Breast Cancer Research Council Meeting Minutes March 19-20, 2015: Council Meeting and Priority-Setting Retreat Waterfront Hotel, Oakland, California

Members Present: Jon Greif, Karuna Jaggar, Marjorie Kagawa-Singer, K. Alice Leung, Melanie Marty, Janice Mathurin, Arash Naeim, Naz Sykes, Sharima Rasanayagam, Ted Schettler, David Wellisch

Members Absent: Maria Caprio, Marjorie Green, Marta Nichols, Kristiina Vuori

Guests: Terri Burgess, Janna Cordeiro, Ysabel Duron, Marj Plumb

Staff: Mary Croughan, Lyn Dunagan, Mhel Kavanaugh-Lynch, Carmela Lomonaco, Katherine McKenzie, Lisa Minniefield, Senaida Poole

Thursday, March 19, 2015: Business Meeting

- I. **Call to Order:** Jon Greif called the council meeting to order at 9:12am and initiated introductions.
- II. **Approval of Minutes:** The council reviewed the minutes from December 5, 2014. Some edits will be made to the CBCPI section and the minutes will be brought back to the council for approval at the June 2015 meeting.
- III. Core Funding Update: Katie briefly presented the 56 applications, submission statistics, timeline, and draft programmatic review booklet. The group will be notified of the triaged applications a few weeks prior to the funding meeting in June. The group discussed the type of researchers that apply and the criterion of the review process. Council members signed up for a committee of their interest and Katie will finalize the committees and send review materials to the members in April. Council members are always welcome to attend scientific review meetings they are not signed up to review themselves.

CBCPI Update

- A. **Prioritizing Concept Proposals**: Mhel gave an overview of the CBCPI, summarizing the early stages of the initiative, including the set-aside funds that were collected over the last decade. In the planning phase of the project, the concept proposals were not prioritized when presented to the council. This resulted in approving approximately \$36 million in proposals, which was over the program's goal of \$24 million. She then presented the budget, funding model, and options recommended from the Steering Committee for how to prioritize the concept proposals to fit within the funding cap. The group discussed the proposals and available funding.
- MOTION: Karuna moved (Sharima seconded) to keep *Women Firefighters Biomonitoring Collaborative Study* in the CBCPI. The motion passed unanimously.

MOTION:	Karuna moved (Jon seconded) to keep <i>Paradigm Model for Breast Cancer: Follow On</i> in the CBCPI. The motion passed unanimously.
MOTION:	Karuna moved (Jon seconded) to the fund 12a <i>Immigration</i> and set-aside12b, a pilot study to bring together a group of experts (scientists and community groups) to determine the needs in the area of immigration. The motion passed unanimously.
MOTION:	Karuna moved (Jon seconded) to fund the <i>Pilots of Preventing</i> <i>Developmental Exposure to Ionizing Radiation from Medical</i> <i>Imaging</i> but not the <i>Full trial of Preventing Developmental</i> <i>Exposure to Ionizing Radiation from Medical Imaging</i> (17b). The motion passed unanimously.
MOTION:	 Jon moved (Margie seconded) to accept the Steering Committee recommendations to the fund the P1s: 1. California's Comprehensive Breast Cancer Primary Prevention Plan 2. Chemical Policy Impact and Effectiveness 3. Hormones in Beef in California 4. Explore Concurrent Environmental and Psychosocial Exposures during Windows of Vulnerability using Animal Models 5. Drinking Water 6. Racial/Ethnic Disparities in Consumer Product Availability, Access, and Use 7. Early Life Adversity 8. Targeted Intervention for High Risk Individuals: Improve Risk Assessment The motion passed unanimously.
MOTION:	 Jon moved (Melanie seconded) to eliminate all four P2s for funding consideration for this cycle: 1. Leverage Existing Cohorts for Opportunities to Explore Concurrent Exposure to Environmental and Psychosocial Risk Factors for Breast Cancer 2. Psychosocial interventions on stress, depression, and coping 3. Developmental Origins of Breast Cancer 4. Race/Ethnicity Disparities and Breast Cancer The motion passed unanimously.

