

Minutes of the Breast Cancer Research Council

October 24, 1995

Kaiser Center, Oakland

Council Members Present: Lisa Bailey, Christopher Benz, Susan Claymon, Liana Lianov, Carol MacLeod, Andrea Martin, Susan Shinagawa, Carol Voelker, Barnarese Wheatley

Council Members Absent: William Comer, Jacquolyn Duerr, (alternate ex officio), J. Patrick Fitch, Patricia Ganz, Sam Ho, Deborah Johnson, John Link, Carol Pulskamp

Guests: Scott Bain, Assistant to Assemblywoman Barbara Friedman, Sandra Michioku, Consultant with Assemblywoman Barbara Friedman

Staff Present: Barbara Fichtel, Charles L. Gruder, Cornelius Hopper, Mhel Kavanaugh-Lynch, Mary Kreger, Annette McCoubrey, Walter Price,

The meeting was convened at 11:20 am by the Chair, Susan Shinagawa. Mhel Kavanaugh-Lynch presented Susan Claymon with a gavel in honor of her hard work serving as Chair of the Council for 1994-95. Mhel also congratulated Carol MacLeod on being promoted to Professor of Medicine.

I. PROCEDURAL AND SCHEDULING ISSUES

Susan Shinagawa noted that, according to established Council policy, there was not a quorum and the Council could not pass motions but could make recommendations, have discussion, and poll the absent members by mail. Mhel Kavanaugh-Lynch handed out a summary of procedural rules reported in the minutes of previous Council meetings. Carol MacLeod suggested that the mail ballot present pros and cons for the issues discussed. Additionally, she stated that the UCSD Academic Senate uses a simple majority in its proceedings and we might want to amend Council procedures to

allow for this in the future. Chris Benz supported this suggestion, noting that the Program must receive timely advice from the Council. Mhel Kavanaugh-Lynch reported that a quorum was expected when the meeting was arranged, but emergencies prevented some members from attending. Susan Claymon suggested that we use the mail ballot and proceed with the agenda. Chris Benz suggested that meetings only be scheduled when two-thirds of the members can attend, but that a simple majority of voting members (8) would constitute a quorum. Several members noted that the only option for today=s meeting, under current rules, is to make recommendations, discuss issues, and use a mail ballot.

RECOMMENDATION: Carol MacLeod recommended that the quorum rule be changed to a simple majority, with the provision that meetings not be scheduled unless two-thirds of the members indicate that they can attend at the time the meeting is scheduled. This was seconded by Chris Benz.

It was pointed out that all members were asked at the time they were being considered for appointment if they would be able to attend Council meetings, because attendance at meetings is critical to the Council=s work. Susan Shinagawa suggested that the Council consider a policy regarding meeting attendance such that members who miss a certain number of meetings would be asked to resign. Andrea Martin recommended that if a member missed a certain number of meetings (2 or 3) in a year, that member could be asked to resign, either automatically or by vote of the Council. All present agreed that this issue should be discussed further at the next meeting.

Susan Shinagawa asked that the minutes of the previous meeting be corrected to show Carol MacLeod as an active, but absent, Council member.

RECOMMENDATION: Chris Benz recommended that the minutes be considered approved if additional corrections to the minutes are not made within a week of the mailing of the minutes to all members.

Lisa Bailey noted that since October is Breast Cancer Awareness Month, perhaps we should avoid scheduling Council meetings during this month.

Susan Shinagawa invited all Council members to contact her with suggestions for new agenda issues for all future Council meetings.

The issue of conducting open Council meetings, circumstances for closed sessions, and how open meetings should be announced was raised and tabled until the next meeting.

