

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

**Minutes of Meeting
Friday, 06 October 2006
[Stockdale Room]**

Members Present:

Scientific Concerns: Marianne Abramson, Roseanna McCleary, Candace Meares
Nonscientific Concerns: Bob Carlisle, Paul Newberry
Community Concerns: Anne Marie Duquette

Members Absent:

Community Concerns: Carolyn Wade-Southard, Pat Mellon
Ex-Officio: David Cherin

Visitors:

Vykha Maldonado & Bruce Hartsell for Protocol 06-82
James Cazares for Protocol 06-87, Isabel Sumaya for Protocol 06-88
Jordan Rude for Protocol 06-89, Anne Duran for Protocols 06-87 & 06-89
Chris Flachmann, Psychology student

CALL TO ORDER:

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

PREVIOUS MINUTES:

Meares moved and McCleary seconded a motion to approve the minutes for the IRB/HSR meeting of Friday, 06 June 2006. The motion was approved 6-0.

ANNOUNCEMENTS:

A. Clarification of appointment termination dates. The appointment letters have had incorrect termination dates of the three-year terms for years. The correct termination dates are as follows:

Dec 2005: Carlisle, Wade-Southard
Dec 2006: Abramson, Newberry, Duquette, Mellon
Dec 2007: McCleary, Meares, Lee

All of the board members whose terms expire in 2005 or 2006 have requested re-appointment, except for Mellon, creating a vacancy to be filled by a new community member. Carlisle and Wade-Southard would be appointed to two-year terms to get the staggering of term expirations corrected. The RERC will be happy to recommend re-appointment of all of those seeking to continue, noting that the Provost could choose to appoint someone else.

B. The meeting schedule for 2006-2007 was announced:

8 a.m. Friday, October 6, 2006 [submission deadline Friday, September 22, noon]
8 a.m. Friday, January 26, 2007 [submission deadline Friday, January 12, noon]
8 a.m. Friday, April 20, 2007 [submission deadline Friday, April 6, noon]
8 a.m. Friday, June 8, 2007 [submission deadline Friday, May 25, noon]

OLD BUSINESS:

A. Further discussion of policy on retention of consent document adopted at previous meeting:

Any signed consent documents must be retained for at least three years to enable research compliance monitoring and in case of concerns by research participants. Consent forms may be stored longer at the discretion of the principal investigator [PI]. The PI is responsible for retaining consent forms. If the PI is a student, the faculty supervisor is responsible for the consent forms. The consent forms must be stored so that only the authorized investigators or representatives of the IRB have access. At the end of the retention period the consent forms must be destroyed [not re-cycled or thrown away]. Please destroy any audio tapes after scoring.

A faculty member had objected to being responsible for storing consent forms. The RERC proposed to store consent forms for faculty who object to keeping them themselves. Members accepted this by consensus.

NEW BUSINESS:

A. Formal Board affirmation of protocols previously approved under standard review, expedited review, and exemption from full review since the June 2006 meeting.

1. Standard Review [none] The standard review listed in the agenda was struck from the affirmation list because it has not yet achieved authorization.

2. Expedited Review [none]

3. Exempted from Full Review [17]

Number	Author	Title	Date	
			Submitted	Approved
06-08	Tracey Black	The Effects of Graphic Organizers on Kindergarten Students' Listening Comprehension	1/13/2006	6/06/06
06-39	Angela LeBeau	Effectiveness of Single-Sex and Coed Cooperative Learning groups on High School Science Achievement Scores	03-30-06	4/20/06
06-41	John Marble	A voice too long Silent" The story of Life for the Kern County Nisei in the 20th century	04-12-06	4/16/2006
06-60	Dianne Turner and Marla Iyasere	CAI Community Outreach Project and Starbucks CA Giving Project	05/26/06	6/16/2006
06-63	R. Steven Daniels	Educational Effectiveness at CSUB: The Second Round Policy-Delphi	06/05/06	6/7/2006
06-65	R. Steven Daniels	Leadership: The Impact of Personality, skills, and style on leader effectiveness	06/14/06	6/15/2006
06-67	Angelina Gardea	How Kern County Summer Bridge Teachers Evaluate the Program's Effectiveness	6/20/06	8/7/2006
06-68	Stacy Hill	A survey on the effects on television violence on Preschoolers	6/20/06	7/18/2006

