

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

Minutes of Meeting
Wednesday 13 June 2012 [DDH A-108]

Members Present:

Scientific Concerns: Anne Duran, Roseanna McCleary, Kathleen Gilchrist
Nonscientific Concerns: Steve Gamboa, Penelope Swenson
Community Concerns: Grant Herndon

Members Absent:

Lily Alvarez, Tommy Tunson

Visitors:

J. J. Wang for **First 5 Kern Report**, Nicola Bayley and Alem Kebede for **Protocol 12-77**,
Sharon Haynes, **GRaSP Administrative Support**, Vincent Oragwam, GRaSP Office

I. CALL TO ORDER

Steve Suter [RERC] called the meeting to order at 7:58 AM, standing in for Chair Paul Newberry.

II. APPROVAL OF MINUTES

A. IRB meeting of Friday, 20 April 2012. It came as no surprise that Duran moved, McCleary seconded a motion to approve the minutes, 5-0 with Herndon abstaining.

III. ANNOUNCEMENTS

A. Farewell to Sharon. Sharon Haynes, capable IRB administrative support person, was bid adieu, as she moves to a permanent position in Facilities Management.

IV. OLD BUSINESS

A. Update on Culminating Project Tracking. The RERC will meet individually with relevant chairs and program coordinators to encourage better tracking and stronger faculty "buy in" with IRB requirements. Problems were noted with the two graduate programs operating through Extended Studies related to lack of oversight. Faculty mentors should be encouraged to obtain the HSPT certification in order to better understand the IRB process.

B. Update on F5K Adverse Event Monitoring. JJ will discuss later a new checklist developed with involvement of Newberry, RERC, and F5K personnel.

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 2012 meeting.

1. Standard Review [nada]

2. Expedited Review [2]

Number	Author	Title	Date Submitted	Faculty Sponsor	Reviewers	Type of Review	Final Approval
12-06	Vanessa Duque	Atheism: Disclosing an Invisible Stigma	1/9/2012	Edna Molina	Gamboa & Duran	Expedited	4/5/2012
13-37	Devin Russell	The Effects of Synthetic Voices on Long-Term Memory	4/5/2012	Marianne Abramson	Gilchrist/Abramson	Expedited	4/20/2012

Revisions and clarifications are not necessarily incorporated into the protocol itself, so that the finished product is the protocol, plus revised documents and IRB communications. It was requested that this be stated in the informal e-mail announcing protocol approval. Swenson moved, Duran seconded, 6-0.

McCleary moved, Herndon seconded, 6-0

3. Third-Party Access to Existing Data [7]

Number	Author	Title	Date Submitted	Faculty Sponsor	Reviewers	Type of Review	Final Approval
12-33	Marilyn Velez	The Effectiveness of Retention in First Grade in Improving Reading Comprehension For ELL Third-Grade Students.	4/3/2012	Ron Hughes		3rd party	4/4/2012
12-41	Roseanna McCleary	Project Esperanza Program Evaluation: Phase II	4/12/2012			3rd Party	4/25/2012
12-50	Phyllis Nance	"CalWorks Cases and Non-Custodial Parent Participation in the Establishment of Child Support"	4/20/2012	Abbas Grammy		3rd Party	4/30/2012
12-55	Tammi Tilford	Organizational Effectiveness of the Federal Institution Data Match and Increasing Child Support Collections	4/24/2012	Abbas Grammy		3rd Party	5/23/2012
12-57	Joi Christy	Program Evaluation of Summer Break Day Camp	4/24/2012	Abbas Grammy		3rd Party	5/7/2012
12-65	Bethany Trojanowski	Examining the California High School Exit Exam: Incentives, Preparation and Funding	4/30/2012	Abbas Grammy		3rd Party	5/2/2012
12-71	Chad Williams	Treatment compliance among Latina women in urban and rural settings	5/7/2012	BJ Moore		3rd Party	5/14/2012

Duran moved, Gilchrist seconded, 6-0, as corrected.

