

MINUTES OF THE BREAST CANCER RESEARCH COUNCIL MEETING

February 6, 1995, 10:00 A.M.

Kaiser Center, Oakland

Council Members Present: Lisa Bailey, Christopher Benz, Leah Cartabruno, Susan Claymon, William Comer, Jacquolyn Duerr, Patricia Ganz, Adeline Johnson Hackett, Deborah Johnson, Liana Lianov, John Link, Edith Perez, Susan Shinagawa, Barnarese Wheatley

Council Members Absent: Andrea Martin
Mary-Claire King

Staff Present: Renee Drellishak, Charles L. Gruder, Annette McCoubrey, Walter Price

Public Present: Barry Hirschowitz

Amendment and Approval of Minutes of the Last Meeting

Coverage of indirect costs (page 6, paragraph 3) was clarified and the minutes were approved.

Overview of Meeting Agenda

Dr. Gruder previewed the agenda for the meeting, which included:

Peer review process, Cycle 1

Research priorities, Cycle 2

Research infrastructure

First Grant Cycle LOIs

Dr. Gruder distributed a list of the LOIs and asked Council members for their thoughts regarding the best way to organize them into groups and to select peer reviewers for the applications. A Council member asked about the representation of various institutions and organizations among the invited LOIs; Dr. Gruder explained that, on the Council's advice, investigators were not asked to identify the applicant institution, if any, or to describe the resources and environment available for conducting the research. The Council wanted to judge LOI applicants' ideas on their own merit, independently of whether the applicant was affiliated with a research institution. Most applications were traceable, however, through their return addresses. The Council members asked staff to determine the institutional affiliation of as many of the invited LOI applicants as possible and provide this information to the members.

A member asked how many of the LOIs represent underserved populations and minority groups. She noted that the mandate for the Breast Cancer Research Program specifically states that research must be accessible and have an impact on underserved populations. Dr. Gruder said that the Call for LOIs and Screening Committee Manual spelled out four criteria that the Council planned to use in making funding recommendations: 1) increase access to underserved populations; 2) translational; 3) multidisciplinary; and 4) innovativeness. Staff agreed to report on the number of LOIs that directly addressed underserved and minority groups, but that it would take some time to determine.

Council Chair Claymon commended the Council for being rationally focused. Unfortunately, several applicants who were not invited to submit full applications have protested the process and outcome. One person alleged that there were improprieties regarding the evaluation of some LOIs, though this person provided no evidence. Several Council members who participated as members of screening committees stated that they saw no evidence of improprieties in their meetings, and in fact thought that the process worked well. The Chair felt that the Council members had been less involved in the process of forming the screening committees than she would have preferred. It was noted that staff adhered to the selection process approved at the previous Council meeting, as reflected in the minutes. Staff solicited the names of potential reviewers from many sources, including Council members. Staff first contacted nominees to determine their interest and availability and to obtain their CVs to determine whether they met the criteria for screening committee membership. Staff sought reviewers who had broad research and evaluation experience in relevant areas. They selected as committee chairs investigators with leadership experience, as well.

The Council discussed options for addressing complaints. A suggestion was made to form a subcommittee to investigate complaints and to evaluate the screening process and make recommendations for changes in the next grant cycle. The Council agreed that such an investigation would be prudent.

Former Council member Barry Hirschowitz, who was present, alleged that the staff had behaved improperly in the processing and evaluation of LOIs, namely, that they had not followed the published procedure. When asked, he neither provided evidence to support these allegations nor revealed the source of his information that there were improprieties. It was noted that Mr. Hirschowitz had resigned from the Council due to a conflict of interest, namely, his company was a major subcontractor on an LOI.

Dr. Gruder and the staff denied these allegations and stated that the published procedure had in fact been followed. He outlined the steps in LOI processing and noted that BCRP retained all original material, including reviewers' comments and staff notes.

After discussion, Dr. Hopper recommended that the Council form a subcommittee to address Mr. Hirschowitz's and other complaints and asked whether the Council felt comfortable proceeding with the application process. The Council decided to appoint a subcommittee and to continue the application process. The Council voted against instituting an appeals process at this time.

Of 490 LOIs received, 58% were invited to submit full applications. Review committee rosters will be released to the public after the grants are awarded.

Recognition of Dr. Perez

During lunch, Dr. Gruder thanked departing Council member Edith Perez for her contributions to the Breast Cancer Research Council and presented her with a framed certificate.