II. OUTREACH SUBCOMMITTEE

Susan Claymon presented a report of Outreach Subcommittee. The subcommittee met via conference call with the goal of making the Call for Applications more user friendly in addition to enhancing the program mailing list. Susan complimented Mhel on her work on the Call and in identifying additional individuals and organizations for the mailing list. A notice for the Call for Applications was placed in the Western Journal of Medicine and many additional names were added to the mailing list. Sources of these

names included the lists and directories of the following groups: American Society of Clinical Oncologists, American Society of Preventive Oncology, the Gay and Lesbian Medical Association, Department of Health Services partnership participants, the Sacramento and Bay Area Breast Cancer Resource Guide listings, Oncology Nurses Association, the Society of Research Administrators, the Association of Women Surgeons, the American College of Surgeons, the chairs of all the hospital Cancer Committees, and many more advocacy groups from various sources. Posters advertising Cycle II were sent to grants and contracts officers, department chairs and deans, and advocacy groups. Additionally, Mhel is handing out flyers at the American Public Health Association meeting in San Diego at the end of October. Mhel views the mailing list as a work in progress.≡ The industry portion, which includes approximately 900 names and organizations, comes from a purchased list, suggestions from Bill Comer, and library research performed by a staff member.

The Call for Applications and the Application Packet for Cycle II are printed on chlorine-free recycled paper with soy-based ink.

Information Meetings and Newsletter

Information meetings for Cycle II begin November 1. An evaluation form is being used this year to collect information about the attendees at the Information Meetings and to solicit their suggestions for improvement. Susan Shinagawa stated that she would like to attend an Information Meeting, although she is aware that last year Council members agreed not to. Larry Gruder said that last year the Council and staff were concerned about Council members being lobbied. Susan suggested that, if members

are lobbied, either in person or otherwise, they should refer individuals to the Program staff. Carol MacLeod said that as a new member it would be helpful for her to attend. It was agreed that Council members could attend the meetings, but would not be identified or introduced.

Mhel passed out the draft text of the first newsletter. The plan is for the newsletter to be quarterly and it is envisioned to contain profiles of Council members, descriptions of research being done, etc. The newsletter will be mailed to everyone in the database, approximately 8,000.

Chris Benz and Susan Claymon noted the quarterly newsletter was ambitious, and it would be less expensive if the newsletter was produced less frequently. Questions were asked about how to best get information to legislators and their staffs. Larry Gruder suggested we work with UC Office of State Governmental Relations to develop the most effective manner of providing information to legislators. Andrea Martin stated the importance of talking with legislators and their staffs to obtain their suggestions. She recommended that the newsletter include photos of Council members and staff with captions and quotes from advocates and funded researchers. Susan Claymon asked Scott Bain and Sandra Michioku from Assembly member Barbara Friedman office for their suggestions. Sandra stated that information is especially important in this time of term limits which causes increased turn over of legislators. She also stated that having a predictable schedule is advantageous because people will expect the publication, and Sandra suggested using photo captions to accent information. Scott suggested using lay terms, accessible format, brevity, and timing newsletters to arrive during those times the California Legislature is not in full session. He noted that June through August is an

especially difficult time due to the intensity of the session.

The Council discussed the timing of the first edition of the newsletter. Questions included whether the goal should be a dazzling first edition with photos and a sophisticated format or instead issuing the first edition as soon as possible, so that it could inform additional potential applicants about Cycle II, which would require a *Aplainer* format. Several members suggested the importance of distributing the newsletter in November. It was agreed that it is important to review the newsletter draft carefully for content now, in order to not delay the production process and that the subcommittee would see a formatted draft.

Mhel also noted that newsletter will be put on the Web, and the Call for Cycle II is available there now. Suggestions were made that biosketches of Council members be placed on the Web, along with the charge and history of the Program. Liana Lianov suggested that a question and answer format could be used. Additionally, other sources of breast cancer research funding could be listed. Lisa Bailey said that the National Action Plan, when complete, will list such sources of funding so we could refer individuals to that Web site.

Mhel reported that in her outreach meetings she has met with Council members individually, expanded her personal network, spoken with individuals who applied and were not funded and those who didn't apply in order to determine any barriers so that the Council can address these issues. She found that people generally were not upset at being rejected for funding. They understand that rejection is part of submitting applications. Individuals have responded favorably to the changes that are being made

for Cycle II. Upon being notified of his BCRP award, one awardee stated, ANCI would never have funded this!,[≡] suggesting that BCRP had, at least in this instance, funded research that does not duplicate what one other major funding agency supports. Many applicants strongly preferred the LOI process used in Cycle I.

