

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

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**Minutes of Meeting**  
**Friday, 28 January 2011 [DDH A-108]**

**Members Present:**

Scientific Concerns: Kathleen Gilchrist<sup>1</sup>, Anne Duran<sup>1</sup>, Roseanna McCleary  
Nonscientific Concerns: Paul Newberry, Thomas Blommers, Yeunjoo Lee<sup>1</sup>  
Community Concerns: Grant Herndon, Tommy Tunson<sup>2</sup>

<sup>1</sup>Absent 9 AM – 10 AM

<sup>2</sup>Arrived 9 AM

**Members Absent:**

Lily Alvarez

**Visitors:**

Aaron Birch for new **Protocol 11-04**  
Rhonda Dugan and Dahna Rasmussen for new **Protocol 11-14**  
**Judy Pedro for new Protocol 11-15**  
J. J. Wang for **Protocol 07-91** Quarterly Report and Renewal

**I. CALL TO ORDER**

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

The agenda schedule was re-arranged due to anticipated problems having a voting quorum.

There was a preliminary discussion about appointment of “alternate members” of the IRB to deal with the infrequent problem of obtaining a voting quorum. The RERC has requested the Academic Senate and Provost to appoint faculty who are former members of the IRB as alternate members, who could serve if needed. These IRB alumni are Marianne Abramson, Bob Carlisle, Jeannie Harrie, and Peggy Leapley, and Steve Suter [the RERC]. The Senate has agreed to appoint Suter an alternate member for the current meeting. The IRB concurred with the alternate member appointment concept.

**II. APPROVAL OF MINUTES**

**A. IRB meeting of Friday, 01 October 2010 [Attachment A]**

In response to Chair query at the previous meeting, Protocol 10-46 was deleted from the list of formal affirmations in the minutes. Duran moved and Blommers seconded a motion to approve the minutes of Friday, 10 October, 2010 as corrected. The motion was approved 7-0.

**III. ANNOUNCEMENTS**

**A. Chair’s Query.** The query about the status of 09-196 and 10-46 in previous minutes was addressed [see immediately above].

**B. Spanish Language Translations.** The RERC noted that the IRB is moving toward providing better guidance to investigators on Spanish language translations. RERC, Tom, and Roseanna have been working on this. These would include a “template” consent form containing the most common stock phrases that are needed in consent materials. Bad translations violate the principles

of “respect” and “autonomy” in the Belmont Report. The following paragraphs have been added to pertinent sections of the Human Subjects protection Training [HSPT] text:

“It is never acceptable to give research participants materials that are the product of a casual translation into another language. Such materials disrespect the literacy of the participants, may contain wording that is not appropriate for formal written documents in that language, or could even be offensive. All of these problems violate the principle of respect in The Belmont Report.”

“For consent forms translated into another language, for consent to be “informed”, the translated consent form must communicate the essential elements clearly, correctly, and in language appropriate for formal written documents in that language. A consent form that lacks these features violates the requirement that the researcher respect the autonomy of the potential participant, as stated in The Belmont Report.”

**C. Electronic Submission/Review/Authorization.** There have been over 40 electronic submissions, since the process was introduced in September 2010. There are no more paper files in the GRaSP Office. No more duplicating, no more mailing. Only faculty may submit – to enhance faculty mentoring. The submission link page was presented and the required affirmations of review and truth were highlighted. Several problems were noted: only the Firefox browser, not Internet Explorer works; all parts of the protocol must be appended into a single document; there are still attempts to submit paper protocols; and the e-mail receipt process went down for three weeks this month.

The Board discussed the technology of doing our meetings face-to-face, but with only electronic materials. There is a recent problem with the Protocol Review Forms being PDF read-only files which is being addressed. Protocol reviews must be submitted as electronic files now, since GRaSP no longer maintains paper files for protocols. The agenda packet for this meeting was e-mailed and posted behind the password-protected “IRB Member Materials” link on the IRB homepage. It will only be posted in the future, with members alerted by e-mail when it is available. Members shared ideas about how to most conveniently use the various meeting files during our deliberations.

