

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

**Meeting Minutes – Fall II 2016
Friday, 19 November 2016 [DDH 108]**

Members Present:

Scientific Concerns: Chandra Commuri, Anne Duran, Roseanna McCleary

Nonscientific Concerns: Nate Olson, Steve Gamboa, Tony Alteparmakian

Community Concerns: Grant Herndon, James Velasquez

Acting RERC: Steve Suter

Absent Member:

Colleen McGauley

Others:

Gwen Parnell, GRaSP

Monique Willis, [Protocol 16-155]

J. J. Wang [Protocol 07-91]

I. CALL TO ORDER

Chair McCleary called the meeting to order at 8:01 AM. There was a round of introductions.

II. APPROVAL OF MINUTES

“More clear” should be changed to “clearer” in IVB [para 2]. Duran/Velasquez moved/seconded a motion to approve the minutes as corrected.

III. ANNOUNCEMENTS

- A.** New IRB member Chandra Commuri is attending his first meeting.
- B.** The recent informal Q/A IRB info session was summarized. Another is coming up on W, 12-07.
- C.** Four webinar-style demos of possible software to handle grants, IRB, and IACUC are coming up. IRB members and other faculty are invited to attend. Gwen will send out formal invites.

IV. OLD BUSINESS

- A.** CITI HSPT and Recertification

Most IRB members have explored various modules and aspects of the training. It is not clear which ones to take, given that there are around 35 that come up, for example those for IRB Members, those for Researchers [and what kind of research?], and as a Refresher. There was a consensus that the materials are well thought out. CSUB has had a license for these for a few years. The “responsible conduct of research” materials are required for NSF and NIH projects. A task group [McCleary, Commuri, Olson] will focus on selecting subsets of modules for persons in particular roles to take. Gwen will explore adding faculty as graders or instructors in CITI so that they can see students’ scores. We will wait to develop policy on recertification.

V. New Business

This flurry of policy and procedure items is prompted by realization that: [a] there are pitfalls in having quite a few “traditions” that are not written down as policy and [b] the need for more systematic record keeping to document the actions of the IRB, especially in case of an external audit.

- A. Protocol Renewal Timeframe.** RERC has traditionally allowed PIs to renew a protocol within a “grace period” after it has formally closed. This could create a problem if something went wrong in research that was being conducted outside of an authorization period. It was noted that PIs are informed of the closure date in three ways: [a] in their authorization letter, [b] in their “impending closure” letter, and [c] in their “final closure letter” in which they are specifically told to stop interacting with subjects. One element of the present proposal is to no longer allow late renewals – “closed is closed”. A second element is that yearly review of protocols is required; therefore, renewal or resubmission of a protocol should require a progress report or summary of activities carried out during the authorization period, which would be reviewed in considering the renewal or resubmission. We will need to develop a form for this. It was decided to also initiate a brief, voluntary closure report at the end of the authorization period even if there is no renewal or resubmission. Commuri moved/Velasquez seconded, 8-0.
- B. RERC Email Protocol Approvals.** Traditionally in cases of time urgency, when a protocol is “good to go” the RERC has informed the PI via email that the research may go forth, with the formal authorization letter to follow. It was decided to continue to allow this, but that this should be formalized in policy/procedure language that states that such an email has standing, so that the research is authorized as of the date of the email. Herndon moved/Olson seconded, 8-0.
- C. Progress Report Policy.** This was covered in the new renewal policy [above].
- D. Appointment of Alternate IRB Members.** Yet another tradition. Departing IRB members are appointed as alternate IRB members, primarily to serve if needed to achieve a meeting quorum. Procedure is the same as for appointment of regular IRB members – RERC nominates to CSUB Academic Senate, Senate advises the Academic Provost, and Provost appoints. There was a motion to make this a policy. Velasquez moved/Herndon seconded, 8-0.

