

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

Meeting Minutes Spring I 2017
Friday, 17 February, 2017

Scientific Concerns: Anne Duran, Rose McCleary, Chandra Commuri

Nonscientific Concerns: Nate Olson

Community Concerns: James Velasquez, Coleen McGauley

Research Ethics Review Coordinator (RERC): Isabel Sumaya

Visitors:

Steve Suter

Gwen Parnell

Protocol 17-09: Gabriel Ruiz & Marianne Wilson

Absent: Steve Gamboa (Sabbatical), Grant Herndon

CALL TO ORDER

Chair, R. McCleary, called the meeting to order at 7:59 am.

APPROVAL OF MINUTES

It was noted that in the minutes there were protocols listed in the exempt categories that were previously affirmed by the board yet were listed again in the current minutes, so duplicated. Parnell will remove those duplications and make the requested corrections. McGauley motioned to approve the minutes with the noted corrections and Velasquez seconded, all approved (6-0).

ANNOUNCEMENTS

Sumaya and the board thanked Suter for stepping in coming out of retirement and serving as acting RERC during the Fall 2017 semester while she was out on sabbatical.

OLD BUSINESS

CITI HSPT and Recertification Task Group. The task group updated the board on the review of the selection of modules. Parnell provided a handout which outlined the required modules for each learner group. The board reviewed the document and agreed with the task group's choice of modules that would be required for each learner group. Further discussion took place about student researchers. Students only have three modules to complete, however, if a student is the lead investigator they must be treated like faculty and complete similar modules as faculty. McGauley gave her impressions of the modules and commented that there was overlap of the information but that the modules were very instructive. She then began a discussion on the issue of cultural norms and how the board may lack perspective when reviewing protocols and that perhaps the board could develop a list of best practices to better understand protocols that involved cultural issues. Chair McCleary motioned to begin a task group on this issue and Velasquez seconded. All voted in favor (6-0). Commuri then added that it might be a good idea to have board members provide mentoring to ~~young~~ new investigators at CSUB. The task group further reported that the group still needed to review the refresher courses and would report on this at the next meeting. Commuri then motioned to approve the roll out of the CITI training for the Fall of 2017. McGauley seconded and all approved (6-0). After it was decided to switch to the CITI training in the Fall of 2017, no longer using our home grown Blackboard modules, it was also

decided that PIs with active protocols would not have to complete the CITI training and would be grandfathered in. The board requested that official policy be written up on all of the matters discussed. The lead on the policy writing would be Parnell with input from Sumaya and McCleary.

What Venues = Reviewable Research? At the request of the RERC, there was a follow-up discussion about what should be reviewed by the IRB when it comes to presentations in class. This is not a gray area. If students are presenting a project as a part of a classroom assignment, presenting to their classmates, this does not go through the IRB. However, if students are presenting at research conferences, presenting outside of their classroom (audience dependent) they must go through IRB. After some discussion, the group came to the consensus that it would be helpful for all if we had a flow chart with concrete examples of what needs to undergo review and what does not. Parnell, Sumaya and McCleary shared that at the recent IRB Chancellor's training workshop they received several good templates of flow charts that other IRB's are using. Parnell will work on a draft of a flow chart to be placed on our website and present it to the board at the next meeting.

Policy & Procedures for IRB Non-Compliance. Although there is a procedure in place for the case for non-compliance, there is no written policy. RERC and Chair will work on drafting a formal procedure document.

Revisit Voluntary Closure Form and Adverse Events Form. Parnell provided a sample of a close out form that is currently being used by CSU Channel Islands. The board reviewed the form finding it sufficient. McGauley asked if PIs would actually report any adverse effects when it came down to it. RERC commented that in the 1 ½ years she has been RERC that she has never had a PI report an adverse effect. Parnell will use CSU Channel Island's form and edit it to fit our needs and have it ready for review at the next meeting.