#### IV. OLD BUSINESS

**A. Non-Compliance Discussion** [moved to Board Training due to meeting length]

#### V. NEW BUSINESS

**A. Formal Board affirmation** of protocols previously approved under standard review, expedited review, third-party access, and exemption from full review since the October 2010 meeting.

##### 1. Standard Review [1]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
10-133	Patricia Henry	Impact of Community and Gang Collaboration on Gang Violence in the Community	9/21/2010	Blommers & Gilchrist	10/6/2010

In response to a question, it was clarified that Protocol 10-133 was only “conditionally approved” at the October 2010 meeting, with full approval having been achieved later, so that formal affirmation was needed.

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

##### 2. Expedited Review [2]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
10-119	Shiva Cohen-Gadol	The Impact Of Media on Young Female's Body Image	6/22/2010	Blommers	11/8/2010
10-146	Bruce Friedman	Point in Time Homeless Survey	10/27/2010	McCleary & Newberry	11/17/2010

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

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

Number	Author	Title	Date Submitted	Reviewers	Final Approval
10-140	Magda Padron	The Bridges Academy's Ability to Reduce Truancy	10/6/2010		10/6/2010

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

### 4. Exempted from Full Review [13]

Number	Author	Title	Date Submitted	Reviewers	Final Approval
10-121	Dr. Staci Loewy	African Array Assessment	6/28/2010		10/21/2010
10-123	Heather Blue	Technology Support in Math	7/12/2010		10/29/2010
10-142	Stacy Teeters	Women and Gender Studies Interest Survey	10/14/2010		10/26/2010
10-143	Stacy Teeters	Tolerance of Ambiguity and Heterosexuals' Attitudes toward Bisexual Women and Men	10/18/2010		10/26/2010
10-144	Danielle Solano	Evaluating the Effectiveness of Chem 195-295, Careers in Chemistry	10/21/2010		11/1/2010
10-149	Jessica Smith	Implementing an Intergenerational Program at an Adult Day Health Care Center in Southern California	11/3/2010		11/9/2010
10-150	Stacy Teeters/ Diana Pogue	Multicultural v. Colorblind Approach's Effect on Tolerance and Acceptance	11/8/2010		11/9/2010
10-151	Carl Kloock	Planning for a Robert Noyce Teaching Fellowship at CSUB	11/9/2010		11/12/2010
10-152	David Henley	The Effect of Realia Discrepant Event Instruction Upon Cue Attendance	11/15/2010		12/2/2010
10-153	Jennifer Wahley (Harter)	Effectiveness of a Comprehensive Sex Education Program vs. Abstinence Only Education in Increasing Knowledge and Responsible Sexual Behavior	11/15/2010		11/18/2010
10-154	Victoria Ndukwu	Does the Integration of Technology into the Classroom Enhance Students Performance in Science?	10/18/2010		12/10/2010
10-155	Courtney Morris	Prevention through Registration: An Analysis of the Creation, Implementation, Use and Maintenance of an Elder Abuse Registry	11/30/2010		12/9/2010
10-157	Curtis Guaglianone	Baseline Preparation Data Survey for Edvention Fellows	12/8/2010		12/20/2010

McCleary commented that it was her recollection that 10-155, which she had supervised was Expedited Review. RERC checked records and found that it was indeed exemption from full review, but carried out by the IRB Chair because the RERC recused.

