

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

Minutes of Meeting
Friday, 29 January [DDH B-108]

Members Present:

Scientific Concerns: Kathleen Gilchrist, Roseanna McCleary
Nonscientific Concerns: Paul Newberry, Thomas Blommers
Community Concerns: Grant Herndon

Members Absent:

Lily Alvarez, Anne Duran [on leave], Yeunjoo Lee, Tommy Tunson,

Visitors:

Bruce Hartsell for **Protocol 10-06**
Brian Hemphill for **Protocols 07-91 & 10-18**
Roy Snyder, Liora Gubkin, & Isabel Sumaya for **Protocol 10-19**
J. J. Wang for **Protocol 07-91**
Steven Boydston, student observer

I. CALL TO ORDER:

Chair Paul Newberry called the meeting to order at 8:00 AM.

II. PREVIOUS MINUTES:

Blommers moved and McCleary seconded a motion to approve the minutes of Friday, 02 October 2009. The motion was approved 4-0-1.

III. ANNOUNCEMENTS:

- A. New IRB Board member Grant Herndon was welcomed. McCleary mentioned that new member Tommy Tunson had expressed to her his consternation about having to miss this meeting.
- B. It was noted that member Anne Duran [Psychology] is on sabbatical leave during Winter 2010.

IV. OLD BUSINESS

- A. **Minor Mothers.** Minor mothers regularly obtain services for their children from First 5 agencies. Should we accept their consent for research participation? Herndon indicated that preliminary research suggested that California has no applicable statute. Are there precedents? Commonly accepted practices? Is the age of the minor mother a consideration? This also involved pregnant minor mothers obtaining services. There was a discussion of possible agencies or programs that should have experience dealing with this issue. Herndon will seek further information. [Later in the meeting, during discussion of Protocol 07-91, Wang stated that he had been told that a statute existed granting the minor mother the right to consent for the health care of her child. He was asked to supply a citation, so IRB could verify.]

V. NEW BUSINESS

Board members spotted several clerical errors in the IRB Master Log entries, which will be brought to the attention of GRASP personnel for correction, but may remain in the Master Log

material in these minutes. All affirmation motions should be interpreted as referring to Master Log material "as clerically corrected".

A. Formal Board affirmation of protocols previously approved under Standard Review, Expedited Review, Third-Party Access, and Exemption from Full Review since the October 2009 meeting.

1. Standard Review [2]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-146	Jennifer Hennick	Impact of Early-Onset Breast Cancer: Perceptions of and Decisions about Genetic Testing	8/24/2009	IRB Board	10/19/2009
09-152	Kenisha Edwards-Ray	Code 288: An Autopsy of the African American Sexual Assault Victim	9/21/2009	IRB Board	12/11/2009

[Blommers moved, Gilchrist seconded -- approved 5-0].

2. Expedited Review [11]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-149	Jessica Prather	Lived Experience: Mothers Using Kangaroo-Care to Promote Attachment with Oxygen-Dependent Infants in the Neonatal Intensive Care Unit	9/17/2009	Yeunjoo & McCleary	10/26/2009
09-159	Lucrecia Molina	Barriers to Nurses Reporting Domestic Violence	10/14/2009	Duran & Bloomers	11/18/2009
09-163	Mahdavapallil Thomas & Jong Choi	Correlates of Resilience Factors and Acculturative Stress Among Asian Adolescents	10/22/2009	Duran & Lee	11/18/2009
09-167	Anthony Pallitto	Identifying Best Practices for Health Care Reform: What Works in the Microcosm of U.S.-Mexico Border Communities	10/23/2009	Bloomers & McCleary	11/20/2009
09-185	Sylvia Coronado	GrandFriends Intergenerational Day Camp Project	11/16/2009	Blommers & Gilchrist	11/30/2009
09-186	Irma Simental-Hernandez	Older Adults and Young Children Unite	11/16/2009	Blommers & Gilchrist	12/2/2009
09-191	Erik Herrera	The Slow Death of at Risk Youth. A Grant Proposal	11/16/2009	Lee & Gilchrist	12/14/2009
09-192	Carol Shertzer	Group Art Therapy for the Elderly	11/16/2009	Newberry & McCleary	12/3/2009
09-193	Salvador Arias	"Parent on a Mission", Does it Work?	11/16/2009	Lee & McCleary	1/5/2010
09-203	Zinal Patel	Process Evaluation on the Patient Education Program and Service Awareness at CBCC	11/18/2009	Newberry & McCleary	1/8/2010
09-213	Catherine Cezar Senining	Stress and Coping Mechanisms Used by Mental Health Nurses in an Acute Psychiatric Unit	12/3/2009	Lee & McCleary	1/16/2010

