

**University of California  
Breast Cancer Research Council  
Breast Cancer Research Program**

**Meeting Minutes**  
May 23, 1994  
300 Lakeside Drive, Oakland

Council members present: Lisa Bailey, Christopher Benz, Leah Cartabruno, Susan Claymon, William Comer, Jacquie Duerr, Patricia Ganz, Adeline Johnson Hackett, Barry Hirschowitz, Deborah Johnson, Mary-Claire King, John Link, Andrea Martin, Edith Perez, Susan Shinagawa Smith, Barnarese Wheatley

Council members absent: None

UC staff: Charles L. Gruder, Susanne Hildebrand-Zanki, Cornelius L. Hopper, Beverly Pachner

Guests: Joanna Beam

**Welcome and Introduction of New Members**

Cornelius L. Hopper, M.D., the University of California (UC) Vice President-Health Affairs, welcomed members to the second meeting of the Breast Cancer Research Council. Dr. Hopper asked three members who had not been at the first meeting to introduce themselves and to describe their affiliations and particular interest in breast cancer research.

**Review of the 3/28/94 Council Meeting Minutes**

Dr. Hopper asked for comments or corrections on the minutes of the March 28th meeting. The minutes were approved as written.

**Council Organization**

A four-member subcommittee prepared its recommendations on Council organization and governance issues. These recommendations were discussed. Item I addressed whether Council members may send alternates and, if so, whether alternates would be allowed to vote. The subcommittee recommendation was not to allow alternates or proxies, in order to encourage members to attend meetings. The Council discussed whether it might be useful to allow alternates to attend to obtain information, but not to vote. It was pointed out that this might be achieved by reading the minutes; however, the minutes might not be detailed enough to give the true "flavor" of any discussions.

It was proposed that members be linked electronically, and that votes be taken in this manner, when immediate action is needed and a meeting cannot be arranged.

A motion was put forward and carried unanimously to adopt the recommendation of the subcommittee not to allow alternates or proxy voters.

Item II of the subcommittee report dealt with the definition of a quorum. The recommendation was that 11 members would constitute a quorum and that a majority (i.e., a minimum of six votes) would carry a motion. In response to a question, it was explained that 11 was picked to assure that most of the members would be present when a vote is taken and would prevent a minority from setting Council policy. Robert's Rules of Order defines a quorum as at least two thirds of the members, which, for the Council, would be 10 members (out of 15 voting members) present. The recommendation of the subcommittee was adopted.

Item III of the subcommittee report addressed the selection and term of appointment for the Council's chair. The subcommittee recommended, and the Council accepted the recommendation, that members would elect a Chair with the following duties and responsibilities: chairing meetings; acting as the meeting facilitator and discussion leader; calling for votes at meetings; and serving as the Council's liaison with the Interim Director for purposes of obtaining input, developing agendas, and other matters. The term of appointment would be one year. In addition, it was recommended that an advocate be selected as the first Chair in recognition of the advocates' role in getting AB 2055 passed.

Item IV of the subcommittee report dealt with the procedures related to communication among Council members and with the public. Members agreed that some form of electronic hook-up among members should be established. Staff was instructed to develop a workable system that takes into account members' existing electronic communication capabilities. It was also agreed that Council business should be widely publicized through a newsletter, press releases, and an electronic bulletin board. It was pointed out that individual members of the Council may be contacted by the press or other interested parties, and it was agreed that Council Members should indicate in their responses that they are speaking as individuals, not for the Council. There was agreement that official Council positions would be communicated through a central source. Dr. Hopper suggested that the Council start out by using Mike Alva, the UC Office of the President news officer assigned to Health Affairs, as a press liaison for official Council business. Dr. Hopper will invite him to attend future Council meetings.

Item V of the subcommittee report addressed policies regarding guests at Council meetings. Two options were considered. The first option would have allowed guests to attend open sessions of Council meetings. In this scenario, an executive session would be scheduled for private discussions involving Council members only; during the open session, guests would be able to submit written questions and comments to the Chair.

