, Herndon seconded, 7-0

Number	Author	Department	E-mail	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval	Comments/ Shredded Data
13-81	Sarah Appleton	Psychology	<a href="mailto:appletons84@gmail.com">appletons84@gmail.com</a>	Assessing the Paternal-Fetal Relationship Using the Marschak Interaction Method Rating Scale	5/23/2013	Kathleen Ritter	Expedited	Roseanna McCleary, Steve Gamboa	6/17/2013	
13-84	Randy Schultz	Teacher Quality Programs	<a href="mailto:rschultz@csub.edu">rschultz@csub.edu</a>	Self-efficacy of credential students who participate in Edvention reform element based professional development	5/24/2013		Expedited	Gilchrist & Newberry	4/11/2013	
13-86	Marie Sampson	Advanced Education Studies Department Special Education Program	<a href="mailto:sampsonfamily05@ymail.com">smpsonfamily05@ymail.com</a>	Teaching Young Children with Moderate to Severe Disabilities Through Teacher-Made Video Mediated Instruction	5/29/2013	Yeunjoo Lee	Expedited	Steve Gamboa, Anne Duran	6/17/2013	

### 3. Third-Party Access to Existing Data [0]

### 4. Exemption from Full Review [4] Gilchrist moved, Gamboa seconded, 7-0

Number	Author	Department	E-mail	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval	Comments/ Shredded Data
13-87	Melissa Danforth	Computer and Electrical Engineering and Computer Science	<a href="mailto:mdanforth@csub.edu">mdanforth@csub.edu</a>	NSF SFS Summer REVS-UP Outreach	6/10/2013		Exemption		6/13/2013	
13-92	Deborah Boschini & Nursing Students	Nursing	<a href="mailto:dboschini@csub.edu">dboschini@csub.edu</a>	A Survey of University Students' Knowledge, Attitudes, and Practices Related to Valley Fever	9/17/2013		Exemption		9/18/2013	
13-94	Carl Kloock	NSM&E, Biology, Bechtel Grant	<a href="mailto:cklook@csub.edu">cklook@csub.edu</a>	An Interdisciplinary Partnership Approach to Science Education: 2013 Undergraduate Science for future Elementary Teachers	9/24/2013		Exemption		9/26/2013	
13-95	Madhavappallil Thomas	Department of Social Work	<a href="mailto:mthomas5@csub.edu">mthomas5@csub.edu</a>	Social Work Education in Australia and the USA: Comparative Perspectives and Contemporary Issues.	9/24/2013		Exemption		9/26/2013	

**B. Formal Board affirmation [0]** 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 2013 meeting.

**C. Formal Board affirmation [5] of Renewals** since the June 2013 meeting. RERC noted that he had decided to request renewal of Protocol 08-110, which was handled by Newberry. Duran moved, Gilchrist seconded, 7-0.

Number	Author	Department	E-mail	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval	Comments/Stripped/Date
08-110	Steve Suter	Psychology	<a href="mailto:ssuter@csub.edu">ssuter@csub.edu</a>	CSUB Vision Lab Visual Neuroscience Research Projects	9/23/2008	Gilchrist & Bashor	Standard		10/20/2008	renewed 5/22/2012 Renewed 6/14/2013
11-129	Danielle Solano	Department of English/Library	<a href="mailto:dsolano@csub.edu">dsolano@csub.edu</a>	Evaluating the Effectiveness of CHEM 290, Careers in Chemistry & Biochemistry.	9/8/2011	Andreas Gebauer	Exemption		9/13/2011	closure 8/12, Renewed 9/11/2012, Renewed 9/12/2013
12-99	Janet Armentor	Sociology Department	<a href="mailto:jarmentor_cota@csu-b.edu">jarmentor_cota@csu-b.edu</a> <a href="mailto:vkohl@csub.edu">vkohl@csub.edu</a>	Managing social relationships and chronic illness: A qualitative study of women with Fibromyalgia	9/25/2012	N/A	Standard		10/9/2012	Renewed 07/02/2013
12-87	Charles Lam	Mathematics	<a href="mailto:clam@csub.edu">clam@csub.edu</a>	CSUB Engineering Calculus and Outreach MSEIP Grant: The Effect of Math Tutoring and Outreach Efforts Upon Student Retention and Matriculation Rate, and Interest in STEM	6/18/2012		Exemption		7/11/2012	Renewed 9/19/2013
12-110	Randy Schultz Ed. D.	Teacher Education	<a href="mailto:rschultz@csub.edu">rschultz@csub.edu</a>	Digital Natives: An analysis of the current technology resources available to incoming freshman and credential students	10/18/2012		Exemption		10/19/2012	Renewed 7/8/2013

**D. Formal Board affirmation of protocol closures [7] (unless renewed)** whose authorization have ended or will end prior to the January 2014 IRB meeting. Herndon moved, Gamboa seconded, 7-0.