[Gilchrist moved, Blommers seconded -- approved 5-0]

3. Third-Party Access to Existing Data [10]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-154	Joe R. Torres	Differences in English and Spanish Speaking Hypertensive Patients Attending A Hypertensive Clinic	9/24/2009		10/12/2009
09-160	Michelle Martinez	Do Children with Behavioral Disorders Progress Better in their Treatment if their Biological Parents are Involved?	10/20/2009	Gilchrist & Newberry	11/12/2009
09-168	Madhavappalil Thomas, Roseanna McCleary & Jong Choi	Predictive Factors of Classroom Performance and Field Instruction Performance of Masters of Social Work	10/27/2009		11/6/2009
09-169	Taneil Green-Wood	Evaluation of Solution Focus Therapy when Working with Clients Diagnosed with Post Traumatic Stress Disorder (PTSD)	10/27/2009	Lee & Gilchrist	11/13/2009

09-172	Adrian Ramirez	Effectiveness of the College Assistance Migrant Program on Migrant Student Achievement in the California State University System	11/2/2009		11/6/2009
09-178	Bobbi Bailey	An Evaluation of the Effectiveness of Wraparound Program for Children and Adolescents	11/10/2009		11/13/2009
09-198	Jeffery Kaya	Access to Healthcare Services by Lesbian, Gay, Bisexual, and Transgender (LGBT) Elders in Kern County	11/16/2009		11/19/2009
09-200	Jami Ekstrom	An Overall Picture of Ethnic Differences in a Local Kern County Foster Family Agency	11/17/2009		11/19/2009
09-207	Kellie Pimienta	Healthy and Effective Teen Parenting: A Home Based Program to Empower Teen Parents to Achieve Their Familie's Maximum Capabilities	11/24/2009		1/11/2010
09-209	Gloria J. Tucker	"...Recidivism in an Outpatient Mental Health Program"	11/24/2009		12/1/2009

[McCleary moved, Blommers seconded -- approved 5-0]

4. Exempted from Full Review [13]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-148	Peggy Leapley	National Children's Study Kern County (Phase 1)	9/14/2009		9/30/2009
09-156	Keri Kehoe	Effective Strategies in Creating Successful Professional Learning Communities	10/6/2009		11/10/2009
09-166	Karen Langston	Home Court Advantage: A Project Plan for Facilities Expansion for CSUB Athletics	10/22/2009		10/23/2009
09-170	Chandrasekhar Commuri	Socialization Experiences of Clients on Social Service Nonprofit Boards	10/27/2009		10/30/2009
09-171	Janice Keenberg	COPE: Community Options Program for Elders- A Needs Assessment and Elder Program Proposal for a Rural Mountain Community in Kern County	10/27/2009		11/2/2009
09-176	Ying Zhong	Universal Design for Learning (UDL in Library Instruction	11/5/2009		11/6/2009
09-177	Natalie Tran & Andreas Gebauer	Motivation for Science Learning	11/9/2009		11/12/2009
09-180	Brenda M. Story	Needs Assessment for the Kern County Mental Health Hotline	11/10/2009		11/19/2009
09-181	Kathrine Parnell	An Analysis of the Effects of Increased Foster Parent Education on Foster Parent's Perceptios of Foster Youth's Behavior	11/12/2009	Newberry & Duran	11/24/2009
09-195	John Stockton	Stakeholders' Perceptions of the Effectiveness of theCurrent Structure of the California Long-Term Care Ombudsman Program	11/16/2009		11/23/2009
09-199	Sherrill Elson	Reducing Personal Bias in Risk Assessment in Child Protective Services at KCDHS	11/17/2009		11/19/2009
09-205	Candace Kerwin	Are Concurrent Planning principles and practices being utilized by Kern County Child Welfare Services?	11/24/2009		1/6/2010
09-211	Danny Osborne	Attidues about the Furlough Program	12/1/2009		12/2/2009

[Gilchrist moved, McCleary seconded -- approved 5-0]

B. Formal Board affirmation [19] of protocols submitted and designated as not falling within the IRB/HSR definition of human subjects research (not within IRB/HSR purview) since the October 2009 meeting.

Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-155	Reginald L. Gridiron	Development of an Emerging Green Collar Workforce Program	10/1/2009		10/2/2009
09-157	Ruby Castillo	Evaluation of Short Term Outcomes of the "Network for the Improvement of Addiction Treatment (NIATx) in Kern County Mental Health Substance Abuse System of Care	10/9/2009		10/9/2009

09-158	Roseanna McCleary and Bruce Friedman	Evaluating Achievement of Advanced Gerontology Skills in a Culminating Experience (Community Project/Thesis)	10/9/2009		10/12/2009
09-162	Tanya Boone	Content Analysis of "Texts from Last Night"	10/21/2009		10/22/2009
09-164	Wesley Allan Coble	Policy Analysis of Food Labeling	10/22/2009		10/23/2009
09-165	Isabel Juarez Gonzalez	The Banning of the Sale of Soda in Schools	10/22/2009		10/23/2009
09-174	Michelle Paez	Anticipatory Grief: A Psychoeducational Program for Adults with a Family Member or Friend Currently Receiving Hospice Services	11/4/2009		11/6/2009
09-175	Melissa Salvador	I am Adopted...I am Loved	11/4/2009		11/6/2009
09-179	Anastasia Kwan	Needs Assessment for High Risk Families Involved in an Emergency Response Referral	11/10/2009		11/13/2009
09-182	Laura Falcon	The Window for California to Enact Parental Notification and Waiting Period	11/16/2009		11/16/2009
09-188	Maria L. Avila	A Bereavement Curriculum for Adult Caregivers to Implement with Grieving Children	11/16/2009		11/17/2009
09-189	Debra Hollers	Social Skills Training for People with Schizophrenia: A Teaching Curriculum for Groups	11/16/2009		11/17/2009
09-190	David Joseph Martinez	A Qualitative Research Proposal to Develop a Policy and Procedures Manual for Mental Health America's Military Resource Center	11/16/2009		11/17/2009
09-201	Waala Rasheed	Master Thesis	11/17/2009		11/18/2009
09-206	Sarah Kittinger	Grief Room and Bereavement Resources for Lancaster Community Hospital	11/24/2009		11/30/2009
09-216	Nicole Love	Mental Health Issues of LGTQ Population/Individuals	12/17/2009		1/12/2010
10-02	Joyce Kearin	Separation and Divorce Support Group Curriculum	1/5/2010		1/7/2010
10-03	John M. Glover	Post-Traumatic Stress Disorder Interventions for acommunity-Based Military Resource Center	1/8/2010		1/11/2010
10-04	Melissa Louise Ray	The California state Budget Crisis	1/11/2010		1/11/2010

[McCleary moved, Blommers seconded -- approved 5-0]

C. Formal Board affirmation [3] of previously approved protocols granted renewals since the October 2009 meeting.

Number	Author	Title	Date Submitted	Reviewers	Final Approval
07-91	Andrew Crawford, Brian Hemphill, Marc Thibault, Jaimie Hogan, Alesha Doherty, David Berri	Evaluation for Kern County Children and Families (KCCFC)	9/21/2007	IRB Board	1/25/2008
08-120	Luis Vega	Students' Knowledge and Attitudes about Intergroup Relations	10/13/2008		10/30/2008
08-109	J.J. Wang, Brian Hemphill, Jamie Hogan, Alesha Doherty, David Berri	Parenting Skills Survey--Protocol 09-91 Evaluation for Kern County Children and Families Commission (KCCFC)	9/19/2008	McCleary, Carlisle	11/21/2008

[Blommers moved as corrected, Gilchrist seconded -- approved 5-0]

D. Formal Board affirmation of protocol closures [58] (unless extension granted) whose authorizations have ended or will end prior to the Winter 2010 IRB meeting.