06-69	Roberta Rasor Ambrosino	Faculty Development Programs Toward the Goal of Academic Accessibility	6/3/06	7/16/2006
06-70	Mercedes Kelsey and Juile Gast	The Relationship of Idealized Media Generated Images, Body Dissatisfaction and Exercise Level in a Sample of College Females	7/17/06	7/24/2006
06-71	Fernanda Ramirez	Understanding the Different Perceptions on Children with Incarcerated Mothers	7/25/06	8/21/2006
06-72	Dr. Terry Kurz	Interactive Course Analysis	7/28/06	8/2/2006
06-73	Elizabeth Lopez	Health Personnels' Attitudes Towards Medication Errors	7/31/06	7/31/2006
06-74	Francis Uwagie Ero	Connections Between Student Perceptions of Quality in Online Distance Education and Retention	8/9/06	8/9/2006
06-76	Roseanna McCleary	CalSWEC Aging Student Internship Pre-Post Evaluation	8/14/06	8/14/2006
06-77	Kathleen L. Gilchrist	CSUB Nursing Program Evaluation Project	8/16/06	8/22/2006
06-79	Dr. Nancy Bringman	Improving Academic Fitness	8/28/06	9/15/2006
06-80	Axelle P. Faughn	Relating proportional reasoning to achievement in trigonometry	9/8/06	9/21/2006
06-81	Brooke Hughes and Randi Brummett-De Leon	Investigating the Formatting of Prompts and Student Responses to Prompts	9/11/06	9/14/2006
06-84	Jacqueline Mimms	Foundations of Excellence in the First College Year	9/21/06	9/22/2006

Authorization date on 06-70 and title on 06-73 were corrected.

[Duquette moved, Abramson seconded, approved 6-0]

4. **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 2006 meeting. [2]

Number	Author	Title	Date Submitted	Date of Action
06-66	Mai Vang	The American and Hmong Friendship During and After the Indo-China War	06/16/06	6/29/2006
06-75	Jennifer Judd	The Effectiveness of a Web-Based Research Project to Support Knowledge, Acquisition, and Organizational Skills	8/10/06	8/10/2006

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

5. **Formal Board affirmation** of previously approved protocols granted **renewals**

since the June 2006 meeting. [7]

Number	Author	Title	Date	Date
			Submitted	Renewed
01-52	John Valdez	The Influence of Cyberspace, Society, and the Internet	sometime in 1998	6/1/2006
03-03*	Steve Bacon	Establishment of a participant pool for the Department of Psychology	1/17/2003	6/1/2006
04-117	Tanya Boone	Homophobia and Condom Use Among Heterosexual Men	9/15/2004	9/20/2006
04-131*	Scott M. Clare & the Garces H.S. AP psyc class	Social Issues in High School Sports	10/25/2004	6/16/2006
05-46	Debra Cook Hirai	Are We Closing the Gap for Reading Comprehension & Decoding for 9-12 Students	4/11/2005	9/20/2006
05-99*	Michael Harville and Beth Rienzi	Evaluation of Counseling Center Services	10/7/2005	9/12/2006
05-102	Debra Cook Hirai	CALLI (Content Academic Language Literacy Instruction)	10/24/2005	9/20/2006

* Renewed with modifications

[Meares moved, Abramson seconded, approved 6-0]

6. **Formal Board affirmation** of protocol **closures** (unless extension granted) whose authorization will end prior to the January 2007 IRB meeting. [33]

