

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

Minutes of Meeting
Friday, 07 October 2011 [DDH A-108]

Members Present:

Scientific Concerns: Kathleen Gilchrist, Anne Duran, Roseanna McCleary
Nonscientific Concerns: Paul Newberry
Community Concerns: Grant Herndon

Members Absent:

Lily Alvarez, Tommy Tunson, Jeunjoo Lee

Visitors:

J. J. Wang for **Protocol 07-91** Quarterly Report
Curt Guglionone & Randy Schultz
for **Protocols 10-157, 11-66, 11-68, & 11-117** Quarterly Report

I. CALL TO ORDER

Chair Paul Newberry called the meeting to order at 7:59 AM. In actual sequence, Item V-F-1 happened next.

II. APPROVAL OF MINUTES

A. IRB meeting of Friday, 08 June 2011.

There was a brief re-discussion of the wisdom of keeping IRB non-compliance issues on the agenda. The Board still thought it would be a good idea to keep this item active under Old Business until further notice.

Gilchrist moved, McCleary seconded approval of minutes – 5-0.

III. ANNOUNCEMENTS

A. Farewell to Yeunjoo. Board members said farewell to Yeunjoo Lee *in absentia*.

B. University Counseling Clinic as Consent Form Contact. There was a discussion of Kathy Ritter's offer for the IRB to use the University Counselor Training Clinic as a contact for distress or adverse reaction on consent forms involving research participants not affiliated with CSUB, to be determined on a case by case basis by Kathy. There was concern that assistance is not available 24/7 and that persons contacting the clinic might very well be experiencing "acute crisis", a problem that the clinic brochure specifically indicates is not within the purview of the clinic. There was agreement that the clinic was probably not a good contact to list on consent forms. McCleary was tasked with determining which telephone contacts, such as hotlines, would be appropriate for use in consent forms, given that some have vanished due to budget cuts.

IV. OLD BUSINESS

A. Update on Spanish Translations. RERC reported that it appears that the CSUB modern Languages Department will not provide this service for the IRB. Members brought up several possible alternatives: [a] an interested person at Bakersfield College via Bob Carlisle, [b] possible contacts of Tom Blommers', [c] translation people at Kern County Mental Health, and [d] other CSUB faculty who might have language translation skills. This discussion also touched on the importance of replacing Tom Blommers with a person having English-Spanish translation skills. There was agreement that the translation materials that have been developed should now be posted.

B. Update on Non-Compliance. The SSE Dean has announced that SSE programs will adopt the culminating project monitoring form developed last Spring by the IRB, unless a program proposes a particular alternative. Because the RERC has seen no proposed alternatives, he indicated that he assumes the form is being implemented. Members of the Board were not quite so sanguine, suggesting that careful follow-up on tracking form implementation is needed. There was also a consensus that there be some kind of communication to faculty about consequences of non-compliance. There was also interest in having the RERC check with other CSU's about the consequences of non-compliance at their institutions.

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 2011 meeting.

1. Standard Review [0]

2. Expedited Review [2]

Number	Author	Title	Date Submitted	Faculty Sponsor	Reviewers	Type of Review	Final Approval
11-118	Gokh Alshaif	Sources of Jordanian Public Opinion of the United States of America.	6/22/2011	Michael Ault	Anna Duran/Paul Newberry	EXPED	7/12/2011
11-130	Barbara K. Godwin-Asten Fowler	Improving Foster Parent Understanding of Children with Prenatal Alcohol Exposure.	9/13/2011	Roseanna McCleary	Duran/Lee	Exped	9/23/2011

Duran so moved, Herndon seconded, 5-0.

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

Number	Author	Title	Date Submitted	Faculty Sponsor	Reviewers	Type of Review	Final Approval
11-117	Sarah Brooks	Edvention Partners-Effects of CSU Teacher preparation on K-12 Student Achievement.	6/20/2011	Provost Coley		NRS	6/20/2011

Gilchrist moved, McCleary seconded, 5-0.