NEW BUSINESS

New Common Rule Changes-IRB Forum Report. Sumaya, McCleary, and Parnell provided an oral report on the IRB forum that they attended at the Chancellor's office. In summary, all felt that the most important information gained from the forum was the insider knowledge about the common rule and its implementation. It was learned that everyone is, or should be, in a holding pattern due to the new administration and its prerogative to reverse the newly approved revisions 60 days from the January 19th 2017 publication in the federal register. So, we will have to wait on updating and revising our policies to meet the new revisions until we find out if they will stand.

Replacement for Tony Alteparmakian-Non-Scientific Board Member. There was a discussion on whether the board should replace the loss of Alteparmakian with another faculty from Education. All agreed this is the direction the board wanted to take. Two names were brought to the table, Calli Lewis Chiu and Briana Santiago Evans. RERC gave some insight on Lewis and stated that Lewis has submitted several protocols and would be a good pick based on the completeness of her protocols. RERC will contact Lewis asking if she would consider the position and will report back at the next meeting.

Internal Forms: Section 118 & Grant Proposal Routing Form-IRB/IACUC Section [Handouts]. The section 118 form is ready to roll out and to be used (Notification that a project may involve human subjects but the specifics are yet known). Members requested a revision to the form which was to place "IRB" in front of "118" on questions 12, 13, and 22. Chair McCleary requested that the form be piloted. Parnell agreed that she would do that. Parnell then requested the board to approve the changes in new language on the Grant Proposal Routing Form. McGauley moved to approve the new changes (from a to b on handout) and Velasquez seconded. All approved (5-0).

Cooperative Agreement & Former CSUB students [Volunteer Form-Handout]. McGauley had misgivings on the request of a SS# on the Volunteer Form. She further stated that requesting a

SS# was too intrusive and this information could be compromised. RERC commented that this a University HR generated form that we could not change. However, it was decided that we would make it an option for our students to either report their SS# or their Student ID.

Chair McCleary on Sabbatical. Although not on the Agenda, Chair McCleary let the board know that she will be on Sabbatical in the Fall of 2017. McCleary asked if anyone would consider taking her place. Olson and Commuri said that they would think about it and will let the board know at the next meeting.

Board affirmation of protocols previously approved under **Standard Review, Expedited Review, Third Party Access** and **Exemption from Full Review** since the November 17, 2016 meeting.

1. Standard Review [0]. There were no standard reviews during this period.

2. Expedited Review [1]

#	PI	Department	Title	Date Submitted	Final Approval	Faculty Sponsor	Type of Review
16-157	Sarah Appleton	Psychology	Impact of Readiness to Change on Methadone Maintenance Treatment Compliance	11/11/2016	12/14/2016		Expedited -See also IRB 3PA 16-159

Duran moved, McGauley seconded, 6-0.

Third-Party Access to Existing Data [2]

#	PI	Department	Title	Date Submitted	Final Approval	Faculty Sponsor	Type of Review
3PA-16-159	Sarah Appleton	Psychology	Impact of Readiness to Change on Methadone Maintenance Treatment Compliance	11/11/2016	12/14/2016		Expedited -See also IRB 16-157
3PA-16-175	Bre Evans-Santiago	Teacher Education	Kern Urban Teacher Residency	12/29/2016	1/4/2017		Exempt

Duran moved, McGauley seconded, 6-0.

Exemption from Full Review [23]

#	PI	Department	Title	Date Submitted	Final Approval	Faculty Sponsor	Type of Review
16-110	Joel Haney	Music & Theatre	Performer Perceptions of Ensemble Interaction in Paul Hindemith's Duo Sonatas	9/5/2016	9/19/2016		Exempt