4. Exemption from Full Review [17]

Number	Author	Title	Date Submitted	Faculty Sponsor	Reviewers	Type of Review	Final Approval
12-32	Ana Peria	Examining Contextual Factors that Contribute to Ethnic Development of Hispanic American Students	3/1/2012	Alem Kebede		Exemption	4/13/2012
12-38	Navneet Kaur Dhindsa	Health Challenges Faced by Sikh Community Members in America.(United States)	4/6/2012	R. Steven Daniels		Exemption	5/9/2012
12-45	Gilchrist/Dawkins	Lessons Learned: Peer to Peer BSN Simulation Rubric Development	4/14/2012			Exemption	4/17/2012
12-46	Drake Massey	Kern County Sheriff's Office Disaster Preparedness	4/19/2012	John Hultsman		Exemption	5/19/2012
12-49	Nathan Martinez	Institutional Dilemma Revisited: Fiscal Loss Abatement	4/20/2012	Abbas Grammy		Exemption	5/9/2012
12-52	Ellen Yuen	Organizational Excellence and Employee Satisfaction	4/20/2012	Abbas Grammy		Exemption	5/7/2012
12-54	William Kuhlemeier	Limits Based Monitoring of Dynamic Flight Test Maneuvering	4/24/2012	Abbas Grammy		Exemption	5/1/2012
12-60	Shannon Franz	Integrating Technology as a Means of Instruction Delivery for Young Students	4/25/2012	Chandra Commuri		Exemption	4/30/2012
12-62	Penelope Wilson	Inverted Teaching through the use of Screen- casting tutorials	4/27/2012	Randy Schultz		Exemption	5/14/2012
12-63	S. Aaron Hegde	Camp to Campus: Oral Histories of Migrant College Graduates	4/27/2012			Exemption	4/30/2012
12-67	Kathleen Gilchrist & Cherie Rector	Health Promoting Behaviors Among Working Public Health Nurses (PHNs)	5/1/2012			Exemption	5/2/2012
12-68	Tyona Ashley	Analyzing the Effects of a Reactive Training Approach to Corporate Finance Managerial Training	5/1/2012	Abbas Grammy		Exemption	5/15/2012

Number	Author	Title	Date Submitted	Faculty Sponsor	Reviewers	Type of Review	Final Approval
12-72	Maria "Jessica" Eaton	Student Retention Analysis – Ed. D. Cohort	5/9/2012	Randy Schultz		Exemption	5/14/2012
12-75	Scott Lockhart	Do TI Nspire (CAS) Calculators Help to Improve Student Learning?	5/8/2012	Michael Lutz		Exemption	5/16/2012
12-76	Sterling N Jones	Implementation Plan for Integrating Electronic Health Records in Clinica Sierra Vista's Kern County Sites	5/17/2012	BJ Moore		Exemption	5/29/2012
12-78	Jeff Payne	Wasco Union High School District Site Leadership Team Program Evaluation	5/24/2012	Abbas Grammy		Exemption	6/1/2012
12-79	Judy Pedro	Diabetes Collaborative Survey	5/26/2012			Exemption	5/29/2012

Duran moved, Swenson seconded, 6-0, as corrected

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 April 2012 meeting.

Number	Author	Title	Date Submitted	Faculty Sponsor	Reviewers	Type of Review	Final Approval
12-35	Maria C. Flores	Healthcare Workers. A Kern County Comparative Analysis.	4/5/2012	BJ Moore		NRS	4/6/2012
12-36	Norica Ruelas	Comparing Healthcare Systems of Two Rural Communities	4/5/2012	BJ Moore		NRS	4/23/2012
12-40	Dawn Swartsfager	A Program Evaluation to Determine if the a Life Interrupted Program is Effective at Reducing Local Teenage Driving Fatalities.	4/11/2012	John Hultsman		NRS	4/12/2012
12-42	Diego Ocampo	Leadership and Effectiveness Issues at a U.S. Navy Training Support Center	4/12/2012	John Hultsman		NRS	4/12/2012
12-43	Jonathan Bristow	Bullying	4/12/2012	John Hultsman		NRS	4/12/2012
12-44	Jungwoo Wajeel	Gun Control: Should there be more or less?	4/17/2012	John Hultsman		NRS	4/17/2012
12-47	Esmeralda Victoria	Lake Isabella Dam: Risk of Failure	4/19/2012	Thomas Martinez		NRS	4/30/2012
12-59	Harold Russell III	CSUB Student-Athlete Alumni Survey	4/25/2012	BJ Moore		NRS	4/25/2012
12-61	Josh Webb	A Case Study of BCS' Abuses of Non-Profit Status	4/25/2012	Chandra Commuri		NRS	4/30/2012
12-69	Chenille Oggs	Employee Impact in Regards to cutting Costs and Maximizing Profit in Organizations	5/1/2012	Abbas Grammy		NRS	6/1/2012
12-73	M. Dolores Giardina	An Analysis of the National Flood Insurance Program's Subsidy Policy	5/15/2012	BJ Moore		NRS	5/16/2012
12-74	Sukhjot Pannu	Quality Assurance Qualifications: In the new Era	5/15/2012	BJ Moore		NRS	5/16/2012

