

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

Minutes of Meeting
Wednesday, 02 October 2009 [DDH A-108]

Members Present:

Scientific Concerns: Anne Duran, Kathleen Gilchrist, Roseanna McCleary
Nonscientific Concerns: Paul Newberry, Yeunjoo Lee, Thomas Blommers
Community Concerns: Gary Bashor

Members Absent:

Lily Alvarez

Visitors:

Linda Switzer for **Protocol 09-136**
Kathrine Powell for **Protocol 09-151**
Bruce Hartsell for **Protocols 09-136 & 09-151**
Denise Dawkins & Debra Wilson for **Protocol 09-125**
Kenisha Edwards-Ray & Bruce Friedman for **Protocol 09-152**
J.J. Wang & Brian Hemphill for **Protocol 07-91** Quarterly Report
Maria Rubolino, Nancy Weinstein, & Gladys Garcia for **Protocol 09-148** Progress Report

I. CALL TO ORDER:

Chair Paul Newberry called the meeting to order at 7:58 AM.

II. PREVIOUS MINUTES:

Duran totally moved and Gilchrist seconded a motion to approve the minutes of Friday, 10 June 2009. The motion was approved 6-0.

III. ANNOUNCEMENTS:

- A. CSU-Wide Survey on Human Subjects Protection Training.** CSU-San Marcos is putting into place Human Subjects Protection Training and surveyed the other CSU's about their programs. There is interesting variation in who must be certified, how long certification lasts, and the nature of the training.

[Bashor arrived]

- B. Resignation of Carolyn Wade-Southard.** Carolyn has had to resign because of scheduling conflicts and other demands on her time. She enjoyed her service and found it to be interesting and worthwhile. The Chair noted that Carolyn often added unique perspectives on human subjects protections because of her experience as a helping professional in the community.

IV. OLD BUSINESS

- A. Spanish Translations.** Blommers, McCleary, and Suter submitted a brief written progress report. A list of essential elements of the consent form – a template – will be constructed in Spanish for investigators to use. RERC needs to get these elements to Blommers. Thus, the IRB will be assured that subjects will be adequately informed on the important elements and the volume of material that would require expert scrutiny will be reduced. Oral back-up is useful

when translated materials are used. Undesirability of “dumbing down” material in Spanish was emphasized in discussion.

V. NEW BUSINESS

Board members detected several clerical errors in the IRB Master Log entries, which were brought to the attention of GRASP personnel for correction, but remain in the Master Log material in these minutes.

A. Formal Board affirmation of protocols previously approved under standard review, expedited review, Third-Party Access, and Exemption from Full Review since the June 2009 meeting.

1. Standard Review [1]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-125	Denise Dawkins & Debra Wilson	Promoting Reflective Learning of Students Using Human Patient Simulators-A Replication Study	5/15/2009	Newberry, Lee, Blommers, Bashor, Gilchrist	6/18/2009

[Duran moved, Bashor seconded -- approved 7-0].

2. Expedited Review [4]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-80	Jennifer Wilson-Leer	A Quantitative Approach on Homophobia in Kern County Universities	4/8/2009	Durane, Blommers	7/13/2009
09-82	Greg Hanel	Needs Assessment of Critical Response Teams in CPS Emergency Response	4/8/2009	Lee, Gilchrist	4/20/2009
09-96	Heather Bosma	Are Senior Nursing Students Culturally Competent	4/20/2009	Lee and McCleary	5/4/2009
09-145	Marianne Abramson, Yi Du, Tyson Smith	Factors Affecting Computer Voice Commands	8/24/2009	McCleary and Newberry	9/4/2009

[Bashor moved, Lee & Duran seconded -- approved 7-0]

3. Third-Party Access to Existing Data [1]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-135	Lessie Greer-Casey	A Comparison of Reunification Rates Between Kin and Non-Kin Placements Among African American Children in Foster Care	5/28/2009	Blommers, Gilchrist	7/24/2009

[Gilchrist moved, Blommers seconded -- approved 7-0]