Although Barry Hirschowitz's contributions as a Council member were also going to be acknowledged at this meeting, he asked that they not be recognized.

State Breast and Cervical Cancer Control Program

Dr. Lianov presented a draft of the statewide plan for breast and cervical cancer control and asked that the Council provide her with any comments. She also said that the state task force would be glad to have current Council members. She reported that the Department of Health Services= (DHS) Breast and Cervical Cancer Advisory Council recommends to the Breast Cancer Research Council that priority be given in funding research to underserved and understudied women. Dr. Gruder asked whether any of the listed activities be jointly done between the DHS and BCRP. Two possible areas of cooperation were noted: 1) research infrastructure, including database maintenance; 2) demonstration projects.

Peer Review of Invited Applications

Dr. Gruder opened discussion of peer review of the invited applications and asked the Council whether the review committees should include advocates, as suggested at a previous meeting. He outlined the application review process. The applications are organized into coherent sets of 20 to 35 each. Peer review committees, known as study sections, are formed for each set of applications. Reviewers will first determine whether the research aims proposed in the applications match the aims approved in the LOIs; reviewers will receive copies of the LOIs, along with the full applications. In some instances, LOI screening committees approved only some of the research aims proposed in an LOI. Next, primary, secondary and tertiary reviewers will evaluate each application for scientific merit and all study section members will assign scores for scientific merit, using the rating scale used by the National Institutes of Health (NIH). Primary, secondary, and tertiary reviewers will each evaluate between 8 and 12 applications. The primary and secondary reviewers will also analyze and make recommendations regarding the requested budget and the four additional evaluative criteria (i.e., innovativeness, underserved, translational, and multidisciplinary). The study section chair does not prepare written reviews, but does read all applications assigned to his or her study section.

The study sections= evaluations will be given to the Council for deliberation at the next scheduled meeting. The Council, in turn, will make the final recommendations to Dr. Hopper as to the grants that should be funded. The University of California will make the funding decisions.

In response to a question, it was noted that BCRP is not bound by any prior commitments to fund particular percentages or numbers of grants. For example, if all sabbatical applications are judged to lack sufficient quality, none will be funded.

The Council discussed its preferences for the application review process and reached consensus on the following three points:

- 1) Investigators from for-profit industry should serve on study sections;
- 2) One advocate should serve on each study section; this member will receive all

applications assigned to the study section and will have a vote, but will not be assigned to evaluate applications for scientific merit;

- 3) Study sections will assign scores on the Council's priority issues (i.e., the extent to which the proposed project is innovative, translational, multidisciplinary, and focuses on underserved populations). The Council will use these scores in arriving at its funding recommendations.

Second Grant Cycle

The Council had previously endorsed the following schedule for the second grant cycle:

March 1, 1995:	Issue Call for LOIs
June 1, 1995:	LOIs due
Aug. 1, 1995:	Applications due

The Council decided to delay the second funding cycle until they evaluate the application process used in the first cycle. That will give rejected applicants an opportunity to respond to the reviewers' critiques and to resubmit in the second cycle. It will also provide the opportunity for BCRP to promote particular priority areas of research in which few applications are received in the first cycle.

Research Infrastructure

Dr. Gruder stressed the need to find out what infrastructure is already being funded by NCI, the Army, etc. so that BCRP does not duplicate infrastructure that is already being created.

Council Replacements

Dr. Gruder asked Council members to submit nominations to Dr. Hopper for a for-profit industry representative to replace Barry Hirschowitz and a scientist-clinician to replace Edith Perez.

LOI Subcommittee

Chair Claymon asked for volunteers to serve on the subcommittee that will:

- 👉 investigate allegations;
- 👉 evaluate the review process;
- 👉 evaluate the composition of review committees; and
- 👉 develop an appeals process.

The Chair appointed Ms. Shinagawa chair of the subcommittee and members Dr. Bailey, Dr. Comer, Dr. Ganz, Dr. Hackett-Johnson, Ms. Wheatley, and herself.

Compensating the State

There was little time left to discuss the issue of requiring for-profit grant recipients to compensate the state so Dr. Gruder said that he would indicate in the annual report to the Legislature that the Council needs more time to address this issue.

ADJOURNMENT

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The meeting was adjourned at 4:00 P.M.