McCleary moved, Gilchrist seconded, 6-0

C. Formal Board affirmation [14] of previously approved granted Renewals since the April 2012 meeting.

Number	Author	Title	Date Submitted	Faculty Sponsor	Reviewers	Type of Review	Final Approval
03-03	Steve Bacon	Establishment of a Participant Pool for the Department of Psychology	1/17/2003			Standard	2/4/2003
04-124	Cherie Rector and Kathleen L. Gilchrist	Are You INN? Outcomes of the INN Program Grant	9/23/2004		Newberry, Bragg, Meares, Lee, Abramson, Leapley	Standard Review	10/11/2004
06-77	Kathleen L. Gilchrist	CSUB Nursing Program Evaluation Project	8/16/2006			Exemption	8/25/2006
08-102	Roseanna McCleary & Bruce Friedman	Hartford Partnership Program for Aging Education Career Tracking Survey	8/13/2008			Exemption	9/10/2008
08-110	Steve Suter	CSUB Vision Lab Visual Neuroscience Research Projects	0823/08		Gilchrist & Bashor	Standard	10/1/2008
09-120	Cherie Rector & Kathleen Gilchrist	Knowledge, Attitudes & Behaviors r/t Water Quality & Safety	5/13/2009		Blommers, Duran	Expedited	6/1/2009
09-142	Jacqueline Mimms	The CSU: Summer Algebra Institute	7/2/2009			3PA	7/2/2009
10-136	senior-level nursing students	Respiratory Hygiene Practices within a Campus Community: An Observational Study	9/4/2010	Deborah Boschini		Exemption	9/24/2010
11-116	Kathleen Gilchrist	Reflections of RN to BSN Nursing Students	6/20/2011			Exemption	6/22/2011
11-117	Sarah Brooks	Edvention Partners-Effects of CSU Teacher preparation on K-12 Student Achievement.	6/20/2011			Exemption	6/20/2012
11-118	Gokh Alsharif	Sources of Jordanian Public Opinion of the United States of America.	6/22/2011	Michael Ault	Duran & Newberry	Expedited	7/12/2011
11-119	Kathleen Gilchrist Denise Dawkins	Peer to Peer BSN Simulation Grading	7/5/2011			Exemption	7/12/2011
11-123	Dirk Baron	Classes: a Strategy of Improving the "Pipeline" from High Schools into University Geology Programs.	7/11/2011			Exemption	7/20/2011
11-130	Barbara K. Godwin-Asten Fowler	Improving Foster Parent Understanding of Children with Prenatal Alcohol Exposure.	9/13/2011	Bruce Friedman	Duran & Lee	Expedited	9/23/2011
11-134	Nada J. Yorke	Implementing a Cost-Free Batterer's Intervention Program in the Community.	10/11/2011	Bruce Friedman		Expedited	10/13/2011