4. Exempted from Full Review [7]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-109	Jesus Barron	A Policy Proposal for Kern County Building Inspection Division: Efficiency and Customer Service	5/6/2009		8/4/2009
09-121	Melody Batelaan	Is Kern County Doing Enough to Prevent Fraud in the In-Home Supportive Services Program?	5/14/2009		7/2/2009
09-141	Annie P. H. Huynh	The Perceptions of Patient Safety Culture among Registered Nurses and Non-RN Nursing Staff	6/29/2009		7/13/2009

09-142	Jacqueline Mimms	The CSU: Summer Algebra Institute	7/2/2009		7/2/2009
09-143	Natalie Tran & Huy Tran	School counselors and Leadership	7/7/2009		7/10/2009
09-144	Philip Patterson and Constance Petit	The Incidence, Training, and Satisfaction of Special Education Teacher Participation in Telephone Conference IEP Meetings	7/27/2009		8/3/2009
09-147	Steven Bacon	Correlates of Support for Global Relief Efforts	9/2/2009		9/3/2009

[Duran moved, Lee seconded -- approved 7-0]

B. Formal Board affirmation [2] 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 2009 meeting.

Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-137	Harleen Kaur Sindher	The Move to Adulthood among Youth Aging Out of Foster Care	6/2/2009		6/3/2009
09-139	Ada Diaz	Should Government Provide Access to Health Insurance to the Uninsured in the U.S?	6/12/2009		6/18/2009

[Duran moved, Blommers seconded -- approved 7-0]

C. Formal Board affirmation [8] of previously approved protocols granted renewals since the June 2009 meeting.

Number	Author	Title	Date Submitted	Reviewers	Final Approval
03-03	Steve Bacon	Establishment of a Participant Pool for the Department of Psychology	1/17/2003	Bragg, Wang	2/4/2003
04-124	Cherie Rector and Kathleen L. Gilchrist	Are You INN? Outcomes of the INN Program Grant	9/23/2004	Newberry, Bragg, Meares, Lee, Abramson, Leapley	10/11/2004
06-77	Kathleen L. Gilchrist	CSUB Nursing Program Evaluation Project	8/16/2006		8/22/2006
07-90	Emerson Case	Connecting High School and College Through a Common Reader Program	9/20/2007		9/24/2007
07-94	Ron Pimentel & Marketing Students (BPA)	Establishing a Front Door for a University: Make the University Experience More Easily Accessible	9/24/2007		9/24/2007
08-101	Roseanna McCleary, Bruce Friedman	Evaluation of the Practicum Partnership Program Adoption Initiative	8/13/2008		9/10/2008
08-102	Roseanna McCleary, Bruce Friedman	Hartford Partnership Program for Aging Education Career Tracking Survey	8/13/2008		9/10/2008
08-110	Steve Suter	CSUB Vision Lab Visual Neuroscience Research Projects	9/23/2008	Gilchrist & Bashor	10/20/2008

[Gilchrist moved as corrected, Duran seconded -- approved 7-0]

D. Formal Board affirmation of protocol closures [36] (unless extension granted) whose authorization have ended or will end prior to the Winter 2010 IRB meeting.

Number	Author	Title	Date Submitted	Reviewers	Final Approval
05-36	Ron Pimentel & Students	Maintaining Fad Products Between Fads	3/15/2005		9/29/2008

