

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

**Minutes of Meeting
Friday, 10 October 2008 [Stockdale Room]**

Members Present:

Scientific Concerns: Anne Duran, Roseanna McCleary, Kathleen Gilchrist
Nonscientific Concerns: Paul Newberry, Robert Carlisle, Yeunjoo Lee
Community Concerns: Gary Bashor, Lily Alvarez, Carolyn Wade-Southard
Robert Horton, Ex-Officio

Members Absent:

none

Visitors:

Kris Grappendorf and Kristina LaGue for **Protocol 08-117**
Josephine Alamillo and Bruce Friedman for **Protocol 08-116**
Lincy Maliyekkal and Julia Robinson for **Protocol 08-93**
Andrew Crawford for **Protocol 07-91** Quarterly Report
Student observers: Jesus Calderon, Kelly Levig, Jared Chapman, Michael Butler, Kristen Huling

I. CALL TO ORDER:

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

II. PREVIOUS MINUTES:

Wade-Southard moved and McCleary seconded a motion to approve the minutes for the meeting of 04 June 2008 with clerical corrections. The motion was approved 9-0.

III. ANNOUNCEMENTS:

- A. This is the first IRB meeting for new Board members Anne Duran [Psychology] and Kathleen Gilchrist [Nursing] who were formally introduced and welcomed. Chair announced that new member hazing would be carried out after the meeting.
- B. The student observers were introduced.

IV. OLD BUSINESS [none]

V. NEW BUSINESS

- A. **Formal Board affirmation** of actions carried out since the June 2008 meeting.: Standard Review Authorizations, Expedited Review Authorizations, Exemption from Full Review Authorizations, Submissions Found to be Outside IRB Purview, Protocol Renewals, Protocol Closures.

1. Standard Review [1]

Number	Author	Title	Date Submitted	Reviewers	Type of Review	Final Approval
08-92	Laura Elton	An Exploration of Strengths and Resilience of the Tubatulabal People as It Relates to Current Tribal Identity	5/21/2008	IRB Board	Standard	6/23/2008

[Bashor moved, Lee seconded -- approved 9-0]

2. Expedited Review [5]

Number	Author	Title	Date Submitted	Reviewers	Type of Review	Final Approval
08-73	Giselle Simmons-Brown	A Program Evaluation of Northern Kern's Repeat Offender Prevention Program from the Participants' Perspectives	4/18/2008	Abramson, Newberry	Expedited	5/19/2008
08-97	Nada J. Yorke	Implementing a Batterer's Intervention Program in a Correctional Setting, Substance Abuse Program	6/13/2008	Lee, Newberry	Expedited	6/25/2008
08-98	Chandra Commuri	The Dimensions of Diversity: How Nonprofit Governors Make Sense of the Board Diversity Issue	6/20/2008	McCleary & Lee	Expedited	8/18/2008
08-101	Roseanna McCleary, Bruce Friedman	Evaluation of the Practicum Partnership Program Adoption Initiative	8/13/2008	Newberry	Expedited	9/10/2008
08-102	Roseanna McCleary, Bruce Friedman	Hartford Partnership Program for Aging Education Career Tracking Survey	8/13/2008	Newberry	Expedited	9/10/2008

Why do **Protocols 08-101** and **08-102** have only one reviewer listed? RERC explained these qualified for Exemption from Full Review, which RERC would normally carry out, but these were passed to Newberry to review because PI was wife of RERC.

Why were **Protocols 08-73** and **08-97** Expedited Review, when the participants would appear to be vulnerable? RERC checked the files and explained that in both cases these were surveys returned anonymously without personal identifiers so there was not significant risk.