[McCleary moved, Herndon seconded – approved 5-0, assuming 10-155 correction if needed]

**B. Formal Board affirmation [6]** 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 2010 meeting.

Number	Author	Title	Date Submitted	Reviewers	Final Approval
10-138	Cecilia Martinez	Kern County Mental Health Providing Substance Abuse Treatment And Services To Foster Care Youth In Placement	9/30/2010		10/6/2010
10-139	Joanna Henry	Implementation of Technology and Web Quests in a Kindergarten Classroom	10/13/2010		10/15/2010
10-141	Victoria Snyder	Westside Housing Consortium: A Program Proposal	10/8/2010		10/8/2010
10-145	Shoshana Schlesinger Hirt	Curriculum Development for Teaching Kings II to High School Students	10/25/2010		10/26/2010
10-148	Tiffany Strickland	Progress Monitoring for Special Education Students	11/1/2010		11/8/2010
10-156	Jenny Meadlin	Solving the Policy Gap in AFRL's Suspense Management Process	11/30/2010		11/30/2010

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

**C. Formal Board affirmation [7] of previously approved protocols granted renewals since the October 2010 meeting.**

Number	Author	Title	Date Submitted	Reviewers	Final Approval
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
08-109	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
09-177	Natalie Tran & Andreas Gebauer	Motivation for Science Learning	11/9/2009		11/12/2009
10-07	Bruce Hartsell & Preston Oppenheimer	An Evaluation of the Effects of a Session Rating Scale on Child Welfare Outcomes	1/14/2010	Lee & Gilchrist	2/4/2010
10-14	Mary Doucet and Thomas Doucet	Student Learning Styles and Assessment of Learning Outcomes for the Introductory Managerial Accounting Course	1/15/2010		2/22/2010
10-56	Roseanna McCleary & Gail Davidson	Evaluation of Knowledge and Attitude Changes in MSW and Nursing Students after Exposure to an Intergenerational Colearning Model	3/3/2010		3/8/2010

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

**D. Formal Board affirmation of protocol closures [35] (unless renewed) whose authorization have ended or will end prior to the April 2011 IRB meeting.**

Number	Author	Title	Date Submitted	Reviewers	Final Approval
09-136	Linda Switzer	A Qualitative Evaluation of a Program for Emancipated Foster Youth as Reported or Perceived by Emancipated Foster Youth	9/18/2009	IRB Board	3/29/2010
09-184	Hilda Esquivias	Students with a Mission (SWAM): Evaluating Peer-to-Peer Mentoring	11/16/2009	Lee & Duran	3/4/2010
09-196	Octavio Magana Jr.	Social Workers Behind Bars: Identifying Barriers to Services Within the Prison Community	11/16/2009	Blommers & Duran	2/15/2010
10-01	Gina Walden	Treating Trauma in Foster Youth: An Intensive Case Study	1/5/2010	Blommers & McCleary	3/12/2010
10-13	Regina Mack	Evaluation of Discharge Statistics and Interventions	1/15/2010	Lee & Gilchrist	4/9/2010
10-17	Jesus Perez	Domestic Violence Related murder-Suicides in Kern County	1/15/2010	Lee & Gilchrist	2/18/2010
10-37	Abimael Prado & Eva Prado	Empowering Citizens Through the Neighborhood Watch Organization	2/10/2010	Blommers & McCleary	3/3/2010