January 2010

Number	Author	Title	Date Submitted	Reviewers	Final Approval
08-116	Josephine Alamillo	Los Angeles County Department of Children and Family - What Permanecey Means to Youth in Long-Term Foster Care: A Focus Group Approach.	9/26/2008	Gilchrist & Newberry	2/20/2009
08-177	Todd Irvine	Driving to Success...(Mentor Program)	12/23/2008	Gilchrist, Newberry & Bashor	2/10/2009
09-01	Jamie Henry	Increasing Self-Efficacy and Knowledge Through a Seizure Education Program for Special Education Teachers: A Partial Replication Study	1/6/2008	Duran and Lee	1/23/2009
09-02	Kimberly Weimer	Needs Assessment for Suggested Additions to Sex Education Programs within Porterville High Schools		Kathleen Gilchrist	1/23/2009
09-03	Jeaniene Reneau	Developing Culturally Responsive Programs to Address Racial Disproportionality in Child Welfare Services	1/7/2009	Paul Newberry & Anne Duran	2/20/2009
09-04	Laura M. Stewart	Needs Assessment of Social Service Work Mentors at the Department of Human Services	1/13/2009	Robert Carlisle & Kathleen Gilchrist	1/28/2009
09-05	Valerie Gallegos	A Program Evaluation of Antelope Valley "Stand Down" Events	1/13/2009	Robert Carlisle & Kathleen Gilchrist	2/3/2009
09-06	Renee Handley	Peer Socialization for Children with Autism	1/13/2009	Robert Carlisle & Kathleen Gilchrist	2/3/2009
09-07	Cindi Dardin	Needs Assessment for Suggested Additions to Sex Education Programs within Porterville High Schools	1/13/2009	Robert Carlisle & Kathleen Gilchrist	1/27/2009
09-09	Joyce Foss	Using Wikis to Promote Better Writing Skills	1/15/2009		2/3/2009
09-10	Denise Buzzini	T.A.I.L.S.-Therapeutic Animal Interventions Lift Spirits: A Program Evaluation	1/15/2009	Lee and Duran	2/4/2009
09-15	Isabella Kasselstrand	Belief or Tradition? A Comprehensive Study of Religious Attitudes in Sweden and the United States	1/16/2009		1/22/2009
09-16	Deirdre Devlin	Curriculum Competencies for Social Work in the Corrections Setting	1/16/2009		2/5/2009
09-22	Janice A. Black	Entrepreneurial Conation & Strategic Cogency (Combination of two Projects previously approved at NMSU)	1/16/2009		2/18/2009
09-26	Monique Castruita	Improving Interdisciplinary relationships between Attorneys, CASA Workers, and County Social Service Workers in Order to Provide Better Outcomes for Foster Care Children	1/20/2009		2/13/2009
09-28	Christy Carlyon	Solution Focused Therapy vs. Cognitive Behavioral Therapy with Teens	1/20/2009	Lee, Gilchrist	2/23/2009
09-30	Marguerite Ashbee	Birth Stories: A Mother's Perspective	1/27/2009		2/4/2009
09-32	Petra Nieto	A Statewide Comparative Study of Celebrating Families in California	2/2/2009		2/13/2009
09-34	Natalie Tran	Parental Engagement in Out-of-School Science	2/3/2009		2/3/2009
09-37	Jacquelyn Ann K Kegley	Study of Substance Use Habits of College Student-Athletes	2/5/2009		2/11/2009
09-38	Natalie Tran, Latish Reed, Christopher Thomas	Hip-Hop Leadership	2/6/2009		2/11/2009
09-39	David Lee, Matthew Braman, Jameson Saberon, Christine Kepenekian	Food Facility Grading Program Evaluation	2/6/2009		2/13/2009
09-42	Natalie Tran	Teacher Candidates' Perceptions of Ethical Standards	2/10/2009		2/11/2009
09-43	Randy Schultz and Michael Simkins	Web 2.0 in the Classroom	2/10/2009		2/11/2009

February 2010

Number	Author	Title	Date Submitted	Reviewers	Final Approval
06-33	Emerson D. Case and Curt Asher	A Survey of English 110 Students Backgrounds in, and Attitudes Toward Library Use	3/28/2006		3/29/2006
09-13	Mannette Rodriguez	Foster Children out of their School of Origin in the Antelope Valley	1/15/2009		3/5/2009
09-36	Jacquelyn Ann K Kegley	Exit Interview of Student-Athletes who have Exhausted their Eligibility	2/5/2009		3/9/2009
09-45	Richard DeAntonio	Improving Outcomes for Families with Incarcerated Parents	2/12/2009	Lee and Duran	3/30/2009
09-53	Monica Sterling	Faith Based Community Resource Manual for DCFS	2/19/2009		3/1/2009
09-55	Laura Roman	Lived Experiences of Public Health Nurses when Utilizing Interpreters in Community Health Settings: A Qualitative Study	2/20/2009	Lee and McCleary	3/4/2009
09-58	Araceli Guzman	College Adjustment and Greek-Letter Membership: Does Ethnicity Matter?	2/27/2009		3/16/2009
09-63	Annette Charron	Ethnographic Study of Generation 1.5 Students in Teacher-Student Comp. Conferences	3/9/2009		3/30/2009
09-64	Ronald Pimentel	Consumption Community Events: Extraordinary Experiences and Self-Presentation	3/10/2009		3/12/2009
09-66	Jennifer Zanke	The Effects of Reading Interest and Attitude on Recall of Textual Events	3/11/2009		3/30/2009
09-67	LaShawn Barefield	Alcohol Needs Assessment: Utilizing the CORE Survey	3/12/2009		3/16/2009
09-71	Beatriz Solano	Factors Preventing Consumer from Qualifying for Mental Health Services	3/13/2009		3/20/2009