Council members discussed the pros and cons of this option. They were advised that Council business is not subject to "sunshine" laws and that the degree of openness of the meetings is

entirely at the discretion of the Council. It was recognized that the Council should be as open as possible in conducting its business. At the same time, it was pointed out that there will be issues that will need to be discussed in closed session (e.g., specific applicants/applications and intellectual property issues).

Having an open session at each meeting would promote public access and input and thus make the Council responsive to its charge of serving the public; however, it would change the nature and tone of the meetings. In addition, there is the logistical issue of where the meetings would be held if the public were invited. The Council expressed concern that having both closed and open sessions at the same meeting might generate suspicion that the most important issues were being dealt with behind closed doors, giving the perception of secrecy on the part of the Council. One member noted that it would probably be most meaningful to have public input when the Council is considering a proposed policy, before a final decision is made.

The Council discussed the importance of issuing a press release immediately following each Council meeting to inform the public of what had been discussed and what decisions had been made.

Members favored the subcommittee's second recommendation on this topic, which called for public Council meetings to solicit input on specific subjects (e.g., research priorities) and for educational purposes. Members agreed that the Council should hold open the possibility of a yearly public meeting to receive input and to provide information. In addition, guests could be invited to Council meetings to address specific concerns. An executive committee will be appointed through which such invitations would be issued. Dr. Hopper added that if the Council aggressively pursues item IV of the subcommittee report, the need for ongoing public meetings would be reduced.

Item VI of the subcommittee report dealt with policies regarding the Council's operational standards for conducting meetings. The full Council accepted the subcommittee's recommendation to use Robert's Rules of Order only as needed (e.g., for purposes of voting), and generally to be more informal in conducting meetings. The primary mode would be to try to reach consensus on issues and to use the Rules when consensus is not possible. The subcommittee also encouraged the Council continuously to reexamine its ways of doing business and to monitor and evaluate the group process.

### **Future Meetings**

Council members agreed that frequent meetings, at least six in the first year, would be required to get the program organized and running. The Council urged that the staff schedule meetings as far in advance as possible.

### **Development of BCRP Research Priorities**

Dr. Gruder provided the members with a handout outlining the decisions that would have to be

made by the Council in order to begin soliciting applications. The handout also delineated the seven major research questions being addressed by other breast cancer research funding agencies, such as the Department of Defense (DoD), the National Cancer Institute (NCI), the Institute of Medicine (IOM), and the California Department of Health Services (DHS).

Members reconfirmed their leaning towards establishing priorities with a "process" rather than a "discipline" focus. Many of the issues raised at the previous meeting were addressed again.

These include how the Program can:

- # ensure that it funds innovative and high-risk research;
- # balance the objective of innovation with the desire for cost-effective, results-oriented research with measurable outcomes;
- # ensure that social science and prevention research is not short-changed;
- # avoid getting trapped into funding what is considered "dogma;"
- # ensure that projects would be supported long enough to allow for the development of a product or an endpoint; and
- # ensure that the Council's priorities are understood by all Study Section members.

It was suggested that before determining the Council's research priorities, two pieces of information would be useful: 1) a survey of ongoing breast cancer research in California, to get a sense of what is being done in the state and to avoid duplication of effort; and 2) a determination of what breast cancer research the DoD will fund. Some members voiced the opinion that so little is known in general about breast cancer research that actual duplication of effort might be negligible. The Council recognized that the Program should make every effort to fund innovative research within existing categories.

It was noted that the DoD will probably fund many fellowships and training grants, but that it will not necessarily fund grants that would provide or maintain a research infrastructure, such as data banks, information systems, transgenic mice, DNA probes, and other potentially shared resources. It might be worthwhile for the Council to consider funding such grants through its program, although the beneficiaries of such resources are likely to be the eventual users, rather than the grantee establishing the resource. In today's global information age, these resources would be available widely. While that in itself is beneficial, it was questioned whether it represented a good investment on the part of the Program or whether such funding should be left to national funding agencies. In addition, there would be the problem of maintaining these resources in the face of declining revenues. This type of investment could be considered if follow-up funding from another source would be available later on. The Council agreed that such investments might become part of the Program's portfolio but should not be a major emphasis.