4. Exemption from Full Review [8]

Number	Author	Title	Date Submitted	Faculty Sponsor	Reviewers	Type of Review	Final Approval
11-114	Chandrasekhar Commuri	A Study of the Philanthropic Practices of Second generation South Asians in California.	6/14/2011	R. Steven Daniels		exempt	6/20/2011
11-116	Kathleen Gilchrist	Reflections of RN to BSN Nursing Students	6/20/2011	Cherie Rector		exempt	6/22/2011
11-119	De Vaughen Bell, Julianna Kroeker, Andrea Padilla	Peer to Peer BSN Simulation Grading	7/5/2011	Deborah Boschini		Exempt	7/12/2011
11-120	Liora Gubkin/Anne Duran	Religious Imagery Pilot Study	7/5/2011	Jacqueline Kegley		Exempt	7/20/2011
11-122	Sarah Brooks	Edvention Partners-Administrative Leadership Study.	7/12/2011	Provost Coley		exempt	7/20/2011
11-123	Dirk Baron	Dual-Credit Physical Geology Classes: a Strategy of Improving the "Pipeline" from High Schools into University Geology Programs.	7/13/2011	Dirk Baron		exempt	7/20/2011
11-128	Sarah Philips	College Readiness Intervention Program with High School Seniors.	9/6/2011	Emerson Case		exempt	9/14/2011
11-129	Danielle Solano	Evaluating the Effectiveness of CHEM 290, Careers in Chemistry & Biochemistry.	9/8/2011	Andrea Gebauer		exempt	9/13/2011

McCleary moved, Herndon seconded, 5-0.

B. Formal Board affirmation [9] 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 2011 meeting.

Number	Author	Title	Date Submitted	Faculty Sponsor	Reviewers	Type of Review	Final Approval
11-110	Daniel Reagan	Student Achievement and GPA.	5/27/2011	Penelope Swenson		NRS	6/3/2011
11-111	Megan Pratt	Substance Abuse Among Welfare Recipients.	6/3/2011	R. Steven Daniels		NRS	6/3/2011
11-112	Julieta Aguirre	Mentor.Manage.Motivate. A Program Proposal to shape a better Millennial Educator in the 21st Century.	6/3/2011	R. Steven Daniels		NRS	6/3/2011
11-113	Scott Kearney	Crossing Educational Disciplines To Make Connections For Kids.	6/20/2011	Penelope Swenson		NRS	6/22/2011
11-115	Tzvi D. Daum	E-Portfolios as an Educational Tool.	6/20/2011	Penelope Swenson			
11-124	Daniel Harbour	Technical Review Board Chairman Guidelines for Conducting Technical Review Boards for Rocket Testing	7/18/2011	Chandra Commuri		NRS	7/20/2011
11-125	Tanya Boone	Student Perceptions and Attitudes Regarding Community Engagement.	7/27/2011	Jane Evarian		NRS	8/1/2011
11-126	James Stockdale	Industry Relevant Exemplar Lessons for Pre-Engineering Pathways	8/23/2011	Ron Hughes		NRS	
11-132	Eric Diego Ocampo	Human Resources and Leadership Theory Implications at Training	9/26/2011	R. Steven Daniels			

Herndon moved, Gilchrist seconded, 5-0.

Danforth Evaluation of Cyber Attack Detection Systems. RERC summarized this project which involves monitoring online traffic to identify potential cyber attacks and the efficacy of particular systems to detects them. Discussion among the RERC, McCleary [having expertise about ethics of online research], and the IRB Chair led to the conclusion that, although persons could possibly be identified accidentally, these incidental events are not sufficient to qualify this project as human subjects research and bring it within the purview of the IRB. An official IRB letter was provided stating that conclusion. This project was not formally submitted to the IRB.