[Bashor moved, Wade-Southard seconded -- approved 9-0]

3. Exempted from Full Review [8]

Number	Author	Title	Date Submitted	Reviewers	Type of Review	Final Approval
08-91	Bonnie K. Holt	Beyond Skin Deep: A Closer Look at Tattoos	5/22/2008		Exemption	5/28/2008
08-95	Teresa Carranza	A Comparison of Achievement Levels of Early and Late Arrival Mexican Students	6/3/2008		3PA/Exemption	6/19/2008
08-96	Kyle Atkin	Using Texas Instrument's TI-Navigator to Facilitate Formative Assessment and the Relation This Has On Teacher Decision Making Within a Lesson	6/2/2008		Exemption	6/17/2008
08-100	P. Michael Lutz, Carl Lager (UCSB)	Todos Secondary Mathematics Projects	8/6/2008		Exemption	9/2/2008
08-103	Jean-Claude Tubajika	Program Evaluation of the Student Health Center	8/18/2008		Exemption	8/28/2008
08-105	David Stricker	Should the National Recreation and Park Association's Aquatic Branch develop a certification for individuals in the field of Aquatic Management	8/28/2008		Exemption	9/22/2008

08-107	Donna Simmons, Judith Pratt & Christine Cruz-Boone	Big West Refinery Expansion Communication Efforts: Media Campaign & Risk Communication	9/10/2008		Exemption	9/23/2008
08-108	Blanca Luz Anderson	Program Planning Study-Clinica Sierra Vista's Behavioral Health Program	9/19/2008		Exemption	9/22/2008

What was **Protocol 08-91**, the tattoo study, about? RERC explained it involved studying the personal significance and attitudes about tattoos among persons having tattoos. An IRB member wondered if the materials used in **Protocol 08-108**, involving Clinica Sierra Vista, were in Spanish. The RERC checked the file and reported that they were not because it was a staff survey.

[McCleary moved, Alvarez seconded -- approved 9-0]

- Formal Board affirmation** 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 2008 meeting. [1]

Number	Author	Title	Date Submitted	Reviewers	Type of Review	Final Approval
08-90	Philip Arias	Does the California Three Strikes Law affect the California Crime Rate?	5/15/2008		Exemption	5/23/2008

[Gilchrist moved, Bashor seconded -- approved 9-0]

- Formal Board affirmation** of previously approved protocols granted **renewals** since the June 2008 meeting. [4]

Number	Author	Title	Date Submitted	Reviewers	Type of Review	Final Approval
03-03	Steve Bacon	Establishment of a Participant Pool for the Department of Psychology	1/17/2003	Bragg, Wang	Standard	2/4/2003
04-124	Cherie Rector and Kathleen L. Gilchrist	Are You INN? Outcomes of the INN Program Grant	9/23/2004	Duquette, Bragg, Wang	Standard	9/1/2004
05-99	Michael Harville, Beth Rienzi	Evaluation of Counseling Center Services	10/7/2005		Exemption	10/11/2005
06-77	Kathleen L. Gilchrist	CSUB Nursing Program Evaluation Project	8/16/2006		Exemption	8/22/2006

Is the Psychology IRB member traditionally recused from voting on **Protocol 03-03**, the Psychology Department subject pool? RERC reported that has not been the case. The Chair lacks a copy of the **Protocol 06-77** renewal letter.

[McCleary moved, Duran seconded, approved 9-0]

- Formal Board affirmation** of protocol **closures** whose authorization will end prior to the Winter 2009 IRB meeting, unless renewal is granted prior to expiration date. [23]

What if a protocol had closed and the PI later wanted it renewed? RERC reported that the practice has been to grant renewal if the request is within a week or so of formal closure, but after that to require submission of a new protocol. What does "3PA" signify for "Type of Review"? The "Third Party Access to Existing Data" procedure was explained. It most often involves a protocol done in the educational setting. Why has McCleary closed her **Protocol 06-24**. McCleary explained that this was because high turnover in clinical staffing had compromised the pre/post design.

October 2008 Closures

Number	Author	Title	Date Submitted	Reviewers	Type of Review	Final Approval
05-102	Debra Cook Hirai	CALLI (Content Academic Language Literacy Instruction)	10/24/2005		Exemption	9/30/2008
07-108	Nan M. Romo	DCFS/DMH Collaboration in Service Area I: The Indicators of and Obstacles to a Successful Agency Collaboration	10/23/2007		Exemption	11/13/2007
07-113	Amy Marie Green	Perceptions of School Nurses Regarding Management of Seizures	10/25/2007	McCleary, Lee	Expedited	11/16/2007
07-114	Jianyu Wang	Relationship Between Perceived Competence and Participation Among College Students	10/31/2007		Exemption	11/21/2007
07-118	Mazaira Lennon	Toward Cultural Awareness: Identifying the Need for an Ongoing Training Program for El Nido Family Centers	11/13/2007		Exemption	11/27/2007
07-119	Barbara Reif	Impact of Striae Gravidarum: Women's Perception	11/15/2007		Exemption	11/18/2007

