

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

Meeting Minutes

October 12, 1994

Doubletree Hotel, Los Angeles, CA

Council members present: Lisa Bailey, Christopher Benz, Leah Cartabruno, Susan Claymon, William Comer, Jacquolyn Duerr, Patricia Ganz, Adeline Johnson Hackett, Barry Hirschowitz, Deborah Johnson, Liana Lianov, John Link, Andrea Martin, Edith Perez, Susan Shinagawa

Council members absent: Mary-Claire King, Barnarese Wheatley

U.C. Staff: Ellen Auriti, Samuela Evans, Charles L. Gruder, Annette McCoubrey, Walter Price

INTRODUCTION

Interim Director Gruder introduced U.C. staff members Annette McCoubrey and Walter Price, who have worked with the Tobacco-Related Disease Research Program and who now will be working with the Breast Cancer Research Program. He also introduced Samuela Evans of Research Administration.

REVIEW OF 8/23/94 COUNCIL MEETING MINUTES

Dr. Gruder asked for corrections or comments regarding the minutes of the August 23rd meeting. The following suggestions were adopted, and the minutes were approved as revised:

- On Page 3, revise the first sentence of the first paragraph to read as follows: "Also related to outreach, Dr. Lianov reported that DHS is using funds from outside the Breast Cancer Early Detection Program to develop a revised treatment brochure as required by law. In addition, the Program is carrying out an educational campaign which focuses on women over the age of 50."
- On Page 5, Line 4, after the word "older" add "and younger."

CHANGE IN PROPOSED TIMETABLE FOR CYCLE 1

Dr. Gruder announced that since the last Council meeting, staff has learned that the money appropriated to BCRP for fiscal years 1993-94 (\$5.4 million) and 1994-95 (\$14.7 million) must be obligated by the end of the current fiscal year (June 30, 1995). Since this is six months sooner than previously anticipated, the recommended timetable (discussed at the last Council meeting as part of the staff recommendations) has been revised.

Under the proposed revised timetable:

- Calls for Letters of Intent (LOIs) would be issued by November 15, 1994;
- Information meetings for people interested in submitting LOIs would be held in early December;
- LOIs would be due on January 6, 1995;
- LOI review committees would meet in late January;
- Invitations to submit full applications would be issued by February 1;
- Full applications would be due on April 1;
- Study sections would meet to review applications in April - May;
- The Council would meet in early June to make award recommendations;
- Awards would be announced by mid-June.

One Council member asked what would happen if, after peer review, the Council found that there were not enough high quality proposals to justify awarding the full \$20 million. Dr. Gruder responded that it would probably be possible to carry forward some of the money if BCRP could show that it made a good faith effort to obligate the funds appropriated to the Program.

One Council member expressed concern about the short time between the January 6 due date for LOIs and the date invitations to apply would be sent out, as well as the short time between the April 1 due date for full applications and the mid-June award date. Dr. Gruder replied that though the schedule is tight, it is, from his experience, feasible.

REVIEW PROCESS

Dr. Gruder stated that before January, BCRP will set up small screening committees to review LOIs. Committees will probably consist of three to four people, and will probably include a Council member. One Council member asked what kind of expertise LOI reviewers would be expected to have. Dr. Gruder responded that BCRP will try to get reviewers with broad research and evaluation experience, so that they will be able to review LOIs on a variety of topics. He noted that the panels reviewing full applications will be larger, and will include reviewers with expertise in particular areas. Dr. Gruder urged Council members to give staff the names of potential LOI screening committee members and of potential reviewers.

Dr. Gruder noted that the Subcommittee on LOI's advised that if there is significant disagreement regarding an LOI, the applicant should be invited to submit a full application. Speaking in favor of the proposed triage process, one Council member noted even if reviewers are instructed to give the benefit of the doubt to LOIs on which there is disagreement, triage will eliminate LOIs that are not relevant to BCRP's stated goals and those on which there is clear agreement not to invite. This process will enable the panels reviewing full applications to spend their time more efficiently.

