

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

**Minutes of Meeting
Friday, 19 April 2002
OLD PUB in the RUNNER CAFE**

Members Present:

Scientific Concerns: Marianne Abramson,
Nonscientific Concerns: Jeanne Harrie, Paul Newberry, J.J. Wang
Community Issues: Ann Marie Duquette

Members Absent:

Kaye Bragg, Nancy Carr, Devin Depner, Peggy Leapley

Visitors Present:

Don Diboll for Protocol 02-18

CALL TO ORDER:

Chair Jeanne Harrie called the meeting to order at 8:12 AM.

PREVIOUS MINUTES:

Duquette moved, and Wang seconded, a motion to approve the minutes for the IRB/HSR meeting of 25 January 2002. The motion was approved unanimously.

OLD BUSINESS:

The agenda was re-ordered to consider policy/procedure revisions with training issues later in the meeting.

NEW BUSINESS:

Formal Board affirmation of protocols previously approved under standard, exempted, and expedited review since the September 2001 meeting.

Standard Review (approved conditionally at September 2001 meeting)

1. **Protocol 01-58:** "Interrater Reliability of a Scale of Functional Ability Ratings for Mental Health," Steven F. Bacon, Psychology Department on 30 January 2002. [Depner, Wang, Bragg]
2. **Protocol 02-03:** "The Effect of Video Training on Administration of Skinfold Test," Kris Grappendorf, Department of Physical Education & Kinesiology on 11 April 2002. [Carr, Harrie, Abramson]
3. **Protocol 02-04:** "Measures of Attitudes Toward Outgroup Members," Anne Duran, Psychology Department on 18 February 2002. [Duquette, Newberry, Bragg]

[Wang moved, Abramson seconded, unanimously approved]

Expedited Review

1. **Protocol 02-02** (Marianne Abramson, Psychology Department) "Relatedness Effects and Memory for Voice Attributes in Silent Reading" on 30 January 2002. [Harrie, Leapley]

[Duquette moved, Newberry seconded, unanimously approved]

Exempted

1. **Protocol 02-06** (Keala Cyrus-Strahan, Nursing Student) "Perceptions of School Nurses Managing Children with Insulin Pump Devices" on 07 February 2002.
2. **Protocol 02-07** (Jennifer Liz Emralino, Nursing Student) "Seeking Care for the Common Cold: A Survey of Patients' Knowledge and Beliefs" on 06 February 2002.
3. **Protocol 02-08** (Wayne Clausen, Public Policy and Administration Student) "YMCA Winter Basketball 2002 Program Evaluation" on 18 March 2002.
4. **Protocol 02-09** (Don Chu, CSU-Chico) "CSU Department Chair Survey" on 18 March 2002.
5. **Protocol 02-10** (David Lyman, Public Policy and Administration Student) "Re-Examination of the Use of Economic Development Incentives by California Cities" on 01 March 2002.
6. **Protocol 02-12** (Lovetta Reid, Public Policy and Administration Student) "An Exploration of the MBA/MPA Programs at CSUB: How Do the Curriculums Address Gender Issues?" on 15 March 2002.
7. **Protocol 02-13** (Cheryl Nelson, Public Policy and Administration Student) "Contract Oversight Implementation at the Taft Correctional Institution" on 15 March 2002.
8. **Protocol 02-14** (John Simmons, Public Policy and Administration Student) "A Look at Land Use Alternatives and Public Policy in the 21st Century and Beyond" on 19 March 2002.
9. **Protocol 02-15** (Lisa Jackson, Public Policy and Administration Student) "The Future of Faith-Based Initiatives" on 20 March 2002.
10. **Protocol 02-16** (Christopher Mausoff, Public Policy and Administration Department) "The Impact of Learning Style on Students' Experiences with Community Service Learning" on 19 March 2002.

[Newberry moved, Abramson seconded, unanimously approved]

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 September 2001 meeting.

1. **Protocol 02-11** (Doris Hall, Criminal Justice Department) "Six-Month Reflection for 9-11" on 12 March 2002.

[Duquette moved, Wang seconded, unanimously approved]

Formal Board affirmation of previously approved protocols granted **extensions** since the September 2001 meeting.

1. **Protocol 01-26** (Penelope Swanson, Advanced Education Department) "Online Courses, Face to Face Courses, and Blended Courses: Effective Methods and the Development of a Learning Community" on 15 March 2002.
2. **Protocol 01-27** (Penelope Swanson, Advanced Education Department) "Early Adopters of Technology in the Classroom: Are Steps to Technology Adoption Identifiable?" on 15 March 2002.
3. **Protocol 01-28** (Penelope Swanson, Advanced Education Department) "K-12 Teacher and Administrator Use of Palm OS Handheld Computers" on 15 March 2002.
4. **Protocol 97-34** (Ann Weed, Nursing Student) "The Impact of Nursing Intervention on Cholesterol Levels in an Employee Population" on 03 April 2002.

[Abramson moved, Duquette seconded, unanimously approved]

Formal Board action **closing** protocols (unless extension requested) whose authorization will end prior to the next IRB meeting.