05-102	Debra Cook Hirai	CALLI (Content Academic Language Literacy Instruction)	10/24/2005		9/30/2008
07-112	Sandra Mackiney	Chronic Sorrow Among Parents of Children with Cerebral Palsy	10/25/2007		9/29/2008
08-106	Roseanna McCleary & Mayra Gonzalez	Dolores Huerta Foundation Community Needs Assessment Project: Follow up data analyses and focus groups	9/8/2008	Lee, Newberry	12/12/2008
08-109	Andrew Crawford, 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
08-122	Debra Wilson (faculty)	First Year Nursing Student's Perceptions about their Potential for Academic Success	10/15/2008		11/24/2008
08-128	Susanna Munoz	Parent Quality Time with Adolescents	10/24/2008		11/4/2008
08-129	Juan C. Becerra	Parental Support in Gender Differences in Hispanics	10/24/2008		11/20/2008
08-130	Margarita Madera	Phonemic Awareness Foundation for Reading	10/24/2008		11/13/2008
08-133	Misty Benavides	The Academic, Behavioral, and Social Benefits of After School Programs	10/24/2008		11/12/2008
08-135	Amy R. Self	Special Education Students and Gang Affiliation During Adolscence	10/24/2008		11/17/2008
08-136	Janel Isaacs	Teacher's Knowledge of ADHD in Helping Children with ADHD Succeed Academically	10/24/2008		11/12/2008
08-141	Denine Tucker (McCoy)	Teacher Perceptions: The Affect of Teacher Stress on Student Achievement	10/24/2008		11/17/2008
08-142	Alejandra Roman	Implementation of School Uniform Policy: The Effects on Student Behavior	10/24/2008		11/13/2008
08-144	Jared Kyle Chapman	Exposure to Intergroup Interactions Combined with Feedback Facilitates Tolerance and Acceptance	10/24/2008	Gilchrist & Lee	11/20/2008
08-145	Virginia Ouderkirk	Best Practices for Working with Parent sWho Were Child Victims of Abuse or Neglect	10/24/2008		11/4/2008
08-146	Ashley Senes	Older Adults and Drugs, Alcohol, and Tobacco; Exploring Contributing Risk Factors for Misuse	10/27/2008	Carlisle & Duran	11/14/2008
08-148	Tiffany Nutt	Multicultural vs. Colorblind Approach's Effect on Tolerance and Acceptance	10/24/2008		11/10/2008
08-152	Christina McDaniels	The Cultural Awareness Program for Foster Parents	11/13/2008	Newberry & Duran	1/14/2009
08-153	Stacy Teeters	Need for Cognition as a Predictor of Attitudes Toward Lesbian and Gay Males versus Bisexual Men and Women	11/13/2008		11/20/2008
08-154	Feraz Ferozali	Changes in Tolerance and Acceptance as a Result of Gender, Race, Ethnicity Courses	11/13/2008		11/18/2008
08-155	Gregory Winkler	Mental health needs assessment for aging HIV/AIDS patients in Kern County, CA	11/14/2008	Carlisle & Gilchrist	1/15/2008
08-156	Laura Gomez	An Assessment of Motivational Interviewing Skills among Child Welfare Social Welfare Workers in Court Intake and Family Services and Reunification Outcomes	11/14/2008		11/20/2008
08-157	Jean Roberts	Utility of an Assessment Tool in Early Identification of Community-Acquired Methicillin-Resistant <i>Staphylococcus Aureas</i>	11/14/2008	McCleary and Duran	12/5/2008
08-158	Kelly Levig	Brain Activity to Real and Illusory Motion	11/14/2008	Newberry and Gilchrist	1/22/2008
08-159	Sarah Phillips & Johanna Alexander	Graduate Student Library Research	11/18/2008	Newberry	12/17/2008
08-160	Barbara Bartholomew	Task Analysis and Observations of Novice vs. Expert Reading Teachers	11/19/2008	Newberry	12/18/2008
08-162	Theresa P. Aberg & Dr. David Parks	Pursuit of the Principalship	11/26/2008	Newberry & David Parks	12/3/2008
08-163	Jennifer Waller	Improving Access to Mental Health Services for Persons with Alzheimer's Disease and other Dementias	12/8/2008	Lee, Gilchrist	1/6/2009

08-165	Cindy Stone	Board and Care Homes for Older Adults: A Historical Timeline and Business Outline for Potential Owners	12/10/2008	Carlisle & Lee	1/23/2009
08-170	Beverly Hooks	An Examination of Team Decision Making within the Department of Children and Family Services	12/17/2008	McCleary & Lee	1/5/2009
08-171	Aaron M. Jones	Community Resource Guide/Website of Healthcare Providers	12/17/2008		1/15/2009
08-172	Alejandro Leon	Kern County Homeless Collaborative Homeless Count Analysis	12/17/2008	McCleary & Newberry	1/12/2009
08-173	Steven Bacon	Correlates of Support for Global Relief Efforts	12/19/2008		12/19/2008
08-175	Alberto Mendoza	Identifying Factors that Contribute to the Detention and Length of Stay of Foster Care Youth	12/17/2008	Paul Newberry & Bruce Friedman	12/22/2008
08-176	Seth Phillips	Intensive Case Study	12/23/2008	Duran & Newberry	1/27/2009