One member asked how the review process for full applications would work. Dr. Gruder explained that in TRDRP, review panels for full applications usually have between ten and 20 study section members reviewing anywhere between 35 and 75 applications. Three study section members review each application, with each study section member reviewing no more than 12 applications. Abstracts, applications, and quality ratings are then given to TRDRP Scientific Advisory Committee members, along with information about the recommended budget and award duration. Committee members then meet and decide which awards to recommend for funding. A similar process could be used for BCRP.

One Council member asked whether full review panels could be smaller than ten people, and whether each reviewer should be required to read every application in his or her panel. Several other Council members responded that it is important to have enough reviewers to ensure diversity of viewpoints and disciplines. They also noted that when each panel has 50 or so applications to review, it is not feasible for every reviewer to read every application; reviewers will read those applications that they have expertise or interest in.

One Council member stated that an advocate should sit on every peer review panel. Several other members also favored this idea.

One member asked if any feedback would be given on the LOIs or on the full applications. Dr. Gruder responded that minimal feedback would be given at the LOI stage -- probably a simple checklist showing which criteria an LOI failed to meet. However, a more detailed critique will be written for full proposals (similar to the NIH pink sheet), and applicants could be given a lightly edited version of this critique.

LETTERS OF INTENT

Council members discussed the issues identified by the Subcommittee on Letters of Intent (summarized at Tab 5 of Council members' meeting notebooks). It was decided that the Call for LOIs should:

- include a mission statement describing the Program's goals and encouraging innovation and translational and multidisciplinary projects;
- make clear that LOIs are required and that they will be subject to triage;
- include information about the required format;
- set out the schedule for submission and review of LOIs;
- list the required components and evaluations criteria for LOIs (which will vary according to award mechanism);
- make clear that the outline of priority research issues included in the Call lists areas of particular interest to the Program, but that projects need not address any of the specific issues listed.

Council members agreed that translational and multidisciplinary research should be encouraged but not required. It was suggested that the Call for LOIs state that such research would be given special consideration; while LOIs would not be triaged based on whether they proposed multidisciplinary or translational work, these factors would be taken into consideration when the Council makes final funding recommendations.

One member asked whether LOIs can be appealed. Dr. Gruder replied that given the tight schedule of deadlines and given that a second grant cycle will start in March, LOI appeals will not be entertained. However, researchers not invited to submit applications in the first grant cycle will be free to submit LOIs for future cycles.

Council members discussed whether people who submit LOIs should be required to provide information regarding the Principal Investigator's background and research environment. It was suggested that such information be optional at the LOI stage. Several members stated that even if background information is optional for some award types, it should be required for people applying for New Investigator, Postdoctoral Fellowship, and Training Program Awards, since the PI's background is relevant to determining eligibility for those awards.

Council members agreed that applicants should not be formally encouraged to contact them for information about the Program or about the application process. One member pointed out that such a policy would enable Council members to remain unbiased, and would avoid the need for members to recuse themselves during any Council discussion regarding funding particular applications. It was decided that potential applicants who do contact Council members should be referred to BCRP staff; this will avoid any appearance of bias, and will ensure that conflicting information about the Program is not disseminated.

APPLICANTS UNAFFILIATED WITH AN ORGANIZATION

A question came up regarding unaffiliated individuals who wish to apply for BCRP funding. Several Council members stated that care should be taken not to discourage such individuals from applying. Dr. Gruder stated that such individuals would be encouraged to apply. However, they should be notified that certain insurance, fiscal management, human subject/animal assurance and other requirements will have to be met in order to obtain funding through U.C. Dr. Gruder stated that such requirements exist to ensure that public money is expended appropriately. He noted that individuals would have to meet such requirements by associating with an organization; this is necessary so that U.C. can demonstrate that it has taken the appropriate steps to prevent misuse of public money, and so that if any improprieties occur, U.C. will have some recourse.