Number	Author	Title	Date
			Submitted
03-80	M. Farrell; M. Tyler Evans	Exploring and Developing a Nursing Department's Community of Interest: A Replication Study	11/25/03
04-05	Donna Luciano and Isabel Sumaya	Sleep Disturbances in Relation to Antipsychotic Treatment in Schizophrenic Patients	1/16/04
05-12	Gary Stephen Mojica	Teaching Spanish Reading Comparing/Contrasting Instruction	1/27/2005
05-38	Gail R. Nelson	Non-Traditional Female College Students: Great Expectations	3/17/2005
05-92	Terri Kurz	Video Case Analysis	9/27/2005
05-93	Kelly Maurice and Rosalinda Sparks	Cognitive Abilities and the Speaker	9/27/2005
05-103	R. Steven Daniels	Transformation Interrupted: The Renewal, Decline (and Rebirth?) of the Federal Emergency Management Agency	10/25/2005
05-104	John M. Glover	Analysis of the impact of the Valley Oasis Program on the Self-Esteem of its Clients	10/26/2005
05-105	Chatisee Fuqua	Life Satisfaction Among College Students	11/2/2005
05-106	Janelle Goh	The Experience of Foster Parents in Helping Foster Youth Be Successful in High School	11/7/2005

05-107	Konni Ollivier	The Correlation of Vision Skills and Reading Ability in One 4th Grade Classroom	11/28/2005
05-108	Stacy Sweeney	The Effects of Direct Writing Instruction Using Various Genres on Second Grade Students	11/28/2005
05-109	BreAnne Maltone	The effects of an incentive program on reading attitudes of fifth graders	12/1/2005
05-110	Terri Kurz	Family Math Night Rep Grids	12/5/2005
05-111	Kathy Gardner	Efficacy of oral reading fluency development on reading comprehension of middle school students	12/8/2005
05-112	Sandra Scott	The Effects of a Comprehensive Reading Program on the Reading Achievement of Struggling Seventh Grade Students	12/8/2005
05-113	Kate M. James	Using self-evaluation in a Kindergarten writing class	12/12/2005
06-01	Steven F. Bacon	Correlates of Support for Global Relief Efforts	1/3/2006
06-02	Shelley Getty	Cognitive Level of Student Learning in a Sketchpad environment	1/5/2006
06-03	Stacey Franciotti, Juan Avila, Angelita White	Recruiting Student Enrollment for the School of Education	1/6/2006
06-04	Kwaifa Kary Mack	Exploration of Pregnant Adolescent's Decisions in Labor Pain Management	1/6/2006
06-05	Tanya Boone	Sexuality Messages from Parents, Peers, Media, and School: Influences on Sexual Attitudes and Behaviors	1/11/2006
06-06	Katrina S. Rodzon	Stereotypes of Lesbians	1/12/2006
06-12	David Chenot	Organizational Culture and Retention in Public Child Welfare Services	1/18/2006
06-13	Huong Nguyeen	Chlamydia on Red Alert: A Program for the Prevention of Chlamydia in Kern County	1/20/2006
06-14	Chandrasekhar Commuri	Knowledge sharing in public-nonprofit organizational networks	1/23/2006
06-15	Leann Kraetsch	Quality Counts in Infant/Toddler Programs in Child Care Centers and Family Home Day Care	1/24/2006
06-17	Ying Zhong	Information Needs and Information Seeking Behavior of CSUB Students	1/26/2006
06-18	Brian W. Hawkins	How to build a new school	1/32/2006
06-20	Geri Mohler, Amy Carter, Deb Kasak, Leslie Raney	The Effect a Literacy Coach has on a Pre-School Classroom	2/7/2006
06-21	Axelle P. Faughn	Relating proportional reasoning to achievement in trigonometry	2/13/2006
06-22	R. Steven Daniels	The Knowledge, Skills, and Abilities (KSAs) of the CSUB Graduate	2/16/2006
06-23	Felipe Rocha	CAHSEE Preparation	2/16/2006

Protocols 05-46 and 05-102 were deleted from the closures because they had been renewed. Title was corrected on 05-108. [Abramson moved, Carlisle seconded, approved 6-0]

e. Protocol Renewals Requiring Re-Review [none]

f. Human Subjects Protection Training [HSPT] Certification Incident

E-mailed exams having identical correct/incorrect answers were received within a period of two minutes from four students during a scheduled class meeting of their course. The RERC interacted with the instructor by e-mail to clarify and express concerns, which were shared with the IRB Chair. Following review of information and discussion, board members were unanimous on the following points:

[1.] It is essential that the integrity of the HSPT certification process be guarded given this is how the CSUB IRB is able to pledge, to the subjects that we protect and to the "outside world," that persons doing human subjects research at CSUB have been adequately trained. The problem faced is twofold – how to deal with this specific incident and what steps to take to make this less likely to happen again.