[Blommers moved as corrected, Bashor seconded -- approved 7-0]

E. New Protocol Reviews

- 1. Protocol 09-136: “A Qualitative Evaluation of a Program for Emancipated Foster Youth as Reported or Perceived by Emancipated Foster Youth”** with Linda Switzer and Bruce Hartsell [Social Work]. Primary readers were Newberry, Gilchrist, Bashor.

Following introductions, Hartsell summarized. This project is the first step in carrying out an analysis of the effectiveness of the Kern County Dream Center [DC] as a resource for emancipated foster youth. The proposed project will involve focus group discussions by emancipated foster youth to develop questions that will be used in the second step, a mailed survey, which is not included in the present protocol.

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

- Q:** So, this is the first step in a several-step research process? **A:** Yes, the focus groups are to develop the questions for the survey.
- Q:** How will the potential participants be contacted? **A:** They will be contacted by mail using the DC address list of emancipated clients.
- Q:** What is the DC – it doesn't say in the protocol? **A:** This is a drop-in facility for emancipated foster youth. It offers a variety of services, including career counseling and information, housing info, transportation guidance, tutoring, and mental health information.
- Q:** Is it potentially an issue for an emancipated foster youth to have others know his/her status? **A:** They usually know who is and isn't a foster youth. Networking among them can be useful and nurture the sense of an extending family. There is a statewide emancipated foster youth network.
- Q:** Would any of the potential participants not want others to know? **A:** No.
- Q:** Where is the DC located? **A:** It's at 1212 18th street, downtown.
- Q:** The consent form mentions possibly having a second meeting, “if needed”. It's not clear what that means. **A:** This would be if we run out of time and need to meet again to clarify anything.
- C:** That should get clarified on the consent form.
- C:** There is a typo on the consent form that needs to be corrected.
- Q:** You point out that there are two categories of foster youth. Does that matter for this study? **A:** No.
- Q:** Have you developed an interview guide? It wasn't with the written protocol. **A:** Yes. [Print copies of the interview guide were distributed to Board members at this time.]
- Q:** Have you done focus groups? **A:** No.
- Q:** How will you learn how to do focus groups? **A:** I have met with MSW students who know how to do focus groups.

- C:** You need to get trained. [McCleary noted that she could help with this.]
- Q:** The sessions will be audio-taped, so if the person doesn't want to be taped, then he/she would be excluded from participation? **A:** Correct.
- Q:** You won't be using names in your report of the data? **A:** Correct, no names.
- Q:** You also mention that a participant could request to have the audio-tape recorder turned off. Clarify with respect to what you said about excluding unless he/she agrees to the taping. **A:** This is if a participant wants not to have a particular comment on tape.
- C:** You should clarify that in your protocol and consent form.
- C:** You need to keep the data and consent forms stored separately.
- Q:** Are there existing surveys that you could use, rather than developing questions in this first phase? **A:** Apparently not, plus this is a very new facility.
- Q:** Are you interested in emancipated foster youth who are not using the DC? **A:** The second phase will involve all Kern County emancipated foster youth, but not this first phase.
- C:** Your questions are all set up to elicit only positive information. You should have some designed as prompts for possible negative information.

When there were no more questions, the student and faculty mentor were excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 09-136**. [Duran moved, McCleary seconded -- approved 7-0]

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

1. Reorganize the protocol to reflect that it deals with the first step of a two-step project.
 2. Develop and include a brief review of the most relevant research literature.
 3. Include a description of the Dream Center, including its activities and goals.
 4. Be more clear in protocol and consent form on the conditions that could prompt a second meeting.
 5. Clarify the circumstances related to possibly turning off the audio recorder.
 6. Provide specifics on storage of consent forms and data in order to keep them secure and confidential.
 7. On consent form, the wording on keeping a copy of the consent form should be "have been".
 8. Fix the typo in the consent form.
 9. Include questions to potentially elicit negative information.
 10. Collect the demographic information in written format, rather than aloud.
 11. Get trained in conducting focus groups before conducting the first emancipated foster youth focus group.
- 2. Protocol 09-151: "An Analysis of the Effects of Restored Sibling Connections on the Level of Perceived Emotional Support While in Foster Care"** with Kathrine Parnell and Bruce Hartsell [Social Work]. Primary readers were Blommers, Duran, Bashor.

