

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

**Minutes of Meeting
Friday 25 January 2013 [DDH A-108]**

Members Present:

Scientific Concerns: Anne Duran, Roseanna McCleary, Kathleen Gilchrist
Nonscientific Concerns: Steve Gamboa, Paul Newberry, Penelope Swenson

Members Absent:

Lily Alvarez, Grant Herndon

Visitors:

J. J. Wang for **First 5 Kern Report**,
Steve Ellwanger for **Protocol 13-06**,
Gwen Parnell, **GRaSP Administrative Support**,
Sarah Brooks for **Edvention Report**

I. CALL TO ORDER

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

II. APPROVAL OF MINUTES

There was a question raised about why the IRB's concern about documenting IRB authorization was limited to graduate projects. It was decided that this was because it was graduate projects that have been causing problems. Duran so moved, Gilchrist seconded a motion to approve the minutes, 6-0.

III. ANNOUNCEMENTS [none]

IV. OLD BUSINESS

A. IRB Tracking. The RERC reported that he had contacted Abbas Grammy, coordinator of the online MS in Administration program taught through Extended University. Grammy would like the RERC to help provide IRB orientation when he teaches the capstone course, ADM 690 in Spring 2013. The RERC will do so. The RERC noted that Molina is no longer coordinator of the Sociology graduate program, but seemed receptive to having an IRB authorization line added to their thesis tracking document. RERC will work with Sasaki, who is acting Sociology Chair.

B. New Community Member. It was noted that the IRB still needs a third community member. McCleary mentioned a MSW graduate working at Kaiser, who is interested. Duran mentioned a psychology MA alumnus who would be good. Newberry mentioned a possible person in the Public Defenders Department. Members will follow up.

C. Posting IRB Meeting Minutes. At the previous meeting there was discussion of the appropriateness of posting IRB meeting minutes, which are public information. It was decided to put this practice into effect. Gilchrist 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 October 2012 meeting.

1. Standard Review [1]

Number	Author	Department	E-mail	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval	Comments/ Shredded/ Date
12-99	Janet Armentor	Sociology Department	jarmorco@csub.edu skohli@csub.edu	Managing social relationships and chronic illness: A qualitative study of women with Fibromyalgia	9/25/2012		Standard		10/9/2012	

McCleary moved, Gilchrist seconded, 6-0.

2. Expedited Review [2]

Number	Author	Department	E-mail	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval	Comments/ Shredded/ Date
12-95	Mary Storey	Psychology, Religious studies	aduran@csub.edu lgubkin@csub.edu	Holocaust Class Learning Outcomes	9/21/2012	Anne Duran, Liora Gubkin	Expedited	Gilchrist & Swenson	10/12/2012	
12-104	Stephanie Underwood	PPA	steph14nca@msn.com rdaniels@csub.edu	Indicators of Job Burnout for 911 Dispatchers	10/1/2012	R. Steven Daniels, Ph. D	Expedited	Newberry & Duran	12/12/2012	

Gamboa moved/Gilchrist seconded, 6-0.

3. Third-Party Access to Existing Data [2]

Number	Author	Department	E-mail	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval	Comments/ Shredded/ Date
12-112	Laura Hecht	IRPA	lhecht@csub.edu	Family Influence on Juvenile Probation Outcomes	11/8/2012		3PA		11/8/2012	
12-114	Kelli Johns	Education	Tennislover1988@aol.com	The Effects of Common Formative Assessments on 1st Grade Benchmark Scores	11/28/2012	Ron Hughes	3PA		12/11/2012	

Gamboa moved, McCleary seconded, 6-0.

