Minutes of the Breast Cancer Research Council Meeting
August 7, 1995
Kaiser Center, Oakland

Council Members Present:
Susan Claymon (Chairperson), William Comer, J. Patrick Fitch, Patricia Ganz, Deborah Johnson, Liana Lianov, John Link, Andrea Martin, Carol Pulskamp, Susan Shinagawa, Carol Voelker

Council Members Absent:
Lisa Bailey, Christopher Benz, Jacquolyn Duerr (alternate ex officio), Sam Ho, Barnarese Wheatley

BCRP Staff Present:
Charles L. Gruder, Marion Kavanaugh-Lynch, Mary Kreger, Annette McCoubrey, Walter Price

Guest:
Joanna Beam

The meeting was called to order at 9:40 AM.

Introductions

Dr. Gruder introduced Marion Kavanaugh-Lynch, M.D., M.P.H., the new Coordinator of the Breast Cancer Research Program (BCRP), and two new Breast Cancer Research Council members, Carol Voelker, Ph.D. and Carol Pulskamp. Dr. Kavanaugh-Lynch described her training in internal medicine, clinical oncology, clinical research, and public health. Additionally, she commented on her commitment to advocacy, activism, and her experience serving on and working with advisory boards. Dr. Voelker represents non-profit organizations. She worked on passage of the Breast Cancer Act with Soroptimist International She has also worked with the Los Angeles City Schools and has served on the boards of non-profit organizations. Ms. Pulskamp is a breast cancer survivor, an activist, and President of the Northern California Coalition for Cancer Survivors.

Approval of Minutes

The minutes of the June 5-6, 1995 Meeting were approved without changes.

General Comments

Ms. Pulskamp asked for clarification of the record in the minutes of the June 5-6, 1995 meeting of a Council member=s concern that the member=s employer was called in the course of the Letter of Intent (LOI) Subcommittee=s preparation of its first report. Council Chairperson Claymon suggested that she and Ms. Shinagawa, who chaired the LOI Subcommittee, speak with Ms. Pulskamp about this complex issue at a later time.

Dr. Comer stated that a newspaper had mistakenly reported that he is now running Cytel Corporation. Dr. Comer is a member of Cytel=s Board of Directors.

Selection of Council Chairperson

Dr. Comer nominated Dr. Ganz for Council Chairperson. Dr. Ganz declined because of the demands of her current research workload. She expressed her view that the Council Chair should be an advocate member, and nominated Ms. Shinagawa. A letter from Lisa Bailey (absent member) was read, also nominating Susan Shinagawa. The motion was seconded, and Ms. Shinagawa was elected Chair by acclamation.

Dr. Gruder thanked Ms. Claymon for her commitment and hard work, and for the exceptional quality of her service as the Council=s first Chairperson.

Conflict of Interest / Confidentiality Agreement

The Council discussed the proposed Conflict of Interest / Confidentiality Agreement that had been drafted, at the request of the Council, by Joanna Beam, attorney in the Office of the General Counsel of the UC Regents who has been working with the Council since its inception. (Ms. Beam joined the meeting while this discussion was underway.)

Dr. Ganz noted that it would be a great sacrifice for Council members if they were prohibited from receiving BCRP funding, not only during the term of their service, but for one year after it ended. Dr. Gruder explained that this provision was included because the Council sets the research agenda and, therefore, a Council member who was awarded a grant within a year after the member=s term ended might well be viewed as having had an unfair advantage. Dr. Ganz noted that this provision was not in effect when current Council members agreed to serve. If this provision were adopted, it seemed reasonable for current Council members to be Agrandfathered in.≅ Dr. Ganz also noted that this provision is more stringent than NIH=s conflict of interest rule for study section members. It was pointed out that this provision would likely make it very difficult for the University to recruit breast cancer researchers to serve on the Council. Dr. Gruder added that most scientists who are nominated for the Council do express some concern about agreeing to forego funding while they serve. Most Council members preferred to preclude members from receiving BCRP grants only during their term of service on the Council.

Ms. Beam asked members to delete the words Aand non-use≅ on page 5 of the draft Agreement.