10-46	Kaytasha Pempleton	Breastfeeding Knowledge Compared in Physicians, Nurse Practitioners, Registered Nurses	2/12/2010	Newberry & McCleary	3/3/2010
10-47	Jeffery Kaya	Access to Healthcare Services by Lesbian, Gay, Bisexual, and Transgender (LGBT) elders in Kern County	2/16/2010	Newberry & Gilchrist	3/4/2010
10-61	April Nilssen	Safely Surrendered Baby Program	3/9/2010	Lee & Gilchrist	3/18/2010
10-62	Dian Fernandez	The Effectiveness of Readers Theater on Fluency	3/10/2010		5/3/2010
10-63	Steven Boydston	Exercise Intentions versus Actions: Theory of Planned Behavior and Social Identity Messages	3/15/2010	McCleary & Blommers	4/16/2010
10-64	Jennifer Soares	Attitudes Toward Sex Offenders: A Comparison of Psychology and Criminology Students	3/15/2010		2/26/2010
10-65	Juan Delgado	Nursing Bioterrorism Preparedness	3/15/2010		4/8/2010
10-68	Bonnie Lords	College Students' Attitudes Toward International Violence Against Women	3/18/2010		3/30/2010
10-70	Lanette Cornford	Use of Singing, Songs and Music in Foreign Language Classrooms	3/18/2010		4/26/2010
10-72	Tyson Smith, Holly Aurness	The Perception of Pain from High Heels as a Sexual Attractor	3/22/2010	Newberry & McCleary	4/9/2010
10-73	Malkreet Johnson	Helping Students Connect and Clarify Main Ideas and Identify Their Relationship to Other Sources	3/24/2010		3/25/2010
10-77	John Guevara	Alternatives to Lower the Recidivism Rate of Camp Erwin Owens	4/1/2010		4/27/2010
10-78	Nada J. Yorke	Implementing a Batterer's Intervention Program in a Correctional Setting	4/1/2010	Newberry & Lee	5/24/2010
10-79	Dallas Lancaster	Educational Leadership: Implementing Leadership and Management Skills in ECE	4/6/2010		4/15/2010
10-80	Sunayana Gandiga Mallik	Program Evaluation-A Study Conducted at Cope Health Solutions to Evaluate the	4/6/2010	Lee & Gilchrist	4/26/2010
10-81	Deborah King	In-Service Professional Training Using ASL with Infants and Toddlers	4/8/2010		4/19/2010
10-84	Stacey McMicken	Ticket to Read: Adding Educational Technology to Reading Interventions	4/8/2010		4/20/2010
10-86	Anne Duran	Changes in Tolerance and Acceptance as a Result of Gender, Race, & Ethnicity Courses	4/9/2010		4/15/2010
10-87	Robin Paggi	Implementing the ADDIE Approach to Training at the Boys & Girls Club of Kern County	4/12/2010		4/22/2010
10-90	W. Brian Monroe	Video Game Postural Habits	4/14/2010	Blommers & McCleary	4/27/2010
10-96	Natasha Weatherspoon	Is the No Child Left Behind Act of 2001 being Implemented at a Local Bakersfield, CA Elementary School	4/20/2010		5/24/2010
10-97	Aaron Voelcker	Assessment Composite Scores Leading to Student Placement in Remedial Reading Evaluation a Weighting Schema for Multiple Measure Placement	4/20/2010		4/22/2010
10-100	Teresa Mendivil	A Cultural View of End-of-Life Decision Making	4/29/2010	Blommers & Duran	5/21/2010
10-103	Andrea M. Douglas	Open Access for All Students	5/10/2010		5/12/2010
10-104	Manuel D. Rodriguez	The Vegetarian Rationale: Who They Are, What They Eat, and Why They Eat It.	5/11/2010		5/17/2010
10-106	Michael Harville, Ph.D.	Survey of Attitudes Towards LGBT Individuals in the CSUB Athletics Department	5/11/2010		5/17/2010
10-108	Amy Alexander	Evaluation of Group Exercise Facility	5/13/2010		5/14/2010
10-111	Ashley Mabee	Causes and Effects of The Foreclosure Crisis in The Bakersfield MSA	5/20/2010		5/21/2010

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

## E. New Protocol Reviews

1. **Protocol 11-04. “Outcome Evaluations of a Mental Health Services Act Program for Older Adults: Wellness, Independence, and Senior Enrichment Services”** with Roseanna McCleary [Social Work Department] and Aaron Birch [Kern County Mental Health]. Primary readers were Lee, Duran, Herndon.

The PI summarized. This involves evaluation of KCMH's WISE program of services to elderly mentally ill. There will be two phases: Phase I [staff focus group and data collection] and Phase II [consumer interviews]. They want to document what is working and how to improve the program. Mental Health Services Act yields money that goes to counties. KERN created the WISE program. PI summarized what the program does. The clients are a very vulnerable population. It's a “full service” intense program to keep clients in their homes. Evaluations have been going to the state, but little comes back. Birch explained that he has password access to data in Sacramento. The two of them will have access to the data that he extracts. The accessed data will include personal identifiers. Anasazi is the big county data base. It's also password protected, but they will need some data from that as well. Above is part of Phase I. They will talk with the staff team to get ideas about what staffers think is a successful participant. They will be using the “success case method” to structure the staff focus group in Phase I and the Phase II consumer interviews.