- E. What Venues = Reviewable Research?** Presentations in class of class projects = no. Written product filed in library or presentation in a university-wide venue, such as the Psy Chi Research Conference or Student Research Scholars = yes. There is a gray area in between where there is doubt and uncertainty as in a recent case in which acting RERC and RERC made different calls. It comes down to the nature of the audience. We need to make consistent the IMPHSR form, which probably needs revision, and any words we add to website and/or policy/procedure document. We should give examples of venues requiring IRB review and authorization and that IRB should be contacted for guidance in cases where there is uncertainty. Duran moved/Commuri seconded, 8-0.
- F. CSUB Senate Resolution 161702 [Research Misconduct].** RERC informed members about this resolution, which put in place a necessary program to prevent and deal with research misconduct. It is noted that this does not include anything dealing with non-compliance with IRB review and authorization procedures or regulations. This leads to the next item.
- G. IRB Non-Compliance.** We have no policy. The IRB and RERC have quite a history dealing with the overall policy question and specific instances of noncompliance, but no formal policy has ever been proposed. Present, traditional procedure is for the RERC and IRB Chair to conduct an investigation, including interviews of the parties involved, when alleged cases surface. A formal report is then sent to students and faculty involved, and the administrative chain of command up to the Academic Provost. The IRB reasoned some time ago that egregious cases would be filed with the CSUB Committee on Professional Responsibility. The reasoning for this is that faculty are required to conform their conduct to CSUB policies; one policy is to implement the federal regulations on human subject protections. Therefore, IRB noncompliance would be subject to sanctions. However, the Committee on Professional Responsibilities has no enforcement powers. IRB has no enforcement powers beyond ordering human research to cease if participants are being harmed. There appeared to be agreement that IRB noncompliance should have consequences. This would require CSUB Senate action, probably and might burn off some of the IRB's good karma. However, it is not good the CSUB students can satisfy degree requirements and faculty can achieve promotion and tenure on the basis of noncompliant human subjects research. RERC argued that it would be desirable for any such policy to originate from the IRB rather than descending from on high. Also Sumaya, the RERC, should be involved in developing policy. McCleary and Sumaya were charged with developing a draft policy for further consideration. Procedurally, this issue was tabled for now.
- H. Policy on PI Meeting Attendance.** Tradition [There's that word again!] has it that the PI must be present for a Standard Review in a meeting. Also IRB requires faculty mentors of student PI's to be present. Unfortunate instances in which a faculty mentor failed to show up and the students had an unpleasant experience were presented. It was agreed that the above attendance requirements should be IRB policy. Commuri moved/Duran seconded, 8-0.

I. Selection of Outstanding IRB Protocol. This would be for AY 2015-2016 for recognition at the 2016 Research Excellence Day. There was a discussion about the procedures used for the previous, and first, such selection. The RERC was charged with picking out three and sending them out to IRB members for a vote. This is thought to be what happened last year.

VI. Formal Board affirmation of protocols previously approved under Standard Review, Expedited Review, Third Party Access and Exemption from Full Review since the September 2016 meeting.

A. Standard Review [0]

B. Expedited Review [3]

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Final Approval	Type of Review
16-98	Josh Uhalt, Casey Harris	Psychology	Sexuality: Definitions and Correlates	7/1/2016	Anne Duran	9/12/2016	Expedited
16-105	Matthew L. McClellan	Public Policy Administration, BPA, MPA	Supporting LGBTQ+ Students: Evaluating CSUB's Campus Support Resources	8/23/2016	Chandra Commuri	9/13/2016 (M), 9/8/2016	Expedited
16-111	Dr. Yong Li, Dr. Jong Choi, Dr. Jaewon Lee	Department of Social Work	Testing the Effectiveness of Strengthening Intergenerational/Int ercultural Ties in Immigrant Families (SITIF)	9/7/2016		9/27/2016	Expedited

Herndon moved/Alteparmakian seconded, 8-0 with abstentions from own protocols.

C. Third-Party Access to Existing Data [0]

D. Exemption from Full Review [15]

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Final Approval	Type of Review
16-88	Antje Lauer, Erin Gaab	Biology	Valley Fever Risk Perception	5/25/2016	n/a	9/1/2016	Exempt
16-106	Dr. Bre Evans-Santiago	Teacher Education	What Effect Does a Male Mentoring Program Have on Minority Male Students in Elementary Schools?	8/24/2016		9/8/2016	Exempt
16-107	Sarah Appleton, Psy.D. Yvonne Ortiz-Bush, Ph.D. Jong Choi, Ph.D. Roseanna McCleary, Ph.D	Psychology	Effectiveness of Champions Training in the Screening, Brief Intervention, and Referral to Treatment Approach	8/25/2016		9/8/2016	Exempt
16-109	Kyle J. Susa	Psychology	General Knowledge Registered Replication Report	9/2/2016		9/13/2016	Exempt
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