The Council was urged to allocate research funds according to the mandate of AB 2055. This bill covers a broad range of categories to be funded and it appears that the Program is obligated to fund research in all areas, not just some. One member cautioned against too narrowly interpreting the precise wording of the statute, and the Council was encouraged to look at the broad legislative intent for what needs to be done.

Section 9(b)(1) of AB 2055 currently states that breast cancer research "includes, but is not limited to" a broad list of topics. Section 8 of the law, adding Section 30461.6 to the Revenue and Taxation Code, states that the Research Program is to award grants and contracts "for research with respect to the cause, cure, treatment, prevention and earlier detection of breast cancer and with respect to the cultural barriers to accessing the health care system...." This wording is in the process of being amended in Assemblymember Friedman's "clean-up" legislation for AB 2055. The precise changes are not known to the Council but will probably include "environmental causation" as an additional area of priority research.

Members also discussed how funds should be allocated. One suggestion was to use 50% of the available funds to cover all areas of research and to use the remaining 50% as a discretionary pool to fund areas of particular concern to the Council. Another suggestion was to make no categorical allocation decisions before research proposals were examined by peer reviewers in order to ensure that only highly meritorious research is funded. Members favored keeping their funding options as open as possible to allow them to keep their focus on the long-range goals, and to fund research accordingly.

The Council agreed that it would be desirable to develop a set of guiding principles which would serve as a basis for all decisions made by the Council. These principles should include support of innovation and risk-taking.

The process of ensuring that appropriate applications get funded will have to start with the wording of the Call for Applications. This is the first opportunity to educate potential applicants about the Program and the type of research being sought. This education process should be continued in the actual application packet. Additionally, Study Section members should be briefed on the goals of the Program and on the Program criteria to be incorporated into the merit review.

With regard to relevance of applications to breast cancer, the Council supported asking applicants to explain the relevance of their project to the goals of BCRP. The Council will later decide what process to use to evaluate such relevance statements. Two possible procedures were discussed: 1) A Council subcommittee could make relevance determinations; or 2) Program staff, with the assistance of experts in the field, could make such determinations. It was pointed out that the Council will have to be prepared to defend its decisions concerning relevance to the scientific community, the public, and the legislature.

The timing of the BCRP application process will depend on when the Program is ready to issue a Call for Applications. Release of the Call for Applications is predicated on the Program having established its research priorities and funding mechanisms. The Council agreed to seek advice on these issues from the scientific community and other sources.

The Council decided to hold a one-and-a-half day meeting to solicit suggestions regarding breast cancer research priorities. Information gained from this meeting would aid the Council in

establishing Breast Cancer Research Program priorities. Participants would include persons knowledgeable about research in the area of breast cancer from within California and nationwide; persons involved in administering other breast cancer research programs, such as DoD; senior NCI and American Cancer Society officials; and representatives of various disciplines affected by and involved in breast cancer research. Members will send recommendations for participants to the Interim Director for potential inclusion in the list of invitees. A total of approximately 20 participants would be invited. Meeting participants would be provided with a short list of questions to be addressed at the meeting. Aside from these questions, the meeting should be kept as spontaneous as possible. Staff was instructed to organize this meeting, to be held within the next six to eight weeks.

### **Department of Health Services Breast Cancer Related Programs**

Jacquie Duerr of the DHS Breast Cancer Control Program briefed the Council on breast cancer research activities ongoing in DHS. Ms. Duerr provided the members with a handout, outlining the various DHS programs, their funding sources, the amount of money available per fiscal year, a program description, and the current status of each program.

DHS is in the process of setting up the Breast Cancer Early Detection Program (BCEDP), which is funded from the same tax revenue as the BCRP. DHS has to spend monies for this program in the fiscal year they were appropriated, which means that \$8.59 million must be distributed by June 30, 1994.