1. **Protocol 01-04** (Luis Vega, Psychology Department) "Psychology 300 Research Projects" end of Spring Quarter 2002.
2. **Protocol 01-18** (Melissa Dulcich, Psychology Student) "Illusory Contour Perception at Primary Visual Cortex: Transient and Steady-State VEPs" end of Spring Quarter 2002.
3. **Protocol 01-19** (R. Steven Daniels, Public Policy and Administration Department) "Rationality, Bureaucracy, and Politics: Crisis Decisions During Hurricane Andrew" end of Spring Quarter 2002.
4. **Protocol 01-20** (R. Steven Daniels, Public Policy and Administration Department) "The Orchestration of Domestic Crises: The Dynamics of Presidential Decision-Making" end of Spring Quarter 2002.
5. **Protocol 01-21** (Ginny Randall, Social Work Department Student) "Mental Health Service Recipients' Views of Spirituality, Spiritual Interventions and Other Issues as Related to Their Recovery" end of Spring Quarter 2002.
6. **Protocol 01-22** (Ken Nyberg, Applied Research Center) "Evaluation for Kern County Children and Families Commission (KCCFC): Phase I Data Collection" end of Spring Quarter 2002.
7. **Protocol 01-30** (Clifton Taylor, Public Policy and Administration Student) "Educator Perceptions of Youth Violence and Preparedness Within Greater Bakersfield" end of Spring Quarter 2002.

[Wang moved, Newberry seconded, unanimously approved]

Protocol Reviews:

Protocol 02-18 [Attachment B]: "Cardiovascular and Metabolic Responses of Endurance-Trained Cyclists to Carbohydrate Consumption During Rest and Moderate-Intensity Exercise" with Don Diboll, Department of Physical Education & Kinesiology. Primary readers were Duquette, Leapley, and Wang. Principal Investigator interview scheduled from 8:30 - 9:00.

Following a round of introductions, Don Diboll summarized the proposed research.

This is a continuation of research previously reviewed by the IRB/HSR, but with several modifications. He will look at metabolic and cardiovascular effects of carbohydrate ingestion (GatorLode) in very fit, endurance-trained cyclists while they pedal (their own) stationary bike. Data involve cardiac monitoring, analysis of respiratory gases, and blood chemistry via a venous catheter to enable four blood draws in each of the two experimental sessions. Following a session in which maximum capacity is established, data will be collected at 65% of maximum capacity following ingestion of carbohydrates or water. A physician's assistant will do the catheter insertion. Emergency procedure is CPR and 911.

Q: How easy is it to stop the bike? **A:** Everything stops when the rider stops pedaling.

Q: What about the gender of the participants? **A:** Participants will be all males to avoid potential confounding with physiological variables and because of convenience of recruiting.

Q: Are there vulnerable subjects involved? **A:** The participants are mainly not CSUB students or employees.

Q: Wouldn't it be a good idea to assess health status prior to each session. **A:** O.K.

Q: What is the time span over which the necessary sessions for a participant would be conducted **A:** Generally two or three weeks.

Q: How will you deal with a health emergency? **A:** Unlikely because the participants do this sort of thing routinely, but CPR is first intervention, and then 911. CPR certification will be current.

Q: On confidentiality, how many persons know who the participants are? **A:** The three additional people in the room know--myself, the Physician's Assistant, and a student research assistant. They will be trained in confidentiality guidelines.

Q: Would participants be compensated for injuries or is there some statement to project you and CSUB from liability? **A:** Open to suggestions and will place a waiver statement in the consent form.

Q: What is GatorLode **A:** It's like Gatorade, but higher in carbohydrates. It's used primarily for carbohydrate "loading" prior to competition and for recovery afterward.

The investigator was excused and **conditions of approval** were agreed upon. These were:

1. Modify the protocol to state that a person with *current* CPR certification will be present at each session involving exercise.
2. Modify the protocol to state that the health survey will be administered prior to each session involving exercise.
3. Add to the consent form a waiver of injury liability.

There was a motion for **conditional approval of Protocol 02-18**.

[Wang moved, Duquette seconded, unanimously approved]

OTHER CONCERNS:

Federal Requirements for Training Human Subjects Investigators. This came up in the Fall/01 audit report. We have agreed to have a training program in place by Fall/02. At present only personnel associated with NIH funding are required, but it is now common for universities to have a training program. The RERC will find out if there are mandated essential elements of such a program. It was suggested that, if possible, we use existing online training programs and limit the training requirement to investigators associated with protocols requiring standard or expedited review. All personnel interacting with subjects must be trained according to the NIH directive, so we would need to explore how to train student research assistants. We would need to keep track of certifications somehow.

Training of IRB/HSR Board Members. The CSUB IRB/HSR document requires an overview training session on protection of human subjects in the Fall and special topic sessions in Winter and Spring. We will add a training segment at the end of the Fall IRB/HSR meeting.

Revision of CSUB IRB/HSR Policy/Procedure Document. It was agreed that an updated, abbreviated version of the present document should become part of the CSUB Handbook. The Chair will coordinate with the committee working on CSUB Handbook revisions.

A subcommittee, made up of Harrie, Newberry, Leapley, and Suter will work on: (a) Investigator training, (b) IRB/HSR member training, and (c) drafting Handbook language for IRB/HSR.

NEXT MEETING:

The next meeting will be Friday, 14 June 2002 - Stockdale Room ("Old Pub")
7:30 breakfast, 8:00 meeting

ADJOURNMENT:

There being no further business, the meeting was adjourned at 9:35 AM.

[Duquette moved, Wang seconded, unanimously approved]

Respectfully submitted

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