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

**Q:** You will be studying both the clients and the care givers? **A:** Yes, looking at staff ideas and the client ideas to compare.

**Q:** How able will the participants be? High functioning? **A:** The clients are dropped from the program if they begin to show even middle level dementia. Some clients may have mild, or early dementia. This should be fine because we are working through the WISE program staff.

**Q:** Why only high and low groups? **A:** That's the success paradigm methodology. It's possible that we could look at middle groups later.

**Q:** What will be the approximate age range? **A:** It will run from 60s into the early 70s. Unfortunately, there are few older clients because they tend to die or become too demented.

**Q:** Is there a shared understanding among staff about what success is? **A:** No, and that's part of the focus of this project. PI has noticed that staff have trouble articulating what they mean by a client “doing well” and hopes that this project may clarify.

**C:** Your interview guide has a question about characteristics of successful clients. **A:** Yes, and hopefully that will prompt the staff to explore the overall concept of the “successful client”.

**Q:** On the interview guide, you will be asking clients about their good days. Would you also want to ask about bad days? **A:** We tend to use recovery model which focuses on the positive, but info about bad days often does come out.

**Q:** Are there issues with transportation? **A:** One goal of the program is to have clients become self-sufficient in transportation. In reality, the staff team provides most of client transportation.

**Q:** Will Aaron remove the names from data extracted from the database? **A:** Yes, then the data needed will be moved into the database for this project without the identifiers.

**Q:** Who has keys to the locked file cabinets? **A:** The PI has the key for hers and Aaron has the key for his.

**Q:** The focus group will yield the clients you want to contact? **A:** That's the plan, although the PI may need to go back to the WISE team and talk about specific clients.

**Q:** Will you make contact with the potential client participants by calling them? **A:** No, the PI would work through the WISE team to set up contact. There would be no calls “out of the blue”.

**Q:** Will you be doing audio taping? **A:** No taping of the focus group, but would like to tape client interviews with consultation of the case manager and consent of the client.

**Q:** Who transcribes? **A:** The PI always does that herself.

**Q:** Is the question about a good day possibly vague? Might you get answers back dealing with the weather or what was for dinner? **A:** Might have to clarify if the answer goes in that direction.

**Q:** The staff focus groups will be at work during work hours, yes? **A:** Yes, and that should be made clear on the consent form.

**Q:** Will the focus group participants have the questions beforehand? **A:** We might be able to provide useful guidance for them if we have certain portions of the data analysis done before the focus group.

**Q:** Will the focus group conversation help the work of the team? **A:** Oh yes, it might even clarify even the goals of the team.

When the questions were over, the investigators and the RERC were excused and the Board convened in executive session. There was a motion to conditionally approve Protocol 11-04 [Duran moved, Herndon seconded, 7-0 with McCleary recusing]. The following conditions were communicated to the investigators upon their return:

1. State in the consent form that the focus group will be at work.
  2. Clarify that the follow-up interview will be face to face.
  3. On the client interview consent form, clarify about the audio recording.
- 2. Protocol 11-14. "Use of the N-Word by Black African/American College Students in Bakersfield, California"** with Dahna Rasmussen and Rhonda Dugan [Sociology Department]. Primary readers were Newberry, Gilchrist, Tunson.

The student PI summarized. They are interested in the modern usage of the N-Word [N-W]. They believe that among the younger generation of African-Americans, usage has shifted toward a term of endearment. They will be looking at that in particular, noting that this means that N-W has dual usage and dual meaning. They want to see what kinds of variables are related to that. They will study African-American students at BC and CSUB using "self-administered" surveys and some follow-up interviews.