Following introductions, Parnell summarized. She had just been told yesterday that Kern County legal council had advised against allowing wards to be interviewed. Therefore, she was denied permission to interact directly with foster youth, meaning that Protocol 09-151, as submitted, is history. However, Plan B is to use observations by the foster parents to evaluate the effects on foster youth of visits with their siblings. These data will be collected pre- and post- with respect to a schedule of supervised visits/activities. Also the proposed age range would be expanded in order to increase the sample.

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

- Q:** The schedule of visits/activities that you will introduce, will this be just for purposes of your research or would you be doing this anyway as part of your work? **A:** This will be done as part of the research.
- Q:** So, you are going to make some changes and see what happens? **A:** Yes, although some way of having contact with siblings is encouraged in the foster care system.
- Q:** So, the visits/activities that you would introduce, will just make that easier? **A:** Correct.
- Q:** How often will these events happen? **A:** These will usually be once per month for four months.
- Q:** "Usually"? **A:** This would have to vary to some extent depending upon the placement.
- Q:** How would you know that there is MORE foster youth X sibling contact involved in your project? **A:** Well, I will be adding one event per month to whatever is ongoing.
- Q:** Who will be signing consent forms? **A:** The foster parents will need to sign for their own participation, but they can't sign for the foster youth.

When there were no more questions, the student and faculty mentor were excused and the Board deliberated in executive session. There was a motion to disapprove **Protocol 09-151** and invite the student and faculty mentor to submit a new protocol dealing with the new proposed research. [McCleary moved, Gilchrist seconded -- approved 7-0]

The student and faculty mentor were advised that the question of permission to interview the foster youth should have been resolved prior to submitting the project for IRB review.

- 3. Protocol 09-146: "Impact of Early-Onset Breast Cancer: Perceptions of and Decisions about Genetic Testing"** with Jennifer Hennick and Candace Meares [Nursing]. Primary readers were Blommers, McCleary, Bashor.

Following introduction, Hennick summarized. She is a breast cancer survivor and oncology nurse. She has firsthand knowledge of some of the obstacles that this research is intended to address. This project involves young women, who face special problems, including a more severe prognosis on average as compared to older women. All will have already had genetic counseling, which is the focus of the project.

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

- Q:** Who will assist the participant in case of distress? **A:** The investigator will do that. There are also always a medical social worker available and the physician. The investigator has organized and runs a support group for the target participant population.
- Q:** You plan to reveal to the participants that you are a breast cancer survivor? **A:** All of them will know already.
- Q:** Is there previous research dealing with attitudes about genetic counseling among younger women diagnosed with breast cancer? **A:** Only one study was located that had two participants under age 40. The research literature is directed toward older women.
- Q:** You will be asking them about their breast cancer experience and with genetic testing and counseling? **A:** Yes.
- Q:** Your flyer specifies women under age 40. Isn't it redundant to list the age requirement again on the consent form? **A:** It is probably still needed because there will be a mailing using the center's database, to which the investigator already has access.
- Q:** You will be getting demographic information? **A:** Yes [A demographic sheet was circulated among Board members.]
- Q:** Tell us about data storage and who will do the transcription. **A:** Investigator will do the transcription; data and consent forms will be stored separately in locked locations.
- Q:** Is that your home contact information on the flyer? **A:** Yes.
- C:** We generally advise against that and recommend using the faculty mentor's office contact info, if she agrees.
- C:** The flyer asks if the potential participant would like to become involved in cancer research. Persons might suppose this means research involving cancer treatments. This should be clarified or deleted.