Exemption from Full Review-Continued

16-119	Martin Rios	AES	Mathematical Procedures Self-Monitoring Checklist for Task Completion	9/22/2016	Calli Lewis Chiu	10/17/2016	Exempt
16-121	Shawnda Smith & Anthony Alteparmakian	Mathematics Department; 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	n/a	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	Anne Duran	10/26/2016	exempt
16-153	Alison Gomez	Psychology	Correlates Between Stigma and Subjective Norms and its Influence on Help-Seeking Behaviors	10/29/2016	Anne Duran	11/3/2016	Exempt

Herndon moved/Alteparmakian seconded, 8-0 with abstentions from own protocols.

VII. Formal Board affirmation [26] 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.

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Final Approval	Type of Review
IMPHSR? 16-112	Michelle Carlin	Athletics	CSUB Softball Sustaining Excellence	9/8/2016	Christine Zingler	NRS by RERC2 on 9-12-16	NRS for Procurement Office Contract
NRS 16-123 IMPHSR?-NO	Jordan Maurice Lee	Public Policy and Administration	Examining the Biggest Difference in QALY/DALY Amongst States	10/9/2016	BJ Moore	10/10/2016	NRS
NRS 16-124, IMPHSR?	Xuan Nguyen	Masters of Science of Healthcare Administration	Preventative Program on Childhood Obesity Based on Best Practices in California	10/11/2016	Chandra Commuri	10/12/2016	NRS

[not within IRB/HSR purview] continued

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Final Approval	Type of Review
NRS 16-125	Kim Thu Tran	Public Policy and Administration	Beyond Any Distance Ever Reached Before	10/12/2016	Chandra Commuri	10/13/2016	NRS
NRS 16-126	Sultan Alotaibi	Masters of Science of Healthcare Administration	Health Care Development in Arar City in Saudi Arabia	10/12/2016	BJ Moore	10/13/2016	NRS
NRS 16-127	Mohammad Alshammar	Masters of Science of Healthcare Administration	Redesigning the Healthcare System in Hail	10/12/2016	BJ Moore	10/13/2016	NRS
NRS 16-128	Arturo Bejar	Public Policy and Administration	Social Media Best Practices for Nonprofits	10/13/2016	Chandra Commuri	10/14/2016	NRS
NRS 16-129	Beatrice Corral	Public Policy and Administration	A Program Proposal to Improve the Accounts Receivable Process at The Housing Authority of the County of Kern	10/13/2016	Jinpin Sun	10/14/2016	NRS
NRS 16-130	Ana Aguayo-Bryant	CSU Chancellor's Office	CSU Systemwide AHEAD Survey	10/17/2016	n/a	10/17/2016	NRS
NRS 16-132	Isabel Medrano	Public Policy and Administration	Best Practices for Increasing Employee Involvement for Employee Based Health Clinics	10/17/2016	BJ Moore	10/20/2016	NRS
NRS 16-133	Febizza Ann Obar	Masters of Science of Healthcare Administration	Safety Concerns in Nursing Homes	10/17/2016	BJ Moore	10/20/2016	NRS
NRS 16-134	Gabriela Castro	Public Policy and Administration	Best Practices for Preventing Amputations on Diabetic Patients	10/17/2016	BJ Moore	10/2/2016	NRS
NRS 16-135	Ibteisam Madhi	Public Policy and Administration	Cross-National Comparison Study of Patient-Centered Health Care	10/19/2016	BJ Moore	10/20/2016	NRS
NRS 16-136	Kiran Khanka	Masters of Science of Healthcare Administration	How Do Six Major Hospitals in Bakersfield Compare on Quality Standards?	10/19/2016	BJ Moore	10/20/2016	NRS
NRS 16-137	Mat Prasser	Public Policy and Administration	Family Dynamics in Firefighter Households	10/20/2016	Martinez	10/21/2016	NRS
NRS 16-138	Jessica Monthe	Public Policy and Administration	Assessment of Resources in the Cameroon Health Care System	10/20/2016	BJ Moore	10/21/2016	NRS
NRS 16-139	Shahahm Alshammari	Masters of Science of Healthcare Administration	Strategic Planning in Reducing Type 2 Diabetes among Children	10/20/2016	BJ Moore	10/21/2016	NRS
NRS 16-140	Jonathan Glover	Public Policy and Administration	Reducing Medication Errors in Group Homes	10/20/2016	BJ Moore	10/21/2016	NRS