16-114	Yvonne Ortiz-Bush, Yeunjoo Lee	Advanced Educational Studies/Special Education	Bullying Prevention and Intervention Workshop for Special Education Teachers	9/12/2016	9/22/2016		Exempt
16-115	Anne Duran	Psychology	Resource and Engagement Survey	9/13/2016	9/14/2016		Exempt
16-116	Co-PIs: Albert C. Cruz and Brian Street	Department CEECS, Kinesiology	Project SQUARE: Skill Quantification for Rehabilitation	9/14/2016	9/15/2016		Exempt
16-117	Anthony Rathburn, CO-PI: Dirk Baron	Geological Sciences	GP-EXTRA: Oceanographic Shipboard and Lab Research for Diverse Students: Experiential Learning as a Gateway to Geoscience Careers	9/15/2016	10/10/2016		Exempt
16-119	Martin Rios	AES	Mathematical Procedures Self-Monitoring Checklist for Task Completion	9/22/2016	10/17/2016	Calli Lewis Chiu	Exempt
16-121	Shawnda Smith & Anthony Alteparmakian	Math; Teacher Education Department	Geometry Teaching Knowledge: Pre-service Development of Specialized Geometry Knowledge	10/4/2016	10/10/2016		Exempt
16-131	Sarah Appleton	Psychology	Self-Efficacy in Counselor Trainees: An Exploration of Clinical Impact	10/18/2016	10/18/2016		Exempt, prior Standard Review
16-144	Kyle Susa	Psychology	Memory for GRE Vocabulary (TE 3)	10/24/2016	10/26/2016		Exempt
16-145	Veronica Shepp	Psychology	Victim Blaming: Agency or Sexism Driven	10/25/2016	11/22/2016 (M), 10/26/2016	Anne Duran	Exempt
16-151	Justin Cordeiro	Psychology	Attachment Style and Divergent Thinking	10/29/2016	11/8/2016	Anne Duran	Exempt
16-152	Luis Rosas	Psychology	Child Discrepancy and Attitudes	10/29/2016	11/8/2016	Anne Duran	Exempt
16-153	Alison Gomez	Psychology	Correlates Between Stigma and Subjective Norms and its Influence on Help-Seeking Behaviors	10/29/2016	11/3/2016	Anne Duran	Exempt
16-158	April LaGue	Teacher Ed: CAFS	Administrator Perceptions of Math Anxiety Levels in Students	11/10/2016	12/2/2016		Exempt
16-161	Anmol Dhillon	Public Policy & Admin (MS) Health Care Admin	Analysis of Aspects Leading to Participation in Medical Tourism by U.S. Residents (Tentative)	11/15/2016	11/17/2016	BJ Moore	Exempt
16-162	Ifeanyichukwu Mordi	Public Policy and Admin	Healthcare Managers and the Decision Making Process	11/15/2016	11/16/2016	BJ Moore	Exempt

16-165	Rabia Sohail	Public Policy Admin (MS-HCA)	Beyond the Glass Ceiling-The Sky is the Limit?	11/19/2016	12/14/2016	BJ Moore	Exempt
16-167	Nicole Jenkins	MS Health Care Admin	Vying for Leadership Roles: Battles Faced	11/23/2016	1/19/2017	BJ Moore	Exempt
16-168	Lauren Ash-Anderson & Erika Delamar	Student Health Services (SHS)	Focus Group- Inclusive Language in Student Health Services	11/29/2016	1/3/2017 Mod 12/22/2016		Exempt
16-171	Kyle Susa	Psychology	Memory Retention 1 (MR1)	12/7/2016	12/8/2016		Exempt
16-172	Rebecca Callaghan	MS Health Care Admin	STDs: What Have We Been DOING in Kern County?	12/9/2016	12/16/2016	BJ Moore	Exempt
16-174	Bre Evans-Santiago	Teacher Education	Kern Urban Teacher Residency	12/23/2016	1/4/2017		Exempt
17-06	Kyle Susa	Psychology	Study Styles Effect on Memory Retention (TE 4)	1/20/2017	1/23/2017		Exempt

For 16-115, 16-145, 16-151, 16-152 & 16-53 (all Duran related), McGauley moved, Olson seconded, 5-0.
For all other protocols, McGauley moved, Velasquez seconded (6-0).

