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

Meeting Minutes Friday, 2 October 2015 [DDH A-108]

Members Present:

Scientific Concerns: Marianne Abramson (alternate), Rosanna McCleary, Kathleen Gilchrist Nonscientific Concerns: Paul Newberry, Randy Schultz, Steve Gamboa, Community Concerns: Grant Herndon, Colleen McGauley RERC: Isabel Sumaya

Visitors:

Protocol 15:84: Kris Grappendorf, Josh Miller, Bree Gage & Protocol 07-91: JJ Wang

CALL TO ORDER

Chair, R. McCleary, called the meeting to order at 8:05 am.

APPROVAL OF MINUTES

IRB meeting minutes of Wednesday, 10 June 2015 were approved. Newberry moved; Gamboa seconded.

ANNOUNCEMENTS

New faculty orientation presentation. McCleary noted that she had to push hard to get the IRB on the agenda for the new faculty orientation. Sumaya and McCleary reported that they were pleased with the presentation and the response from faculty despite the limited amount of time that was allotted to the IRB.

Interviewing new student assistant at GRASP. G. Parnell is in the final stages of interviewing for the new assistant at GRASP office. The new student hire will help Parnell in logging in protocols and getting approval letters out to investigators. Sumaya provided the update for G. Parnell who could not the meeting because she was in the final stages of interviewing students.

IV. OLD BUSINESS

First deferral on a multi-campus CSU research project. At the June meeting Sumaya was asked to contact CSULB to get permission to use their IRB Authorization Agreement form. Prior to contacting CSULB Sumaya found that CSULB's form was the exact template form that the PHS provides on their website. Sumaya took this template and customized it for CSUB IRB use. Herndon moved to approve the form and Gilchrist seconded. In response to McCleary's question of whom would be the signatory official on this form, Sumaya said it would be the Provost as she is the official listed on the FWA website. **Personal liability**

protection of CSUB IRB members. At the June meeting Sumaya was asked by Herndon to look into the written documentation that protects IRB members from personal liability. Sumaya consulted with S. Suter (former RERC) for documentation. There is documentation that makes a general statement about the protection of IRB members. Sumaya will send Herndon the documentation for review.

Discussion on award for best protocol for Research Excellence Day 2016 (April) – Criteria. The board agreed that this was a great idea. It was discussed that it would be a good idea to also award a student protocol. It was decided that McCleary and Sumaya would work out the details and report back to the board in January.

NEW BUSINESS

Formal Board Affirmation of protocols previously approved under **Standard Review**, **Expedited Review**, **Third Party Access** and **Exemption from Full Review** since the June 2015 meeting. As usual members abstained from voting on protocols with which they are affiliated.

1. Standard Review [1]

Numbe	r Pl	Dept.	Title	Date Submitted	Date Approved	Type of Review
15-67	Sarah Appleton	Psychology	Self-Efficacy in Counselor Trainees: An Exploration of Clinical Impact	4/29/2015	6/17/2015	Standard

Herndon moved, Newberry seconded, (7-0).

2. Expedited Review [0]

3. Third-Party Access to Existing Data [0] > Low risk to subjects – RERC only

4. Exemption from Full Review [7]

Number	PI	Dept.	Title	Date Submitted	Date Approved	Type of Review
15-74	Sandra Bozarth and Chris Livingston	Library	Open Source and Digital Textbook Survey	5/27/2015	6/2/2015	Exemption
			Access to General			
			Education Curriculum and			
	Calli Lewis-	Advanced Education	Instructional Materials for Students of Alternatively			
15-76	Chiu	Studies	Certified Teachers	6/3/2015	6/9/2015	Exemption

15-78	Tracy Kelly, Justin Peppars, Melissa Bradex	Social Work	Teachers' Perceptions of the Effectiveness of the Bakersfield City School District's Summer School Preparation Training	6/15/2015	6/15/2015	Exemption
15-79	Andrea L. Medina	NSME	How does an undergraduate first year experience in the Fab Lab effect underrepresented minority (URM) STEM retention rates?	7/15/2015	9/4/2015	Exemption
15-80	Josh Uhalt	Psychology	Scale Development: Logical versus Psychological Opposites	7/27/2015	9/29/2015	Exemption
15-82	Lauren Ash- Anderson and Erika Delamar	Student Health Services	National College Health Assessment	8/17/2015	9/28/2015	Exemption
15-83	Yeunjoo Lee and Calli Lewis-Chiu	AES	Program Evaluation of PROJECT PURPOSE (Preparation Using Research-based Practices to Optimize Special Education): A Project Funded by the US Department of Education Project Scholars Grant (ED 524 B)	8/18/2015	9/28/2015	Exemption

Herndon moved, Newberry seconded, (7-0).

Formal Board affirmation [1] 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 2015 meeting

Number	PI	Dept.	Title	Date Submitted	Date Approved	Type of Review
	William		A Policy Analysis for Foster Care Youth: Assembly Bill			
15-77	Jackson	PPA	12	6/5/2015		NRS

Herndon moved, Newberry seconded, (7-0).