Number	Author	Department	E-mail	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval	Comments/Stripped/Date
12-04	Natalie Thompson	Anthropology	<a href="mailto:nthomps@gmail.com">nthomps@gmail.com</a>	A League of Their Own: An Exploration of Gender and Ritual in the Bakersfield Diamond Divas Roller Derby Team.	1/12/2012	Brian Hemphill	Standard	Alvarez, Duran & McCleary	2/8/2012	
12-104	Stephanie Underwood	PPA	<a href="mailto:steph14nca@msn.com">steph14nca@msn.com</a> <a href="mailto:rdaniels@csub.edu">rdaniels@csub.edu</a>	Indicators of Job Burnout for 911 Dispatchers	10/1/2012	R. Steven Daniels, Ph. D	Expedited	Newberry & Duran	12/12/2012	
12-112	Laura Hecht	IRPA	<a href="mailto:lhecht@csub.edu">lhecht@csub.edu</a>	Family Influence on Juvenile Probation Outcomes	11/8/2012		3PA		11/8/2012	
12-113	Christine Cruz-Boone	Communications	<a href="mailto:ccruz_boone@csub.edu">ccruz_boone@csub.edu</a>	Community Partners' Role in Facilitating Undergraduate Interview Speeches	11/14/2012		Exemption		11/21/2012	
12-114	Kelli Johns	Education	<a href="mailto:Tennislover1988@aol.com">Tennislover1988@aol.com</a>	The Effects of Common Formative Assessments on 1st Grade Benchmark Scores	11/28/2012	Ron Hughes	3PA		12/11/2012	
12-115	Andres Sanchez	Sociology Department	<a href="mailto:acsanchez1986@hotmail.com">acsanchez1986@hotmail.com</a> <a href="mailto:jarmentor_cota@csub.edu">jarmentor_cota@csub.edu</a>	Facebook and Friendships	11/29/2012	Janet Armentor	Exemption		1/8/2013	
12-116	Alex A Nwankwo	HEAL	<a href="mailto:alex.nwankwo@waldenu.edu">alex.nwankwo@waldenu.edu</a> <a href="mailto:felicia.blacher-wilson@waldenu.edu">felicia.blacher-wilson@waldenu.edu</a>	A Case Study of Student's Learning Experiences and Perceptions of Online Course Content and Interactions	12/4/2012	Dr. Felicia Blacher-Wilson	Exemption		12/12/2012	

## E. New Protocol Reviews [2]

1. **Protocol 13-96.** “The Effects of Aerobic Exercise, Aerobic Fitness, and S-allylcysteine on Hemorheological Factors in Response to Prolonged Inactivity in Healthy Adults”. With Michael Smith [PEAK]. Primary readers were Gamboa, Gilchrist, and Schultz.

The PI summarized. Blood viscosity is a problem associated with inactivity. Can exercise help? Blood viscosity in healthy, active adults will be monitored via blood draws across periods of immobility, such as experienced during travel, followed by exercise to see if this reverses the blood viscosity changes. Effects of garlic extract will also be examined. Questions Followed:

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

**Q:** Who will start the IV, do the blood draws, and handle the blood samples? **A:** He will start the IV. He has his own equipment for analyzing the blood samples for the variables under study.

**Q:** Are you CPR certified? **A:** Yes.

**Q:** Are you qualified to interpret EKG info? **A:** Yes, he’s EKG certified and can recognize activity that would signal discontinuation in the presence of chest pain.

**Q:** Who will pay for the costs of the lab analyses? **A:** He will do the analyses himself, so there will be no costs.

**C:** You should make it more clear what will happen in the event of an emergency. As is, it sounds like the researcher will be making a medical diagnosis. Not clear what “the study doctor” designates. Also, the wording on financial responsibility could be more clear. In general, item 12 on consent form needs to be re-worded for clarity.