[not within IRB/HSR purview] continued

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Final Approval	Type of Review
NRS 16-141	Dustin L. Parker	Masters of Science of Healthcare Administration	Medication Adverse Events—Likelihood According to Health Care Intuition Size	10/20/2016	Daniels	10/21/2016	NRS
NRS 16-142	Karina Bravo	Masters of Science of Healthcare Administration	Telecommuting the Aging Mind: Identifying Best Practices for Telemedicine and Alzheimer's Disease	10/22/2016	BJ Moore	10/24/2016	NRS
NRS 16-143	Cynthia Urias	Public Policy and Administration	What Are the Best Practices in Addressing Resources Development for the Elderly Health Care Needs	10/22/2016	BJ Moore	10/24/2016	NRS
NRS 16-146	Jasmeen Riar	Masters of Science of Healthcare Administration	Security Breach: Designing the Best Patient Health Information Security Platform	10/24/2016	BJ Moore	10/26/2016	NRS
NRS 16-147	Colin Rambo	Masters of Public Administration	Bakersfield Bike Path: A Needs Assessment	10/24/2016	Rebecca Jamison	10/27/2016	NRS
NRS 16-148	Sandeep Kaur Dhand	Masters of Science of Healthcare Administration	Improving Responsiveness to Call-Lights	10/25/2016	BJ Moore	10/26/2016	NRS
NRS 16-149	Guadalupe Herrera	Masters in Public Administration	Proposal to Modify Current Employee Performance Policy Towards A More Comprehensive Employee Evaluation System	10/26/2016	Thomas Martinez	10/27/2016	NRS
NRS 16-154	Ramandeep Dhaliwal	Public Policy and Administration	Best Practices in Pain Management	11/2/2016	BJ Moore	11/3/2016	NRS

Duran moved/Olson seconded, 8-0 with abstentions from own protocols.

VIII. Formal Board affirmation [3] of previously approved protocols granted **Renewals** since the September 2016 meeting. For 15-53 there were changes in the PI and research assistants. For 15-84 one PI was removed and a new test was added. Protocol 15-102 added survey items previously authorized in another protocol for that PI. Formal Board affirmation [26] 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.

Renewals

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Final Approval	Type of Review
15-53	DR. KATHLEEN MADDEN, Matt Chalker, Andrea L. Medina (Research Assistants)	NSME	REVS PUP/UP S-STEM Attitudes Survey	4/6/2015	Dr. Luis Cabrales	9/19/2016 (ren w mod) gp. 6/2/2015 (O)	Exemption
15-84	Kris Grappendorf, Joshua Miller, Eugene Wang, Kristina LaGue, Bree Gage	PEAK	Runner Read & Ride Program: A Pilot Study	8/31/2015		11/1/2016 (Renewal)gp. 11/2/2015 Approval Letter, Conditions Letter - sent 10/13/2015	Standard
15-102	Jeremy Woods, (Lead Investigator, Faculty) David Olson, (Faculty) – (not listed on revised) & Derek Stotler (Student)	Management and Marketing BPA	Advancing the Measurement of Familiness in Family Business Research	11/6/2015		10/28/2016 (M2) gp, 2/5/2016 (M) gp, 11/16/2015	Exempt

Duran moved/Olson seconded, 8-0 with abstentions from own protocols.

IX. Modification [8] of previously approved protocols since the September 2016 meeting. New co-PI was added for 15-105. For 16-03 a new health survey and an exercise measure were added. New research assistants were added for 16-09, 16-28, 16-31, and 16-101. For 16-43 the survey was reorganized and items added. A new subject recruitment flyer was added for 16-105.