Formal Board affirmation [9] of previously approved granted <u>Renewals</u> since the June 2015 meeting. Protocol 14-81 was modified removing one investigator.

Number	PI	Dept.	Title	Date Submitted	Date Approved	Type of Review
08 - 110	Steve Suter	Psychology	CSUB Vision Lab Visual Neuroscience Research Projects	9/23/2008	10/20/2008	Standard
14-51	Melissa Danforth	CEE/CS - NSF SFS Grant	NSF SFS Summer REVS- UP Outreach	5/19/2014	5/20/2014	Exemption
14-69	Rhonda E. Dugan Dahna L. Rasmussen	Sociology	College Student Perceptions of the N-Word in the Post-Civil Rights Era	6/3/2014	6/26/2014 - 7/3/2014	Standard
14-77	Dale Willits	Sociology	Delinquency and the Social Network Characteristics of Employed and Unemployed Adolescents	7/14/2014	7/14/2014	Third Party Access
14-81	Kathleen Gilchrist and 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	Waiver
14-82	Carol Raupp	Psychology	Students' Attitudes and Behaviors Associated with Taking College Courses	9/10/2014	9/12/2014	Exemption
14-84	Roseanna McCleary, Sam Jenkins	Social Work	Comparison of Skills Mastery in an Integrated Blended Learning Course and Face-to-Face Courses	9/11/2014	9/17/2014	Exemption
14-87	Leigh Collins, Bruce Hartsell, Roseanna McCleary	Social Work	Evaluation of a Special Topics Social Work Professional Writing Course	9/16/2014	9/17/2014	Exemption
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	Exemption

Herndon moved, Newberry seconded, (3-0). Gilchrist abstained due to her affiliation with 14-81. Shultz abstained due to his affiliation with 14-93. And, McCleary abstained due to her affiliations with 14-84 & 14-87.

Modification [3] of previously approved protocols since the June 2015 meeting. New research assistants were added to 14-70, and minor changes were made with ambiguous words and video recordings as requested by grantor to 15-01 and 15-39.

Number	PI	Dept.	Title	Date Submitted	Date Approved	Type of Review
14-70	Randy Schultz	Teacher Quality Program	Self-Efficacy of Pre-Service Teachers after Intensive Field Experience and PD	6/3/2014	7/7/2014	Exemption
15-01	Charles Lam	NSF IUSE Grant	STEM Retention and Graduation: An Integrated Approach	1/2/2015	1/7/2015	Exemption
15-39	Charles Lam	Mathematics	Developing Sustainable Interdisciplinary STEM Programs for First and Second Year Underserved Students in the Southern San Joaquin Valley	3/31/2015	4/7/2015	Exemption

Herndon moved, Newberry seconded, (6-0). Shultz abstained due to his affiliation with 14-70.

Formal Board affirmation of protocol **closures [13]** (unless renewed) whose authorization have ended or will end prior to the January 2016 IRB meeting.

End of October 2015 Closures:

Number	PI	Dept.	Title	Date Submitted	Date Approved	Type of Review
		Masters of Public Administrati	Indicators of Recurrence of Child Maltreatment for Tulare County Child Welfare			
14-103	Erika Flores	on	Services	10/24/2014	11/25/2014	3PA
14-104	Brian D. Street	Physical Education & Kinesiology	Lateral Balance and Mobility After Knee Replacement Surgery	10/25/2014	11/12/2014	Expedited
14-105	Debra Jackson	Philosophy	Increasing PHIL 102 Student Success Through Asynchronous Learning in a Flipped Classroom	10/28/2014	11/3/2014	Exemption
14-106	Phyllis A. Heintz, PhD, RN	Nursing	Nursing Student Knowledge and Attitudes Regarding Care of Older Adults	10/29/2014 Revision 2/26/2015	11/3/2014	Exemption
14-109	Michael Sloan	PPA	Assessment of an Electronic Grievance Tracking System in a Healthcare Setting	11/2/2014, revised 11/4/2014	11/4/2014	Exemption

Herndon moved, Newberry seconded, (7-0).

End of November 2015 Closures:

Number	PI	Dept.	Title	Date Submitted	Date Approved	Type of Review
		Philosophy				
	Debra	and		11/25/2014,		
	Jackson et	Religious	General Education Core	12/5/2014,		
14-112	al.	Studies	Competency Assessment	12/15/2014	12/12/2014	Exemption
	Belinda		Aspiranet Wraparound			
14-113	Vieyra	Social Work	Program Evaluation	11/26/2014	12/2/2014	3PA
			Implementation of a Clinical			
	Victor		Integration Program			
14-114	Comaianni	PPA	Evaluation	12/1/2014	12/15/2014	Exemption

Herndon moved, Newberry seconded, (7-0).