Duran moved, Gilchrist seconded, 6-0, as corrected

D. Formal Board affirmation of protocol closures [12] (unless renewed) whose authorization have ended or will end prior to the October 2012 IRB 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
09-145	Marianne Abramson, Yi Du, & Tyson Smith	Factors Affecting Computer Voice Commands	9/21/2009		McCleary and Newberry	Expedited	9/4/2009
09-148	Peggy Leapley	National Children's Study Kern County (Phase 1)	9/14/2009			Expedited	9/30/2009
10-135	Jerome Harris	The Effects of Increased Focus on Vocabulary Comprehension in a Math Class using Word Clearing	9/21/2010	Penny Swenson		Exemption	9/27/2010
11-121	Lindsey Pruitt	High Situational Interest Promotes Student Achievement: Motivating Student Learning with Interesting Topics.	7/11/2011	Randy Schultz		Exemption	10/4/2011
11-122	Sarah Brooks	Edvention Partners-Administrative Leadership Study.	7/12/2011			Exemption	7/20/2011
11-127	Jacinta Weitiz	Strategy Upon Content area (Social Studies) Student Test	8/24/2011	Ron Hughes		Exemption	10/21/2011
11-128	Sarah Philips	College Readiness Intervention Program with High School Seniors.	9/6/2011	Emerson Case		Exemption	9/14/2011
11-131	Shana Morda	Wiki E-Portfolios.	9/20/2011	Ron Hughes		Exemption	10/13/2011
11-135	Mary Storey	Beliefs About (Hetero)Sexual Relationships and Homophobia	10/10/2011	Anne Duran		Exemption	10/20/2011
11-136	Frank Lauro	Evaluation of the 2011 Air & Waste Management Association – Golden Empire Chapter	10/24/2011	BJ Moore		Exemption	10/24/2011
11-137	Rhonda Dugan	"Evaluation of Classroom Exercises, Assignments, and Student Projects"	10/24/2011			Exemption	10/25/2011

Duran moved, Gilchrist seconded, 6-0, as corrected

E. New Protocol Reviews

- 1. Protocol 12-77. "Coping Mechanisms, Family Dynamics, and Intervention of Suicide Survivors"** with Nicola Bayley and Alem Kebede [Sociology Department]. Primary readers are Alvarez, Gilchrist, Swenson.

Following introductions, Bayley provided a brief summary. Initial participants will be her acquaintances who have experienced the suicide of a person close to them. Interviews will be an hour or more with possible follow-up. A list of questions have been included with the protocol, which are guides to help collect information about "the whole experience" from learning about the suicide through resources that the person has found useful or would have found useful. Info on programs available locally will also be collected. The emphasis will be on coping, coping skills, and resources.

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

Q: Where will you be doing the interviews? **A:** She will leave this up to the participant. Some will be open to talking in a relatively public setting, others not. It could be in the library [It was later pointed out that rooms can be reserved.] or in the participant's home.

Q: It isn't clear who will be doing the coding and data entry and how the data will be protected. **A:** She will do all that and keep the data at her home, destroying the transcripts when finished.

Q: How will you be analyzing the data? **A:** She will be looking for similarities among responses and themes.

Q: Are there subject selection criteria related to how long after the suicide a person would be appropriate for this study? **A:** Not really, it could be months or years.

C: Related to the previous consideration, you should make Question #57, on "accepting" the suicide more open-ended in case the participant really has not yet "accepted" the suicide.

Q: How will you get info about services available? **A:** Not from the interviews. Some of this will come from the KCMH suicide survivor support group leader.

Q: How, again, will you recruit participants? **A:** At first among friends and also from the KCMH group coordinator and possibly fellow members of her suicide support group.

C: Keep in mind that you will be interviewing persons who may not be representative of suicide survivors, because those persons reluctant to talk about it might have weaker coping skills.

Q: Where will you get the list of resources available that you will give to your participants? **A:** Initially from speaking with the KCM suicide group leader.

C: Make sure that you have this list together and ready to provide to participants in need.

C: There are developmental aspects of suicide, so you might find different patterns in the data related to the age at which the survivor experienced the suicide loss.

When there were no more questions, the investigators and the GRaSP support person were excused and the Board deliberated in executive session. There was a motion to conditionally approve protocol 12-77 with the following conditions:

1. In the protocol, specify who will do the data transcription, coding, entry, and analysis. Describe the specific steps that will be taken to ensure security and confidentiality of the data.
2. Describe in the protocol more specifically how you will analyze the data.
3. Re-write Question #57 in order to accommodate responses from persons who have not come to accept the person's suicide.
4. Provide the list of local resources available for suicide survivors. Include the KCMH support group leader and her hotline if she allows that.

