University of California
Breast Cancer Research Program
Breast Cancer Research Council

Meeting Minutes
August 23, 1994
300 Lakeside Drive, Oakland

Council members present:	Lisa Bailey, Christopher Benz, Susan Claymon, William Comer, Patricia Ganz, Barry Hirschowitz, Deborah Johnson, Mary-Claire King, Liana Lianov, John Link, Andrea Martin, Edith Perez, Susan Shinagawa Smith, Barnarese Wheatley
Council members absent:	Leah Cartabruno, Adeline Johnson Hackett
U.C. staff:	Adele Amodeo, Ellen Auriti, Lourdes De Mattos, Charles L. Gruder, Susanne Hildebrand-Zanki, Cornelius L. Hopper, Annette McCoubrey, Patricia Orr, Beverly Pachner, Walter Price
Guests:	Michael Alva (U.C. News and Public Affairs) Laura Lund (California Dept. Health Services) John Young (California Dept. Health Services)

REVIEW OF 5/23/94 COUNCIL MEETING MINUTES

Interim Director Gruder asked for corrections or comments regarding the minutes of the May 23rd meeting. One Council member suggested making the following changes on Page 4 of the minutes:

- In the second full paragraph, strike the first part of the last sentence ("While it might be impossible and undesirable to generate additional areas of research"). The last sentence should read, in its entirety, "The Council recognized that the Program should make every effort to fund innovative research within existing categories."
- The last two sentences of the last paragraph should be combined and revised to read, "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."
- In the last paragraph, the second word of the second sentence should be changed from "bill" to "law."

The Council adopted the suggested changes, and approved the minutes as amended.

MEETING GOALS

Dr. Gruder reviewed the agenda, noting that the main goal of the meeting was for the Council to recommend research priorities. He noted that the agenda also included time for the Council to

discuss (1) how research funded by the Breast Cancer Research Program could complement DHS's Breast Cancer Early Detection Program; (2) the role the California Tumor Registry could play in research funded by the Breast Cancer Research Program; (3) strategies for publicizing the Program and Council activities.

Council Chairperson Claymon stated that the Council would try to reach consensus about research priorities, but that, if necessary, decisions could be made by a vote in areas where consensus cannot be reached.

CALIFORNIA DEPARTMENT OF HEALTH SERVICES

Dr. Lianov reported on the major issues discussed at the July 26th meeting of the Breast and Cervical Cancer Advisory Council, which advises the Department of Health Services on both the federally-funded Breast and Cervical Cancer Control Program and the state-funded Breast Cancer Early Detection Program. She discussed the three pieces of the DHS Breast Cancer Early Detection Program: clinical services, outreach, and provider education.

Regarding the clinical services piece of DHS's Program, Dr. Lianov stated that as of July 1, 1994, any Medi-Cal provider and any provider who applies for a special Breast Cancer Early Detection Program identification number can provide services to financially-qualified women (i.e., women whose incomes are 200% of the poverty line or below) and can bill through the Medi-Cal billing system. Providers can call a special toll-free number for information on how to enroll and provide services to qualified women.

Dr. Lianov emphasized that only a limited amount of data (e.g., woman's age and race, provider's name, type of procedure, and result) will be collected as a result of the clinical services program. Several Council members asked whether DHS planned to do exit interviews of women receiving services through the program, to evaluate quality of service. Dr. Laura Lund, who is part of DHS's Evaluation Unit, responded that there is currently no funding for conducting such interviews or for handling additional data entry and paperwork.

Regarding provider education, Dr. Lianov reported that the DHS Council has formed sub-groups which are currently working with experts to develop a provider curriculum. The curriculum will focus on several modules, including patient-provider communication and techniques for improving clinical breast examination and mammography. The curriculum will be field tested and available in 1995.

Regarding outreach, Dr. Lianov stated that the DHS Council wants to ensure that the DHS program reaches certain target groups, including the underserved, various ethnic groups, and women over age 50. Dr. Lianov pointed out that health services research is needed to help determine how best to reach women in various target groups, and that this would be one area where research funded by the Breast Cancer Research Program could facilitate the DHS's provision of services.