Board affirmation [8] of protocols submitted and designated as **not** falling within the IRB/HSR definition of human subjects research (**not within IRB/HSR purview**) since the September 2016 meeting.

#	PI	Department	Title	Date Submitted	Final Approval	Faculty Sponsor	Type of Review
NRS 16-160	Ruchi Bhatt	Public Policy and Admin	A Policy review of Denti- Cal: Does Centralization of the Management Decrease Access?	11/12/2016	11/16/2016	Jinping Sun	NRS
NRS 16-163	Karnell Grimes	MS Health Care Admin	University Weight Room Project Plan	11/16/2016	11/18/2016	BJ Moore	NRS
NRS 16-164	Heidi B. Martinez-Forsythe	Public Admin	Systematic Approach with a Faith-Base Twist	11/17/2016	11/17/2016	Thomas Martinez	NRS
NRS 16-166 IMPHS R? No	Karina Morga	Public Policy and Admin	Work-Site Wellness Programs	11/21/2016	11/22/2016	BJ Moore	NRS
NRS 16-173	Morgan Alcala	Public Policy and Admin	Civil Rights versus Religious Freedom: An Examination of Policy Narratives	12/22/2016	12/22/2016	Chandra Commuri	NRS
NRS 17-01	Yaquelin Barrera	Masters in Public Admin	Minimum Wage Increase Evaluation	1/4/2017	1/4/2017	Thomas Martinez	NRS
17-05 NRS-IMPHS R?-NO	Parveen Khangura	Public Admin	A Proposal Plan to Reduce Adolescent Suicide in Kern County	1/17/2017	1/19/2017	Thomas Martinez	NRS

NRS 17-07	Sennuwy Y. Smith	Masters in Public Admin	Program Form Juvenile Recidivism	1/24/2017	1/25/2017	Thomas Martinez	NRS
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For NRS 16-173 (Commuri related), McGauley moved, Duran seconded, 5-0. For all other protocols, McGauley moved, Velasquez seconded (6-0). For all others, Duran moved, McGauley seconded (6-0).

I. Formal Board affirmation [12] of previously approved protocols granted Renewals since the November 18th, Fall II meeting.

#	PI	Department	Title	Date Submitted	Final Approval	Faculty Sponsor	Type of Review
07-91	J.J. Wang, B. Hemphill M. Thibault, J. Hogan, A. Doherty, D. Berri	Corp. for Standards & Outcomes (CSO)	Evaluation for Kern County Children and Families (KCCFC)	9/21/2007	1/25/2008		Standard
11-01	Douglas Dodd & Curt Asher Chris Livingston	History/ Walter Stiern Library/ Public History Institute	CSUB Campus Oral History Project	1/6/2011	1/30/2011		Exempt
12-05	Matt Leon	Psychology	The Neural Basis of Human Time Perception	1/17/2012	2/13/2017 2/27/2012		Expedited
15-01	Charles Lam	NSF IUSE Grant	STEM Retention and Graduation: An Integrated Approach	1/2/2015	12/22/2016 1/7/2015		Exempt
15-02	Joshua Miller	PEAK	Normative Values of the Functional Movement Screen in Athletes	1/6/2015	12/15/2016. 1/20/2015		Expedited
15-39	Charles Lam	Math	Developing Sustainable Interdisciplinary STEM Programs for First and Second Year Underserved Students in the Southern San Joaquin Valley	3/31/2015	1/8/2017 4/7/2015		Exempt
15-95	Jeanine Kraybill	Political Science	In Their Own Words	1/2/2016	2/3/2016		Standard
15-105	Jaewon Lee Roseanna McCleary, Yong Li	Social Work	Analysis of Perceptions of Successful Aging Among Non-English Speaking Older Immigrants in California	11/13/2015	2/13/2017 9/30/2016 (M), 3/7/2016		Exempt
15-108	Kathleen Madden, Jaimi NSME	NSME Dean's Office and Advising Center	School of Natural Sciences, Mathematics, and Engineering Retention Analysis	12/15/2015	1/13/2017 (Renewal) 2/8/2016		Exempt
16-03	Joshua Miller, Brian Street	PEAK	Metabolic Syndrome in College Students: Prevalence and Individual Criterion	1/5/2016	12/15/2016 (Renewal) 9/13/2016 (M), 2/18/2016		Expedited
16-20	Sarah Appleton, Yvonne Ortiz-Bush, Jong Choi, Rose McCleary	Psychology Educational Counseling, and Social Work	Effectiveness of Training in the Screening, Brief Intervention, and Referral to Treatment Approach	2/5/2016	1/25/2017 (R+M), 2/12/2016		Exempt