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

**Q:** So, how do you plan to get the information that you need? **A:** Using the surveys and the follow-up interviews.

**Q:** Can you elaborate on why this research should be done? Is there no existing research? **A:** There has been some research, but very little systematic research. There is not an empirical literature.

**Q:** Has this shift in usage happened in the past or is this a new phenomenon? **A:** There seems to be a shift with this generation.

**C:** A Board member noted from personal experience that this word has been used as term of endearment for quite some time.

**Q:** So, what is it that makes you think things have changed? **A:** The PI grew up in Bakersfield and then moved to Southern California and heard new meaning. Plus she has recently had conversations with her multi-racial son, who introduced her to the new meaning.

**C:** Several writers in the past have talked about this, notably Eldridge Cleaver and Ernie Smith. It doesn't seem to clear that there has been a shift across generations.

**C:** The Board would like to have a more systematic statement of what is known and what this is intended to add.

**Q:** What is deductive research? **A:** Starting from the questionnaire leading to ideas, or maybe this is backwards.

**Q:** Can you describe the interview? **A:** The actual interview questions will be developed from the initial quantitative data collection.

**C:** We'll have to decide how to deal with the interview content procedurally – as a separate protocol perhaps.

**Q:** Do you want to seek approval of the white participant data? **A:** Maybe.

**Q:** Will everything be locked up in PIs office? **A:** We'll put the consent forms in Dugan's office.

**Q:** How will you connect the two elements of the data – the surveys and the follow-up interviews? **A:** She won't be able to connect people to their survey data.

**C:** The demographic data seem to be important. Won't you need to know the demographics of the person being interviewed? **A:** We will collect new demographic info at the interview.

**Q:** Where did you get the survey? **A:** Some are from previous data; some are her own.

**C:** Should pilot the survey to refine wording if needed. **A:** Will do.

**Q:** You are using the CSUB counseling center for adverse reaction referrals. Do they know? **A:** The PI plans to inform the CSUB CC.

**Q:** Are you comfortable talking with people about the topic? Are you OK with using the whole word? **A:** Very comfortable and would use the whole word if subjects are comfortable. The faculty mentor and PI have talked about this, but the PI is sensitive, being a Caucasian woman, that use of the whole word might put off black subjects.

**C:** Maybe you should change usage in the protocol to use the word "nigger".

**C:** The spelling and pronunciation -- "nigga" vs. "nigger" -- is really important. This should be an element of the research to help clarify what's going on. Probably should simply add a question asking how they pronounce the word if they use it.

**C:** You propose using students in own class. Normally the IRB does not allow that because of student vulnerability. We could waive written consent and instructor would not be present so she wouldn't know who agrees to participate.

**Q:** Have you done the HSPT? **A:** Yes [faculty mentor has not].

**C:** Fix the typo re "every discourse".

When the questions were over, the investigators were excused and the Board convened in executive session. There was a motion to conditionally approve Protocol 11-14 [Duran moved, Tunson seconded, 8-0]. The following conditions were communicated to the investigators upon their return:

1. Provide a clear statement of how this builds on previous research – stating what is known and what the research is specifically intended to add to that existing knowledge.
  2. Include in the consent form that the interviews will be taped.
  3. Correct the inductive/deductive word usage.
  4. Modify the consent form wording to include data regardless of ethnicity.
  5. Modify the protocol to request waiver of written consent for the survey.
  6. Clarify that you will get the important demographic info again in the interview.
  7. Add approximate time needed to complete survey to that consent form
  8. Clarify that what you are studying is usage among college students, not usage among a particular age group.
  9. Re-word paragraph 4 of the interview consent form to separate withdrawal vs. turning off the tape.
  10. The IRB encourages the faculty mentor to do the HSPT certification.
  11. The Board suggests that you try to determine, if the participant uses the N-word, how the participant pronounces it.
  12. Clarify in the consent forms that the decision to participate or not has no connection with assessment of their performance in any course.
  13. When you have arrived at the interview questions, submit these to the RERC for review as a proposed protocol modification prior to using of them.
- 3. Protocol 11-15. "Community Preventive Health Collaborative [CPHC]" with Judy Pedro [Nursing Department]. Primary readers are Blommers, McCleary, Tunson.**

CPHC is designed for nursing students to provide health education and health screening to underserved populations. Nursing students enrolled in a community service learning course will do screenings in the community, give info on health care based on screening results, and follow up to see if participants get the services. Nursing faculty will supervise all this. It's Kaiser funded. There are educational benefits to the student nurses. They will be using the ICS paradigm. The PI will supervise some of the students.