March 2010

Number	Author	Title	Date Submitted	Reviewers	Final Approval
07-91	Andrew Crawford, Brian Hemphill, Marc Thibault, Jaimie Hogan, Alesha Doherty, David Berri	Evaluation for Kern County Children and Families (KCCFC)	9/21/2007	IRB Board	1/25/2008
08-167	Bruce Hartsell and Debra Morrison-Orton	Counselor Perceptions of Motivational Interviewing Training Results	12/10/2008	Duran and Carlisle	4/30/2009
09-17	Chuck Tate	Attitudes about Informal Mentoring	1/16/2009		4/27/2009
09-18	Chuck Tate	Attitudes about Bisexuality	1/16/2009		4/27/2009
09-19	Chuck Tate	Cognitive Representations of Sexual Orientation	1/16/2009		4/27/2009
09-20	Chuck Tate	Prediction Processes	1/16/2009		4/27/2009
09-21	Chuck Tate	Racial Jokes and Prejudice	1/16/2009		4/27/2009
09-29	Jasmine Reed	An Analysis of Blending Cluster Onsets and Cluster Rimes: Is One More Difficult Than the Other	1/21/2009		4/20/2009
09-59	Kim Nickell	Formative Assessment in a Learning Community to Access Student Learning	3/3/2009		4/1/2009
09-60	Elvira Coria	On Their Way Out	3/3/2009	Gilchrist	4/9/2009
09-65	Jennifer A. Godinez	The Effectiveness of CBT; Intensive Case Study	3/10/2009	Newberry	4/15/2009
09-69	Jose Adolfo Munoz	Needs Assessment no Mental Health Training for Foster Parents of Children with Mental Disabilities	3/19/2009		3/31/2009
09-72	Kristen Cornell	The Effects of Alertness on Word List Recall and Recognition in the DRM Paradigm	3/19/2009	McCleary & Lee	4/3/2009

09-73	Fathima Abdulla Gutierrez	The Relationship Between Stress and Age of Parents of Infants in the NICU	3/20/2009	Newberry & Duran	4/15/2009
09-78	Janet Armentor-Cota	Report on the Status of Women and Girls in Kern County	4/7/2009		4/9/2009
09-79	Charles Brown	Affects of Stricter Admission Standards on BC Paramedic School of Attrition Rates	4/9/2009		4/16/2009
09-86	Sonia Diaz	Meaningful Performance Measurements	4/14/2009		4/20/2009
09-87	Cindy Goodmon	Research Related to Balancing Budgets in California State University Athletic Program	4/14/2009		4/29/2009
09-93	Jinping Sun	Budget Strategy: A Survey of California County Governments	4/21/2009		4/16/2009
09-97	Angelica McKay	Children Creating PowePoint Presentation	4/20/2009		4/30/2009
09-98	Alicia Dowd	Pathways to STEM Bachelor's and Graduate Degrees for Hispanic Students and the Role of Hispanic-Serving Institutions (Case Studies)	4/27/2009		4/28/2009

[Blommers moved, McCleary seconded -- approved 5-0]

E. New Protocol Reviews

1. **Protocol 10-06: "An Evaluation of the Effects of a Session Rating Scale on Child Welfare Outcomes"** with Bruce Hartsell and Preston Oppenheimer [Social Work]. Primary readers were Newberry, Gilchrist, Alvarez.

Following introductions, Hartsell summarized. There is some research on the importance of the client/therapist relationship in therapeutic outcomes, but little or nothing specifically with respect to the client/social worker relationship and case outcomes. The idea is to get the social worker to devote more attention to the relationship with the adult client in hopes of reducing child removals and trauma associated with various elements of the cases. Introduction of a session rating scale is the vehicle to enhance attention to the relationship that will be tested. There is no interest in the actual scores obtained on the session rating scales.