November 2008 Closures

Number	Author	Title	Date Submitted	Reviewers	Type of Review	Final Approval
06-124	Rebecca Fields	What Effect Does Participation in Preschool or Summer School, Prior to Kindergarten, Have in Mid-Year Kindergarten and First Grade Test Scores	12/4/2006	RERC	3PA	12/17/2006
07-99	Sarah Johnson	Predicting Preschooler Acceptance: Evaluating the Role of Ethnicity	9/27/2007	Newberry, McCleary	Expedited	11/28/2007
07-112	Sandra Mackiney	Chronic Sorrow Among Parents of Children with Cerebral Palsy	10/25/2007		Exemption	9/29/2008

December 2008 Closures

Number	Author	Title	Date Submitted	Reviewers	Type of Review	Final Approval
05-36	Ron Pimentel & Students	Maintaining Fad Products Between Fads	3/15/2005		Exemption	9/29/2008
06-03	Stacey Franciotti, Juan Avila, Angelita White	Recruiting Student Enrollment for the School Of Education	1/6/2006		Exemption	1/10/2006
06-24	Roseanna McCleary, Jong Choi	Clinician Competency in Provision of Treatment to Adults with Serious Mental Illness	2/22/2006	Carlisle, Abramson	Exemption	3/2/2006
08-01	Janet Armentor-Cota & Doreen Anderson-Facile	Online Gambling and College Students	1/2/2008	Mearns, Carlisle	Expedited	1/22/2008
08-02	Tanya Boone	College Students' Social, Emotional, and Physical Well Being	1/2/2008	Lee, McCleary	Expedited	1/23/2008
08-03	Terri Kurz	Use of Video Analysis	1/7/2008		Exemption	1/9/2008

January 2009 Closures

Number	Author	Title	Date Submitted	Reviewers	Type of Review	Final Approval
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05-46	Debra Cook Hirai	Are We Closing the Gap for Reading Comprehension & Decoding for 9-12 Students	4/11/2005		Exemption	9/30/2008
07-02	Kristina LaGue	Foster Youth Services /CSUB Tutor Connection Program	1/10/2007	IRB Board	Standard	2/9/2007
07-15	Grace Marie Erickson	Public Health Nurses' Attitudes and Practices after an Educational Program on Advance Directives	2/2/2007		Exemption	3/2/2007
08-06	Patty Jamal	Consumer Satisfaction with the Tulare County Full Service Partnership	1/17/2008	Abramson & Lee	Expedited	2/12/2008
08-09	Colleen McGauley	Analysis of Recruitment Strategies of CASA of Kern County	1/25/2008		Exemption	2/6/2008
08-12	Josh Webb	Renegotiating Our Conversational Consensus: Interactions Between the D/HH and the Language Barrier	1/28/2008		Exemption	2/8/2008
08-17	Teresa McFarland	Evaluation of a Pilot Continuing Education Module on the Mature Gravida	2/7/2008		Exemption	2/11/2008
08-22	Loy Anne Du Val	Needs Assessment for Differential Response Parent Partner Handbook and Resource Guide	2/15/2008		Exemption	2/21/2008

[Wade-Southard moved, Duran seconded -- approved 9-0]

B. New Protocol Reviews

1. **Protocol 08-110: "CSUB Vision Lab Visual Neuroscience Research Projects"** with Steve Suter [Psychology]. Primary readers were Gilchrist, Newberry, & Bashor.

PI summarized. This is a generic request to cover a variety of studies in the Psychology Department Vision Laboratory that involve recording brain activity from scalp electrodes while participants look at visual stimuli presented on a video monitor. This qualifies for Expedited Review, but has been submitted for Standard Review because it is a generic request. Participants will either be recruited using typical procedures, "Ordinary Participation", or students will be carrying out lab assignments for a laboratory course in Sensation and Perception, "Lab Assignment Participation". In the latter case, informed consent is not for participating in the lab activity, which is a required element of the course, but for release of the data obtained for research purposes.