III. CONFIDENTIALITY AND CONFLICT OF INTEREST STATEMENT

The current document reflects the consensus of the subcommittee (Susan Claymon, Carol Voelker, Carol Pulskamp, Mhel Kavanaugh-Lynch, working with Joanna Beam). Chris Benz suggested that these minutes ask Council members to read this statement and come to the next meeting ready to vote on it. Scott Bain asked why the Council has developed this document. Susan Shinagawa explained that the Council asked the staff to develop such a document to clearly delineate the Council responsibilities related to Confidential materials (e.g., investigators, intellectual property rights, etc.). Larry Gruder explained aid that there are two parts of this document: (1) the confidentiality statement; and the (2) conflict of interest statement. The Council agreed that these terms of Council membership need to be in writing. Several Council members noted that NIH, DoD, and the American Cancer Society all require confidentiality statements, and that the NIH requires institutions that are awarded grants to have conflict of interest policies in place. Carol MacLeod noted that the Council should not discuss who or what was reviewed at any time so the five-year time limit should be deleted. The statement in an earlier draft that prohibited applications for one year after council membership ceased has been dropped. Further discussion was tabled until the next meeting.

IV. PUBLIC RELATIONS

Andrea Martin reported that USC held a Women=s Breast Health Day on September 23, 1995 in L.A.. The BCRP was invited to attend and announce the Cycle I grants. BCRP kicked off the day with a presentation by Andrea, followed by Mhel who presented large mock-ups of checks to two USC researchers who were featured at the event. The proceedings were attended by 500 women and covered by two television stations in Southern California. In San Francisco, Willie Brown held a press conference on the fact that the Bay Area has the highest breast cancer rate in the world. Speakers included Assemblywoman Barbara Friedman, Andrea Martin and Mhel. Mhel stated that the executive summary (included in the Council meeting attachments) has been sent to the State legislators and was handed out at USC.

Susan Shinagawa reiterated Council policy that all Council members speaking with the press state that they are speaking for themselves and not as representatives of the Council. Please refer issues for the Council to Susan Shinagawa or Mhel and they will go through proper channels to address the issues.

V. PROGRAM=S RESPONSE TO REPORT II OF THE SUBCOMMITTEE

Issue: A letter to rejected LOI applicants

Discussion: Council members agreed that to send this out special letters to require LOI applicants at this time would cause confusion. The Call for Applications addresses the issue of unsuccessful LOI authors.

Issue: LOI Screening Process

Discussion: Susan Shinagawa stated that, Debbie Johnson would like to have the issue of the LOI process revisited in the future. Chris Benz indicated that an evaluation after completion of Cycle II may be a better time to determine if the LOI process should be revisited. Criteria for evaluation could involve the expense of each process, distribution of scores, and the work effort of reviewers and applicants. In Cycle II, all applications will be forwarded to review committees. Those that fall below a certain level of enthusiasm will receive reviews, but will not be scored for funding.

A question could be added to the Information Meeting evaluation forms, asking researchers for their views on the advantages and disadvantages of the LOI process. Mhel pointed out that one way to reconsider the LOI process would be to use it only for new mechanisms to be introduced in Cycle III, which would provide the opportunity to try a revised LOI process before using it for all mechanisms.

Issue: Selection of Reviewers

Discussion: Mhel pointed out that this recommendation was made after the LOI process, which was conducted under severe time pressures, and that application reviewers were significantly more diverse. A table delineating diversity of review committee members clearly shows a significant improvement over NIH review committees. Some study sections had more than 50% women and others had more than 50% non-university researchers. It was noted that experts in some fields (molecular genetics, for example), work almost exclusively in academic institutions. Likewise, many research fields remain heavily dominated by men. Staff asked the Council to consider the need for balance between reviewers' experience and diversity

of perspectives on review committees. The staff have received very positive comments about the quality of the review summary statements. The review of research proposals is an art, that requires experience to perform well. This experience is mostly gained through service on NIH study sections. To some extent, when we diversify the review committees to include reviewers from different venues who do not have this experience, we lose that perspective. In addition, we rely heavily on the reviewers to evaluate duplication of funding, which they are able to do because of their experience on other study sections where they see the range of applications being submitted and funded. Again, to the extent that we replace NIH study section reviewers (who are almost all from academic institutions) with reviewers from other venues, we will be losing this perspective and will receive less information on duplication of funding. This is not an argument against diversifying the review committees, but rather information for the Council to consider in advising the staff on the extent to which diverse perspectives should be represented.