Swenson moved, Herndon seconded, 6-0

The decisions and conditions were then announced to the investigators when they returned.

F. Continuing Review and Renewal of Authorized Protocols

1. **Edvention and Related.** Quarterly Report with Penelope Swenson standing in for Randy Schultz. Primary readers are all members.

The various activities continue to go well. **Protocol 11-122**, involving interviews with administrators has been completed. The Edvention Fellows held a symposium on their activities for an audience of faculty, family members, and persons from the community. This was a big, thrilling success. Randy has moved seamlessly into the role of overall coordination. Resistance continues with the data collection on student performance. Herndon offered to help if it would be useful because it appears that the legal hurdles have been conquered smoothly for the Bakersfield area participating schools.

Q: How many Edvention Fellows have there been thus far? **A:** There have been about 30, including several drop-outs related to personal/family crises. Participation requires doing an additional 6 quarter units above the course work specified for the regular graduate program.

There was a motion to approve the Edvention report.

Gilchrist moved, Herndon seconded, 5-0 [Swenson recusing]

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

A new checklist for adverse event monitoring has been developed via a process involving IRB and F5K personnel. Members were in agreement that this looked like a fine and useful document. The revised Confidentiality Training includes reference to the checklist and its anticipated use to encourage agency personnel to be thinking about the various elements that will be monitored. The Confidentiality Manual has been revised, however this was not distributed to board members in the agenda materials. New project director, Jan St. Pierre, was given an award by the League of Women Voters for "Making Democracy Work" at the F5K board meeting.

The investigator and the GRaSP support person were excused and the Board deliberated in executive session. There was a motion to approve the Protocol 07-91 report.

Duran, moved the heck out of that, Gilchrist seconded, 6-0.

VI. OTHER CONCERNS:

Vincent Oragwam, Director of Grant Management Operations, GRaSP Office, briefed the members about the Collaborative Institutional Training Initiative [CITI] materials. CSUB has purchased access to CITI. This includes online training in human subjects protections, humane care and use of animal subjects, and several additional research-related ethics issues, such as research integrity and conflict of interest. Personnel on NSF grants are required to have this broader "responsible conduct of research" training, which has been previously provided via workshops at CSUB. With the paid subscription, CITI will keep records on certifications. It is possible to import institution-specific materials into the CITI training materials. The training materials are updated every three years. IRB needs to decide what to do. At a minimum, the board should decide if we want to count the human subjects protections parts of CITI training as equivalent to our HSPT that has been in use at CSUB since January 2003. Would we want to use CITI instead of our HSPT? One disadvantage is the cost of CITI and the consequences if CSUB were to decide to end its subscription; another might be ensuring that persons do the correct parts of the training.

VII. MEETING DATES FOR 2012-2013:

Fall 2012: October 5th, 2012

Winter 2013: January 25th, 2013

Spring 2013: April 19th, 2013

Summer 2013: June 12th, 2013

VIII. ADJOURNMENT:

At 10:13 AM Duran moved, like nobody's business, McCleary seconded, 6-0.

IX. BOARD TRAINING:

A. Spot check of protocols authorized since last meeting:

1. **Protocol 12-57 [Joi Christy & Abbas Grammy, MSA Program]** "Program Evaluation of a Summer Break Day Camp" Submitted 4-20-12; authorized 5-07-12, following "third-party access" review.

This is a good example of what can happen if the student does not provide the information needed by the IRB and the faculty mentor does not ensure that the student communicates accurately with the IRB. The student submitted incomplete materials. The RERC provided detailed feedback based on these, which turned out to be irrelevant, because the student eventually stated that existing data would be used and she did not intend to collect new data. The student eventually accurate information using the correct protocol and the project was authorized.

2. **Protocol 12-52 [Ellen Yuen & Abbas Grammy, MSA Program] "Organizational Excellence and Employee Satisfaction"** Submitted 4-20-12; authorized 5-07-12, following exemption from full review.

The initial protocol did not include the survey or the interview questions to be used, a consent form, and, in general, provided few specifics about the conduct of the research. There was no summary of existing research on the topic with an explanation about how the proposed research was intended to fit in. However, once these were provided, the review and authorization process went smoothly.