4. Exemption from Full Review [13]

Number	Author	Department	E-mail	Title	Date Submitted	Faculty Sponsor	Type of Review	Final Approval
12-102	Yvonne Ortiz-Bush	Educational Counseling	yortiz-bush@csub.edu pwenson@csub.edu	Bullying Prevention and the Pre-service Counselor: A Collaborative Effort	10/1/2012		Exemption	10/2/2012
12-105	Yangsuk Ko & Dana Abouelnasr	Mathematics/Physics and Engineering	yko@csub.edu dabouelnasr@csub.edu	Perceptions of Students Taking Calculus	10/12/2012		Exemption	10/12/2012
12-106	Dr. Kristina LaGue	Teacher Education and Teacher Quality Programs	klague@csub.edu	Perceptions of the Academics Literacy Academy	10/12/2012		Exemption	10/25/2012
12-107	Jenny Holland	Political Science	j_holland@wsu.edu kprice@csub.edu	Age and Political Opinions	10/12/2012	Kent Price	Exemption	10/19/2012
12-109	Yvonne Ortiz-Bush	Educational Counseling	yortiz-bush@csub.edu pwenson@csub.edu	School Counselor Awareness of California Anti-Bullying Legislation	10/18/2012		Exemption	10/24/2012
12-110	Randy Schultz EdD	Teacher Education	rschultz@csub.edu	Digital Natives: An analysis of the current technology resources available to incoming freshman and credential students	10/18/2012		Exemption	10/19/2012
12-111	Robert Bravo, Nick Smith, Linda Medina	Psychology	robertbravo7@gmail.com	Student Ethnicity and Gender: How it relates to in-class participation	10/26/2012	Anne Duran	Exemption	10/27/2012
12-113	Christine Cruz-Boone	Communications	ccruz_boone@csub.edu	Community Partners' Role in Facilitating Undergraduate Interview Speeches	11/14/2012		Exemption	11/21/2012
12-114	Kelli Johns	Education	Tennislover1988@aol.com	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	acsanchez1986@hotmail.com jarmentor_cota@csub.edu	Facebook and Friendships	11/29/2012	Janet Armentor	Exemption	12/11/2012
12-116	Alex A Nwankwo	HEAL	alex.nwankwo@waldenu.edu felicia.blacher-wilson@waldenu.edu	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
13-01	Mary Storey	Psychology	aduran@csub.edu bullwinky@gmail.com	Need for Closure and Preferences for Psychology Courses	1/7/2013	Anne Duran	Exemption	1/11/2013
13-03	Joshua Carter	Psychology	joshua.evan.carter@gmail.com aduran@csub.edu	Morality Effects of Attitudes Toward Atheists	1/11/2013	Anne Duran	Exemption	1/11/2013

Swenson pointed out that she should not be listed as Faculty Sponsor on 12-102 and 12-09, since the PI is a faculty person. McCleary moved as corrected, Duran seconded, 6-0.

B. Formal Board affirmation [5] of protocols submitted and designated as not falling within the IRB/HSR definition of human subjects research (**not within IRB/HSR purview**) since the October 2012 meeting.

Number	Author	Department	E-mail	Title	Date Submitted	Faculty Sponsor	Type of Review	Comments/ Shredded/ Date
12-100	Shannon Renee McDonald	PPA	stevendaniels@csub.edu Shannon1thegreat@yahoo.com	Bullying and the Relationship to School-Age Suicides	9/26/2012	R. Steven Daniels	Not HSR	
12-101	Christina Salas	PPA	Christinasalas89@yahoo.com	Evaluation of Bureau of Land Management Bakersfield Field Office Safety Orientation	9/26/2012	John Hultsman	Not HSR	
12-103	Sara Mackey	PPA	sarabethmackey@gmail.com mrdaniels@csub.edu	Program Proposal for Drug Testing and Rehabilitation of Welfare Recipients	10/1/2012	John Hultsman	Not HSR	
12-108	Maridelle Joy Invina	PPA	jhultsman@csub.edu	An Evaluation on a Non-Profit Blood Bank's Social Media Impact	10/18/2012	John Hultsman	Not HSR	
12-117	Michelle Henry	PPA	toocool4lawschl@gmail.com mrdaniels@csub.edu	CSUB Music Program Evaluation	12/6/2012	R. Steven Daniels	NRS	

It was suggested that "PPA" be used consistently as the Department designation for Public Policy and Administration. Duran moved as corrected, Gilchrist seconded, 6-0

C. Formal Board affirmation [3] of previously approved granted **Renewals** since the October 2012 meeting. The only modifications were personnel related.