The Program is committed to increasing the diversity of the review panels. Mhel reported that all Cycle II review committees will include two voting advocate members. Additional suggestions for sources of reviewers included: The American Cancer Society national reviewers and awardees, Department of Defense awardees, and grant awardees from the Department of Energy and NIH. Junior investigators who lack review experience, but may bring in a fresh perspective, will also be asked to participate.

Mhel asked the Council to decide if the requirement that scientists on review committees be from outside California should also apply to advocate reviewers. The reason for using reviewers from outside California is to reduce conflict of interest. It is recognized that advocates are less likely than scientists to have conflicts of interest with

applicants, but, since one goal is to encourage collaborations with community-based organizations, conflict of interest may become more of an issue for advocates in future cycles. On the other hand, having California advocates involved in the review process may be a good way to demonstrate that the review process is objective, fair and effective. Lisa Bailey suggested that California advocates from NBCC=s Project Lead serve as non-voting observers, who would be invited to report back to the Council and program on the process. This will be discussed at the next meeting.

RECOMMENDATION: All voting reviewers (including advocates) must be from outside California.

Issue: Reviewer Recruitment Subcommittee

Discussion: Debbie Johnson, in written comments submitted to the Council, advocated strongly against this suggestion, commenting that it would be micro-managing the staff.

Members agreed that Council should not establish this subcommittee, but the importance of members submitting names of potential reviewers was stressed.

C. Issue: A Workshop for advocates.

Discussion: Suggestions were made that we link with Project LEAD but not conduct our own training.

Issue: Outreach

Discussion: Extensive outreach efforts as described previously, have already been implemented. Future efforts will be discussed under Cycle III in the meeting agenda.

Issue: Outreach to Anon-traditional[≡] and community-based applicants..

Discussion: Bonnie Wheatley pointed out that the use of the word Anon traditional[≡] is awkward, and does not reflect the Council intent. A Non-university-based[≡] would be more appropriate. Again, outreach efforts are already underway and new outreach mechanisms are being discussed with, and formulated by, the Council.

Issue: F. Information Meetings.

Discussion: The Information Meetings are designed to address these issues.

Evaluation forms collected at the Information Meetings will help determine if the needs of non-university-based researchers are being met.

Issue: Duplication of research

Discussion: As discussed earlier, reviewers are the primary source of this information, which may become less reliable as we use more reviewers who do not also review applications for other agencies. Applicants in Cycle II are required to discuss the distinction of the proposed work from other funded work. Andrea Martin brought up the issue of having investigators explain why they are competing with other labs, instead of collaborating. Larry Gruder mentioned some of the benefits of competition between labs, and the fact that collaboration is not always the best route to solving a problem. He will provide the Council with a published account of the advantages of competition. Carol MacLeod agreed with this hypothesis.

Issue: Check off box for type of organization

Discussion: This analysis can be done for both Cycle I and Cycle II.

Issue: New award mechanisms.

Discussion: In Cycle II, there is one new mechanism for the two new priority areas, innovative treatment and innovative models of care. Staff are considering new mechanisms for Cycle III and will present these to the Council at a future meeting.

Issue: 8a, Carol MacLeod asked for an account of the extent to which the Council's funding recommendations for Cycle I diverged from the rankings based on scientific merit scores assigned by the review committees.

Discussion: Susan Shinagawa reported that the Council's funding recommendations, in some instances, diverged from these rankings based on research priorities and/or the secondary scores for special considerations. Some members stated that the Council needs more time with the abstracts in the future in order to be able to provide more input. Additional discussion centered on the scientific merit score cutoff point below which grants would not be examined.

Issue: Council review of feedback to applicants.

Discussion: All future notification letters to applicants will be reviewed by the Outreach Committee.

Issue: Appeals process.

Discussion: There was no appeals process for the LOI review. There is an appeals process for applications, which is described in the Application Packet.

Issue: Nominating subcommittee for Council members.

Response: The Council discussed the best means for Council members to have input into the selection of new Council members. Debbie Johnson proposed, through discussion with Susan Shinagawa, that the University select two to three candidates and provide a synopsis of their qualifications to the Council members. Individual Council members would provide input in confidence to the University and the Program would make final decisions regarding new members. Bonnie Wheatley stated that she was concerned that this was micro-managing the staff and that one person could provide information that would damage a candidate's reputation.

