

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

**Minutes of Meeting
Friday, 08 June 2001
Blue Room, Student Activities Center**

Members Present:

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

Members Absent:

Kaye Bragg, Nancy Carr

Visitors Present:

Ginny Randall for Protocol 01-21
Ken Nyberg and Edwin Sasaki for Protocol 01-22
David Ost, Ephemeral Acting Dean of Graduate Studies and Research

1. Chair Jeanne Harrie called the meeting to order at 8:03 AM.
2. Announcements: David Ost is leaving as Ephemeral Acting Dean of GS&R to be replaced by Janice Chavez as Interim Dean of GS&R.
3. Duquette moved, and Leapley seconded, a motion to **approve the minutes** for the IRB/HSR meeting of 13 April 2001. The motion was approved unanimously, with 7 "aye," 0 "nay," and 0 "abstentions."
4. Old Business: The Research Ethics Review Coordinator reported on the status of the **IRB/HSR outreach program**. He forgot to include the new wording at the bottom of the call for protocols this time, but would try to remember next time. He has: (a) prepared a document that provides a brief overview of IRB/HSR function, (b) visited a class in the Master's in Social Work program, (c) attended a meeting of the School of Education, (d) and begun coordination to meet with new faculty at the beginning of the new academic year in September 2001. The Board members provided suggestions for revising the overview document.
5. The Board **formally affirmed the following actions** taken between the April 2001 and June 2001 meetings of the IRB/HSR:

Standard Reviews (approved conditionally at the April 2001 meeting):

Protocol 01-04

Depner moved, Park seconded, unanimously approved

Protocol 01-11

Duquette moved, Depner seconded, unanimously approved

Expedited Reviews (since the April 2001 meeting):

Protocols 01-07, 01-16, and 01-18

Leapley moved, Park seconded, unanimously approved

Exemptions (since the April 2001 meeting):

Protocols 01-14, 01-15, 01-17, 01-19, and 01-20

Depner moved, Park seconded, unanimously approved

Extensions (since the April 2001 meeting):

[none]

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

Protocols 00-006, 00-46, and 00-47

Park moved, Duquette seconded, unanimously approved

6. **[Standard Review] Protocol 01-21** "Mental Health Service Recipients' Views of Spirituality, Spiritual Interventions, and Other Issues as Related to their Recovery" with Ginny Randall (Social Work). Leapley was substituted for Carr as one of the primary reviewers. Ms. Randall explained that the research is a survey of the services that recipients consider important for their recovery, based on a previous survey used in a doctoral dissertation. The investigator has added questions addressing spirituality, the focus of her project. She provided an overview of the methodology, including procedures for subject recruitment and maintenance of confidentiality. A dialog followed:

Q: Does the Consumer Group get both consent and survey forms? A: Yes.

Q: There is never any identification by name? A: Right, never.

Q: Will subjects really be able to answer the questions and provide consent? A: Adequate mental status is suggested by previous research, her own experience, and legal definitions and procedures having to do with the mentally ill. Persons under conservatorship would be excluded.

Q: Can subjects withdraw and howso? A: Yes and will clarify procedures in consent.

Q: Can the confidentiality of the community mode of distribution be made more solid?
A: The box could be sealed and distribution could be at a meeting.

Q: The reliability and validity of the survey was questioned. A: Data were provided from her thesis proposal.

Q: There is a typo on the survey. A: Thanks.

Q: Will the participants understand what is meant by "spirituality?" A: Will add clarification.

Q: There doesn't seem to be enough emphasis in consent form about voluntariness and ability to withdraw. A: Will clarify.

When there were no more questions, the investigator was excused. A discussion followed in which the concerns of the Board expressed during the question period were reviewed. It was decided to attach the following conditions to approval:

- a. Revise the protocol to specify methods to exclude those under conservatorship or experiencing a psychiatric crisis.
- b. Revise the protocol to include detailed instructions and an orientation session for those persons functioning as recruiters in order to ensure voluntariness of participation and preservation of confidentiality.

- c. Revise the protocol to specify use of separate sealed envelopes for the consent form and survey which are placed by the participant in separate sealed boxes.
- d. Revise the consent form to clarify and further emphasize voluntariness of participation, that the participant may withdraw, and the procedures for withdrawal from the study.

Depner moved, Leapley seconded conditional approval, approved unanimously.

7. **[Standard Review] Protocol 01-22, "Evaluation for Kern County Children and Families Commission (KCCFC): Phase I Data Collection"** with Dr. Ken Nyberg and Dr. Edwin Sasaki (Applied Research Center). Dr. Sasaki explained that ARC had received a grant to evaluate various agencies that provide services to children in the Bakersfield area. This is Phase 1 of data collection which will involve "process evaluation" and "outcome evaluation" all of which will be based on existing sources of information, including case management files. Some of the data will be provided via a contracted third party agency which will put the data into a common format across agencies. The data to be collected in Phase 2 will be partly determined by results of Phase 1, but are anticipated to include new data provided by recipients of services. A separate Phase 2 protocol will be submitted to the IRB/HSR. Drs. Nyberg and Sasaki answered questions

Q: Who is at risk and in what way? A: The children are at low risk via breaches of confidentiality.

Q: How will the organizational data be handled? A: Also confidentially. [The standard operating procedure for data handling at ARC was then summarized by the investigators.]

Q: The data will be analyzed by agency? A: Yes, will be able to identify all agencies that have had contact with a child.

Q: What are the possible uses of the data? A: To provide information to the agencies and for possible publication.

When there were no additional questions regarding the protocol, the investigators were excused. It was decided to grant full approval.

Park moved, Depner seconded approval, approved with 6 "aye," 0 "nay," and 1 "abstention" due to one of the Board members working with several of the agencies involved.

8. There was a brief discussion of concerns about clearly defining research that falls within Board purview in some disciplines, such as Public Administration, and of possible additional outreach efforts to ensure compliance with IRB/HSR regulations. The following were suggested:

(a) Faculty who have submitted protocols might be surveyed to identify areas of the submission process needing improvement.

(b) Example protocols and consent forms could be routinely made available, perhaps placed on reserve in the library.

(c) In the fall the Board should urge those disciplines in which human subjects research is

carried out to include coverage of IRB/HSR review procedures in appropriate undergraduate and graduate courses.

9. The next meeting will be Friday, 21 September, 2001.
10. There being no further business, Chair Jeanne Harrie adjourned the meeting at 10:10 AM. Duquette moved, Leapley seconded, unanimously approved.

Respectfully submitted

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