

Institutional Review Board for Human Subjects Research (IRB/HSR)
California State University, Bakersfield
9001 Stockdale Highway, Bakersfield, CA 93311-1099

Minutes of Meeting
Friday, 30 January 2009 [Stockdale Room]

Members Present:

Scientific Concerns: Anne Duran, Roseanna McCleary, Kathleen Gilchrist
Nonscientific Concerns: Paul Newberry, Yeunjoo Lee
Robert Horton, Ex-Officio

Members Absent:

Lily Alvarez, Gary Bashor, Robert Carlisle, Carolyn Wade-Southard

Visitors:

Andrea Staffero, **Administrative Coordinator, GRASP**
Todd Irvine and Bruce Friedman for **Protocol 08-177**
Larissa Ogden and Bruce Friedman for **Protocol 09-14**
Jennifer Culbertson, Norm Keltner, and Candace Meares for **Protocol 09-11**
Kimberley Brewer and Bruce Friedman for **Protocol 09-24**
Andrew Crawford for **Protocol 07-91 Quarterly Report & Renewal**

I. CALL TO ORDER:

Chair Paul Newberry called the meeting to order at 7:59 AM.

Approval of previous minutes, announcements, old business, and formal board affirmation of actions carried out since the October 2008 meeting, were deferred to ensure enough time to carry out business with the necessary quorum.

IV. NEW BUSINESS

B. New Protocol Reviews

1. **Protocol 08-177: "Driving to Success"** with Todd Irvine [MSW Student] and Bruce Friedman [Faculty Mentor]. Primary readers were Gilchrist, Newberry, & Bashor.

PI summarized. He is an MSW student, but also works at DHS with emancipated foster youth [EFY]. Few have a driver's license and so must rely on public transportation which limits employment opportunities. This project is a needs assessment to see if a personal driver's education service staffed by mentors from faith-based organizations might be useful and feasible. He will run focus groups of EFY, social workers, and community members. Being able to legally drive could give EFY a leg up in getting jobs and succeeding.

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

- Q:** This is a needs assessment? **A:** Yes, but from my study of existing data, the need seems clear. This would be verification and to see if there are any locally-specific barriers in the Bakersfield area.
- Q:** Part of the needs assessment involves identifying the community persons who might be resources? **A:** Yes, faith-based groups are available but not much used.
- Q:** Are you really going to be asking the same questions to each focus group? **A:** Could do different questions. The project is really about verifying the existence of the problem and then searching for the nature of the solution.

- C:** It looks like you should sequence the focus groups, doing the EFY first to confirm the problem and then moving to the other groups to explore solutions. **A:** Could do.
- Q:** Are there any existing programs that do this? **A:** No. Not in this area. I've looked at research literature on both the nature of the problem and the sorts of possible solutions.
- Q:** Will you be doing audio-taping? **A:** Yes and then I'll transcribe myself, then destroy the audio tapes.
- Q:** Can you describe how you plan to analyze the data? **A:** [PI doesn't really address the question.]
- Q:** Where will the focus groups meet? **A:** There is a meeting room at Building Blocks for the EFY group. Others could be transported. I transport clients as part of my work.
- Q:** Will you have access to EFY not at Building Blocks? **A:** Could arrange that, but probably wouldn't need to since of the EWF there only one out of 12 has a driver's license.
- Q:** Are the EFY at Building Blocks an adequate sample? **A:** It's a good starting point to affirm the problem and then go to the social workers and community people for solutions.
- Q:** Will you be collecting any demographic information? **A:** No, all demographics seemed to lead into personal information that I want to avoid.
- Q:** What are the qualifications of the mentors? **A:** Mentors would need to be 18 and have a driver's license. However, this proposal is not to teach driving, but to do a needs assessment for teaching driving.
- Q:** Are you, yourself, qualified to deal with possible adverse reactions? **A:** I have personal experience in my work at DHS, am skilled at re-directing as the occasion arises, and have a good sense of humor.

