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

Minutes of Special Meeting [revised 1-28-05]
Friday, 15 October 2004
DDH B-108

Members Present:
Scientific Concerns: Kaye Bragg, Rose Anna McCleary, Candace Meares
Nonscientific Concerns: Paul Newberry, J.J. Wang
Community Concerns: Ann Marie Duquette, Pat Mellon, Carolyn Wade-Southard

Members Absent:
Scientific Concerns: Marianne Abramson, Peggy Leapley
Nonscientific Concerns: Emerson Case, Yeunjoo Lee
Administrative Oversight: Edwin Sasaki

Visitors:
Gwendolyn Morris and Robert Mejia for Protocol 04-123 Second Review
Brent Egemo and Candace Meares for Protocol 02-127 Review

CALL TO ORDER:

Chair Paul Newberry called the meeting to order at 9:30 AM.

The only business conducted was review of 04-123 and 04-127.

REVIEW OF PROTOCOLS

Protocol 04-127. "Support Groups and Coping Behaviors in Women with Breast Cancer" with Brent Egemo & Candace Meares.

Following a round of introductions, Egemo summarized the proposal. He works at an oncology clinic in Lancaster that has support groups for patients undergoing treatment for breast cancer. His informal observations suggest that the program is effective. He wants to collect more systematic data about effects of support groups on coping by comparing responses to a questionnaire for women who are and are not in support groups across the early stages of treatment.

Q: Why are you excluding persons from participation who attend church regularly? A: This might confuse coping afforded by the support group with that provided by the church.

Q: So, you are trying to find patients without other support, beyond the actual support groups? A: Basically, yes. The church exclusion is used only for participation in the control group so that potential participants would not lose out on the support groups if they happen to attend church regularly, so the exclusion would not seem to increase vulnerability.

Q: Is the role of religion something that you might look at in a later study? A: Yes.

Q: How will you first contact the participants? A: Patients are sent to Egemo following the initial visit to the oncologist and he would bring up the study at this time when the availability of support groups is first mentioned.

Q: Do you have any concerns about any perceived pressure that might compromise a free, voluntary decision to participate or not? A: Steps will be taken in discussion and in the consent form to minimize that.

Q: When will the first [pre-] questionnaire be filled out? A: At the first chemotherapy visit.

Q: How long will prospective participants have to decide after you have raised the possibility of participation in your research? A: It is about three weeks from the first oncology office visit to the beginning of chemotherapy.

Q: This is basically a pre/post design using the same questionnaire, correct? A: Yes, we want to see if there are differences depending on whether patients are in the support groups.

Q: How many persons are ordinarily in the support groups? A: There are about 20 at any one meeting, although more persons are enrolled in the support group program at any one time.

Q: What approximate numbers of participants are you seeking? A: The target is 30 per condition over the six-month data collection period.

Q: When does support group participation start? A: Right after the first chemotherapy treatment.

Q: Is the support group run on an “open group” basis? A: Yes participations can come and go from meeting to meeting.

Q: What kind of license does the social worker have? A: The social worker is an LCSW.

Q: The participants seem extremely vulnerable right after they have been diagnosed and are entering into treatment. You need to be extremely sensitive about the exclusion based on church attendance. A: [Discussion followed during which it was agreed that it would be best not to apply the religious exclusion to participation, but to possible use of the data later, so all would fill out the questionnaires.]

Q: How will data security be accomplished at the facility? You might need more secure data storage. A: Several other nurses, and security personnel, have access to the room. The data could be kept in a secure lock box.

Q: What is meant by added the data to a “database?” Will this be like an computer file? A: Yes and it could be password protection.

Q: How long will you keep the data and when will it be destroyed? A: The data and identifiers will be destroyed after the data have been analyzed.

Q: The patient identifier numbers that are mentioned are numbers assigned by you and not social security numbers? A: Yes.

Q: There doesn’t seem to be a statement on the consent form that non-participation will not affect receiving treatments or services. A: I will add that.

Q: Will the participants fill out the questionnaire at the clinic? A: Yes, this will be done in an area that provides privacy.

Q: Why do you ask about address changes? A: This is in connection with obtaining information about why a participant might have dropped out.

Q: You have an inclusion factor that refers to having attended all of the weekly meetings. Do you really want to do that? A: Rather than 100% attendance it would be more practical to include persons who attended "regularly."

Q: The phone number that you provide on the consent form is what? A: This is my work number at the clinic.

Q: We need to look at the potential benefits in deciding about approval. Do you expect the subjects, themselves, to get anything out of this? A: The support groups are not a benefit of the research, because they are already offered as a service of the clinic.

Q: What new knowledge do you expect to come from this? A: Most of the earlier research has looked at benefits of support groups in terms of medical outcomes. This research will look primarily at coping mechanisms.

When there were no further questions, the investigators were excused from the room and further discussion followed in executive session. There was a motion to conditionally approve **Protocol 04-127** [Duquette moved, Mellon seconded, approved unanimously].

The conditions of approval were as follows:

1. Indicate in your protocol that the data will be kept in a secure lock box and state this in the consent form.

2. Indicate in your protocol when the data will be destroyed and state this in the consent form.

3. In the consent form:

    a. State that non-participation will not affect treatments or services that are provided.

    b. Substitute a more effective word for "aggregate" and edit the wording referring to subjects who "are selected" to participate.

Protocol 04-123. "Do Mentoring Programs for Children of Incarcerated Parents Benefit the Children and Their Families" with Gwendolyn M. Morris & Gigi Nordquist, MSW. Second Review, originally reviewed at the 08 October 2004 meeting.

In the absence of Gigi Nordquist, Robert Mejia [MSW Program] attended with Morris. Following a round of introductions, Morris clarified several elements of her revised materials submitted on 13 October 2004 and e-mailed to the IRB members. In particular, she noted that her research design involves three different mentoring programs, at each of which there will be three focus groups made up of parents, mentors, and adult children of incarcerated parents. Thus, there will be nine focus groups.

Q: You will be testing your research questions using exclusively subjective data? A: Correct.

Q: You are getting self-ratings of variables such as anxiety and self-destructiveness, all of which can be strongly influenced by many other variables? A: These questions ask the participants to reflect back with respect to status on these variables at an earlier period.

Q: For your Question #6, how old will the adult children be? A: They will need to be 18 years of age and out of high school.

Q: You note in your responses to IRB concerns that research on these questions has not yet been done in Kern County specifically. Will you be looking at program evaluation data that exist for the PAL program? A: No, we're not looking at that.

When there were no further questions, the investigators were excused from the room and further discussion followed in executive session. There was a motion to conditionally approve **Protocol 04-123** [Bragg moved, Duquette seconded, approved unanimously].

The condition of approval was as follows:

1. Describe a referral procedure to be used if events occur during the focus groups that would require such action.

ADJOURNMENT:

There being no further business, the meeting was adjourned at 11:00 AM.

[Wang, Mellon seconded, approved unanimously]

Respectfully submitted

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