C. Formal Board affirmation [10] of previously approved protocols granted Renewals since the June 2011 meeting.

Number	Author	Title	Date Submitted	Faculty Sponsor	Reviewers	Type of Review	Final Approval
08-101	Roseanna McCleary & Bruce Friedman	Evaluation of the Practicum Partnership Program Adoption Initiative	8/13/2008			Exemption	9/10/2008
08-102	Roseanna McCleary & Bruce Friedman	Hartford Partnership Program for Aging Education Career Tracking Survey	8/13/2008			Exemption	9/10/2008
09-145	Marianne Abramson, Yi Du, & Tyson Smith	Factors Affecting Computer Voice Commands	8/24/2009		McCleary and Newberry	Expedited	9/4/2009
09-148	Peggy Leapley	National Children's Study Kern County (Phase 1)	9/14/2009				9/30/2009
10-86	Anne Duran	Changes in Tolerance and Acceptance as a Result of	4/9/2010			Exempt	4/15/2010
10-120	Jenifer Pitcher	Gender Stereotypes Affect on US Political Candidates	6/22/2010	Dr. Kent Price			8/4/2010
10-136	senior-level nursing students	Respiratory Hygiene Practices within a Campus Community: An Observational Study	9/24/2010	Deborah Boschini		Expedited	9/24/2010
10-142	Stacy Teeters	Women and Gender Studies Interest Survey	10/14/2010				
10-150	Stacy Teeters & Diana Pougé	Multicultural v. Colorblind Approach's Effect on Tolerance and Acceptance	11/8/2010	Anne Duran			11/10/2009
10-157	Curtis Guaglianone	Baseline Preparation Data Survey for Edvention Fellows	12/8/2010				12/20/2010

Gilchrist moved, Herndon seconded, 5-0.

D. Formal Board affirmation of protocol closures [12] (unless renewed) whose authorization have ended or will end prior to the January 2012 IRB meeting.

Number	Author	Title	Date Submitted	Faculty Sponsor	Reviewers	Type of Review	Final Approval
10-119	Shiva Cohen-Gadol	The Impace Of Media on Young Female's Body Image	6/22/2010	Dr. Randy Schultz			11/0810
10-123	Heather Blue	Technology Support in Math	7/10/2010	Ron Hughes	Yeunjoo Lee		10/29/2010
10-144	Danielle Solano	Evaluating the Effectiveness of Chem. 195-295, Careers in Chemistry	10/21/2010				11/1/2010
10-146	Bruce Friedman	Point in Time Homeless Survey	10/27/2010		McCleary & Newberry	Expedited	11/17/2010
10-149	Jessica Smith	Implementing an Intergenerational Program at an Adult Day Health Care Center in Southern California	11/3/2010	Jong Choi			11/9/2010
10-150	Stacy Teeters & Diana Pouge	Multicultural v. Colorblind Approach's Effect on Tolerance and Acceptance	11/7/2006	Anne Duran			11/9/2010
10-151	Carl Kloock	Planning for a Robert Noyce Teaching Fellowship at CSUB	11/8/2006				11/12/2010
10-152	David Henley	The Effect of Realia Discrepant Event Instruction Upon Cue Attendance	11/14/2006	Ron Hughes			
10-153	Jennifer Wahley (Harter)	Effectiveness of a Comprehensive Sex Education Program vs. Abstinence Only Education in Increasing Knowledge and Responsible Sexual Behavior	11/14/2006	Penelope Swenson			11/1810
10-154	Victoria Ndukwu	Does the Integration of Technology into the Classroom Enhance Students Performance in Science?	10/17/2006	Penelope Swenson			12/1010
10-155	Courtney Morris	Prevention through Registration: An Analysis of the Creation, Implementation, Use and Maintenance of an Elder Abuse Registry	11/29/2006	Jong Choi			12/9/2010
10-156	Jenny Meadlin	Solving the Policy Gap in AFRL's Suspense Management Process	11/29/2006	Thomas Martinez		DRS	11/30/2010
10-157	Curtis Guaglianone	Baseline Preparation Data Survey for Edvention Fellows	12/7/2006				12/20/2010
11-01	Douglas Dodd & Curt Asher	CSUB Campus Oral History Project	1/6/2011	Jeanne Harrie			1/14/2011

There were renewal requests for Protocols 10-150 and 10-157, which had been approved, so these protocols were removed from the closure list.