Number	Author	Department	E-mail	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval	Comments/ Shredded/ Date
11-01	Douglas Dodd & Curt Asher	History/ Walter stiern Library/ Public History Institute	ddodd@csub.edu	CSUB Campus Oral History Project	1/6/2011		Exemption		1/9/2011	11/30/11 renewed 12/07/12 renewed
11-146	Roseanna McCleary	Social Work	Bullwinky@gmail.com	Project Esperanza Program Evaluation	11/14/2011		Expedited	Newberry & Gilchrist	1/23/2011	Renewed 9/28/2012
12-05	Matt Leon	Psychology	mleon6@csub.edu	The Neural Basis of Human Time Perception	1/17/2012		Expedited	Gilchrist & Newberry	2/27/2012	Renewed 1/14/13

McCleary should be listed as the author on 11-146 since Storey is no longer on the protocol. Duran moved as corrected, McCleary seconded, 6-0.

D. Formal Board affirmation of protocol closures [11] (unless renewed)
 whose authorization have ended or will end prior to the April 2013 IRB meeting.

Number	Author	Department	E-mail	Title	Date Submitted	Faculty Sponsor	Type of Review	Reviewers	Final Approval	Comments/Revised/Date
09-148	Peggy Leapley	National Children's Study/Nursing	pleapley@csub.edu	National Children's Study Kern County (Phase 1)	9/14/2009		Exemption		9/30/2009	renewal 5/25/2010 closure 9/12
10-130	Marianne Abramson & Tyson Smith	Psychology	mabramson@csub.edu	Pain and High Heels As Sexual Attractors	8/18/2010		Expedited	McCleary & Newberry	9/1/2010	renewal 1/10/12
10-142	Stacy Teeters	Psychology	stacy.teeters@gmail.com	Women and Gender Studies Interest Survey	10/14/2010	Anne Duran	Exemption		10/26/2010	renewal 9/11
10-157	Curtis Guaglianone	Edvention Partners: Teacher Quality Programs	cguaglianone@csub.edu	Baseline Preparation Data Survey for Edvention Fellows	12/8/2010		Exemption		12/20/2010	renewed 9/27/11
11-138	Phyllis Heintz	Nursing	phintz@csub.edu	Comparison of Student Learning Outcomes between Students in Online and Lecture Nursing Research Classes	10/31/2011	Deborah Boschini	Exemption		11/4/2011	
11-139	Josh Carter & Kevin Novak	Psychology	Kevinnov131@msn.com	Attitudes of Atheists as Hostile and Untrustworthy Job Applicants	11/3/2011	Anne Duran	Exemption		11/8/2011	
11-142	P. Michael Lutz	Mathematics	plutz@csub.edu	Development and Pilot Test of a Scalable Professional Development System for Formative Assessment of Mathematics for Teacher Leaders in a Professional Learning Community	11/9/2011	Javier Trigos	Exemption		11/28/2011	
11-143	Leslee Martinez	Psychology	LesleeMartinez08@gmail.com	Tattoos, Gender, and Perceived Pain	11/10/2011	Anne Duran	Exemption		11/16/2011	Renewal 2/6/12
11-144	Omar Craviotto	Education: Curriculum & Instruction	omarcraviotto@att.net	Advantages and Disadvantages of Online Process Overview Training for Manufacturing	11/14/2011	Ron Hughes	Exemption		12/9/2011	
11-145	Patricia Acosta	McNair Scholars Program	p_acosta13@hotmail.com	Students' Attitudes and Knowledge of Schizophrenia	11/14/2011	Isabel Sumaya	Exemption		11/28/2011	
12-02	Kristen Phillips	Communications	Kristen.phillips@mavs.utah.edu	Identifying Meida Literacy Skills in College Students	1/11/2012	Donna Simmons	Exemption		1/23/2012	

Gilchrist moved, Swenson seconded, 6-0.

E. New Protocol Reviews

1. Protocol 13-06. "Shakin' but not Stirred: The Effects of Herbal Remedies on Field Sobriety Breathalyzer Tests" with Steven Ellwanger [Criminal Justice Department]. Primary readers are Gamboa, Gilchrist, Herndon.