B. Occupational Exposures: Carmela gave a brief summary of the Occupational Exposures RFP and why there weren't any applications submitted. The staff had a meeting with two PIs that showed interest in the project. After requesting feedback,

suggested enhancements were added to the RFP. The program asked the council to change to the funding mechanism of the project from an RFP to a Program-Directed Solicitation and invite the PIs to work together as team.

- MOTION: Jon moved (Melanie seconded) to accept the change in the funding mechanism to a Program-Directed Solicitation. The motion passed unanimously.
- IV. Policy Update: Mhel updated the council on the progress of the initiative noting that the Call for Topics was released in January and asked council members that work on policy to submit ideas. She also gave a brief update on the Policy Research Advisory Group's (PRAG) inaugural meeting. Carmela reviewed potential topics the group suggested including environmental exposures, access to quality care, risk factors, and disparities. Carmela also summarized the outreach efforts the program developed to announce the RFQ that included both in-person and web-based presentations. In early March, they met with researchers at RAND, UCLA, UCI, and UCD and held a webinar.
- V. Community Initiatives Update: Senaida briefly updated the group on the CRC applications that were submitted and will be scientifically reviewed in May. She encouraged members who will not be reviewing the CRC applications to attend the review meeting. She also gave an update on the QuickStart Training Program noting that the implementation of the 2014 program is complete and QS 2015 is in the planning stage. The QS staff is hoping to invite 10 teams to the program. The trainings will take place in July and August, which will allow the teams to prepare to submit grant applications for 2016.

VI. Committee Reports

- A. Finance: Arash summarized the resource allocation report focusing on the program's operational expenditures. The committee set targets for the Administration and Research Support and Evaluation so total amounts would be under 20%. All other budget line items are much like expenses in past years. Mary added that the program will be spending less in rent due to giving up office space to other departments within UC.
- **B.** Outreach: David presented the committee's plan to hold a one day conference in early 2016. He gave an overview of the objectives and general structure of the event, including the parameters and target audience. The group discussed hiring a science writer, having a theme, and adding a public health piece to the event. The next steps in planning process are to identify potential venues, speakers and facilitators.
- **C. Policy:** Melanie briefly summarized the committee's progress to date. They met three times since December to discuss implementation of the initiative. They brainstormed candidates for the PRAG, reviewed the RFQ and Call for Topics and the outreach efforts made to get ideas for more topic areas.
- **VII. Council Member Nominations:** Mhel announced that the program will be recruiting six new council members. She asked the members for their input on the quality of

representation that they think will round out the council. The group discussed criteria of potential members, including searching for someone with expertise in genetic counseling and fundraising.

- VIII. Nominations for Chair/Vice Chair: Jon nominated Sharima for Chair and Marjorie K-S for Vice Chair. No other nominations were made announced.
 - MOTION: Jon moved (Melanie seconded) to elect Sharima Rasanayagam as Chair and Marjorie Kagawa-Singer as Vice Chair. The motion passed unanimously.
 - IX. Fundraising: Jon suggested ideas for fundraising such as Amazon Smile, crowd funding, capital campaign, and sponsoring silent auctions and extravagant dinners. The group discussed various ways to raise money for the program, including hiring an external fundraiser, partnering with the NIH, and the Stand Up to Cancer program. They determined that focusing on the tax check-off is the best option for now. Jon, David, Janice, and Naz agreed to form a fundraising committee along with an incoming council member with expertise in fundraising.
 - X. Legislation: Jon briefly spoke about the SB1207 that didn't pass last year. He suggests elevating awareness on what bills are coming through the legislature.