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Final Approval	Type of Review
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	Roseanna McCleary	9/30/2016 (M), 3/7/2016	Exempt
16-03	Joshua Miller & Brian Street	PEAK	Metabolic Syndrome in College Students: Prevalence and Individual Criterion	1/5/2016		9/13/2016 (M), 2/18/2016	Expedited
16-09	Casey Harris	Psychology	Rape Empathy: Clinicians' Attitudes Toward Sexual Offenders	1/13/2016	Anne Duran	1/21/2016	Exempt

Modifications continued

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Final Approval	Type of Review
16-28	Chandra Commuri	Public Policy & Administration	Professional Identity Work During Times of Crisis: Law Enforcement Work in the Post-Ferguson Era	3/1/2016		3/23/2016. Modification approved 10-18-16 RERC2.	Expedited
16-31	Ashley L. Stapley	Psychology	Relational Peer Victimization and its Impact on Cognition	3/9/2016	Marianne Wilson (Abramson)	9/21/2016 (M). 4/5/2016	Exempt
16-43	Ji Li, Jeremy Woods, and Di Wu	Accounting and Finance, Management and Marketing	Contributions of Accounting Training and Skills for Small Businesses	4/13/2016		9/8/2016 (M). 6/12/2016	Expedited
16-101	Kyle J. Susa	Psychology	VF2 Verbal Facilitation	7/1/2016		7/26/2016	Exempt
16-105	Matthew L. McClellan	Public Policy Administration, BPA, MPA	Supporting LGBTQ+ Students: Evaluating CSUB's Campus Support Resources	8/23/2016	Chandra Commuri	9/13/2016 (M), 9/8/2016	Expedited

Alteparmakian moved/Velasquez seconded, 8-0 with abstentions from own protocols.

X. Formal Board affirmation of protocol **closures** [10] whose authorization have closed since the September 2016 meeting

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Final Approval	Type of Review
15-75	Kristina Rios	Special Education MA	Assignments in Increments and Academic Achievement	6/2/2015	Calli Lewis-Chiu	9/4/2015	Expedited
15-82	Lauren Ash-Anderson and Erika Delamar	Student Health Services	National College Health Assessment	12/2/2015 (M), 8/17/2015		12/2/2015 (MOD)	Exemption Modification

Closures continued

Number	Author	Department	Title	Date Submitted	Faculty Sponsor	Final Approval	Type of Review
15-85	Leigh Collins and Courtney Nathan	Social Work	When a Parent is Seriously Ill: An Exploration of Related Family Experiences and Resource Utilization	9/4/2015		10/9/2015	Expedited
15-86	Bruce Friedman	Social Work	Economic Costs of Not Providing Health Care for the Uninsured	9/9/2015		10/15/2015	3PA
15-87	Marisa E. Sanchez	Sociology	Impacts of Racial Composition and Space on Racial/Ethnic Identity Development for Mexican Origin Latinos at a Hispanic Serving Institution	9/18/2015		10/15/2015	Expedited
15-90	Kyle J. Susa	Psychology	Face Perception	9/24/2015		10/1/2015	Exempt
15-91	Kathleen Nicole Smith	Sociology	Which California State University, Bakersfield Student Athlete Academic Support Programs Help Student Athletes Achieve Academic Success?	9/24/2015	Rhonda Dugan		Exempt
15-92	Brian Street	Physical Education and Kinesiology	Accelerometer Measured Activity Levels After Total Knee Replacement	9/28/2015		10/14/2015, 10/21/2015	Expedited
15-94	Paul Georgi	Psychology	The Role of Confidence Validity and Racially-Dissimilar Relationships in the Cross-Race Effect: Identifying Strategies for the Detection and Reduction of Minority Misidentifications During Eyewitness Testimony	9/30/2015	Anne Duran	10/15/2015	Exempt
15-97	Brooke Whitehead	Sociology	First-Generation College Students: The Role of Social and Cultural Capital in Academic Success	10/7/2015	Alem Kebede	1/31/2016 (M) 10/21/2015 (Original)	exempt

Herndon moved/Gamboa seconded, 8-0 with abstentions from own protocols.

XI. Continuing Review of Authorized Protocols

Protocol 07-91. “Evaluation for Kern County Children and Families Commission [KCCFC]”. J. J. Wang. Quarterly Report and Annual Renewal. Primary readers are all members.

The PI summarized: Consent form use and confidentiality training continues as required in Protocol 07-91. The yearly report to the state this fall highlighted the Ready to Start program which includes over 20 CSUB student interns in their preschool programs. In addition, an intern has been hired directly to F5K from the CSUB PPA program. The relationship between CSUB and F5K continues to build community connections. There have been several presentations and one impending journal articles based on data collected under Protocol 07-91.

The PI was asked to find out if the new person doing confidentiality training is certified in human subjects protection training. The PI will report back to the Board.