Also related to outreach, Dr. Lianov reported that DHS is using funds from outside the Breast Cancer Early Detection Program to develop a treatment brochure to be used as part of its educational campaign, which focuses on yearly mammograms for women over the age of 50. She noted that starting in October, women will be able to call a toll-free number for information on the Breast Cancer Early Detection Program.

Dr. Lianov also reported on the Tax Check-off Program, noting that an ad-hoc group of DHS Council members will convene in the fall to launch the next cycle of funding for that program. That group will look at the kinds of research the Breast Cancer Research Program decides to fund, and will try to ensure that the two Programs are complementary.

Finally, Dr. Lianov announced that Dr. Gruder will be an ex officio member of the DHS Breast and Cervical Cancer Advisory Council. This will ensure that members of both Councils are kept informed of one another's activities.

RESEARCH PRIORITIES

Letters of Intent

Council members discussed the idea of using Letters of Intent (LOIs) as a way of initially screening potential proposals. There was general agreement that requiring LOIs is a good idea. It was noted that LOIs could be used to:

- Screen out proposals not relevant to the Program's goals.
- Encourage applications from junior-level investigators who have never before written a full proposal and may be reluctant to do so without some idea that it is viable.
- Help decide nature and composition of the study sections.
- Monitor the number and types of proposals that can be expected; if there are certain areas that are neglected, this information can be used in writing more targeted Requests for Applications (RFAs) for the next grant cycle.

It was pointed out that a disadvantage of using LOIs is the possibility that decisions will be subjective or biased. Several members suggested ways to combat this, however. One Council member suggested that LOIs be reviewed anonymously. An applicant's experience or "track record" could be taken into account by devising a point system (awarding a specific number of points for certain specific past accomplishments). Several Council members stated that potential problems could be eliminated by clearly stating specific criteria on which LOIs will be evaluated.

While LOIs could be used simply for informational purposes, several Council members favored using them as a method of "triage." In a triage system, all applicants would be required to submit LOIs; only a subset would be invited to submit full applications. Researchers submitting LOIs which are promising but which need work could be encouraged to resubmit during a

subsequent grant cycle. Researchers submitting LOIs that are not promising or not relevant to the Program's goals would not be invited to submit full proposals.

Council members discussed the optimum length of LOIs. Lengths varying from one to five pages were discussed; several members felt that one page would be too superficial. It was suggested that applicants be required to provide a statement regarding the relevance of their projects to the research focus set out in the call for LOIs, a statement of their specific aims and proposed scientific methods, and a general estimate of costs (but not a specific budget).

Dr. Gruder reported that he has spoken with staff from the Robert Wood Johnson Foundation, which has found that LOIs work very well. However, he pointed out that the Robert Wood Johnson Foundation is private, and thus subject to fewer restrictions in how it conducts its application process. One Council member suggested that staff speak to AMFAR, which has also made use of LOIs.

The Council members agreed that the solicitation for LOIs should be widely distributed to traditional science sources, to advocacy organizations, and to industry. Dr. Gruder reported that staff is in the process of compiling mailing lists from U.C.'s Tobacco-Related Disease Research Program (TRDRP) and AIDS Research Program, as well as from breast cancer organizations like CABCO. He noted that, once the solicitation has been issued, informational meetings hosted by staff and Council members could be set up throughout the state for people who might be interested in submitting applications. Such meetings were successfully used in the initial stages of the TRDRP.

It was suggested that a subcommittee be put together to develop guidelines for soliciting Letters of Intent. Dr. Gruder stated that he would prepare suggestions regarding procedures and criteria to be used in connection with LOIs. These suggestions could be used as the starting point for a discussion by a subcommittee.

Research Issues

Dr. Gruder reviewed the Staff Recommendations document included in Council Members' meeting binders. He noted that, based on the discussion at the National Advisory Meeting and on the written answers submitted by meeting participants, the staff recommends that the focus of the initial grant cycle be on etiology, pathogenesis and prevention of breast cancer, including research on detection. Dr. Gruder recommended that the Council narrow the research issues targeted in the call for applications as much as possible, with the goal of getting a large number of good research proposals in a few circumscribed areas.