[2.] Although the IRB will implement preventive measures, we do not believe that graduate students taking an exam that is individually scored for persons, and has an announced outcome based on person's scores, could possibly imagine that it is OK to work together and submit a single exam having different names.

[3.] Neither the instructor, who regularly supervises student research, nor the students in this class, understands the first two points. This incident would not have happened if the instructor had provided an appropriate introduction to research ethics and provided adequate supervision of the students as they worked on the HSPT tutorial. Apparently HSPT certification was presented as a time-limited task – allowing two hours of class time with sanctions for taking more time.

The IRB arrived at the following courses of action:

[1.] Online revisions will be carried out so that access to the HSPT tutorial will be via a page having instructions about taking the exam individually following agreement to those conditions. This page will include a presentation of the rationale for doing this.

[2.] An alert will be sent to all faculty whose names have appeared on IRB protocols in 2005 and 2006 informing them on the expectations of HSPT exams being submitted by individuals and the rationale for doing so.

[3.] A similar alert will be sent to each of the school deans indicating the concerns of the IRB and expectations that faculty provide appropriate orientations and supervision when leading their students into the HSPT certification process.

[4.] The IRB will not accept further HSPT exams from these students – the instructor's suggestion notwithstanding that the students could be asked to retake the exam. The RERC will refer the students to the NIH HSPT tutorial to obtain certification should they wish to pursue human subjects research at CSUB – HSPT certification being a federal requirement for conduct of human subjects research. This URL is <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

[5.] The reaction of the IRB to this incident will be communicated in writing to the instructor involved.

g. New Protocol Reviews: [4]

Number	Author	Title	Date	Primary Readers
06-88	Marianne Abramson, Isabel Sumaya, Melissa Dulcich	Effects of Bright Light Exposure on Alertness and Cognition	9/22/06	Meares, Carlisle, Duquette

Following introduction the PI summarized. This is an extension of Protocol 05-90 with modifications. The original protocol involves possible effects of light exposure on cognitive function. The primary modifications here are to assess changes in perceived alertness, compare morning and evening oriented persons, and restructure to have a within-S design which will make it easier to detect effects.

Q: What is the basis of the 05-90 protocol? **A:** We were looking at sleep diaries, light exposure, and cognitive performance as assessed by some cognitive tests.

Q: The MEQ is used to determine morningness and eveningness? **A:** Yes, and scores on this are correlated with some physiological measures. The MEQ will be scored in class and discussed in relation to circadian rhythms.

Q: This is set up as extra credit, due at the end of the quarter? **A:** Yes, and Isabel is not involved in the data collection.

Q: Are there risks of the light exposure, like a tanning booth? **A:** No, it's more like a sunny day outside on the beach. Subjects sit and read and can discontinue if they feel discomfort. We have seen no discomfort in our pilot study.

Q: What about people who are wearing light-sensitive lenses? **A:** Good catch – we will ask persons to remove lenses. We do need to ensure reasonable acuity in order to do the cognitive tests.

C: Something about alertness needs to be added to the first sentence of the consent form. **A:** A specific mention of alertness might bias the data.

When there were no more questions the investigators were excused and the IRB/HSR deliberated in executive session. There was a motion to conditionally approve Protocol 06-88 [Meares moved, Duquette seconded, 6 -0]. The conditions were:

1. Explain in the protocol how information will be kept confidential
2. Explain in the protocol how the element of "alertness" will be handled in instructions and the consent form.

Number	Author	Title	Date	Primary Readers
06-87	James Cazares	Affect and Cognition in Development of Attitudes Stemming from Political Ideology	9/22/06	McCleary, Carlisle, Wade-Southard

Both emotions and reasoning are involved in formation of attitudes related to political ideology. The hypothesis here is that reason will be more salient in processing information related to a congruent political view whereas emotion will be more salient in processing information related to an opposing political view.