End of December 2015 Closures:

Number	PI	Dept.	Title	Date Submitted	Date Approved	Type of Review
			STEM Retention and			
		NSF IUSE	Graduation: An Integrated			
15-01	Charles Lam	Grant	Approach	1/2/2015	1/7/2015	Exemption
		Physical				
		Education	Normative Values of the			
	Joshua	and	Functional Movement			
15-02	Miller, DHSc	Kinesiology	Screen in Athletes	1/6/2015	1/20/2015	Expedited
	Efrain					
15-07	Rodriguez	Psychology	Perceptions of Language	1/12/2014	1/13/2015	Exemption
13-07	Rodriguez	1 Sychology	T erceptions of Language	1/12/2014	1/13/2013	LXemption
			Supporting Former Foster			
	Maria		Youth: Do Foster Youth			
15-08	Hernandez	Psychology	Know the Resources?	1/12/2014	1/28/2015	Exemption
			Economics or Culture?			
			Factors Contributing to the			
	Mayra		Decrease of Latino Male			
15-09	Tenorio	Psychology	Enrollment in College	1/12/2014	1/28/2015	Exemption
	Edgar					
	Abelardo		Knowledge of Water Scarcity			
	Ruiz-		is Linked to Water			
15-12	Arzapalo	Psychology	Conservation Behavior	1/14/2015	1/22/2015	Exemption

Herndon moved, Newberry seconded, (7-0).

New Protocol Reviews [1]

Protocol 15-84. "Runner Read & Ride Program: A Pilot Study" with Kris Grappendorf [Kinesiology]. All on the board served as Primary Readers.

Following instructions and introductions, the investigator summarized the protocol. Grappendorf was accompanied by Josh Miller and Bree Gage, all from the department of Kinesiology. The study seeks to provide a read and ride program for local elementary students to increase exercise and decrease body fat. The investigators gave an overview of the study and highlighted the benefits to the community.

[Q: Question A: Answer C: Comment] (G: Grappendorf, M:Miller)

Q: What happens to children that cannot afford the proper exercise clothing? You need to state that in your protocol. Will you just exclude them? This would not be fair to the children that do not have the clothing. **A.** (G) Yes, I agree. We will provide the proper gear if necessary and will state in our protocol that we will do so.

C: You will need to develop a plan to deal with possible medical issue if they arise from the exercise they will participate in. For example what will happen with student that have asthma? **A.** (M) Exercise actually doesn't cause Asthma. Exercise is actually beneficial to asthmatics. This research has shown this. C: Wow, we all known people and children, and we personally have had exercise induced asthma. A. We will have access to the school nurse and their inhalers if this occurs.

C: Please add to your protocol more details about the supervision of the participants while they are at CSUB being measured by the Bod Pod. **A.** Yes, we will do that.

Q: What is the RPE scale and what is meant by "somewhat hard". Please clarify in your protocol. **A**. It is a measure of exertion and we will spell out what is meant by this.

C: You may want to include a picture of the Bod Pod in the informed consent for. This might help parents more fully understand what they are agreeing to. **A:** Yes, we thought about doing this.

C: You are missing several important items in your informed consent form. Please be gender specific, include the storage and disposal of data, the time required for participation, who has access to the data and any adverse effects. **A:** Yes, we will add these items.

Q: Do you have school board approval? If so, please submit a letter. **A:** Yes, we have approval and will include the letter of approval in the revision submission.

Q: Are there Spanish speaking families in this community? If so, you will need to submit an informed consent in Spanish for approval. **A.** We will do this.

C: In your protocol you do not include info on who will administer the informed consent. You need to include this. **A:** We will include this.

C: Although anecdotally we know there is a need in our communities for such a program, a more extensive literature review that clarifies and supports the purpose and rational for the program must be added to the protocol. **A:** Yes, we will do that.

There were no more questions or comments and the investigators were asked to leave so that the IRB could deliberate in executive session. There was a motion by Herndon to approval the protocol conditionally. All voted to approve.

Continuing Review and Renewal of Authorized Protocols

Protocol 07-91. "Evaluation for Kern County Children and Families Commission [KCCFC]". Wang stated that this was a new funding period and as such no data were collected. However, during this period two manuscripts were submitted and approved for publication with revisions as well as the switch over to a new data management system. McCleary commented that the informed consent had issues of readability and needed to be reworded. The committee requested the rewording of the form.

The PI Wang was excused and the IRB deliberated in executive session. There was a motion to accept the First Five quarterly report at it was seconded. All approved to accept the report. The investigator was applicated for his good work on the grant.

Edvention and Related (Protocols 10-157, 11-66, 11-68, 11-117, 13-117 14-05, 14-70,14-93) With Randy Schultz. The PI had to leave for a meeting at the AV campus so the board tabled the report on the Edvention related protocols for the next meeting. Herndon motioned to table the report. Newberry seconded. All approved the tabling of the report.

VI. OTHER CONCERNS: (None)

VII. MEETING DATES FOR 2016:

Winter 2016 Friday, 22 January 2016 Spring 2016 Friday, 15 April 2016 Summer 2016 Wednesday, 08 June 2016

VIII. ADJOURNMENT: The meeting was adjourned at 9:45 am.

IX. BOARD TRAINING: No training was scheduled for this meeting.