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

**Q:** Where does the research come in? **A:** Surveys will be given to participants after their interview. These amount to program evaluation.

**Q:** Some of the consumers might be undocumented. How will they be protected? **A:** We won't ask about documentation, but will get names, addresses, phone numbers. For the screening itself only name and date of birth are required.

**Q:** You will be providing the materials in Spanish? **A:** Yes.

**C:** These will need to be submitted to the IRB for review prior to authorization of the protocol.

**C:** You will need to separate the consent to get the services -- for which it is OK to have a waiver of liability -- from consent to provide data for research purposes, for which it must be made clear that consent is not necessary to receive the health services.

**Q:** Could you be more specific about what are you trying to find out in the survey? **A:** For example, we will want to see how many participants have positive diagnostic indications, how many get referrals, how many follow through and get services. The survey has questions intended to get at why a person did not end up with services.

**Q:** This is getting confusing. You are going to link the survey data to the care that is received? **A:** Yes. For example we would look at the survey results separately just for the positives. However, we won't be associating particular survey results with specific screening results.

**C:** Then, you will want to have the positive findings and important demographics added to the survey.

**Q:** Would you want to add scales rather than yes/no choices for some of the questions? **A:** It's not clear that the clients served would all be able to use scales. We might add "I don't know" to some of them.

**Q:** So, your real goal is . . . ? **A:** The important focus of the survey is CPHC program evaluation.

**Q:** Are you going to ask the students about their experiences? **A:** The nursing students are enrolled in a course and this has a reflection assignment at the end of the course.

**C:** You could ask for IRB approval to use the reflection data.

**Q:** What's the focus of the research part, again? **A:** To see how many people with health problems get detected and get services. We want to see how many persons are detected with health problems and how many of them actually get services and for those who don't get services, why.

**C:** The survey includes a number of items that don't focus on the above.

**Q:** Will you include homeless persons? **A:** Yes.

**Q:** How about persons literate in other languages? **A:** At present, we can only provide English and Spanish materials.

**C:** It might be a good idea to put the demographic info at the end of the survey – it's often done that way

**Q:** Describe how you will be storing the data and completed consent forms. **A:** Nursing has a designated storage area for confidential info.

**C:** The PI might look at the community health needs assessment that Roseanna was involved in for the Lamont area.

When the questions were over, the PI was excused and the Board convened in executive session. There was a motion to conditionally approve Protocol 11-15 [Lee moved, Duran seconded, 7-0]. The following conditions were communicated to the investigators upon their return:

1. Clarify the major research questions that you want to answer and explain how the specific data to be collected will answer these.
2. Describe how you will train the students to administer the surveys.
3. Submit the Spanish materials for review.
4. Add to the survey the important demographic questions and a place to check off or indicate positive diagnostic findings from the screening.
5. Add to the protocol a request to use the nursing student reflective data.
6. If the students have not already affirmed that they will keep patient information confidential, add a confidentiality form to the materials.

7. Describe the Nursing Department data storage to be used in the protocol.
8. Provide separate consent for services and consent to provide research data. The former may include a waiver of liability and the latter must include a statement that receipt of services is not linked in any way dependent upon the research consent.
9. Only students with HSPT certification may participate.

**F. Continuing Review and Renewal of Authorized Protocols**

1. **Protocol 07-91: “Evaluation for Kern County Children and Families Commission [KCCFC]”** with J. J. Wang. Primary readers are all members.