Q: Is this individual or group data collection? **A:** It's individual, but there could be a couple of persons present at a time. They would be doing the tasks individually, though.

C: You need to add the number of subjects to the protocol.

- Q:** You mention persons from other classes besides Psyc 100 participating. How is that going to happen? **A:** Other people might sign up on their own, or just come by.
- Q:** How is deception involved in this study? **A:** Subjects are not informed about the hypothesis about cognitive vs. emotional factors.
- C:** Consent form should explain that they will be doing tasks and reading material.
- C:** Explain purpose more clearly in the protocol.
- Q:** What has been done and hasn't been done on this topic? **A:** Same thing has been explored with specific candidates, but not with ideology separated from candidates – it could be clearer this way.
- Q:** How do you decide who gets which scenario? **A:** That's random.
- C:** The data analysis needs to be explained.
- C:** KCMH isn't an appropriate referral source for persons upset about a research task.
- C:** Purpose needs to be communicated accurately in the consent form, rather than the purpose is to do what we ask you to do.
- Q:** How were the scenarios developed? **A:** The basic info came from online sites that take positions on these issues and then were modified for research purposes.

When there were no more questions the investigators were excused and the IRB/HSR deliberated in executive session. There was a motion to conditionally approve Protocol 06-87 [Duquette moved, Abramson seconded, 5 -0 – Carlisle had departed]. The conditions were:

1. Elaborate on the purpose with a systematic review of what is known relative to the specific hypothesis being tested and what this research has the potential to add.
2. Explain how the quantitative scale data will be analyzed with reference to the hypothesis.
3. Explain what you intend to do with the free response data. Is it qualitative or perhaps a content analysis leading to statistical analysis? This element is very weak.
4. State the number of participants to be studied.
5. Delete KCMH as a referral source for persons experiencing distress.
6. State the purpose in the consent form in a meaningful way.
7. Create a realistic statement of possible risks to participants in the consent form.

Number	Author	Title	Date	Primary Readers
06-82	Vykha Maldonado	Parent-training for Defiant Children	9/15/06	Abramson, Lee, Duquette

The purpose is to test an intervention package designed to reduce defiant behaviors in children. The participants are the parents who will attend special classes at Clinica Sierra Vista. The student is doing one of the first "graduate projects" in the MSW program intended to have the students carry out activities that connect them with the community.

- C:** These parents are socially and often economically disadvantaged.
- Q:** The intervention will be done as a class? **A:** Yes.

- Q:** Parents will be sharing experiences in the classroom? **A:** Yes.
- Q:** They will be encouraged to share their experiences? **A:** Yes, we will be discussing each of the steps as we go along and they are practiced at home.
- Q:** This intervention is a particular program? **A:** Yes.
- Q:** Is there existing research on this program? **A:** Yes, it has been evaluated previously.
- Q:** Is there something new about the review and feedback elements of the way you're doing this intervention? **A:** No, we're just testing the whole package overall – does it work – it's a program evaluation for Clinica Sierra Vista.
- Q:** How many families do you think you will need to study to evaluate the intervention? **A:** No more than 15 families.
- Q:** What data will be analyzed? **A:** The Form 4 scale will be given every three sessions and then after 30 days following conclusion for follow-up.
- C:** The time scale doesn't make sense on Form 4 and needs to be corrected.
- Q:** Form 6 also deals with family data – why isn't this one used? **A:** Just to keep things manageable.
- C:** There may be issues of test/retest reliability with those scales.
- Q:** How will you connect the pre/post and demographic data by families? **A:** We will use a code.
- C:** You need to specify how you will do the coding.
- Q:** Participants will be only English speaking? **A:** Yes, that's specified.
- Q:** You are using a focus group. How will you manage confidentiality? **A:** Protocol says they will be asked to preserve confidentiality, but we will add a form to be signed.
- C:** Consent form needs to be simplified and state about how much time will be involved.
- C:** Mandated reporting needs to be stated more clearly on consent form.
- C:** Address confidentiality procedures in detail on consent form.
- C:** Is there any inducement to families to participate? **A:** No.
- C:** Who does the diagnostics on the children? **A:** CSV staff.
- Q:** What happens to the children of non-participating families? **A:** They go into existing CSV interventions.