Following introductions, the PI summarized. A new product, the Breathalyzer Equalizer [BE] is pitched as a way to reduce false positives in breathalyzer tests of blood alcohol content [BAC], but is heavily marketed around bars. Whereas avoiding false positives from having used mouthwash would be a good thing, creating false negatives in BAC would be a bad thing. There have apparently been no studies of the effects of BE on BAC readings. In this study BAC readings for students who have used BE will be compared with controls having approximately equal BAC induced by drinking beer. The study will be conducted on campus at "The Roost". The PI plans to add a procedure whereby participants trade in tokens for beer in order to limit consumption to the desired levels. Questions followed.

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

Q: How does BE work? **A:** It is not specified.

- Q:** Is there a risk for persons having allergies? **A:** Advertising states “all natural ingredients”..
- Q:** Can a participant drop out? **A:** Yes, this is stated in the consent form.
- C:** The protocol and consent form should state that a drop out will be required to stay until the BAC is back down.
- Q:** Why are you having them drink so early in the morning? **A:** This is necessary for their BAC to get back down before it gets too late, hopefully by 6 PM.
- Q:** No blood draws for BAC? **A:** No, this will be limited to breathalyzer data.
- Q:** Are there provisions for presence of medical personnel? **A:** It was considered that the nearness of Mercy Hospital Southwest and presence of police officers should be adequate.
- C:** Someone who is CPR certified should be present.
- C:** Looking online it appears that almost nothing is stated about the ingredients beyond “food quality ingredients” and the product would not have been examined by the FDA.
- C:** Somebody could sneak out during a restroom visit. You should prevent this by monitoring to prevent a participant with elevated BAC from leaving and possibly driving.
- Q:** No research like this has been published on this product. **A:** Apparently not.
- Q:** Could you share the results with the IRB. **A:** Sure.
- Q:** What classes will you use to get the student volunteers? **A:** This is somewhat up in the air.
- C:** The IRB will ask you not to use students from your own classes.
- Q:** Have you worked out how to get the food and so forth? **A:** Once the IRB has approved the PI will work with the necessary people on campus on the implementation.
- Q:** Will you get useful information about the effects of BE on false positives? **A:** Not directly, although one might infer such effects if it produces large differences in BAC readings involving alcohol.
- C:** You probably want to avoid emotionally laden activities as you occupy their time at the Roost.

When there were no more questions, the PI was invited to leave and the Board deliberated in Executive Session. Following discussion, the following conditions were agreed upon:

1. State that the data and signed consents will be stored separately. State who will have access to both.
2. Add the procedure involving the beer tokens to the protocol.
3. Modify description of withdrawal from study procedure in both protocol and consent form to state that participant must remain on site until BAC is back down, even if withdrawing from the study.
4. Add to protocol that a CPR-certified person will be present throughout the experiment.
5. Monitor restroom visits to ensure that a participant does not leave before BAC is down.
6. Do not use students from classes currently taught by either investigator.
7. Add a statement affirming good health to the consent form.

McCleary moved, Gamboa seconded, 6-0.

The PI returned and was so informed.

F. Continuing Review and Renewal of Authorized Protocols

1. **Edvention and Related.** With Sarah Brooks. Primary readers are all members.

Protocol 10-157: “Baseline Preparation Data Survey for Edvention Fellows”

Protocol 11-66: “Cycle of Activity Model [CAM] Participant Survey”

Protocol 11-68: “Discussion Responses Regarding iPad Use Among a Select Group of Pre-Service Teachers”

Protocol 11-117: “Edvention Partners – Effects of CSU Teacher Preparation on K-12 Student Achievement”

Protocol 12-106: “Perceptions of the Academic Literacy Academy”

Following introductions, Brooks summarized. Brooks is standing in for Schultz, who is in Paso Robles on Edvention-related activities. A recently-presented poster by the Edvention group was displayed to the admiration of board members. Brooks proceeded protocol by protocol

Protocol 10-157 [Edvention Fellows]. The only change is that the planned expansion to all students in teacher education at CSUB has been implemented. A promotional flyer was distributed to the board. Although iPADS cannot be issued to every student, they are available on a checkout basis. Two additional protocols will be submitted to the IRB to cover evaluation of these activities.

Protocol 11-66 [Cycle of Activity Model (CAM)]. This involves partnering to implement 15 reform elements. Data collection continues.