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

- Q:** Will research assistants and laboratory assistants for the course involved have HSPT certification? **A:** Yes.
- Q:** Who will have access to the data? **A:** The PI and research assistants. Lab assistants would have access while the data still have "lab assignment status".
- Q:** How are the materials stored? **A:** The signed consent forms are kept in a locked file cabinet, but the data sheets, without personal identifiers, are placed in file cabinets that are not locked. The electronic data files, without personal identifiers, are stored on computers that are not password protected.
- Q:** How are student participants recruited? **A:** Some will probably be from the Psychology Department subject pool, but others will be recruited by making presentations in classes and asking interested students to provide name and phone numbers on a sign-up sheet.
- C:** Circulating a sheet where other students can view another student's phone number does not seem like such a good idea. **A:** We could pass out blank slips and have students drop them in an envelope that circulates.
- Q:** What sorts of stimuli are used? Are any of them disturbing? **A:** Often they are just simple stripes and checkerboards, but sometimes certain types of illusions are used. None of these have any disturbing emotional content.
- Q:** Do any of your studies get at "tacit knowledge" -- subtle, perhaps unconscious effects of earlier experiences? **A:** No, we are studying lower level processing.
- Q:** Are there any risks to pregnant females or elderly person if they were to participate. **A:** No and if vulnerable populations, such as children or persons with reading disabilities, were to be studied, we would send through a specific protocol for such a study.

When there were no more questions, the investigator was excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol -08-110**.

[Duran moved, Carlisle seconded -- approved 8-0, with McCleary recusing]

The following condition was announced to the PI when he returned:

1. Both the consent form and the protocol need to clarify how and where the data and consent forms are stored to ensure confidentiality.
2. **Protocol 08-117: "Enhancing the Self-Efficacy of Female Foster Youth Through Physical Activity"** with Kris Grappendorf [PEAK] and Kristina LaGue [Teacher Education]. Primary Readers were McCleary, Carlisle, & Wade-Southard.

PIs summarized. This is the third year of a grant-funded program to bring foster youth to the CSUB campus for academic mentoring by CSUB students. They have added a regular physical activity component and want to assess how this might be related to self-efficacy among the adolescent female participants, along with what these foster youth believe about the benefits of physical activity and any barriers to physical activity that they experience.

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

- Q:** Do the participants know each other? **A:** Many know each other from foster homes and get to know each other via their time spent together at CSUB.
- Q:** What are the selection criteria for participation? **A:** Foster Youth Services screens the potential participants. We have discussed with them what we would like to avoid at CSUB, such as acting out extreme behaviors or running away and they screen accordingly. Many of the kids are doing poorly in school which makes them good candidates for academic mentoring. To participate, the group home must be able to transport the participant.
- Q:** So, participation is like a "perk" for the youth? **A:** Yes. All of the participants are volunteers.
- Q:** What sorts of physical activities are they involved in? **A:** For example, flag football, swimming – we do something different almost every day.
- Q:** Are you collecting data on physical fitness? **A:** No, we are not looking at body composition or anything like that. We are administering the self-efficacy scale and getting informal information from them about their other physical activities.
- Q:** Why aren't you also looking at males? **A:** Some other studies have found gender differences with special correlates of physical activity or lack of among females, so we thought we would limit this to the females. Most of the foster youth in the program are actually males.
- Q:** Are you providing any experiences designed to enhance group cohesiveness? Many foster youth are deprived of such experiences. **A:** We don't focus on that, but some activities would involve cohesiveness, such as team sports. We just had a birthday party for all the kids with October birthdays. So, there are elements of group cohesiveness in the overall mentoring program.
- Q:** What would happen if there is an injury, like somebody gets hurt playing flag football? **A:** We would immediately contact the kid's group home and involve supervisors.
- Q:** You mentioned collecting qualitative data. Could you explain what that is about? **A:** We'll be noting who participates in the physical activities, having informal interviews with the kids, and keeping anecdotal notes on what we notice.
- Q:** When will you start collecting data? **A:** As soon as IRB authorizes the protocol and the necessary personnel have been HSPT certified. What we are calling "pre" will happen as soon as we can start.
- C:** In the consent forms, you need to provide information about the approximate time that will be involved for participation. Add something about the possible benefits of physical activity and the possible risks. Also, the use of the term "stress" should be made more clear.
- Q:** You mention using the results to possibly make recommendations, but it isn't clear to whom. **A:** Recommendations would be to foster agencies about the effectiveness of the physical activity elements.
- C:** Given that participation in the mentoring program is desirable for the youth, you need to be sensitive to them possibly feeling pressured to volunteer for the research aspects.