**Q:** Where will you post your flyers soliciting participation? **A:** All over the place, not just on campus.

**Q:** What is your study intended to add to the earlier research from which you are adapting the immobility protocol? **A:** It’s only the protocol that will be identical. The present study is novel.

**Q:** Is it possible that somebody could get a blood clot? **A:** Possible, but extremely unlikely.

**C:** You should add a question about recent dental procedures to the screener.

**Q:** How will you exclude pregnant persons? **A:** Using the screener and a female assistant if the participant prefers.

When there were no more questions, the PI was asked to depart and the Board deliberated in executive session.

There was a motion to conditionally approve Protocol 13-96. Gamboa moved, Schultz seconded, 7-0.

The PI was informed of the following conditions when he returned:

- **Formal qualifications for doing blood draws and starting IV’s.** We want this to be established more specifically for person[s] performing these procedures. Following are several suggestions, but IRB is not limiting resolution to these options: [a] PI provides IRB with formal evidence of his training/expertise on these procedures, [b] PI obtains formal certification, [c] PI does these procedures under the direct supervision of an appropriately certified person, [d] Another person, formally certified, does these procedures.
- **Clarify Section 12 of consent form.** State clearly that in the event of a health problem, the participant should seek treatment without implying that PI will provide a diagnosis. State explicitly that payment for treatment is the responsibility of the participant. Suggested: “If you suffer an injury associated with participation in this study, you should obtain medical treatment by contacting the CSUB Health Center [661-654-2394], your physician, or calling 911, as appropriate. Payment for treatment will be your responsibility.”
- **Human Subjects Protection Training.** All personnel, including PI, interacting with participants in collecting data and/or obtaining informed consent must have HSPT certification. PI must provide IRB with names of research assistants before they become involved.
- **Phone number on consent form.** It’s 654-3152.
- **Suter contact info.** Provide contact info for Suter on consent form for concerns about rights and treatment as a research participant.
- **Participant safety.** Affirm that you will limit data collection to times that physician is present at Student Health Center.

2. **Protocol 13-97.** "Identification of Social Policy Issues of Incarcerated Older Adults Using Collateral Sources". With Roseanna McCleary [MSW Program]. Primary readers were Duran, Gamboa, and Herndon.

The PI summarized. This research will be part of a California Senior Legislator [CSL] field practicum to gather data to inform possible policy proposals at the CSL, which may lead to policy proposals at the actual California legislature. The PI and students regularly go to Sacramento to attend the CSL sessions. Elder prisoners are a very vulnerable group and are increasing in numbers much faster as compared to the rest of the inmate population. The aging process is accelerated in prisons. The study has a health focus and will work through the network of contacts of one student co-investigator with families of elderly persons on the inside. The problem relates back to the indeterminant sentencing law of 1977 that created a situation in which one must prove to have been rehabilitated to get out. It's extremely expensive to hold elder prisoners. Questions followed:

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

**C:** The question about the physical environment might be re-worded since the respondent isn't on the inside, something like "how does the family member describe it . . .".

**Q:** What if you get disturbing information? **A:** We will provide family members with a list of resources, which we already have. Department of Rehabilitation also has resources listed online.

**Q:** How does this fit in with existing research? **A:** There is some research, but it is only descriptive. We will be specifically looking for issues that could be handled within a policy framework. An example would be health problems related to overcrowding, for which a long-term solution will be needed.

**C:** The question about rehabilitation services might not be clear to family members. Maybe this should be broken down into parts.

**C:** Be careful with literacy levels for understanding of the questions and the consent form.

**Q:** Will you maintain confidentiality with respect to medical info that might come out? **A:** Yes.

**Q:** Is leaving out Spanish-only language users an issue? **A:** We plan to start with English and may expand. Overall, this is a human rights issue. Even "compassionate release" has problems.

When there were no more questions, the PI and the two students were asked to depart and the Board deliberated in executive session.

There was a motion to conditionally approve Protocol 13-97. Gilchrist moved, Schultz seconded, 6-0, with McCleary abstaining.

The researchers were informed of the following conditions when they returned:

- Convert interview guide questions and telephone consent script to spoken English.
- Revise the language in questions #7 and #8 to make these more specific.
- Submit a list of resources that will be provided to the participants.
- Clarify the way distress is addressed in the consent form, including providing a specific referral source.