Council members agreed that the statement of issues in the Staff Recommendation document was a good start for developing language for the first call for applications. They suggested converting the outline into a narrative form. One member suggested including in the call for applications a disclaimer that not all the areas mentioned in the outline are believed to be equally

meritorious. Dr. Gruder suggested accomplishing this by stating that applicants whose proposals involve a controversial research issue should explain why the issue is worthy of research. Research areas that individual Council members requested be added to the outline included studies regarding post-ten-year survivorship and research regarding breast cancer in older women.

Dr. Hopper asked whether Council members wanted the Program to fund large-scale clinical trials. Several members felt that doing so would not be a good idea because it would be difficult for the Program, with its limited resources, to compete nationally in this area. They suggested that the Program not fund Phase III randomized clinical trials.

One member suggested that the call for applications should encourage proposals which entail multi-site investigations and population-based prevention. He felt that the BCRP should strive to achieve grand objectives by making awards that are relatively large in amount and in duration, rather than funding many small short-term grants. Another member suggested that the call for applications should make clear that excellent proposals that do not fit precisely into the specific areas identified in the outline will not automatically be rejected.

Council members agreed that they want to encourage collaboration among researchers in different fields and between junior and senior investigators. Several ways to encourage collaboration were discussed. First, it was suggested that the call for applications require cross-disciplinary proposals or proposals which include both senior and junior investigators. Second, it was suggested that funded researchers be required to attend a meeting which would facilitate collaboration and innovation. It was pointed out that the NIH SPORE ("Specialized Program of Research Excellence") program requires investigators to attend an annual investigators' meeting. Another suggestion was that such a meeting include not only funded researchers, but all researchers invited to submit proposals on the basis of their LOIs. Such a meeting could encourage researchers to exchange ideas, collaborate, and develop networks from the very beginning. However, one member warned that a meeting held before funding decisions are made could degenerate into a forum in which the participants seek advice on how to get their projects funded.

One member pointed out that the disadvantage of requiring proposals to include a collaborative element is that it shuts out young and new investigators who have not yet established networks. This member suggested encouraging collaboration by requiring funded investigators to attend an initial meeting in which certain researchers are asked to discuss their ideas with one another in break-out groups.

Timing of Grant Cycles

One Council member asked whether there would be enough money for two grant cycles. Dr. Gruder referred to page 11 of the Staff Recommendations, which sets out a proposed timetable through 1996. The timetable proposes two grant cycles, and shows the deadlines under two

different scenarios: one using Letters of Intent (LOIs), and the other not using LOIs. Dr. Gruder stated that there is no reason to think that two grant cycles would not be possible. He noted, however, that no commitments of money to specific researchers will be made until the Program is certain that the money is available. One Council member expressed concern that two grant cycles in one year might not be feasible. Dr. Gruder responded that the proposed timetable could be adjusted if it does not prove to be feasible.

Dr. Gruder explained that the two cycles would work as follows: A call for Letters of Intent for the first grant cycle would be issued by the end of 1994. The first round of LOIs would be due before the second call was issued. Thus, the Council would know, based on the first round of LOIs received, which areas to target in the second cycle. Another advantage of having two cycles is that it would allow a longer lead-time for those types of applications which may take longer to put together (i.e., applications from new researchers, innovative or non-traditional proposals, and collaborative efforts). Researchers wishing to put together that type of proposal would hear about the first call for applications, and could begin preparing a proposal to be submitted in the second grant cycle.

AWARD MECHANISMS

In the afternoon, Dr. Gruder asked the Council members to discuss the types of mechanisms the Program should fund, and the optimal amount of money to distribute via different award mechanisms.

Available Funding and Amounts of Awards

Dr. Gruder began by discussing the amount of funding available. He explained that the initial projection was that there would be approximately $14 - 15 million a year available for research. The tobacco tax was collected starting January 1, 1994. For the first six months of 1994 approximately $7 million should have been collected; however, the amount actually collected was closer to $5.4 million, due to the tobacco distributors' stockpiling in December before the tax was initiated. Staff member Beverly Pachner is currently working with the U.C. Budget Office to get an accurate estimate.