Protocol 11-68 [Using iPads]. There were presentations by Edvention Fellows at the Kern CEU Conference. Swenson has been invited to talk at a technology-focused SIG. The Edvention Fellows tend to become the technology experts at their schools, which is a positive for perception of CSUB in the education community “out there”.

Protocol 11-117 [Student Achievement]. Evaluation data on the first-year students is being collected and the struggle continues to obtain student performance data to enable a comparison of students taught by Edvention Fellows as compared to control students. The “n” is small.

Brooks and Swenson were invited to leave and the Board deliberated in Executive Session. There was a motion to accept the quarterly report and renew all of the protocols. It was noted that if LaGue wished to modify Protocol 12-106, this would be handled via a protocol modification request.

McCleary moved, Gilchrist seconded, 5-0, with Swenson recusing.

Brooks and Swenson returned and were so informed.

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

Protocol 07-91. The PI commented. F5K had coauthored a funded grant proposal, “California Signature Program” that included a data analysis position. This was previously described as a F5K activity, but the grant is formally to the Kern County Superintendent of Schools, which has been updated. Questions followed.

Q: How is the agency dealing with the discomfort noted for the question about the birth father? **A:** This specific question is required by the state F5K evaluation procedures. Related is a question about smoking during pregnancy, which participants sometimes perceive as an attempt to place blame on them. Agency personnel explain that the data are for evaluation of the program and that they don’t need to answer. However, all do answer.

Q: Provide an update on involvement of CSUB students, which was a factor in obtaining CSUB administrative support for continuing IRB coverage of F5K? **A:** There are several graduate students involved and a former student is the F5K CEO.

Q: But, there are no intern-type arrangements for CSUB students? **A:** There are some issues about obtaining adequate training of such students, but there are some former CSUB students involved as research assistants with F5K.

C: Continuing CSUB student involvement would help justify involvement of our IRB in F5K human subjects protections. **A:** It's possible there would be continuing interest at PPA.

Q: Do they still take CSUB student interns at the F5K office? **A:** Not sure.

The PI was invited to leave and the Board deliberated in Executive Session. There was a motion to accept the F5K report, renew Protocol 07-91 and to include in the authorization letter a request from the IRB to: [a] systematically determine the extent of CSUB student involvement in F5K; [b] to interact with the CSUB Community Engagement folks to attempt to facilitate "service learning" experiences in F5K, and [c] to emphasize to F5K officials the importance of CSUB student involvement in the decision for CSUB to allow the IRB to provide human subjects protections. The PI returned and was informed.

Duran so moved, Gilchrist seconded, 6-0.

VI. OTHER CONCERNS:

There was discussion of an issue involving Protocol 03-03, the Psyc 100 research participant pool, and Duran's need for more participants in her research protocols this quarter. Following a summary of recent communications among Duran, the RERC, Newberry, Raupp [Subject Pool Coordinator], and Bacon [Psychology Department Chair], there was a consensus that: [a] Duran could be authorized to recruit from other classes by requesting modification of her protocols and [b] those students could be allowed to use the Psyc 100 participation pool sign-up sheets. This would not require a modification in Protocol 03-03.

VII. REMAINING MEETING DATES FOR 2012-2013:

Spring 2013: April 19th, 2013
Summer 2013: June 12th, 2013

VIII. ADJOURNMENT:

At 10:16 AM Swenson moved, Suter [serving as an alternate member] seconded, 6-0.

IX. BOARD TRAINING:

A. Spot check of protocols authorized since last meeting:

RERC advised that scrolling backwards through the accumulated e-mails on a protocol is the best way to grasp the investigator X IRB interactions that were involved in reviewing and authorizing protocols. The two protocols selected for the spot check, Protocols 12-104 and 12-114, were not discussed.

B. Report on the CSU IRB Forum at CSU-San Marcos, 18 January 2013:

The attendees, RERC and McCleary, commented briefly. There were about 50 participants from 20 CSU campuses in attendance, split about equally between IRB members and IRB administrators – “compliance officers” is what the RERC is called elsewhere. There was a brief summary of useful info gleaned from this forum. Other IRBs grapple with the same issues as CSUB.