- Q:** Do you need to be aware of type of treatment and cancer stage of your participants? **A:** No.
- Q:** You will interview at the center? **A:** Yes, there is a private room, or wherever the participant is most comfortable.
- Q:** There are some men with breast cancer . . . **A:** Yes, but they are almost always older men.
- Q:** The protocol mentions the Breast Cancer Navigator. What is that? **A:** It's actually a person, who at present is a nurse practitioner. She will have already done the genetic counseling.

When there were no more questions, the student and faculty mentor were excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 09-146**. [Duran so moved again, Gilchrist seconded -- approved 7-0]

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

1. Include a brief review of the most relevant research literature in the protocol.
 2. In the consent form, provide the specific contacts in case of distress.
 3. Delete the statement about participating in cancer research in the flyer.
 4. Indicate that you will store the consent forms and data in separate secure locations.
 5. State more clearly the potential location of interviews in protocol and consent form.
 6. Add the choice, "domestic partner", to the demographics.
- 4. Protocol 09-152: "Code 288: An Autopsy of the African-American Assault Victim"** with Kenisha Edwards-Ray and Bruce Friedman [Social Work]. Primary readers were Lee, Duran, Bashor.

Following introductions, Edwards-Ray and Friedman summarized. "Code 288" is a code used for a call for a social worker following a sexual assault. She will ask questions to find out what African-American victims of sexual assault have in common. There are higher re-victimization rates of African-American sexual assault victims and there don't seem to be many services specifically for the African-American community. Are the effects of disclosure different for African-American victims? Perhaps the information from this project could lead to an action-plan to better serve the needs of the African-American community.

- Q:** Your participants will be recruited from your church? **A:** Yes. The investigator is aware of a number of sexual assault victims at the church. Her father is the minister.
- Q:** All of the participants will be at least 18 years of age? **A:** Yes.
- C:** Your protocol mentions a number of different goals – understanding development, service options, particular needs of African-Americans, ethnic differences in service delivery, and effects of disclosure. Getting good data on any one of these would be a big task and you are only studying a few individuals. Wouldn't it be better to narrow this down and focus on something more specific? **A:** This project involves exploring many broad areas in order to see how to narrow this research eventually. It's exploratory.
- Q:** You mention about sexual assault possibly slowing down a developmental process. Are you going to follow participants across time? **A:** No, there will be a single interview and the purpose is to look for themes.
- C:** It seems that maybe you are really most interested in services. It seems like you could get that information using a survey.
- Q:** This is an extremely sensitive group that is known to be prone to "re-traumatization". We are concerned about how you can get the information that you want, but still keep the participants safe from harm. Your referral for distress is a CSUB faculty person, who might not be available. Can you come up with some effective support that is more immediate? **A:** Barbara Reifel would interact with the participant and then provide a specific referral. However, Friedman notes that it should be possible to provide a specific, immediate source.
- C:** Your sample will not be representative of African-American victims of sexual assault. It's really Christian church-goers, so you won't be able to generalize much.
- Q:** How will you get your recruitment information to potential participants and allow them to establish contact with you without them being stigmatized? **A:** Investigator will stand up in church and announce the research project. [Student was not specific about what would happen next.]

- C:** The typos and errors on the consent form need to be fixed.
- Q:** Who will transcribe the audio interviews? **A:** The investigator will do that.
- Q:** This approach is described as qualitative research. Do you have experience with qualitative research? **A:** No. [Faculty mentor notes that it might be more like “grounded theory”.]
- Q:** Describe how you plan to analyze the data? **A:** Investigator will rely upon the assistance of the faculty mentor. In general, the data will be searched for common themes across participants.
- C:** You need to clarify how the data will be handled, explaining how it will be secure and confidential.
- Q:** What is the word “autopsy” about again? **A:** This was tied to a story from the Christian bible and personal experiences.

When there were no more questions, the student and faculty mentor were excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 09-152**. [Duran moved, Lee seconded -- approved 7-0]

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

1. Clarify the focus of your research. Then create a specific rationale for this focus, including a brief review of existing knowledge on that topic.
2. Revise the interview questions so that they directly address the focus of your research.
3. Provide the specific details of your planned recruitment of participants, including how you will get the necessary information to them and how they will establish contact with you.
4. Describe what you will do with the interview data in order to address the focus of your research.
5. State what direct, immediate resources will be made available in case of distress and provide the contact information in the consent form.
6. Remove the word “autopsy” from the consent form and any other recruitment materials and substitute other language.
7. Use years of age to operationally define what you mean by the word “adult”.
8. Create a “clean” consent form without errors.