Dr. Gruder reported that the tax revenue has been projected to be $5.4 million in fiscal year 1994; $14.7 million in 1995; $14.1 million in 1996; and $13.5 million in 1997. This is based on an assumption that there will be a 5% annual decline in tobacco purchases. He explained that money for a fiscal year is appropriated as of July 1. For example, the money for fiscal year 1995 was appropriated July 1, 1994. It is projected that approximately $45.3 million will be available for grants through fiscal year 1997 (taking into account that 5% of the BCRP budget will be used for administrative costs).

Dr. Gruder noted that some of these figures are "soft," and that in the call for applications, there is no need to guarantee a specific dollar amount that would be allocated to every category and type of research. It would be better to give a general sense of how much will be available.

One member asked how much of a researcher's salary could be paid with the grant money. Dr. Gruder replied that up to 100% of base academic salary could be allowed, if requested and approved by peer review. He noted that the TRDRP has considered requiring that principal investigators spend a minimum percentage of their time (e.g., 25%) on the funded project.

Dr. Gruder noted that the statute authorizing the Breast Cancer Research Program specifies that the overhead rate allowed by the Program will be the rate approved by the federal government for a particular institution. However, University of California campuses will not receive any overhead from the Program, since they receive their overhead from state appropriations.

One member asked how the overhead rate would be determined for non-profit organizations which have no federally-determined rate. Lourdes De Mattos, from U.C.'s Contracts and Grants Office, replied that, in the past, the rates requested by such organizations have been routinely approved because they are low (e.g., 10%). Another member asked how an overhead rate would be determined for private industry researchers who do not have federally-determined rates. Dr. Gruder replied that Staff will follow up on this question, including investigating how NIH determines rates for private industry grant recipients.

For-Profit Grant Recipients: Patent Rights, Royalties, Fees, Grant Payback

Council members also discussed the issue of patent rights, royalties, and grant payback for private industry researchers receiving Program funds. Dr. Gruder noted that, according to the statute, intellectual property rights are to be retained by the recipient institution. The statute does not address royalties, fees and grant payback. However, the latest version of AB 3391 [distributed to Council members at the meeting] includes a provision requiring U.C. to evaluate the desirability and feasibility of requiring for-profit grantees to compensate the State in the event that a grant results in the development of a profit-making product, including the possibility of a royalty payment. The University is to make recommendations regarding these issues in the annual report to the Legislature due on or before December 31, 1994.

Dr. Gruder informed the Council that he has met with other units from within U.C. to discuss these issues, and that a follow-up meeting will be scheduled soon. Dr. Hopper noted that personnel in U.C.'s Technology Transfer Office and Contracts and Grants Office are concerned that a policy of requiring royalty payments might create a disincentive for industry researchers to take part in the Program. They are also concerned that such a policy might be harmful to the University as a whole, since it could encourage the use of a general model under which products of research funded by grants would be subject to future royalty payments (i.e., without regard to whether the researchers are not-for-profit or for-profit). The same concerns apply to a policy of requiring grant payback.

Dr. Gruder noted that one of the issues raised in the U.C. meeting was that it might be difficult to determine exactly whether and when a profit is made. Furthermore, if profits are not realized until 10 years after the grant was made, it might be problematic for the Program to monitor compliance with royalty or payback requirements. Dr. Gruder noted that some representatives of private industry expressed the view that a royalty or payback requirement would not be a disincentive to participate in the BCRP. Nevertheless, he advised the Council to carefully consider the potential impact a payback requirement might have on achieving BCRP's goals. He also suggested considering how such a requirement would be perceived by the public and by the Legislature (i.e., does it look like a responsible way to obtain more funding for breast cancer research, or does it look like a disincentive to private industry research?)

Types of Awards

Council members discussed whether the Program should fund pilot projects (i.e., small awards for one year or less, to see if an idea is feasible) in addition to more traditional research project awards. Although one member felt that pilot projects are not necessary in California, others favored the idea of pilot projects, and discussed two options regarding how such projects should be funded. Under Option One, the Program would fund a pilot project for a specified time (e.g., one year), and would guarantee additional funding if certain goals are achieved in that time. Under Option Two, small (e.g., $50,000) one-year awards would be made for pilot projects, with no guarantee of future funding. Under Option Two, pilot grant recipients would submit competitive renewal applications.