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

- Q:** Clients are in families for which some kind of complaint has been filed? **A:** Yes, and the social worker has been assigned to work with the family.
- Q:** Has the child been removed? **A:** Some would have already been removed, if the social workers decide to begin using the scale with existing clients. The child would still be in the home in other cases.
- Q:** Who fills out the scale? **A:** The social worker gives it to the adult client to rate the session. Scale scores are then examined to look for changes with respect to the previous session, which are supposed to lead to discussion between the social worker and the client.
- Q:** You will randomly assign social workers to the experimental and control groups? **A:** Yes, using random numbers. The purpose is to avoid bias that might be introduced by self-selection.
- Q:** Related to this, could control participants change to the experimental condition if it seems to be working? **A:** I would be willing to consider that.
- Q:** This would involve moving the analysis up in time. Could you do that? **A:** Yes, we could take a look at six months. You may be more optimistic about large treatment effects than we are.
- Q:** The regional administrator will "invite" participation? **A:** Yes, the purpose is to indicate to the social workers that it is OK to participate and that administration does not have issues about loss of productivity associated with the time taken to deal with the scales.
- Q:** Could you get a letter of support from the administrator, and then you would invite participation? That way, participants could more freely consent or not without possibly feeling pressured by administration. **A:** Yes.
- Q:** Describe the methods used to get data associated with names across sessions. **A:** The data do not have to be associated with names at all.

- Q:** The study is about the social workers, right? **A:** Yes, and whether outcomes change, but we don't need to know anything about the actual scale scores.
- Q:** However, you will be getting the completed scales to make sure that they are being used and they will have client names on them, correct? **A:** Yes, but the names aren't needed for anything.
- C:** You should have the names taken off and work from photocopies without client names.
- C:** Note that LA County DCFS now requires their own authorization, in addition to our IRB authorization.
- Q:** Describe the steps you will take to guard confidentiality in the data. **A:** I will enter and analyze the data myself on my password protected computer.
- C:** Please add that to the consent form.

When there were no more questions, the PI was excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 10-06**. [Blommers moved, Herndon seconded -- approved 5-0]

The following conditions were announced to the investigator when he returned:

1. Test for a statistically significant treatment effect after 6 months and, if it exists, offer participants in the control condition the opportunity to switch to the experimental condition.
 2. Obtain an administrative letter of support, which may be used to enhance your recruitment effort, but solicit participation directly, yourself.
 3. Arrange to have the completed scales provided for your inspection without client personal identifiers so you will not be able to identify client or associate ratings with particular clients.
 4. Add to the consent form a description of the steps that will be taken in collecting, storing, using, and disposing of data in order to protect the data and guard confidentiality.
- 2. Protocol 10-18: "A Dental Investigation of the Biological Affinities of the Ibaloi: An Indigenous Group from the Province of Benguet, Philippines"** with Marie De Guzman and Brian Hemphill [Anthropology].
Primary readers were Blommers, McCleary, Herndon.

Following introductions, Hemphill summarized. Not much is understood about the initial peopling of the Philippines. There are big questions remaining. A new group of people seem to have suddenly appeared, perhaps from Taiwan according to archeological evidence. Lots of this is based on linguistic differences. The idea here is to get dental casts from members of an isolated, rural group and see how the dental variables relate to known groups. Head masters at schools will provide proxy consent and students will assent to participate. The student investigator is a dental assistant. There will be protection against infection. Kids will get a small reward.

Questions followed [**Q** = question, **A** = answer, **C** = comment]

- Q:** This is basically the same thing that you did in the Pakistan study we reviewed last year? **A:** Yes.
- Q:** Describe what you'll be doing to guard against infection? **A:** We'll be using the same disinfectant that is used in dental offices. We had no problems reported in the Pakistan study, although those subjects were not testing afterward for infection. The specific solution that will be used will be determined by what is available in dental supply houses in the Philippines.
- Q:** What is dental care like for this group of people? **A:** Dental care is only provided for emergencies. Dental care is basically tooth extraction.
- Q:** You want to study only Ibaloi people? How will you identify them? **A:** In some cases it will be by self-report; in other cases it will be based on identification by the head master, as we did in the Pakistan study.
- Q:** Can you talk about the proxy consent set-up for this study? Is it culturally similar to the Pakistan tribe? **A:** Yes, very much so. The head master has an authoritarian role among these people. Also, the social clock moves much faster over the years for these kids. In addition, seeking consent from the parents would be a logistical nightmare; having them sign papers could well be confused with police activity.
- Q:** What would you do if somebody does get infected? **A:** Not sure, since this has never happened, as far as we know. No person will be allowed to participate with a tooth abscess. We have moved up the minimum age to

ensure that all of the teeth will have erupted, which should minimize bleeding problems with loose teeth. If an infection happened we would consult with local medical services.