Dr. Gruder explained that applicants need not supply proof that they could meet all the requirements until funding is awarded; no proof is necessary at the LOI stage. If a grant is awarded to an unaffiliated individual, the award could be made contingent upon the individual associating with an organization that could meet U.C.'s funding requirements and which could supply the proper assurances.

One member suggested investigating the possibility of obtaining bonding or insurance for unaffiliated individuals through a state program. Another member suggested that unaffiliated individuals could meet funding requirements by contracting with a public accounting firm.

RESEARCH PRIORITIES

During a working lunch, the Council discussed BCRP's research priorities. Dr. Gruder noted that the outline of priority research issues [provided at Tab 3 of members' meeting notebooks] was revised based on the discussion at the August 23rd Council Meeting. Council members agreed that while the outline of priority research issues should be included in the Call for LOIs, the Call should make clear that the outline is not an exhaustive list, and that proposals need not be confined to the specific issues listed.

AWARD MECHANISMS

Council members discussed the details of the proposed award mechanisms [summarized at Tab 4 of members' meeting notebooks]. Proposed award mechanisms include:

- **Research Projects** (awards for fully developed investigator-initiated projects)
- **Pilot Projects** (one-year awards for early stages of research emphasizing innovative approaches. Also known as Innovative Developmental and Exploratory Awards.)
- **New Investigator Awards** (for junior investigators who have finished their training and who are independent researchers)
- **Fellowships** (stipends for researchers who are still in training, working in the lab of a mentor)
- **Sabbaticals** (support for researchers who want to leave their current employment for a year to move into breast cancer research or to learn new skills in an area of breast cancer research.
- **Traineeships** (awards given to institutions to train students for careers in areas related to breast cancer research)

Dr. Gruder noted that a Council subcommittee on fellowships developed a proposal [included at Tab 4 of members' meeting notebooks] regarding potential award mechanisms for career development. He noted that the types of award mechanisms suggested by the subcommittee included Postdoctoral Fellowships, Institutional Training Programs, and Individual Student Traineeships. He stated that staff recommends implementing the first two types of award mechanism in Cycle 1, but delaying the implementation of Individual Student Traineeships until a later cycle. He stated that the reason for the delay is that an award mechanism designed for individual student awards will require the development of new criteria and procedures, and that there is not sufficient time to adequately analyze all the relevant issues in time for Cycle 1.

One member felt that too many of the award mechanisms focused on training; he stated that he feared this would make BCRP seem too much like an educational program rather than a research program. Other members responded that the training and fellowship awards are important, because they encourage young and new investigators to go into research at a time when the average age of award recipients has gone up significantly. These members felt that the training awards would not discourage research, but would encourage applications from people who might not otherwise apply for funding. It was pointed out that having specific award types for new investigators and postdoctoral researchers would encourage applicants to apply because they would be competing against people of similar levels of experience. In addition, it was noted that any researcher could apply for a Research Project Award, regardless of the researcher's level of experience or seniority.

Council members agreed there should be a cap on direct expenses for each award type. Members favored the caps listed at Tab 4 of their meeting notebooks (\$50,000 for Pilot Projects; \$75,000 per year for New Investigator Awards; \$35,000 per year for Postdoctoral Fellowships; \$50,000 for Sabbaticals; and a per-student maximum for Training Programs, depending on the length of the program and whether students are undergraduate or graduate). However, in order not to discourage broad or ambitious research projects, Council members decided that the \$100,000 annual cap for Research Awards should be a "soft cap." That is, Research Project Award applicants should be told that if they demonstrate strong justification, they may be awarded more than the recommended budget. Dr. Gruder noted that indirect costs would be paid at the federally-determined rate (except that no indirect costs are to be awarded to U.C. campuses).