When questions ceased, the investigator and faculty mentor were excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 08-177**.

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

The following conditions were announced to the PI and faculty mentor when they returned:

1. Specify that you will sequence the focus groups, beginning with the EFY, and that questions could emerge from a focus group to be included in a later group. Any new questions must be submitted for IRB approval before use.
 2. Spell out the analysis of the data.
 3. Describe handling of the consent forms and data emphasizing security and confidentiality.
 4. Affirm that no driving lessons will be included in the activities authorized for this protocol.
- 2. Protocol 09-14: "Needs Assessment for a Comprehensive Emergency Shelter/Drop-In Center for Transition Age Youth"** with Larissa Ogden [MSW Student] and Bruce Friedman [Faculty Mentor]. Primary Readers were Duran, Lee, and Alvarez.

PIs summarized. Such a facility is not available for transition-age youth [TAY]. She will be studying TAY living in homeless shelters and at residential facilities, such as Building Blocks.

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

- Q:** What are you going to be asking them about? **A:** Would you use such a facility? What services should be offered at the center? Depends upon the goals of the kids. It starts with finding out what is already available and the barriers to accessing what is available.
- Q:** Have you looked at existing research on this problem? **A:** Yes, and I have an idea from this that there is a need.
- Q:** We need more details on the interviews. When? Where? Taped? How transcribed? **A:** I will probably do these at the housing location for the TAY, will audio-tape, and do the transcribing myself.
- Q:** Will transportation be involved? **A:** Yes. The workers involved could transport. DHS employees are sometimes involved transporting clients.

- Q: How will you contact the potential participants? A: I work with TAY and have access to the contact information.
- C: The reading level of the consent form is too high and needs to be lowered from college freshman level to about 8th grade reading level. A: Will do.
- C: You have done a good job creating neutral questions to ask whether there is a need.
- C: On the consent form, provide the contact info for adverse reaction rather than saying you will if deemed necessary.
- Q: What if a participant provides enough info in the interview to reveal his/her identity? A: I will obtain written permission to use that information as it comes up.
- Q: The primary language needs to be English? A: Yes. Well actually English could be the 2nd language if the person is literate in English.
- Q: You mention using secondary data. That is all public information? A: Yes.
- Q: You need to keep the consent forms separate from the data. A: Will do.
- Q: You state that the information will be shared with others. With whom and in what form? A: It may be shared with people in mental health to seek funding for such a facility. What's shared will be aggregate findings. There will also be a presentation of aggregate findings at CSUB.

When there were no more questions, the PI and faculty mentor were excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 09-14**.

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

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

1. Spell out how you will analyze the data.
 2. Provide a written release form in case of significant self-identification risk from interview data.
 3. Describe how the consent forms and data will be handled separately to enhance confidentiality.
 4. Provide the contact info for adverse reactions on the consent form.
 5. Lower the necessary reading level on the consent form.
3. **Protocol 09-11: "Chronic Sorrow: The Experience of Parenting Children with Autism"** with Jennifer Culbertson [Nursing Student] and Norm Keltner [Faculty Mentor]. Primary Readers were McCleary, Carlisle, & Wade-Southard.

PI summarized. Her background is Special Education and Nursing. She'll be doing semi-structured interviews using an existing instrument. About 20 participants or until data saturation are anticipated. Recruitment will be from HEARTS, a local care giver/parent support group, from whom a permission letter is forthcoming.