- Q: It doesn't seem like you would be able to generalize to all foster youth from this study. A: We aren't interested in doing that.
- Q: Please clarify the screening criteria. A: We don't really screen. We express our overall concerns about wanting appropriate behaviors from the participants and they take that into account on the other end.
- Q: Are you interested in age differences? A: We could look at that, but that isn't our focus.
- Q: Explain how the survey will be administered. A: It will be given by one of the PIs on a one-on-one basis in order to answer questions and explain anything that is necessary.
- Q: How will the data be stored? A: In a locked office. C: Please add to the consent form.
- C: Correct the reference to "my rights" in the guardian consent form. A: Will do.
- C: In consent form, you state 3 months between pre and post, but since that will vary, the interval should be stated in a less specific way in order to be correct.
- Q: What happens if one of the kids chooses not to participate? A: Nothing. C: Make that clear in the consent form, clearly stating that there is no penalty for not participating.
- C: It would give a better feeling to the consent materials to use the word "participant" consistently instead of "subject".
- Q: How will you connect the pre and post surveys for data analysis purposes? A: We'll use identification numbers.

When there were no more questions, the investigators were excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 08-117**.

[Wade-Southard moved, Carlisle seconded -- approved 9-0]

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

1. Explain more specifically how this research may contribute to what we already know, in particular the evidence suggesting that foster youth may be different with respect to issues of physical activity and that there may be special concerns about physical activity among females.
2. Address the specifics about screening criteria, that is how the potential youth are selected in and selected out for your program.
3. Clarify and justify the "pre/post" perspective you present for your proposed research, given that the physical activities are already underway.
4. Specify clearly who the participants in your study will be and how many there will be.
5. Board members would like a more specific presentation of what physical activities and/or sports will be involved – this is not to prohibit you from deviating from whatever physical activities you list.
6. Describe more specifically the processes of informal interviewing and anecdotal observations, explaining what data will be collected.
7. Specify how you will use identification numbers to pair up the pre/post data. Are there any other data elements that will need to be associated in this fashion?
8. Explain how injury liability is being handled. Provide info from the CSUB Safety and Risk Management Officer if needed. [This condition was deleted following a post-meeting e-mail discussion and vote in which it was agreed that the physical activities themselves are not part of Protocol 08-117.]
9. Add to the consent and assent forms:
 - a. Info about time involvement.
 - b. Info about possible benefits and risks of physical activity. [Deleted as per #8, above]
 - c. Clarify use of the term "stress".
 - d. Specify data storage for confidentiality.
 - e. Edit out the "my rights" wording on the guardian consent.
 - f. State the time interval between pre and post in a more general fashion.
 - g. Use "participant" rather than "subject" throughout.

3. **Protocol 08-116: "What Permanency Means to Youth in Long-Term Foster Care: A Focus Group Approach"** with Josephine Alamillo [MSW Student] and Debra Morrison-Orton [Faculty Mentor]. Primary Readers were Duran, Lee, and Alvarez.

PI summarized. Foster youth are chronically deprived of "permanency", meaning an enduring relationship with family. It is thought that this may play a role in poor outcomes for foster youth. The aim of the proposed research is to have foster youth in focus groups talk about permanency. Several examples of question prompts were provided. Perhaps this could lead to advice for other foster youth. PI works with foster youth in LA County Dept of Children and Family Services.