Susan Shinagawa suggested that this be an agenda item for the next meeting.

Issue: I, E-mail for Council members.

Discussion: Providing E-mail for Council Members is beyond our capabilities at this time. Mhel indicated that BCRP staff will fax/mail any communications Council members wish to distribute to the full Council.

Larry Gruder stated that the Program will investigate the possibility of installing an 800 number.

Dr. Hopper joined the Council meeting, and stated that the National Research Council rankings show that the University of California is an outstanding public institution, and that the Berkeley campus compares very favorably with Harvard and MIT. He stated that one of the challenges for the coming era of increased tuition fees and repeal of affirmative action policies is to attempt to maintain access to the University. He also stated that he feels the BCRP has been a very successful experiment and its inclusion of advocates can be used as a model for other states. He also noted that as smoking

decreases; there will be a need for a replacement of the tax revenues that fund the Program; therefore the Program's continued success will be important in securing sufficient funding in the future. Dr. Hopper thanked the Council members for their time and commitment to this Program.

VI. DEPARTMENT OF HEALTH SERVICES MASTER PLAN

Liana Lianov and Bonnie Wheatley discussed the Department of Health Services draft Master Plan. Bonnie serves as the Council liaison to the Master Plan Task Force. Liana asked Council members to review this draft, especially pages 25-28. She would like comments, by fax or telephone, at least one week before the next Council meeting. Comments on the Master Plan should also be forwarded to Bonnie. Liana noted that the goal of this plan is to be in place by the year 2000 and is to address access to breast cancer screening, treatment, and funding in California.

VII. IRB APPROVAL FOR CYCLE I GRANTS

Mhel Kavanaugh-Lynch raised the issue of how long the Program should reserve funds if a principal investigator has not yet received approval for a human or animal subjects protocol. Mhel will convey to any investigators currently in this situation that the Council is very concerned about this and wants them to obtain approval expeditiously.

VIII. CYCLE III PLANNING

The Council discussed a proposal submitted by Susan Shinagawa for an advisory meeting to assist the Council in developing for Cycle III, expanding on the model of the National Advisory Meeting for Cycle I. Lisa Bailey noted that the proposal is very

ambitious, and while she finds it laudable, she was concerned that all the stated goals cannot be achieved in one meeting. Susan Shinagawa noted that her preference would be to provide technical assistance on various topics in rural areas and to minority populations, but that this option is very expensive. Susan Shinagawa noted that the meeting would be important to the Council in reaching at least two of the major goals of the Council and the Program for this year: outreach and linkages. Carol Voelker suggested two one-day meetings, one in San Francisco, and one in Los Angeles. It was suggested that the Council clearly frame the structure, purpose and agenda of these meetings, to ensure that the program=s needs are met.

Mhel reviewed considerations for when the meeting should be held::

January 12, 1996	applications are due for Cycle II.
April 1996	applications reviewed
May 1996	Council recommends applications for funding
July 1996	Call for Cycle III must be complete
August 1996	Call for Cycle III needs to be mailed.
January 31, 1997	Cycle III applications will be due.

In order to have the Cycle III Call issued by July, 1996, the Council must have decided on the priority issues and award mechanisms by April or May, 1996 at the latest.

Susan Shinagawa will appoint a subcommittee to work on the meeting and to develop a proposal which addresses the most critical goal (determining the direction of

the program for Cycle III) and which we can accomplish between now and February.. Planning must be done quickly. It was noted that consultants may be sought from outside the Council.

Larry Gruder briefly discussed the collaborative prevention initiative implemented by the University-wide Aids Research Program, which requires collaboration between academic researchers and community-based service providers. This may be a model the Council would like to consider. Susan Shinagawa suggested that representatives from the AIDS Task Force be invited to make a presentation at the next Council meeting.

Mhel suggested the possibility of issuing a single Call with two deadlines, with the later deadline for new award mechanisms.

Due to lack of time, remaining Agenda items were deferred until the next meeting so that the Council could consider a funding issue remaining from Cycle I. This issue was considered in a closed session and the Council adjourned at 7:25 pm.

The next meeting of the Research Council has tentatively been set for Dec. 15, 1995.