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

- Q: What are you trying to learn in this project? A: The sorrow of parents with respect to other kids with chronic illnesses has been studied, but not for parents of autistic kids.
- Q: So, is it a given that the parents will be experiencing sorrow? A: Probably, but the aim of the study is to explore that.
- Q: Is there an accepted definition of chronic sorrow? A: Yes, that's defined in the research literature.
- Q: What are the rule outs for parents? A: They need to be biological parents and at least 18 years of age.
- Q: What does "HEARTS" stand for? A: Don't know, but it's a resource center for parents with kids having chronic illness, particularly developmental delay and autism.
- C: Submit the invitation letter to us. A: Will do.
- Q: Do you anticipate changes in chronic sorrow across age or since the diagnosis of the chronic illness of the child? Is it hardest at first and then parents tend to "get over it"? A: Hard to tell. One study found that it got harder for parents later on as milestones came up, like going to school or going out for sports.

- C: On the consent form, you shouldn't say it's about sorrow, rather that it's about emotions. Otherwise you will bias the data.
- Q: You mention asking other questions at the bottom of p. 2. What are these? A: These would be demographics such as age, marital status, employment, and ethnicity.
- Q: Parent participants need to be 18 or over. A: This will be specified.
- Q: The interviews are one on one? A: Yes and I'll be recording.
- Q: How will participants inform you of their interest? A: I'll add phone contact info.
- Q: Do you really think you will get 20 volunteers? A: I think so. Parents tend to want to talk about their kids.
- C: Make clear in consent form that they can terminate whenever, and without any loss of services.
- Q: How will you analyze the data? A: [PI doesn't address the questions].
- Q: Will you audio-tape? A: Yes, and will take field notes to enrich the record. I'll transcribe myself and lock up the tape. Data will be listed with subject codes, not actual names.
- Q: How will you establish reliability and validity of your data? A: Several participants will be asked to review the data, for a look at face validity.
- C: If you might contact participants again later, then that needs to be in the consent form. A: Will do.

When there were no more questions, the PI and faculty mentor were excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 09-11**.

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

The following conditions were announced to the PI and faculty mentors when they returned:

1. Eliminate the word "sorrow" from the title of the consent form and test instrument. Try to be open-minded about what you will find.
 2. Submit the invitation letter to be sent out for recruiting.
 3. Specify the parents must be 18 or over.
 4. In the consent form:
 - [a] State the participant can terminate without consequences.
 - [b] Add that follow-up is a possibility.
 - [c] Add that there will be audio-taping.
4. **Protocol 09-24: "Effective Assessments Can Contribute To Better Recommendations For Families In the Child Welfare System"** with Kimberley Brewer [MSW Student] and Bruce Friedman [Faculty Co-Mentor]. Primary Readers were Gilchrist, Carlisle, & Alvarez.

PI summarized. The PI is an MSW student and a drug dependency investigator [DI] for Department of Children and Family Services in LA County. Recommendations at present are based on personal opinions following informal assessments. The proposal is to develop a standard assessment tool for DI's to use. After giving DI's experience using the tool, she will do individual and group interviews on their experiences. The purpose is to try to get more structured information about abuse and drug use to inform DI recommendations.

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

- Q: What types of recommendations does the DI make? A: These include recommendations about entry into drug programs. It is useful to know which drugs are being used and for how long.
- Q: Do DI's make a recommendation on reunification? A: Yes, but the problem is that it is based on limited information, which this project might help address. The original decision about disposition of the child follows a structured model, but the later decisions are much less systematic.

