

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

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**Minutes of Meeting  
Friday, 13 April 2001  
Old Pub/Runner Café**

**Members Present:**

Scientific Concerns: Kaye Bragg, Peggy Leapley, Dick Noel  
Nonscientific Concerns: Jeanne Harrie, Paul Newberry, Eun-Ja Park  
Community Issues: Nancy Carr, Devin Depner, Ann Marie Duquette

**Members Absent:**

none

**Visitors Present:**

Luis Vega for Protocol 01-04  
Jess Deegan and Sharyn Eveland for Protocol 01-11  
David Ost, Acting Dean of Graduate Studies and Research

1. Chair Jeanne Harrie called the meeting to order at 7:58 AM.

Four **new IRB/HSR members were introduced and welcomed** to the Board: Devin Depner (Community Concerns), Ann Marie Duquette (Community Concerns), Dick Noel (Scientific Concerns), and Paul Newberry (Nonscientific Concerns).

2. Carr moved, and Park seconded, a motion to **approve the minutes** for the IRB/HSR meeting of 22 September 2000. The motion was approved unanimously, with 9 “aye,” 0 “nay,” and 0 “abstentions.”
3. The Board **formally affirmed the following actions** taken between the September 2000 and April 2001 meetings of the IRB/HSR:

Standard Reviews (approved conditionally at the September 2000 meeting):

Protocols 00-40 and 00-41

Carr moved, Leapley seconded, unanimously approved

Expedited Reviews (since the September 2000 meeting):

Protocols 00-39 and 01-03

Park moved, Leapley seconded, unanimously approved

Exemptions (since the September 2000 meeting):

Protocols 00-43, 00-45, 00-46, 00-47, 00-48, 01-01, 01-05, 01-08, 01-09, and 01-10

Leapley moved, Carr seconded, unanimously approved

Extensions (since the September 2000 meeting):

Protocols 97-34, 99-14, 00-24, 00-34, 00-35, and 00-37

Duquette moved, Carr seconded, unanimously approved

Closures (protocols whose authorization will end prior to the next IRB/HSR meeting)

Protocols 00-09, 00-15, 00-22, and 00-32

Bragg moved, Park seconded, unanimously approved

4. **[Standard Review] Protocol 01-04, "Psychology 300 Research Projects"** with Dr. Luis Vega (Department of Psychology). Dr. Vega explained that the protocol covers research projects that will be conducted in a course required of psychology majors, dealing with how to do research. Board approval is sought because some of the projects are presented externally, so that the activities involved formally constitute research. No deception will be involved; all of the investigations will be survey-type research, which ordinarily is considered exempted from IRB/HSR review. Several examples were given. Dr. Vega also distributed an addendum seeking to include similar activities for Psychology 312-Lab (Social Psychology Lab). A dialog followed:

Q: Does Vega approve the content of surveys? A: Yes.

Q: Can subjects not participate? A: Yes

Q: About how many projects are there per course? A: Four or five

Q: Students create consent forms and Vega approves? A: Yes

Q: Are the students adults? A: Yes

Q: How is confidentiality maintained? A: Unmarked surveys are put in an envelope

Q: Do students have to do research? A: Yes, but it has not come up.

When there were no more questions, the investigator was excused. A discussion followed in which it was debated whether: (a) the protocol actually constituted exempted activities, (b) there should closer IRB/HSR oversight, or (c) the "generic pre-approval" sought was appropriate. It was decided to attach the following conditions to approval:

- a. Alter the consent form so that Steve Suter is listed as the contact for participants who have concerns about their treatment as research subjects.
- b. Prior to the conduct of each specific research project covered by this protocol, the procedures and materials, including consent form and survey content, should be submitted to Steve Suter for review in order to verify that the project falls within the "Exempt Status" category as proposed in the overall protocol.

Noel moved, Carr seconded conditional approval, approved unanimously.

5. **[Standard Review] Protocol 01-11, "Sex, Sexual Orientation, and Gender Identity: Do These Impact Cognitive Task Battery Results?"** with Dr. Jess Deegan and Sharyn Eveland (Department of Psychology). Ms. Eveland explained that this research is based on studies indicating gender differences in performance of certain cognitive tasks. The major question here is whether differences in sexual orientation might mirror the established gender differences. The general procedures, including the sorts of test to be used were summarized. Ms. Eveland and Dr. Deegan answered questions from the Board:

Q: How will confidentiality the sexually-related info be preserved A: Shredding

Q: Who will have access to the records? A: The three researchers

Q: How will participants be recruited? A: Newspapers, listservs, networking

Q: About how many participants will be involved? A: On the order of 50 per group

Q: Is any possible distress anticipated? A: No, unless a breath of confidentiality

Q: Will participants get feedback about their relative performance on "male" vs. "female" oriented tests? A: No

Q: Do students have to do research? A: Yes, but it has not come up.

When there were no additional questions regarding the protocol, the investigators were excused. Following more discussion, it was decided to attach the following conditions to approval:

- a. Alter the consent form so that Steve Suter is listed as the contact for participants who have concerns about their treatment as research subjects.
- b. Add a forewarning statement to the consent form if questions about steroid use and reproductive status are to be asked.
- c. Clarify the wording about withdrawal of participation in the consent form.
- d. Make consistent the wording about the 90-minute duration of participation in the consent form.
- e. State that only the researchers will have access to the master list in the locked file.

Noel moved, Carr seconded conditional approval, approved unanimously.

6. **Insuring the purview of the IRB/HSR**

There was discussion of the following wording proposed to be added at the bottom of the periodic call for submissions:

The CSUB definition of research with human subjects is from *The Code of Federal Regulations: Title 45, Public Welfare, Part 46, Protection of Human Subjects*, which has been adopted in the CSUB Policy for the Protection of Human Subjects in Research:

"Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" [p. 5, CSUB policy].

Activities such as making behavioral observations of humans in a natural setting, having persons fill out surveys, collecting data to compare effectiveness of several teaching methods, or studying patient records would qualify as research if the activities are designed to lead to "generalizable knowledge." It does not matter whether the investigators are faculty or students. The IRB/HSR assumes that the intent is to contribute to "generalizable knowledge" if the results are presented in any forum, including meetings or publications, external to this institution. Thus, the criteria used to determine if an activity is research involve both the nature of that activity and the purpose of that activity.

Duquette moved, Noel seconded, unanimously approved.

There was a brief ensuing discussion about possible avenues of "outreach" that might be pursued in order to further insure the purview the IRB/HSR. These included possible presentations at department/school faculty meetings and workshops for interested faculty. Further discussion was suggested for the June 2001 meeting.

7. The next meeting will be Friday, 08 June 2001.
8. There being no further business, Chair Jeanne Harrie adjourned the meeting at 10:30 AM. Duquette moved, Leapley seconded, unanimously approved.

Respectfully submitted

Steve Suter, Ph.D.  
Professor of Psychology

and IRB/HSR Secretary