[Newberry departed]

F. Continuing Review and Renewal of Authorized Protocols

1. **Protocol 07-91:** CS&O Quarterly Report 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.

RERC provided context of this renewal -- Wang has replaced Crawford, but Hemphill and IRB were not informed, so that Wang first interacted with the IRB when the CS&O report was requested about one week ago. The RERC quarterly report included a list of changes and status of compliance X agencies. Following introductions, Wang summarized. Wang indicated he has read the CS&O X CSUB contract and their Protocol 07-91. He is aware of the need for authorized consent forms at the agencies and that personnel must be trained. He plans to be proactive, as his predecessors have been. He mentioned several levels of human subjects protections including the IRB, CS&O monitoring, and the personnel at the agency level. He will pursue adverse event monitoring and look for possible improvement. Wang has created a record keeping document to keep track of and report to the IRB compliance monitoring visits to agencies.
- C:** Hemphill added that he hoped that the positive relationship between CS&O and the CSUB IRB will continue. Hemphill will continue as liaison between the CS&O researcher [Wang] and the CSUB IRB.
- C:** The IRB is appreciative.

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, Bashor seconded -- approved 6-0]

It was announced that the IRB will request that the quarterly report include a systematic listing of CS&O visits to agencies to monitor human subject protections and detect adverse reactions. The RERC, Wang, and Hemphill will meet about halfway toward the next quarterly report to coordinate and assess performance.

VI. OTHER CONCERNS:

A. National Children's Study Progress Report. CSUB was picked as a site in the federally-funded nationwide longitudinal study of health in a developmental context. We're in the second wave of participating sites, following New York and Orange County. We are in Phase I, which involves setting up the sampling, or the "geo-coding" in public health talk, to select the participants. Next step, personnel will go door to door to solicit participants, looking for pregnant or soon-to-be pregnant women. Then health care delivery agencies and physicians will get involved. A total of 250 participants per year will be recruited for four years, for a total of 1,000 local babies to track until they reach 21 years of age. Many health-related variables will be assessed across the developmental process.

C: RERC noted that Protocol 09-148 is for the Phase I geo-coding only and that these activities have already been reviewed and authorized by a statewide IRB. At CSUB, this qualifies for "Exemption From Full Review" for the participation of CSUB personnel, who won't have access to any personal identifiers in this phase. There will probably be Standard Reviews for the activities at later phases as the actual data collection begins.

The NCS personnel were thanked for their presentation.

B. IRB Non-Compliance Update. SOE non-compliance with human subject protections continues, the only "culture of non-compliance" at CSUB. The RERC and IRB Chair have asked to meet with the Provost, but she has not yet set up a meeting. The Senate Chair, Jess Deegan, and Interim SOE Dean, Craig Kelsey, want to attend this meeting. The IRB will promote CSUB Handbook changes and the Senate Chair has stated he will facilitate. Kelsey does not believe that changes in SOE will be from "bottom-up". Solutions are simple, but for many years SOE faculty have resisted the procedures in place in other graduate programs.

A. Possible New Community Members. Several possible new community members were discussed. Tommy Tunson is the Chief of Police at Arvin and serves on the Kern County Behavioral Health Board with McCleary. McCleary recommends him, noting he has a J.D. and is doing well in a difficult environment. Bashor indicated that Tunson is widely respected in the Arvin community. Grant Herdon is an attorney with the Bakersfield City School District. He lives down the street from Roseanna and Steve. Paul knows him socially and vouches for his smartness and being a good guy. As the discussion proceeded, Gary noted that he has accepted a job in the LA area and will be leaving. Michael Clark was proposed as a member, but he is associated with the university via part-time teaching and cannot serve, because community members must not be connected with the university.

VII. NEXT MEETING:

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

VIII. ADJOURNMENT:

There being no further business, the meeting was adjourned at 11:30 AM.

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

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