16-32	Kathleen Gilchrist & Cherie Rector	Nursing	Health Promoting Behaviors of RNs	3/11/2016	1/9/2017 (Renewal) 3/15/2016		Exempt
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For 15-105 (McCleary related), Duran moved, Olson seconded, 5-0. For all other protocols, McGauley moved, Velasquez seconded (6-0). For all others, Duran moved, McGauley seconded (6-0).

Modification [7] of previously approved protocols since the November 18th meeting. The modifications include the change of PI (16-76), the addition of a co-PI (16-85), the addition of student researchers (16-20, 16-156), a change of title (16-149), the use of the Psychology participant pool (16-145), and changes in wording of recruitment invitation and an increase in length of interview sessions (16-168).

#	PI	Department	Title	Date Submitted	Final Approval	Faculty Sponsor	Type of Review
16-76 3PA	Debra Jackson Anna Laven	School of Arts & Humanities	School of Arts and Humanities Learning Community Analysis – Fall 2015 and Fall 2016 Cohort	5/7/2016	1/9/2017 (M), 5/13/2016		Exempt
16-85	Chandra Commuri	Public Policy and Admin	Appeals to Values in Policy Framing: 'Duty Based' Versus Engaged Citizenship	5/19/2016	12/2/2016 (M), 5/25/2016		Exempt
16-20	Sarah Appleton, Yvonne Ortiz-Bush, Jong Choi, Roseanna McCleary	Psychology, Educational Counseling, and Social Work	Effectiveness of Training in the Screening, Brief Intervention, and Referral to Treatment Approach	2/5/2016	1/25/2017 (R+M), 2/12/2016		Exempt
16-145	Veronica Shepp	Psychology	Victim Blaming: Agency or Sexism Driven	10/25/2016	11/22/2016 (M), 10/26/2016	Anne Duran	exempt
NRS 16-149	Guadalupe Herrera	Masters in Public Admin	Proposal to Modify Current Employee Performance Policy Towards A More Comprehensive Employee Evaluation System	10/26/2016	12-08-16 (M), 10/27/2016	Thomas Martinez	NRS
16-156	Alberto Cruz & Brian Street	Department of Computer & Electrical Engineering & Computer Science; Kinesiology	Automatic Gait Abnormality Detection from Video	11/6/2016	1/13/2017 (M), 11/8/2016		Exempt
16-168	Lauren Ash-Anderson & Erika Delamar	Student Health Services (SHS)	Focus Group- Inclusive Language in Student Health Services	11/29/2016	1/3/2017 (M), 12/22/2016		Exempt

For 16-85 (Commuri related), Duran moved, McGauley seconded, 5-0. For 16-20 (McCleary related) McGauley moved, Velasquez seconded, 5-0. For 16-145 (Duran related) McGauley moved, Olson seconded, 5-0. For all other protocols, McGauley moved, Velasquez seconded (6-0).

Formal Board affirmation of protocol **closures [11]** whose authorization have closed since the November 18, 2016 meeting.