Ms Claymon asked whether a breach or threatened breach of the Agreement, which the draft indicates would require action by the UC Regents, could be referred to the Council for consultation. In a similar vein, Ms. Martin asked whether BCRP policy

could call on the Regents to seek the advice and consent of the Council in such cases. Ms. Beam responded that the Regents must act in such matters because they accepted responsibility from the State for the administration of BCRP and a breach of a Conflict of Interest / Confidentiality Agreement would be sufficiently serious to warrant their action. Dr. Gruder and Dr. Ganz pointed out that before an Agreement is adopted, misconduct should be defined and procedures for dealing with any misconduct should be outlined. It was decided that Ms. Beam, Dr. Kavanaugh-Lynch, Ms. Claymon, Ms. Voelker, and Ms. Pulskamp would constitute a subcommittee to work on the development of methods to determine, investigate and deal with breaches of the agreement and to incorporate these into the draft. They will present this at the next meeting.

Dr. Gruder noted that unfunded applications always remain confidential. If a grant is funded, though, the abstract and some additional elements in the application do become public; however, research plans described in applications remain confidential.

Compendium of Awards

Dr. Gruder reported that the titles and abstracts of grants funded in the first cycle, which will be published in the *Compendium of Awards*, were edited by staff and principal investigators so that they clearly convey the relevance to breast cancer and are understandable to educated readers who are not scientists. Dr. Ganz moved to congratulate the staff on the impressiveness of the abstracts and the hard work that went into producing them; the motion passed.

Cycle I Grants

Dr. Gruder reported that there was approximately $19 million available to fund Cycle I grants. The funding plan endorsed by the Council at the June meeting encumbered $18.2 million. The unencumbered balance is being held as a reserve to deal with contingencies, such as indirect cost rate (i.e., institutional overhead) changes that occur before funds are transferred. He explained that BCRP will fund applications on the Council=s Apay-if≅ list (i.e., grants to be awarded if funds are available) once the funding process is far enough along so that staff are confident that further contingencies are unlikely to arise.

All but one of the applications on the Apay-if≅ list have already been funded. The Council reviewed the staff proposal for additional grants to be added to the contingency list. After discussion concerning these grants, the Council opted to leave the one remaining grant on the contingency list and to not add any other grants to this list.

The process of transferring funds has begun. This process can be time-consuming because formal agreements must be executed with organizations other than University of California campuses before checks can be issued.

Cycle II Issues

The Council discussed the staff proposal for Cycle II, and endorsed the proposed details for Cycle II, except as discussed below.

The proposed plan for screening applications for responsiveness to BCRP=s mission and to the research priority issues was discussed in detail and a variety of options were proposed.

Dr. Johnson reflected that the LOI process in Cycle I had worked fairly well.

Members discussed alternative proposals for triaging and conducting streamlined reviews. ATriaging≅ refers to short-circuiting discussion of applications that peer reviewers determine will not be competitive. NIH triages approximately 50% of applications. Proposals that NIH peer reviewers designate non-competitive are neither discussed nor assigned scientific merit scores by the study section. They are not presented to the NIH institute council for funding consideration and they are not funded. Principal investigators of such applications do receive written evaluations of their proposals.

Dr. Ganz suggested that a subcommittee first determine whether applications are non-competitive because they do not fit BCRP=s goals or current research priorities.

The Council decided to adopt the NIH triage model: applications will be evaluated on their responsiveness by the reviewers as part of the review. When the review committees meet, the first part of the review for each application will be a discussion of responsiveness; applications which are judged by the committee to be not responsive will not be further discussed, will not receive a score for scientific merit and will not be considered by the Council for funding. Applicants will receive summary statements which detail the reasons for a judgement of unresponsiveness.

Ms. Claymon suggested that one research topic listed under the priority research issues in the Cycle I Call for LOIs, Aprevent progression of disease,≅ should be re-worded in Cycle II because some investigators interpreted this as an invitation to submit proposals on breast cancer treatment though treatment was not a priority.

Dr. Comer suggested that Atranslational research≅ should be defined in the Cycle II Call for Applications. A proposed definition was: Aputting new ideas into a patient treatment area.≅ He felt that BCRP should continue to give priority to applications that involve translational research. He also noted that animal models are not very predictive in humans. He further urged soliciting applications that propose to move *in vitro* studies into patient treatment areas.