Ms. Duerr pointed out that breast cancer advocates, some of whom are members of this Council, were involved in setting priorities for the Breast Cancer Research Tax Check-off Program; however, they were not involved in developing the actual RFP. At the present, there is no timetable for defining or awarding the next set of grants in that program. Ms. Duerr felt that BCRP might boost interest in the tax check-off program. However, all check-off programs are in danger of being eliminated by legislation currently under consideration. The relevant portion of that legislation (AB 3631) states that despite any other "sunset" date specified by law, if contributions to any single tax-designated check-off program fall below \$250,000, that program would be discontinued. In the event that the Breast Cancer Research Tax Check-off Program is discontinued for this reason, the Council might want to adopt some of that program's principles. If the check-off program continues, it would probably be beneficial to have some integration between the two programs.

As part of BCEDP, DHS will create a database containing client-specific records for clinically served patients. The California Tumor Registry will use its 5% of the two-cent tobacco tax increase to examine regional differences in breast cancer rates and will report these data. At this time, there is no mechanism in place to allow other researchers access to these data. There will likely be problems with non-uniformity of reports entered into the Registry database, and the long-term usefulness of the data to other researchers might be low. It was suggested that Dr. Young of the Registry should be invited to speak to the Council and answer any questions members have about this potential research resource.

## **Payment of Indirect Costs on Grants**

The Council was advised by Dr. Gruder that University of California campuses are not eligible to receive indirect costs on awards made with state dollars, although AB 2055 specifies that all other institutions will receive indirect costs based on their federally determined indirect cost recovery rate. The rationale for not paying indirect costs to UC is that the State already funds maintenance of the UC research infrastructure and paying additional indirect costs would be "double dipping."

## **Selection of Council Chair**

Dr. Hopper asked the Council members for nominations for the chair. Susan Claymon was nominated; two subsequent nominees both declined. Therefore, being unopposed, Susan Claymon was named Chair of the Council for a one-year term ending June 30, 1995.

## **Conflict of Interest**

Joanna Beam of the UC General Counsel's Office briefed the members on issues regarding conflict of interest. The UC General Counsel will provide legal advice on an ongoing basis to this Program. Ms. Beam explained to the Council members that she serves in an official capacity only with respect to official Council business, and that all other interactions between her and Council members are not subject to the attorney/client confidentiality privilege.

She pointed out that impartiality is the basis for conflict of interest analysis and that usually financial factors create potential bias.

AB 2055 states that the Program should conform with the conflict of interest provisions in the NIH Manual [Chapter 4510 (item h)] and any conflict of interest provisions in state law. Ms. Beam handed out a pamphlet entitled "University of California Political Reform Act (PRA) Disqualification Requirements," to which all UC employees are subject. Members of the Council are also subject to these provisions by virtue of their service on the Council. Ms. Beam explained the PRA provisions. She pointed out that there are different levels of exclusion, based on the nature of a conflict of interest. These range from simple disclosure to disqualification from the decision-making process. Disqualification is the ultimate solution to a potential conflict of interest problem.

All members agreed that every attempt should be made to avoid even the appearance of conflict. Potential problems can be discussed with the General Counsel and, if necessary, brought to the attention of the Council. The Council would look at specific cases and decide whether a conflict of interest exists. It was suggested that once a year, at the time funding decisions are made, all members sign a form disclosing any potential conflicts of interest.

Staff was instructed to generate a set of policies for consideration by the Council.

### **Royalties on licensing agreements**

Ms. Beam was asked whether there is a legal possibility for BCRP to retain rights to products, such as patents or licensing agreements, resulting from research funded through BCRP. It was suggested that this might be way of supplementing the tax revenues. It was noted that in its small business grant program, NIH apparently gets any resulting license for two years and also imposes a built-in fee. It might be possible for BCRP to impose such a fee on private businesses. This will be investigated further; however, if it is the intent of the BCRP to retain rights to any license, this should be explicitly stated in the Call for Applications.

### **Follow-up Items**

Members were asked to send suggestions for participants in the advisory meeting as soon as possible, so that a list of invitees can be generated.