A new 3-year First 5 funding cycle started July 01, 2010. Everything continues as before except start-up for Black Infant Health program, which was delayed, has now started. CS&O is monitoring. Confidentiality training continues with site visits to affirm the training in place, as does adverse event monitoring, with no adverse events reported.

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

**Q:** Theresa continues to monitor? **A:** We have a second person hired who is being trained to help.

**Q:** Explain the site visit log. **A:** The numbers are keyed to what actions were carried out as shown in the notation above the table.

**Q:** How often do you go to each site? **A:** It depends upon the workload. We no longer have to do quarterly visits. We do the log each time we go.

When the questions were over, the PI was excused and the Board convened in executive session. There was a motion to approve the quarterly report for Protocol 07-91 and to approve a one year renewal of authorization [McCleary moved, Gilchrist seconded, 7-0].

The investigator was congratulated for doing a good job.

**VI. OTHER CONCERNS: [none]**

**VII. REMAINING MEETING DATES FOR 2010-2011:**

Weds, 08 June 2011

**VIII. ADJOURNMENT:**

There being no further business, the meeting was adjourned at 11:35 AM.

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

**IX. BOARD TRAINING:**

**A. Non-Compliance [moved to Board Training due to meeting length]**

The first approach involves prevention. Paul, Yeunjoo, and Steve have been working on a tracking form for culminating activities that would include a line to indicate the date of the IRB authorization letter. The first step is to create a form that can be adopted across all programs in SSE. At present there is no theme across programs in how they handle IRB authorization. Only the Psychology MA has a line to indicate that the IRB has authorized the proposed activity. Education programs use a form with a line indicating when the project was *submitted to* the IRB. PPA and MSW require that a document from the IRB accompany every written product that is filed with the library, but do not monitor IRB submission or authorization. The Sociology form does not mention IRB. Yeunjoo developed a modification of the Education document, but we had to abandon that effort because that form includes so many other elements that it would not be appropriate for other programs. Therefore we created a very simple form with the IRB line, showed it to the SSE Dean, who said

she would get feedback from her Chairs and Program Directors. Feedback was “not another form” and objection based on the idea that a culminating activity must first be approved by the committee before it is submitted to the IRB. There was a consensus among Board members that simply moving the IRB line down -- so it is situated under the supervising committee members’ sign-off, above the final sign-off by the Chair or Program Director authorizing the culminating activity proposal – would address this problem. The RERC will do so and re-submit the form to the SSE Dean. He will offer to attend the meeting where this will be discussed and plea for support for our prevention-oriented approach to the problem on IRB non-compliance.

A complimentary approach involves establishing consequences of non-compliance. The university has no policy on the consequences of IRB non-compliance. In the absence of this, however, the Board agreed that the IRB does have one clear basis for action, as follows:

The university has affirmed to the federal government that it promises to comply with Code of Federal Regulations 45, Part 46 – the code that spells out the human subjects protections, policies, and procedures that the CSUB IRB implements. The Board believes that this written promise makes observing 45CFR46 a regulation of the university. In the CSUB University Handbook [Appendix F – “Responsibilities of Faculty”] there is the following statement “As a member of an institution, the professor observes the stated regulations of the institution provided they do not contravene academic freedom”. Therefore, the Board is of the opinion that it is a CSUB policy that faculty must comply with IRB policies and procedures. Furthermore, section 303.8 of the Handbook states that any member of the campus community may make a written referral to the Committee on Professional Responsibility for violations of the professional responsibilities stated in Appendix F.

There was a consensus of the Board that instance of IRB non-compliance could be referred in writing by the IRB to the Committee on Professional Responsibility, in addition to the formal report that is routinely generated following investigation of each non-compliance case.

**B. Information from IRB Webinar.** Summary was attached to agenda, but not discussed due to meeting length.

**C. Protocol Spot Checks.** Information attached to agenda, but not discussed due to meeting length.

Respectfully submitted

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and IRB/HSR Secretary