When there were no more questions the investigators were excused and the IRB/HSR deliberated in executive session. There was a motion to conditionally approve Protocol 06-82 [Duquette moved, Meares seconded, 5 -0]. The conditions were:

1. Clarify in the protocol that the purpose is to carry out an invited program evaluation.

2. Fix the time scale with reference to the child on Form 4.
3. Specify how the scale and demographic data will be coded by families.
4. Simplify the language on the consent form and state the time investment requested.
5. In the consent form, explain the confidentiality methods to be used including for the focus group and deal with mandated reporting requirements explicitly.
6. Add a confidentiality pledge to be used for members of the focus group.

Number	Author	Title	Date	Primary Readers
06-89	Jordan Rude	The Role of Negative Affect in Information Processing and Attitude Formation	9/22/06	McCleary, Newberry, Wade-Southard

This research deals with the role of negative emotions in forming attitudes about others and how information is processed about others. Fear versus anger will be compared using scenarios that are supposed to evoke each of these emotions, followed by filling out attitude scales. We predict less information processing in the fear condition as compared to the anger condition. Will attitudes differ in these conditions?

- Q:** How will you determine if they are experiencing fear or anger? **A:** The reasoning of the interpersonal threat theory has been used to create scenarios. Fear is associated with events that will occur, but anger is associated with events that have occurred.
- Q:** Ok, but how do you know if the emotion has occurred? **A:** We will do a pilot study to determine whether the persons experience fear or anger.
- Q:** And, in the pilot study, you will determine if a particular emotion is being determined in what way? **A:** The scenarios are constructed in order to induce the two emotions.
- Q:** Is there research on inducing emotions this way? **A:** Yes.
- Q:** You mentioned asking about empathy toward the character. Is empathy equivalent to fear?
A: [no response]
- Q:** So, how will you tell if the emotion has been induced? **A:** There will be several scales imbedded among other scales.
- C:** An explanation is needed stating what this will add to a systematic statement of what is known with respect to this hypothesized relationship.
- Q:** Is the fear/anger hypothesis about attitudes an original hypothesis – never tested? **A:** Yes.
- Q:** You mention extra credit assignments, but you are using the Psyc 100 subject pool. **A:** This is just in case I need to go to other classes which would need to have some alternative assignment for extra credit.
- Q:** You wouldn't be going to Anne's classes? **A:** No.
- C:** You state that there are no risks, but you need to acknowledge realistically the small risks or potential costs involved.
- C:** A few things need to be cleaned up on the consent form: stating the purpose in a meaningful way, noting they can refuse to participate, various clerical errors, and explaining how confidentiality will be achieved.

Q: How will this expand the knowledge of participants? **A:** They will learn about the research process. Also they will get copies of the results if they want.

When there were no more questions the investigators were excused and the IRB/HSR deliberated in executive session. There was a motion to specify the following course of action for Protocol 06-82 [Duquette moved, McCleary seconded, 5 -0]. This was:

1. Submit the planned pilot study via expedited review so the IRB can evaluate the efficacy of the manipulation of emotions.
2. Then, resubmit Protocol 06-89 via expedited review, incorporating what you have learned from the pilot study.
3. Use the following guidance in pursuing revisions:
 - a. Seek standard scales as state indices of fear and anger, having established reliability and validity.
 - b. Present a systematic review of what is known with respect to this hypothesis and what your research is designed to add.
 - c. Revise the consent form to: state the purpose more usefully, add that they can refuse to participate, clean up clerical errors, state how confidentiality will be achieved, and clarify the potential benefits to participants.

OTHER CONCERNS: There was a consensus that research was reaching the IRB without the rationale having been clearly worked out. It was suggested the purpose sections be circulated in advance of standard reviews in order to upgrade what we are asked to review.

NEXT MEETING:

8 a.m. Friday, January 26, 2007 [submission deadline Friday, January 12, noon]

ADJOURNMENT:

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

[Duquette moved, Mellon seconded, approved 5-0]

Respectfully submitted

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