Several members spoke in favor of Option Two. However, one member pointed out that the disadvantage of that option is that a researcher would have only a year to do the research, and would then have to spend almost a year writing a new proposal and awaiting a funding decision. Other Council members felt this was not an obstacle; they suggested that the pilot project grant be considered seed money, and that additional funding could be sought from NIH or elsewhere.

One member argued against treating private industry separately, and suggested eliminating the "industry project" award type listed on page 8 of the Staff Recommendations. This member suggested that private industry researchers should be able to apply for both research project funds and pilot project funds.

Council members also discussed the duration of awards. Dr. Gruder stated that the TRDRP has awarded grants with a maximum three-year duration because that is the amount of time that U.C. has to spend money allocated to it by the State. Payments are made annually and are contingent on submission of progress and fiscal reports.

One member suggested adding an additional funding mechanism to those listed in the Staff Recommendations -- a scholarship program for undergraduates in California colleges. Several Council members spoke in favor of the idea of sponsoring a scholarship or internship program,

noting that such programs had been instrumental in starting them on their scientific careers. Several different models for a scholarship program were discussed. One member noted that scholarships akin to National Merit Scholarships could be awarded to promising undergraduates who need money to go to school; such money would not be contingent upon performing specific research. Dr. Hopper noted that such a model might not be consistent with the statute. Other members favored an internship model, where the Program would provide money for a student to work in a lab with a BCRP-funded investigator. Some people felt that a summer program would work; others felt that a summer was too short to be of value.

Dr. Hopper noted that the TRDRP has awarded Minority Training Supplements to encourage investigators to bring minority students into their labs. Such a program relies on investigators to apply for supplemental funding; this is different from having students apply directly to the Program for funding. Although some Council members favored the idea of targeting minority students with a scholarship program, one member pointed out the dearth of available programs for non-minority students.

Several members felt that the goal of an internship program should be to encourage promising students to pursue careers in science and, specifically, in breast cancer research. They warned that it would be unrealistic to expect research results from student interns. They also noted that it can be time-consuming and expensive for a researcher to sponsor unexperienced undergraduates in a lab, which must be taken into account when looking for sponsoring labs.

Dr. Gruder suggested that a subcommittee be formed to discuss the feasibility of establishing a scholarship or fellowship as one award mechanism, and to discuss the strengths and weaknesses of various options.

Council members also discussed adding sabbatical support as another award mechanism. Sabbaticals would offer researchers an opportunity to investigate new directions and develop new skills in breast cancer research. Several members favored offering sabbatical awards, which could support teachers or clinicians working in labs for a period of time, or which could allow a researcher to explore a new area.

Dr. Gruder noted that it is not necessary to define in advance the specific number of each type of grant (post-doctoral fellowship, new investigator award, etc.) that will be awarded. He recommended announcing the different award mechanisms available, without making a commitment as to how many of each type will be funded.

PEER REVIEW PANELS

One member asked whether patient advocates would serve on the peer review panels. It was noted that a diversity of expertise is important in peer review panels, and that patient advocate representation might be particularly appropriate for study sections evaluating proposals regarding quality of care issues. It was also noted that SPOREs, the Tax Check-off Program and

some NIH programs have included patient advocates as peer reviewers. One member suggested finding patient advocates who are also experts in specific research areas.

Council members were reminded to submit peer review nomination forms to Program staff. Dr. Gruder reminded members to focus on nominating peer reviewers from outside California, to avoid conflicts of interest. He noted that peer review nomination forms have been sent to numerous groups, including members of NIH study sections and advisory councils. He also noted that he is in the process of trying to get the names of DoD peer reviewers. Efforts are also being made to obtain names of private industry researchers who might be suitable to sit on peer review panels.

CALIFORNIA TUMOR REGISTRY

John Young, Chief of DHS's Cancer Surveillance Section, gave a presentation regarding the availability of data from the California Cancer Registry for use by researchers. He stated that the Registry captures data from approximately 98% of new cancer cases in the state each year.