Gilchrist moved, McCleary seconded, 5-0, on the motion to approve the revised closure list.

E. New Protocol Reviews [none]

F. Continuing Review of Authorized Protocols

- Edvention and Related.** With Curtis Guglianone and Randy Schultz.

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"

The investigators summarized. These activities are part of the third year of a 5-year DOE grant, hoping to improve teacher education across the U.S. Theirs involves five universities in Central California working with 18 schools. The four goals and 15 reform elements were summarized. The investigators provided updates on the four IRB protocols in progress thus far. Additional protocols and modifications of existing protocols are anticipated.

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

Protocol 10-157. Baseline survey data on needs and expectations have been collected from the initial group of Edvention Fellows. IRB approval has been granted for collecting the same data from the 2011-2012 cohort. The knowledge gained here is intended to be applied throughout the whole project.

Q: You recently sent through a modification request on the new cohort, didn't you? **A:** Yes.

Q: Are you interested in publishing your results eventually? **A:** Yes. The major purpose is to reform teacher training within the participating institutions, but a smaller aim is to disseminate what we learn more broadly.

Protocol 11-66. The "cycle of activities" [CAM] part deals with the reform elements – applying them in courses being taught, and then ultimately testing to see if implementation has positive effects on the students being taught by these teachers. Data will include surveys of the CAM faculty, looking at their course syllabi, and getting feedback from the teachers on what seems to be working and what needs changing.

Q: You are interested in whether other teachers adopt some of these reforms. How will you find out? **A:** That will be in another IRB protocol to be submitted fairly soon.

Q: How do the results look so far? **A:** In general good, but we are finding that coordination across four universities is very difficult.

Protocol 11-68. This is primarily Swenson's work, looking at use of the grant-supplied iPads. Student feedback has been collected for the 2010-2011 Edvention Fellows, with the results presented at a conference. The survey has been modified, with IRB approval, for use with the 2011-2012 group.

Protocol 11-117. This protocol includes the research looking at the effects of the teacher preparation reforms on K-12 student achievement. Presently, the main focus is getting the various districts to comply in gathering the necessary baseline data. Only a minority of the schools are expected to eventually comply.

Q: In the large, standardized databases, can you match up student achievement data with specific teachers in order to link this to the Edvention Program? **A:** The statewide data do not appear to be accessible. Social security numbers could be used to pair up

the data and their legal advice is that this could be done, since it is strictly educational institutions involved.

Q: When you publish, it will be aggregate data? **A:** Yes.

Q: Would you be able to specifically identify CSUB-trained teachers to see how they are doing? **A:** Yes and could also see if children in classrooms taught by students trained recently in this program do better as compared to those taught by earlier CSUB-trained teachers. Will also be able to look at particular reform elements.

Protocol 11-122. This is school administrator training. New principals are being interviewed. Thirteen have been interviewed so far and more interviews are planned, along with an eventual publication.

Q: Is Vineland among the local schools included. **A:** No, there are a number of other rural clusters that are included and we may pick up an additional district.

When there were no more questions, the investigators were excused and the Board deliberated in executive session. There was a motion to accept the quarterly report and authorize continuation of these protocols. The investigators were informed.

Duran so moved, Herndon seconded, 5-0.

- 2. Protocol 07-91:** "Evaluation for Kern County Children and Families Commission [KCCFC]" with J. J. Wang.

The investigator summarized. He, the IRB Chair, and the RERC had coordinated over the summer on revisions to the training manual dealing with acronym changes – OCERS to GEMS and CS&O to First 5 Kern, in various places in the manual. In addition the contracts of two programs are expiring, so they will not appear in the next report. New trainings are underway and data collection has been suspended until training has been completed. Questions followed.