- Q:** How did you develop these questions? **A:** I looked at other programs and reviewed what they do and compared the information gathered with DSM criteria for abuse and dependency.
- Q:** Wouldn't DI's already be asking these questions anyway? **A:** They should. Some might, some wouldn't, but you can't tell. At present we don't know what their recommendations are based on.
- Q:** Why hasn't anyone out there done this already? **A:** Maybe this shows the benefits of the academic preparation offered by an MSW program.
- Q:** Is there any research on this problem? **A:** There seems to be info available on sexual abuse, but it appears that the problem is widespread.
- Q:** What is the education level of DI's? **A:** All DI's are BA level and above.
- Q:** Maybe you need to get consent from the families involved? **A:** I'm not looking at the answers to the questions, just how the DI's feel this tool is working for them. The tool doesn't introduce whole new lines of questioning. Current policy and practice require that these sorts of questions be asked. They just aren't asked systematically.
- Q:** So these don't introduce new topics or risks? **A:** Not really.
- Q:** Your design is to use the questions, then not use them, then interview the participating DI's. How about the ethics of that, if the tool appears to be working? **A:** The only way to assure that the tool is working and guiding decisions is to have something to compare it with.
- C:** Maybe you could give the DI's a choice of continuing with it or not.
- C:** Maybe you could collect pre- and post- data on how the DI's are getting their recommendation info. Also you could use a control group.
- Q:** Will you train the DI's on using your tool? **A:** Hadn't really thought of that, but I will do that.
- C:** You should re-state Item #4 in Appendix II in a neutral way.
- C:** You need to address data analysis.
- C:** Handling, storage, and disposition of the data need to be spelled out.
- C:** After DI's have used your materials, you should get feedback from them on adding or modifying questions.

When there were no more questions, the PI and faculty mentor were excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 09-24**.

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

The following conditions were announced to the PI and faculty mentor when they returned:

1. Create a neutral title for the consent form.
2. Describe how you plan to analyze the data.
3. Describe the handling, storage, and disposition of the consent forms and data.
4. Revise the design and make it stronger.
5. State item #4 in Appendix II in neutral wording.
6. Provide justification for the particular questions used in Section I and Section II.
7. Add to the design getting feedback from DI's about modifying and adding questions.

C. Monitoring and Renewal of Continuing Protocols

1. **Protocol 07-91:** CS&O Quarterly Report for activities conducted assessing performance and outcomes of First 5 agencies in Kern County with Andrew Crawford.

Crawford summarized. During this period one program terminated and one was suspended for several months. Two dental programs started up. The Nurse Family Partnership staff were not getting consent, so their data from this period were not used. They have received confidentiality training and are obtaining proper consents now. Personnel at 7 programs received confidentiality training during this period. The problem with consent from minor mothers for their children to receive services was mentioned, which is being considered by the IRB outside of the present renewal request. [A brief discussion followed outlining the dimensions of the problem.]

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

- C: The IRB Chair expressed his appreciation for the diligence and seriousness of Andrew and Brian in their roles dealing with potential issues involving human subjects protections among the First 5 programs.
- Q: To what extent are CSUB students accessing the data? A: CS&O is working out how to have students involved in internship-like roles at CS&O. There are concerns about actually exporting any of the data though.
- Q: Could CS&O pay a little bit? A: Maybe.
- C: Coordination with Mike Butler at CSUB could facilitate placements.

When there were no more questions, Crawford was excused and the Board deliberated in executive session. There was a motion to accept the quarterly report for Protocol 07-91 and authorize renewal of the protocol for one year.

[McCleary moved, Lee seconded, 5-0]

The elements of the above motion were described to Crawford when he returned. The IRB requested that CS&O: [a] include a section in their quarterly reports describing activities of CSUB faculty and students involving the CS&O data and [b] explore means to facilitate such access.

Discussion about CSUB student/faculty access to the data followed. Crawford indicated that students were needed for data entry level work, but that they might be able to follow the data forward to see the program evaluation implications and how they reflect on services provided by First 5 agencies. CS&O was working with a test instrument developed in a CSUB MA student thesis. It was noted that Mike Butler, who coordinates student community placements for academic purposes would be an excellent contact. It was suggested that, in addition to sociology students, MSW students needing community projects, psychology undergraduates satisfying their Applied Experience degree requirement, and students doing projects in Public Policy and Administration might all be interested in interacting with the CS&O data.

VI. OTHER CONCERNS: [none]

VII. NEXT MEETING:

Friday, 24 April 2009 [please mark your calendars!]

VIII. ADJOURNMENT:

There being no further business, the meeting was adjourned at 10:45 AM.

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

IX. BOARD TRAINING: [cancelled]

Respectfully submitted

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