Dr. Young noted that although breast cancer accounts for only 15% of all cancers, 90% of the requests that he gets to use the Registry are to study breast cancer. Since there are so many requests to work with the Registry, one of the jobs of Registry staff is to try to prevent patients from being contacted by multiple groups for multiple studies. The Cancer Registry requires anyone who wishes to use Registry data to have a human subjects review; there are written guidelines [which are being sent to BCRP staff] regarding which group has the first right of access when multiple groups wish to study the same patients.

Dr. Young noted that the two patient groups most studied by researchers using the Registry are young patients and minority patients. In addition, patients in major urban areas are more heavily studied than patients in outlying areas. Currently, every new breast cancer patient under age 35 is involved in some study. Other patients currently being studied are white women in Los Angeles between ages 55 and 64 and black, Latina and Asian women in Los Angeles between ages 35 and 64.

Dr. Gruder suggested that the BCRP require applicants who plan to use Cancer Registry data to include with their applications a letter of support from the Registry. Dr. Young endorsed this suggestion. [Dr. Young stated that applicants should be instructed to contact him or Dr. William Wright, Chief of DHS's Research and Surveillance Program].

Dr. Young gave members a handout regarding distribution of breast cancers in California by age, race, and region. The most recent set of data available is from 1991; 1992 data should be available in October, and 1993 data should be available in February, 1995. Dr. Young explained that some Registry information, such as that included on the handout, can be accessed without having to contact individual women. Every year, a public use tape containing non-confidential data is available from the Registry on request. Although data by county are available, counties

with small numbers of cases are grouped together so that there is no chance of identifying patients. If specific investigators wish to investigate a hypothesis using data not on the public use tape (e.g., census-tract data), the Registry will create a special use tape for them.

Dr. Young noted that DHS plans to use its portion of the money from the Breast Cancer Fund to do a cohort study of approximately 500,000 teachers. Teaching was chosen because it is a largely female profession and because teachers believe that they are at a high risk for breast cancer.

One Council member asked for an estimate of how much it would cost an investigator to contact a patient listed with the Registry. Dr. Young replied that it costs approximately $100 per case for a completed interview (including initially contacting the patient and physician and finding and interviewing the patient).

PUBLIC INFORMATION

Mike Alva, Senior Public Information Representative in the News and Public Affairs department of U.C.'s Office of the President, gave a brief presentation regarding strategies for disseminating information about the Breast Cancer Research Program. Mr. Alva stated that he is part of a larger unit called University Relations, which provides media relations for the University system as a whole. Each U.C. campus has its own public information office dealing with specific campus-related matters. Thus, when grant awards are made, Mr. Alva will send out a general news release to the media, newsletters, and to the campuses; individual campuses will publicize grants made to their researchers.

Mr. Alva noted that his office works with the U.C. Governmental Relations Offices in Sacramento and Washington, D.C. Thus, when it comes time to provide information to the Legislature, he can work with the Legislative Coordinators and the Governmental Relations staff in those offices.

Mr. Alva proposed issuing a news release to announce the establishment of the BCRP. He is in the process of writing profiles on three Council members (Susan Claymon, Andrea Martin, and Susan Shinagawa Smith) who are breast cancer survivors. He felt that personalized stories would be an effective way to reach the mainstream non-medical media. Additional press releases could be distributed when the call for applications is released and when the awards themselves are made. Mr. Alva noted that he may call on individual Council members to obtain information for developing future feature stories.

Mr. Alva suggested that when Council members speak about the Council to the media or in public, they should make clear that they are speaking as individuals (unless they are reporting an official Council position). He invited Council members to call him if they have questions about dealing with the media in relation to the BCRP.

Mr. Alva cautioned that because the Council is part of the University, everything that Council Members record becomes subject to the public records act. He warned people to keep this in mind when sending information to him or to staff.

CONCLUSION

Dr. Gruder stated he would follow up on several items raised during the meeting, would appoint subcommittees, and would let members know when the next meeting (to be held in Los Angeles) would be set. Items on the agenda for the next meeting include:

- finalizing details regarding the call for LOIs
- discussing support for research infrastructure
- discussing the possibility of issuing contracts to collect additional Registry data

The meeting was adjourned at 4:00 p.m.