- Q:** You will be doing the dental casts during school hours? **A:** Yes, so we'll be using the resources of the school. We will have a letter of permission from a Philippine health administrator and one of our study personnel will be on site afterward, which will help with any possible problems later on.
- Q:** Doesn't the vocabulary of the consent form seem very advanced? **A:** Our experience from the Pakistan study is that the actual consent form is not read carefully; it is the verbal description of the consent form that really communicates the information.
- Q:** So, explain how the consents will be obtained? **A:** The administrator will sign off and then each child will assent separately, as was done in the Pakistan study.
- Q:** How will you keep the data secure? **A:** I am setting up a center for dental research here and the data will be on a machine there having a secure log on. We are also going to collect some demographic information.
- C:** You should add that information to the protocol.
- Q:** What about the missing local address information on the consent form? **A:** That will be filled in.
- C:** The PI is setting up a research database for the dental information so that it can be accessed from anywhere, including by people where the data were originally collected. Many personal relationships have developed between the PI and persons in the data collection regions. Sometimes his work is published in out of the way periodicals with which some of these people are associated as a way to "give back" to them.

When there were no more questions, the PI excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 10-18**. [Blommers moved, Gilchrist seconded -- approved 5-0]

The following conditions were announced to the investigator when he returned:

1. File the completed version of the consent form with the IRB, when the local contact information has been added.
2. When the local language translation of the consent and assent forms has been completed, file those documents with the IRB.
3. Describe the steps that will be taken in collecting, storing, and using the data in order to protect the data and guard confidentiality.
3. **Protocol 10-19: "Identity: Religious Affiliation in the LGBTQ Community"** with Roy Snyder and Liora Gubkin [Religious Studies]. Primary readers were Blommers, Gilchrist, Tunson.

Following introductions, Snyder summarized. This will be a qualitative approach, from the perspective of the participants, looking at the experience of LGBTQ persons in the context of their religion at the Grace Episcopal Church in Bakersfield.

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

- Q:** Q stands for "queer"? I thought Q signified "questioning". **A:** No, it's queer. If you wanted to add in questioning, it would be LGBTQQ.
- Q:** Are all of the questions to be used provided in the protocol? **A:** The closed-ended questions are provided, but not the open-ended interview questions, because they cannot be specified in detail.
- C:** Provide a general description of the open-ended questions to be pursued.
- Q:** Could you elaborate on the purpose, in terms of what is known and what is not about your subject population in such a religious setting? Have you done a review of the existing research literature? **A:** There are some quantitative studies. This is a fairly new field. There is very little from the LGBTQ person's perspective, which is the aim of this research project.
- Q:** You have been in contact with the minister? **A:** Yes. The minister is Tim Vivian, a CSUB faculty member.
- C:** Please affirm that you will obtain permission and provide written documentation of this.

- Q:** Why are you studying parishioners of the Grace Episcopal Church? **A:** It is local, so it is convenient, and it is very supportive of the LGBTQ members.
- Q:** Is the LGBTQ acronym widely enough recognized to communicate effectively with persons inside and outside of that membership group? **A:** Yes. [Snyder then read a revised, briefer solicitation of participants.]
- C:** Submit the new recruitment material.
- C:** You indicate that participants can choose an interview setting with which they are comfortable, but it should go beyond that and ensure privacy.
- Q:** The consent form doesn't indicate the approximate duration of the interviews. How long will they be? **A:** The initial interview will be about 40 minutes and the possible follow-up would be more like 20 minutes.
- C:** Add that info to the consent form.
- Q:** Could you be more specific about what you'll be looking for in the data? **A:** One angle is that what is professed or preached and what is practiced might differ.
- Q:** Given the division among Episcopalians on this issue, this would seem to be an unusually supportive religious setting within which to study LGBTQ experiences. Are you concerned about the inability to generalize to more typical religious settings? **A:** That is recognized. Perhaps we will discover something that could be extended to other settings to facilitate inclusivity.
- Q:** How will you handle the raw interview data to extract the information of interest? **A:** [Some discussion of statistical analysis followed, but this did not address how to extract information from interview data.]
- Q:** Is that your personal phone number on the recruitment document? We usually discourage, but do not prohibit, doing that. **A:** No, the number is for a cell phone that will be used only for this research.
- Q:** Do you have any idea of the approximate number of participants you will have? **A:** There are maybe 30 potential participants, but the number who consent will probably be more like 10 to 15.
- C:** Transcribing and scoring that much interview data will be an enormous amount of work!
- Q:** What will happen to the tapes? **A:** They will be destroyed afterward.