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

- Q:** You say that you would exclude a participant for mental health issues but include if stabilized OK on meds. How would you determine this? **A:** I'll use my own global judgment and talk to the relevant social worker as needed and rely on his/her input.
- Q:** Describe how you will contact prospective participants. What other approaches did you consider? **A:** I thought about talking to social workers and soliciting referrals, but I thought that doing telephone contacts would give a more representative sample. I will call from lists to which I already have access.
- Q:** Wouldn't it be kind of weird for a kid to get such a phone call? Wouldn't it seem strange to the kid? **A:** No. They get lots of calls from personnel within the department for delivery of services, therapy, and so forth. The PI would probably know most of the kids already through her work.
- Q:** Clarify the purpose of your call? It's to recruit participants? **A:** Yes. PI has tried a trial run and it went well.
- C:** This call is part of informed consent and we'll need a specific script of what you will say to them.
- C:** It isn't clear that prospect participant foster youth have a contact in case they experience distress in recruitment or perceive they have been disadvantaged by not participating. They need a clear IRB contact for that.
- C:** Specify that this is an MSW project for a degree requirement in the consent materials.
- Q:** How else might the info be used beyond your MSE project write-up and presentation? **A:** The agency would get a copy of the write-up, but not individual level responses that could possibly be linked to individuals.
- C:** The issue of adverse reaction or distress needs a specific remedy, that is a licensed mental health professional immediately available [in person] if needed.
- Q:** The focus group questions you gave use the word "permanency" as if the foster youth would know what that means. That's not clear. Also, just talking about this issue may very well create distress that did not exist before. Also, wouldn't it be expected for them to blame the social worker, and so there you are leading a focus group on this. **A:** The PI can consult with contacts within the agency on this. Plus, she works as an emergency response person in the social work setting.
- Q:** Will you transcribe the audio tapes? **A:** Yes, I will do that myself or have an assistant do that.
- Q:** How will you get consent from legal guardians? **C:** [Discussion ensued indicating this needs to be worked out.]
- Q:** You don't have much to offer about existing research on foster youth and permanency. Why not? **A:** Existing research was not focus groups, mostly interviews and standardized surveys. There are some retrospective studies of persons who were foster youth.
- C:** You need to specify about storage of data and dealing with the audio tapes in terms of confidentiality on the consent materials.
- Q:** What if a participant does not agree to be audio taped? **A:** Then that participant would not be part of the focus group.
- C:** You have a dual role as a provider of services and a researcher for these kids. You must be careful to present yourself as a researcher in this project, including in the initial telephone solicitation for participation.
- C:** You should elaborate on your professional qualifications in the protocol, given the nature of the research.
- C:** The few questions you list in the protocol don't give an adequate presentation of the nature of the discussion in the focus group.

C: Add to the consent form the purpose of the research, including that it satisfies a degree requirement for the MSW, and the possible benefits.

C: You need an assent form for the foster youth participants as well as a consent form for the guardians.

When there were no more questions, the PI and MSW representative were excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 08-116**.

[Wade-Southard moved, Carlisle seconded -- approved 9-0]

The following conditions were announced to the PI when she returned:

1. Provide a detailed script for the initial telephone solicitation spelling out what you will say to the prospective participant – please explain if the guardian may be involved in this conversation and spell out what would be said in that case.
2. Verify that a licensed mental health professional will be immediately available in case of adverse reaction during the focus group and describe how this will be set up.
3. Specify the assistant who would be transcribing tapes, relationship with possible participants, provide a confidentiality statement for that person to sign, and affirm that the transcriber will have HSPT certification.
4. Elaborate on your professional qualifications in the protocol with respect to the nature of this project.
5. Spell out the information, instructions, prompts you will provide to the focus group. State areas that would be consider "out of bounds" for the focus group discussion.
6. Provide an IRB contact [Suter] clearly specified in case there are concerns about the recruitment process or about consequences of failure to participate – that is, make the contact for "rights as a participant" more inclusive.
7. Provide an assent form written with appropriate level vocabulary.
8. Consent can only be provided from parent, guardian, or guardian *ad litem*. Consent form must be constructed so that the consenter verifies which of these roles he/she represents.
9. Add to the consent and assent forms:
 - a. That this is an MSW project and the write-up will be shared with agency.
 - b. Explanation of data/consent storage re confidentiality, tape transcribing, destruction of tapes.
 - c. Clarify use of the term "stress".
 - d. Specify data storage for confidentiality.
 - e. Edit out the "my rights" wording on the guardian consent.
 - f. State the time interval between pre and post in a more general fashion.
 - g. Use "participant" rather than "subject" throughout.
 - h. Include in the assent form an instruction to respect confidentiality of information shared within the focus group.
4. **Protocol 08-93: "Self-Management Knowledge of Patients in a Rehabilitation Hospital: A Needs Assessment"** with Lincy Maliyekkal [Nursing Student]. Primary Readers were IRB Members.