## **F. Renewal of Authorized Protocols [none]**

## **G. Continuing Review of Authorized Protocols [2]**

1. **Protocol 07-91:** "Evaluation for Kern County Children and Families Commission [KCCFC]" with J. J. Wang. Primary readers were all members.

The PI indicated that 22 interns have been hired from CSUB. First 5 Kern is developing a new RFP, so there were no site visits since the previous IRB meeting. However, the new evaluation form developed over the summer, has been approved by F5K and will be implemented for the Fall 2013 site visits. Confidentiality training was carried out in a number of programs since the June 2013 IRB quarterly report. Questions followed.

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

**C:** Members were pleased with the CSUB intern situation.

**Q:** Are the interns given useful training? **A:** Yes. One has been hired as an adjunct instructor in Sociology and some have worked as assistants in our summer bridge type programs.

When there were no more questions, the PI was asked to depart and the Board deliberated in executive session.

The Board unanimously approved the quarterly report. Gilchrist moved, Duran seconded, 7-0.

The PI was informed when he returned and thanked for his diligence. There was a discussion about why Protocol 07-91 is reviewed quarterly. Newberry explained that this is the only external activity for which the CSUB IRB provides human subjects protections and the liability concerns associated with it. Thus we monitor the program more closely as compared to others. We also ask for quarterly reports from the Edvention projects because there are so many activities going on.

**2. Edvention and Related [Protocols 10-157, 11-66, 11-68, 11-117, 11-122, 13-84].** With Randy Schultz and Sarah Brooks-Arriola. Primary readers were all members.

The PI summarized. There have been few changes since the June 2013 report. Notably, Sarah has a new job in the SEE Dean's Office and will be replaced in this project. A new focus is looking at self-efficacy of the Edvention Fellows under their Protocol 13-84. They are moving forward accessing performance data on students being taught by Edvention Fellows. They will be sending through a protocol to collect pre/post data in connection with a bullying prevention training event coming up. This will be for students in the credential program. The academic literacy protocol has led to a published article. Questions followed:

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

**Q:** Can you provide an update on the iPad project? **A:** Because their training has been extended to all students in the program, they don't have enough iPads, so they are being made available on a check-out basis. Giving students in Lamont experience with iPads was a big hit, along with their video contest. Students brought up Google images of soccer stadiums around the world. They are developing a grant to provide an iPad for each Lamont teacher.

**C:** This was applauded by members.

**C:** There was a brief discussion of the special problem of Vineland District which is too small for most funded programs and has basically nothing in the way of support for instruction.

When there were no more questions, Schultz and Brooks-Arriola were asked to depart and the Board deliberated in executive session.

The Board unanimously approved the quarterly report. Gilchrist moved, Duran seconded, 6-0, with Schultz abstaining.

**VI. OTHER CONCERNS:** [none]

**VII. REMAINING MEETING DATES FOR 2013-2014:**

Winter 2014: Friday, 24 January 2014

Spring 2014: Friday, 18 April 2014

Summer 2014: Wednesday, 11 June 2014

**VIII. ADJOURNMENT:** There was a motion for adjournment at 10:33 AM. Duran moved, Herndon seconded, 7-0.

**IX. BOARD TRAINING:**

**A. Spot check of protocols authorized since last meeting:**

**1. Protocol 13-94 [Carl Kloock, Biology] "An Interdisciplinary Partnership Approach to Science Education: 2013 Undergraduate Science for Future Elementary Teachers"** Submitted 9-24-13; authorized 9-26-13; following exemption from full review. [Attachment F1: Protocol 13-94; Attachment F2: 13-94 e-mails, reverse chronological order]

The RERC described the protocol. The only issues involved having the PI clarify in the consent document the several surveys involved.

**2. Protocol 13-86 [Marie Sampson & Yeunjoo Lee, Special Education] “Teaching Young Children with Moderate to Severe Disabilities Through Teacher-Made Video-Mediated Instruction”** Submitted 5-29-13; authorized 6-17-13, following expedited review. [**Attachment G1**: Protocol 13-86; **Attachment G2**: 13-86 e-mails, reverse chronological order]

The RERC described the protocol. This study involved direct observations of standing-in-line behaviors of children with disabilities. There were few concerns and the PI responded successfully to these in a single document.