Based on these suggestions, the Council decided to offer a new funding mechanism. This would fund therapeutic approaches that involve 12 to 18 patients in a

clinical research phase which precedes full-scale clinical trials. These seed dollars for pilot research could involve collaboration between investigators in universities and biotechnology companies, with an emphasis on innovative translational research. A maximum award $100,000 per year, with a maximum of 2 years was chosen, because this type of research requires about $5,000 per patient and usually requires no more than twenty patients. The Council agreed that the areas they are interested in funding are innovative and creative treatment modalities, and not trials looking at new combinations of standard chemotherapy agents.

Ms. Martin brought up the priority issue of the mind-body connection and asked for ideas that would stimulate this sort of proposal. Dr. Ganz commented that the tools for performing this type of research are not yet developed. She suggested, however, that a related issue is the types of care that women receive, including supportive care. She therefore proposed another new mechanism to fund research on innovative models of care, which could include psychosocial research and research in health services and methods to deliver treatment and breast cancer screening. The Council agreed to develop this as another new funding mechanism, with similar conditions as the innovative treatment mechanism.

Dr. Pricenoted that epidemiologic and social/behavioral studies typically require large numbers of subjects, as well as labor-intensive (and therefore expensive) methods such as individual interviews. The $100,00 per year budget cap is a significant barrier to receiving quality applications in these areas. The Council agreed to raise the cap for research awards to $125,000 for epidemiologic and social/behavioral research.

The Council discussed the evaluative feedback provided to applicants. LOI authors received only very brief comments, in some cases, no more than a sentence or two. A number of LOI authors complained that this terse feedback was uninformative or misleading. Dr. Gruder noted that principal investigators of full applications will receive detailed evaluations, called Asummary statements,≅ which will include the peer reviewers= detailed written comments.

It was suggested that the Cycle II Call for Applications should include a section summarizing the topics of the grants awarded in Cycle I.

Ms. Shinagawa suggested that, when preparing the Cycle II Call for Applications, a Council-staff subcommittee would meet and decide on content. A draft would then be written and faxed to all Council members, who would have the opportunity to comment. The following suggestions to include in the revision of the Call for Applications and the Application Packet were made: remove all references to the LOI process; describe the triage process; eliminate Aprevention of disease progression≅ from the lists of examples of topics; add the innovative treatments and innovative models of care mechanisms; eliminate the word Arelevant≅ from the criteria.

Cycle II time line: The Call for Applications is scheduled to be issued on or about October 15, 1995. Applications will be due January 10 or 15, 1996.

The following suggestions were made for expanding the mailing list for the Call for Applications in California: Contracts and grants officers at research institutions; biotechnology companies; USDHHS mailing list; ASCO members; CMA specialty lists; ASPO members; Oncology Nurse=s Assn. members; National Medical Assn. Members; AMWA; individual researchers; previous applicants; minority health organizations; medical staff of hospitals; NCI reference on WWW page; chair of hospital cancer committees; American College of Surgeons members; contract with public relations firm; purchase mailing lists.

Publicity

The Council discussed methods of publicizing the program and the first cycle awards. It was suggested that the Publicity Committee (Andrea Martin) and staff meet and contact Barbara Friedman to involve her in the process. It was agreed that a press release and an executive summary of the Compendium of Awards should be prepared.

Federal Funding for Breast Cancer Research

A member asked how BCRP funding complements federal funding for breast cancer research (i.e., NCI and the Department of Defense). Dr. Gruder explained that staff have not yet done this analysis, but that we do have the lists of breast cancer research grants awarded by NCI and DoD.

Compensating the State

The Council resumed the discussion from previous meetings of the advisability of adopting a requirement that for-profit grantees compensate the State. The development of a policy is problematic because of the ramifications of policy alternatives that the Council previously considered:

- obtaining the highest quality applications
- nature and duration of monitoring award recipients
- price controls for public sector (Dr. Fitch noted that addressing the private sector raises the issue of whether a policy should apply to the public sector, including universities. He thought it would be better to have a single policy for all award recipients.)

Future Meetings

The next meeting was scheduled for October 11, 1995. Members were asked to hold December 15, 1995 for the following Council meeting.

Adjournment

The meeting was adjourned at 4:15 p.m.