PI summarized. Knowledge about diabetes among diabetic patients is thought to be a good thing. A pre-/post-administration of a standard test of diabetic knowledge is intended to assess how well the present informal approach to diabetic education is working in her particular hospital.

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

Q: What kind of diabetic education happens in between pre and post? A: It's the program that the hospital has in place. This includes info about diet and various elements. She will give this to RNs and try to make sure that it gets to the patients, but this is very informal. The idea is to see if the existing system is working.

Q: So, there is a diabetes education kit that is supposed to be used? A: Not clear if this is required. PI thinks it is the professional responsibility of nurses to use this info, but some do and some don't.

Q: What are you trying to get at with this study? A: [question is not answered]

- Q:** Are you changing something that is in place with this study? **A:** No, but she will remind nurses to provide the diabetes education information to patients. It would be up to them to actually deliver the information.
- Q:** You want to see if there is change from pre to post. What will be the basis for deciding if a lot of change or not very much change has happened? **A:** [question is not answered]
- Q:** Is there anything against which you might want to compare the scores you get, given you are using a standardized test of diabetes knowledge that is probably used in many settings? **A:** No.
- Q:** Describe how you will store the data. **A:** At home, then eventually turned over to CSUB and then destroyed.
- Q:** What if there were a home burglary? **A:** That does not seem very likely.
- Q:** How will you be able to connect the pre and post surveys? **A:** Patients will put their names on the surveys.
- Q:** Describe the selection criteria for the participants. **A:** They will be 40 or older and English readers. PI will use her global assessment from the intake interview to determine if patient will be able to consent and complete the survey.
- Q:** Why are you excluding younger patients? **A:** They might be different in some way.
- Q:** Why not collect data from everyone, regardless of age and see if age really does make a difference. **A:** Could do that.

When there were no more questions, the PI and Nursing representative were excused and the Board deliberated in executive session. There was a motion to conditionally approve **Protocol 08-93**.

[Bashor moved, Alvarez seconded -- approved 6-0. Note -- Lee, Wade-Southard, and Newberry had departed. This protocol was reviewed after the Protocol 07-91 quarterly report described next, because Protocol 08-93 was added to the agenda at the last minute]

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

1. Store data in a secure location on campus. Describe how data and consent will be stored to preserve confidentiality.
2. Affirm that there will be no patient names or other personal identifiers on the surveys. Participant code numbers must be used. Explain how you will do this.
3. Specify clearly that this is a "baseline" measurement for diabetes education at this hospital. Provide a clear description of your role, distinguishing clearly between your responsibilities as a provider of services to the patients and as a researcher. Add variables to the post data collection yielding specific information with respect to what information about diabetes was provided to each patient -- orientation sessions, the kit, etc.
4. Eliminate your home phone number from the consent form.

C. Monitoring 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. No dramatic changes, but in 2010 all programs will have to re-apply. Confidentiality training has been tightened up. As before, all personnel at a new agency get trained initially, but now on the last Thursday of every month there is training for new people, and their training is logged. There has been good cooperation with this. A new CS&O web portal is up so that data are now entered directly at the agencies with nothing transported on disk anymore.

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

- Q:** Describe the security of this system. **A:** Crawford explained.

Crawford described for the Board a proposed "unattached modules" modification that had been discussed in e-mails with the IRB over the past several days. The purpose is to collect limited data from clients whose only contact with First 5 might be a single workshop, for example some kind of parent training or health education

presentation. These clients are probably not "in the system" in terms of broader data collection and having signed the global CS&O consent form. Clients could show up as having had services and outcomes data could be entered, for example pre/post knowledge about something. Such clients would be assigned a random identification code that is not linked to any personal identifiers, nor would it enable linkage to any other data they might have in the system.