RESEARCH INFRASTRUCTURE

Council members discussed the recommendation made at the last Council meeting that BCRP should fund projects designed to improve the research infrastructure for breast cancer. [Material related to this issue was included at Tab 6 of members' meeting notebooks.] Dr. Gruder noted that contracts, rather than grants, could be used to fund infrastructure-building projects. He stated that the idea behind this would be for BCRP to contribute to the creation of breast cancer research resources accessible to all researchers in the state. Several members spoke in favor of funding such projects; one member noted that this was one way to ensure that BCRP money is used to fund something of tangible benefit.

Among the possible infrastructure projects suggested by Council members were the enhancement of tissue banks and the development of a cohort of California women or adolescent girls for a prospective study of breast cancer. One member suggested working with DHS's Breast Cancer Early Detection Program or with the California Cancer Registry to supplement their data collection. Responding to the suggestion that BCRP fund a tissue bank project, one member warned that developing tissue banks is not necessarily the best use of funds; this member noted that due to evolving research interests and techniques, it is difficult to ensure that today's tissue and data collection will meet the needs of future researchers.

Several members felt that before funding a project of its own, the Council should find out what infrastructure already exists. They noted that there are currently infrastructure-building projects taking place, at least at the national level. Dr. Gruder suggested that BCRP could contract with someone to prepare a report regarding existing infrastructure for breast cancer research. Such a commissioned report could include a catalogue of data resources available in the state, and an analysis of the areas where data is weak or missing. Council members agreed that this was a good idea. Several members also expressed interest in holding a scientific forum (similar to the National Advisory Meeting) regarding the development of infrastructure. One member stated that such a meeting of experts should be convened before a study is commissioned. Dr. Gruder stated that staff would look into commissioning a report on available infrastructure.

COMPENSATION TO THE STATE

Council members discussed options for requiring for-profit grantees to compensate the state in the event that they market products developed with BCRP funds. Dr. Gruder explained that recent legislation (AB 3391) requires U.C. to make recommendations to the Legislature regarding various repayment options (including grant repayment, royalty payments, and providing the product at cost to certain state programs). He referred members to Tab 7 of their meeting notebooks, which contained a summary of pros and cons of various repayment options, developed by staff after a series of internal U.C. inter-departmental meetings. Dr. Gruder noted that there are many complexities and costs involved in developing and implementing a repayment policy. He stated that factors to consider include 1) whether sufficient money would be recaptured to justify the repayment policy; 2) whether the cost of implementing the policy would be reasonable; 3) whether such a policy would be a disincentive to industry applicants; and 4) whether implementing such a policy would be perceived as fiscally and socially responsible, especially in the view of the Legislature.

Several members spoke in favor of requiring some sort of repayment from for-profit grantees. One member explained that the idea behind requiring repayment is that if a company makes a windfall profit using public money, then the company must do something to compensate the public. Another member stated that entrepreneurs will be eager for the chance to get funding, and that a repayment requirement would not be a disincentive to applying for funds. However, several members noted that the cost of translating research into a marketable product is very high, and that BCRP funding is likely to be only a small fraction of that cost. These members felt that it would be too difficult to determine what role BCRP funding played in developing a profitable product.

One member stated that BCRP should not even consider requiring companies to provide their products at cost; this would be too complicated, and too big of a disincentive. This member felt that the best option is negotiating a royalty agreement with for-profit applicants; such an agreement could be structured so that the bigger the windfall, the bigger the payback. This member felt that the next best option would be to require a profit-making company to repay BCRP up to twice the amount of the grant.

Several members pointed out potential problems with instituting a payback requirement. For example, it was noted that having a different policy for for-profits and not-for-profits might give rise to objections. Also, there are cases where both a University and a for-profit company cooperate in the development of a product; it is not clear how such cases should be treated under a policy requiring repayment only from for-profits. Dr. Gruder agreed that there were many complex issues involved, and stated that he might call upon Council members for additional input before making a report to the Legislature.

CONCLUSION

Dr. Gruder stated that he follow up on the idea of commissioning a report on available infrastructure resources for breast cancer research. He also stated that he would fax the Call for LOIs to Council members before sending it to the printer, but emphasized the need for fast turnaround time.

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