#	PI	Department	Title	Date Submitted	Final Approval	Faculty Sponsor	Type of Review
14-81	Kathleen Gilchrist, Shalise Pollock Charles Collom	Nursing	Predictors of Success on the Comprehensive Predictor Exam and the NCLEX Exam of Two Graduating Classes	8/26/2014	9/8/2014	Kathleen Gilchrist and Shalise Pollock	Waiver
14-84	Rose McCleary S. Jenkins	Social Work	Comparison of Skills Mastery in an Integrated Blended Learning Course and Face-to-Face Courses	9/11/2014	9/17/2014		Exempt
14-87	Leigh Collins, Bruce Hartzell, Roseanna McCleary	Social Work	Evaluation of a Special Topics Social Work Professional Writing Course	11/12/2015, 9/16/2014	9/17/2014		Exempt
14-90	Adrian Villalta-Cerdas	Chemistry	Effect of Self-Explaining on Chemistry Conceptual Learning	9/23/2014	9/25/2014		Exempt
14-93	Randy Schultz	Teacher Quality Program	Impact of a STEM Camp Program on Student Achievement and Attitudes Toward STEM Education	9/29/2014	9/30/2014		Exempt
15-46	Evangelos Demestihias	Public Policy and Admin	Police Motorcycles: Weighing the Benefits and the Risks	4/2/2015	6/2/2015	Dr. Thomas Martinez	Exempt
15-103	Jessly Meza, Pearlina Santiago, Chyna Parker	Psychology	Study of College Students' Perception, Attitudes, and Knowledge	11/6/2015	11/11/2015	Luis Vega	Exempt
3PA 16-01	Anna Laven	Advising Center School of A&H	Do minors matter? Policy considerations and data analysis of undergraduate minor selections	1/4/2016	1/31/2016		Expedited
16-02	Brian Street	PEAK	Knee Arthroplasty: Outpatient Rehabilitation and the Effect of Age on Outcome	1/5/2016	1/8/2016		Exempt
16-05	Lauren Lynch	Sociology	Beyond Color: An Examination of Interethnic and Biracial Identity	1/13/2016	4/19/2016/21/2016	Rhonda Dugan	Exempt
16-09	Casey Harris	Psych	Rape Empathy: Clinicians' Attitudes Toward Sexual Offenders	1/13/2016	1/21/2016	Anne Duran	Exempt

For 14-84 & 14-87 (McCleary related), Duran moved, McGauley seconded, 5-0. For 16-09 (Duran related) McGauley moved, Olson seconded, 5-0. For all other protocols, Velasquez moved, McGauley seconded (6-0).

New Protocol Reviews

Protocol 17-09 [Gabriel Ruiz & Marianne Wilson, Psychology]. The Impact of Emotional State on Logical Reasoning Abilities in College Students. Primary Reviewers: Commuri and McCleary

Following instructions and introductions, the student investigator summarized the protocol. Mr. Ruiz explained that his study will investigate the relationship between logic and depression and that this study will serve as his senior thesis.

[Q: Question A: Answer C: Comment]

Q: How will you deal with students scoring high on the DASS-21 and making sure they are okay once they complete the experiment? **A:** We are glad that you asked that. We wanted to get your feedback on the best way to do this. **C:** First, you need to provide all students with referrals regarding where they can go get counseling. Then you will need to be very careful about the ones that score high. **Q:** But how do I do that? Do I contact them later? How will that work? **C:** No, the way to better address this issue is that you will need to score their DASS-21 on the spot and provide them with their scores immediately so you can then make sure that you provide them with the information on the spot. Then you will need to give everyone follow-up calls to make sure they are okay. Also, please add to your consent form the Suicide Hotline number and at the session.

C: Please add to your consent form the information about the destruction of the consent forms, after three years. **A:** Yes, I will.

Q: Will you be using the Psych participant pool? **A:** Yes, I will. **C:** Please add to your protocol. **A:** Yes, I will.

There were no more questions or comments and the investigators were asked to leave so that the IRB could deliberate in executive session. McGauley motioned to approve the protocol with conditions. Olson seconded [6-0].

OTHER CONCERNS: None

ADJOURNMENT: Chair McCleary adjourned the meeting at 10:28.

BOARD TRAINING: The board was assigned to review the revised Common Rule Packet for the Spring II Meeting.