- Q:** What if such client families got services on several occasions, at the same or different agencies? **A:** They would get a different random identification number each time and the data could not be linked. This is too bad in terms of research methodology, but it appears to be necessary.
- Q:** Would you be looking at outcomes or just performance data? **A:** This would include outcomes, such as pre/post measures around whatever service was provided.
- Q:** Isn't there indirect risk to participants of losing a service by releasing data that led to termination of that program? That should be stated in the consent form. **A:** There would also be potential benefits from improving a program based on results obtained from clients.
- Q:** Who gets these data? **A:** The CS&O evaluation data are sent to First 5 at the Kern County level and also to the state.
- Q:** Clients with data transmitted via the proposed unattached modules would have the random identification number, even if you know they are in the system? **A:** Yes. Again, this is almost painful from a research methodology perspective, but it seems like the most straight-forward way to do this, and is far better than at present when we get no data at all for such clients or have to do the full process of entering them into the system.
- Q:** Do any clients coming in for these one-shot services sign the global CS&O consent form? **A:** Don't think so. What we need to know from the Board is do we need consent at all, could it be the existing global consent , or should it be a narrower, shorter, simpler consent form?
- Q:** Could a new, specialized consent form just be used for those who are not in the system? **A:** The global consent form refers to some possibilities that are really not accurate for a family just receiving a single narrow service.
- C:** It looks like a brief, specific consent for all clients whose data will be included in an unattached module would be ideal.
- Q:** What about the issue that some persons are in the system and some aren't? **A:** All would get random identification numbers. Nothing would be tracked, so there would be no way of knowing who was in the system.
- C:** A Board member was concerned about several words in the Spanish translation of the global CS&O consent form.

When there were no more questions, Crawford was excused and the Board deliberated in executive session. There was a motion to: (a) **accept the quarterly report for Protocol 07-91**, (b) **authorize the modifications** proposed in the quarterly report, (c) **approve the use of unattached modules** as specified in e-mail communications of 10-08-08 and 10-09-08 between Crawford and the RERC, and (d) authorize use of data already collected via the unattached module procedure only for those client families for whom **consent for data release** could be obtained.

[Gilchrist moved, Wade-Southard seconded -- approved 8-0. Note -- Lee had departed. This report was reviewed prior to the review of Protocol 08-93.]

The elements of the above motion were described to Crawford when he returned.

VI. OTHER CONCERNS: [none]

VII. NEXT MEETING:

Friday, 30 January 2009 [please mark your calendars!]

VIII. ADJOURNMENT:

There being no further business, the meeting was adjourned at Noon.

[Bashor moved, McCleary seconded, approved 6-0]

IX. BOARD TRAINING DURING TEMPORARY MEETING ADJOURNMENT:

- A. Spanish Translations.** Several recent incidents suggest that this should be handled more carefully. Quite a few projects come through the IRB that involve consent, interview, or survey materials in Spanish because there are many Spanish speaking or Spanish literate persons in the Bakersfield area. The IRB asks that the PI accomplish the English-Spanish translation and then have an independent person conduct a Spanish-English "back translation" to verify the accuracy of the English-Spanish translation. Recently, the RERC, who knows no Spanish, authorized a protocol after having been provided with the Spanish documents and having been told that the proper back-translation process had been followed. Soon after authorization, the PI contacted the RERC to report that the Spanish materials were riddled with serious errors which need to be corrected. Also, a Board member has her own protocol in progress containing materials translated into Spanish, which she has shown to a colleague who is more proficient in Spanish and who shared the materials with a Spanish instructor at the university. Their judgment was what the translation was seriously deficient, including the possibility that persons literate in Spanish who read the materials would be offended.

What should we do? Possibilities including using a professional translating service, as is done by CS&O, or involving Spanish-literate faculty and advanced students at the university. These approaches would probably require fees for services. There was a consensus that consent forms should be the primary focus, because consent cannot be informed without an appropriately written consent form. Verbal consent could be an important back-up in cases of language issues, which could be structured along the lines of telephone consent, with consent elements listed and checked off as the conversation proceeds. Perhaps a standardized template could be constructed in Spanish and authorized for use, with PIs to plug in their own information as appropriate. Carlisle, a Board member, is a linguist and English/Spanish literate as is his wife, who has provided translation services in other settings. They could be of assistance. The RERC and Carlisle will explore. The RERC was charged with soliciting information from other IRBs on this problem.

Respectfully submitted

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and IRB/HSR Secretary