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

Q: With First 5 Kern replacing CS&O, what has become of the participation by CSUB students in the program evaluations? This was a major selling point in getting the CSUB Academic Provost to endorse the continuing involvement of the CSUB IRB. **A:** They are still involved – the same CSUB student team members.

Q: Perhaps you should include something on CSUB student involvement in your quarterly reports? **A:** Will do, starting with the next [January 2012] report.

Q: What is the status of the language change, the use of "may" with different meanings in the document? Should this be submitted to the Board? **A:** These usages were all reviewed and eventually approved by the IRB Chair. **C:** The Chair noted that he had not recalled doing this, but was agreeable.

Q: When will data collection resume? **A:** When confidentiality training has been completed.

When there were no more questions, the investigators were excused and the Board deliberated in executive session. There was a motion to accept the quarterly report and authorize continuation of this protocol. The investigator was informed.

Herndon moved, Duran so seconded, 5-0.

VI. OTHER CONCERNS:

A. Modification of IRB Authorization Letter. There was a non-compliance case over the summer in which the investigator made significant departures from the authorized protocol. She mailed a single copy of the consent form, rather than two, and included a single return envelope, rather than two, which precluded the anonymity that was promised in the consent form. The investigator took corrective action following a discussion with the IRB Chair and RERC. An additional outcome was that a sentence was added to the IRB authorization letter: **“In conducting this research, the investigator must carefully review the final, authorized version of the protocol to ensure that the research is conducted as authorized by the IRB”.**

This addition to the IRB authorization letter was approved.

Duran so moved, Herndon seconded, 5-0.

B. Deferral Between CSU IRBs. This involves a proposal that will possibly be implemented at the next CSU-wide Research Administrators meeting on 10-14-11. A series of attachments provided by Vincent Oragwom from the GRaSP Office spell out procedures that would enable IRBs to defer to another CSU IRB in the case of research involving multiple campuses. Although Board members were unable to specifically endorse this process, as it appears that a number of elements are still under debate, the IRB did endorse, in principle, establishing such a procedure.

Gilchrist moved, McCleary seconded, 5-0.

VII. MEETING DATES FOR 2011-2012:

Fall 2011: October 7th, 2011
Winter 2012: January 27th, 2012
Spring 2012: April 20th, 2012
Summer 2012: June 13th, 2012

VIII. ADJOURNMENT:

McCleary moved, Duran so seconded, 5-0.

IX. BOARD TRAINING:

A. Proposed Revisions in 45CRF46. RERC brought Board members' attention to a PowerPoint presentation and his own brief summary of a series of proposed changes in the federal regulations the IRB implements. The changes that would seem to most impact our IRB are: [a] possible revisions in the concept of “exempt”, [b] making deferrals to another IRB easier, and [c] uniform standards across all protocols for data security.

B. Spot check of protocols authorized since last meeting:

1. **Protocol 11-120 [Leora Gubkin, Philosophy & Religious Studies Department, Anne Duran and Leslie Reyes Psychology Department] “Religious Imagery Pilot Study”** Submitted 7-05-11; authorized 7-13-11; following exemption from full review.

[Note that discussion of this protocol was moved to the convened meeting, so Board action could be taken]. Investigators in this protocol proposed to collect data from students in their own classes for convenience. Although the research would have involved very little risk, time, or potential abuse of students' vulnerable status, investigators were told not to use their own students, because "no use of own students" is the default position of the IRB. In doing so, the IRB Chair and RERC agreed that this issue should be discussed at the Fall 2011 IRB meeting. Would the IRB like to amend this policy? There was a consensus to keep the present policy in place, but to allow exceptions on a case by case basis.

2. **Protocol 11-129 [Danielle Solano, Chemistry Department] "Evaluating the Effectiveness of Chem 290: Careers in Chemistry & Biochemistry"** Submitted 9-08-11; authorized 9-13-11, following exemption from full review.

Board members were informed that this protocol was authorized without change. There were no questions or comments.