When there were no more questions, the student and faculty mentors were excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 10-19**. [Herndon moved, Blommers seconded -- approved 5-0]

The following conditions were announced to the investigators when they returned:

1. Submit a general description of the open-ended questions to be used.
2. Obtain a signed permission document from the minister of the church granting access, and file this with the IRB.
3. Submit the revised recruitment document.
4. Add to the consent form the approximate anticipated duration of the initial interview and the possible follow-up interview.
5. Add to the consent form a statement that participants must be at least 18 years of age.
6. Submit for approval any new data collection scales or questions that were not included in the protocol filed with the IRB.
7. Submit any modifications in procedures or documents to be used for approval before they are implemented.
8. Describe the steps that will be taken in collecting, storing, using, and disposing of the data, including the audio tapes, in order to protect the data and guard confidentiality.
9. Describe more specifically the persons who will be used as resources in the event of adverse reactions by participants, including their qualifications to provide such support.
10. Modify the wording with respect to the interview setting to specify that interviews will be conducted in a setting that ensures privacy.

11. Using the commonly accepted language of qualitative research methodology, spell out the specific steps that will be taken to obtain useful information from the raw data.

F. Continuing Review and Renewal of Authorized Protocols

1. **Protocol 07-91:** CS&O Quarterly Report and request for renewal of authorization for activities conducted assessing performance and outcomes of First 5 agencies in Kern County with J. J. Wang and Brian Hemphill. Primary Readers were all Board Members.

Following introductions, Wang summarized. IRB had specified following the previous review in October 2009 that several steps should be taken to ensure a smooth transition following the departure of Andrew Crawford. Wang and Hemphill should meeting with Newberry and Suter for an interim report late in Fall 2009. Reports should specifically include documentation of usage of consent forms, human subject protection training of agency personnel, and adverse event reporting. All this has happened. The minor mother issue remains up in the air. Wang has checked with other counties and someone reported that minor mothers have the right to consent for medical treatment of their children. Does this extend to pregnant mothers?

- C:** It would be very helpful if you could obtain the citation for the pertinent statute. **A:** I will do that.
- Q:** The First 5 funded programs continue as before without change? **A:** Yes.
- C:** The IRB is appreciative of the diligence and care of Wang and Hemphill in help protect rights of subjects.
- C:** Wang mentioned that a CSUB student has been hired by CS&O, as was encouraged by the IRB at the October 2009 meeting.
- Q:** Confidentiality training of new personnel that was anticipated in your memo of 1-06-10 did take place? **A:** Yes.

When there were no more questions, Wang and Hemphill were excused and the Board deliberated in executive session. There was a motion to accept the 07-91 quarterly report. [Blommers moved, McCleary seconded -- approved 5-0]

The outcome was announced to Wang and Hemphill upon their return.

VI. OTHER CONCERNS:

- A.** Should consent be waived to bypass reluctance to consent?

A protocol is under review in which the PIs request waiver of consent to access student grades because students with poor grades might disproportionately decline consent, thus biasing the subject sample. However, the purpose of the requirement for informed consent is to allow persons to decline to participate in research if they so choose. Discussion followed at the end of which it was concluded that the methodological considerations did not outweigh the ethical obligation to obtain consent. It was suggested that the PIs be encouraged to explain this methodological concern when soliciting consent, to indicate to students that their earlier grades will not be accessed until grades have been recorded for the course that is being studied, and that procedures for data handling, storage, and analysis, be spelled out to prospective participants to help them understand that their information will be held confidential. IRB should investigate to see how faculty accessing of student records for research purposes squares with existing California law.

VII. NEXT MEETING:

Friday, January 29th, 2010 [please mark your calendars!]

VIII. ADJOURNMENT:

There being no further business, the meeting was adjourned at 10:41 AM.

[Blommers moved, Lee seconded, approved 5-0]

IX. BOARD TRAINING: [followed adjournment]

- A.** Spot check of protocols authorized since last meeting [Exemption 09-32, Exemption 09-78]
- B.** Review of therapy case studies proposed as research.

IX. BOARD TRAINING:

- A.** Spot check of protocols authorized since last meeting [Expedited 09-82, Exemption 09-142]

Postponed due to the length of the meeting.

Respectfully submitted

Steve Suter, Ph.D.
Professor of Psychology
and IRB/HSR Secretary