The PI was asked to leave the room and the Board discussed Protocol 07-91 in executive session. There was a motion to accept the quarterly report and renew Protocol 07-91 for an additional year. Velasquez moved/Commuri seconded, 8-0.

The PI was informed when he returned and congratulated for his good work on behalf of the human subjects involved in the F5K programs.

XII. Review of New Protocols

Protocol 16-155 [Monique Willis, Psychology]. “Minority Parents’ ASD Narratives Study”.

Following introductions, the PI summarized. “Minority Parents’ Autism Spectrum Disorder Narratives Study.” The PI would like to study the impact of ASD on minority populations. Research related to ASD and minority families is scarce. The proposed research is a qualitative study that focuses on issues related to raising a child between the ages of 2 to 18 who has been diagnosed with ASD. Study participants will be recruited from minority populations and a couple dynamic will be a focus.

Questions followed.

[Q: Question A: Answer C: Comment]

Q: Please clarify the level of respondent in the research. Is it individual, couple, or group, and are there differences of how you will approach each level? **A:** It will be all three. Questions in the interview guide are general enough to cover each level of respondent.

Q: You use the term “psychotherapist” in the protocol and informed consent related to adverse reactions. Please change this to the broader term: “mental health professional.” **A:** Agreed.

- Q:** On the parent questionnaire form, please add something that indicates the confidentiality of the questionnaire. **A:** Agreed.
- C:** PI discussed the issue of concerns about adverse reactions. She stated that in a prior similar study, some respondents did have some anxiety, however, some thought that the interview was a cathartic experience, and that participants would be able to get some insight into issues of parenting an ASD child.
- Q:** During an interview, can a participant opt out of the audiotaping of the interview? **A:** Yes. **C:** Please make this clear in the consent and protocol. **A:** Agreed.
- Q:** Who will be transcribing the interviews? **A:** An out-of-state professional transcribing service.
- Q:** Do you have a form specific to the research that transcribers can sign to ensure confidentiality? **A:** No, but I can get one. **C:** Follow up: See if there is an example that PI can use.
- Q:** Where will the interviews take place? **A:** It depends on the needs of the participants. Most of the time (about 75%), the interviews are done in the home.
- Q:** What about safety issues related to this? **A:** I will have at least one student with me when doing the data collection.
- C:** Please state in the protocol and informed consent where the interviews will be taking place and that participants' privacy will be ensured during the interviews. **A:** Agreed. **C:** All students have or will be taking the CITI HSP Training. The students involved have also had experience with ASD.
- Q:** Please describe the data analysis. **A:** I will use a grounded theory method. Data will be analyzed line by line using focused and then axial coding. Students will be involved in this process to ensure validity and trustworthiness of the analysis.
- Q:** What about participants who speak Spanish? **A:** I will be excluding monolingual Spanish speakers due to the lack of resources at this time. **C:** Please note this in the participant exclusion criteria.
- Q:** You use the term "short" interviews in the consent form. Ninety minutes may not be considered a "short" interview. Can you please omit "short?" **A:** Agreed.
- Q:** There is an inconsistency when referring to participants' income level. Are you targeting low and middle income or just low income? **A:** I broadened the population to both low and middle. **C:** Please make this consistent in the protocol. **A:** Agreed.
- Q:** Can you clarify access to mental health services? **A:** Yes, I will include additional resources in the consent form.

The PI was asked to leave the room and the Board discussed Protocol 16-155 in executive session. Following discussion there was a motion to conditionally approve Protocol 16-155. Velasquez moved/Duran seconded, 8-0.

When the PI returned she was so informed and the following conditions were announced to her:

1. Clarify level of respondent in the protocol
2. Change the term “psychotherapist” to “mental health professional”
3. Add language about confidentiality in the parent questionnaire.
4. State in the protocol and informed consent that interviewees can opt out of audiotaping of the interview.
5. Provide a signed confidentiality form to be used by professional transcribers
6. State where interviews will take place and how you will ensure privacy in the protocol and informed consent
7. Give more detailed information related to analysis of data
8. List under participant exclusion criteria, that persons who do not speak English will not be included in the study.
9. Take out “short” interview in the consent form (replace with just “interview”)
10. Make the protocol consistent when referring to low and middle income participants
11. Clarify access to mental health resources on the consent form.

XIII. Adjournment

Chair McCleary adjourned the meeting at 10:18 am. Duran moved/Velasquez seconded, 8-0.