XI. Director's Report

- **A.** Mhel presented an excerpt from the governor's budget. She briefly reported on the expected funds for the upcoming year indicating a small decline from the previous year.
- **B.** The Action Items list was provided to the group showing that the council meeting action items have been completed.

The Business Meeting adjourned at 2:00pm

Thursday, March 19, 2015: Priority-Setting Retreat (Day 1)

- I. **Call to Order:** Jon Greif called the Priority-Setting (PS) Retreat to order at 2:45pm and initiated introductions.
- II. **Priority-Setting Background:** Marj Plumb briefly previewed the Priority-Setting (PS) activities. Sharima presented an overview of the PS process highlighting the overall rationale and timeline. She reviewed the recommendations and data gathered from the committee that addresses the programmatic goals and financial realities, including projected revenue and the impact of the set-aside funds. She also briefly previewed the upcoming presentations.
- III. **Small Group Instructions:** Marj passed out the small group assignments and outlined the charge of the discussions and report back to the council.

- **IV. Small Group Discussions:** Council members divided into three groups to discuss funding strategy recommendations.
- V. Small Group Report out to Large Group: The council reconvened and each group reported on their amendments to and/or approvals of the priority-setting committee's funding recommendations.

<u>Group A:</u> Sharima reported on the recommendations for CRC, Conference Awards, and Special Research Initiatives. The committee revised the following recommendations:

- "Continue Program Directed Set- Aside at a minimum of 50%" by adding "that does not require a minimum dollar amount per year".
- Added: "Topics for Set-Aside: Continue disparities, environmental links, and population level prevention interventions" by adding "with an emphasis of social determinants of health throughout".
- Change "Review Population Level vs High Risk Individual approach to prevention" to "Review Population Level vs High Risk Individual Interventions".
- "Strengthen set-aside investment in disparities", use more specific language: "by identifying higher impact disparities initiatives"
- Change: "Flesh out the program's rationale for investigating disparities" to "Clearly define disparities for the CBCRP Program Initiatives, similarly to how environment is defined.
- "Continue the CRC Mechanism", by adding: "...as currently structured".
- Added recommendation to "establish committee that focuses on Public Health Outcomes" in response to "Ask CRC applicants to describe what public outcome they are targeting, how they will plan to address sustainability (and implementation in practice), as appropriate."

<u>Group B:</u> Jon reported the committees' revisions to the IDEA and Translational Awards recommendations. . The committee modified the following recommendations:

- Revised: "Ask applicants to make public health outcomes more explicit as part of the critical path discussion as part of their IDEA application, as appropriate." To "Form a committee to make a clear definition of Public Health Outcomes and operationalize how the program will require applicants to address Public Health Outcomes in the application materials in the cycle 22 application materials"
- Revised (changes in *italics* and strike through): "Add a formal step to the programmatic review again to ensure the Program is not passing up funding to the strongest proposal most promising proposals. (Innovation)
 - a) At programmatic review, continue conducting a final review examining the grants with the highest overall component score for each award type (e.g. Innovation for IDEAs, Translational Potential for Translation, and Partnership for CRCs). Conduct a final review *examining grants* with the highest component scores for each award type
 - b) If there are any grants NOT selected for funding that have the highest *overall* or relevant component score, consider those grants again"
- "Find ways to continue to encourage addressing disparities and underserved populations in IDEA and Translational projects. (Disparities & Underserved)" by adding: to have staff define underserved for the application materials in Cycle 22.

(This is not a formal recommendation, the committee is just requesting staff make some changes)

- Revising: "Evaluate the Translational award mechanism after at least 10 projects are completed. Gather consistent data as projects are completed." (Translation & Dissemination) to "By the winter of 2016, evaluate the Translational award mechanism after at least 10 projects are completed. Gather consistent data as projects are completed."
- "Consider focusing the topic areas for Translational Awards (Prevention only) (Translation & Dissemination)." The committee requested a committee be formed to make a clear definition of public health outcomes and operationalize how the program will require applicants to address public health outcomes in the application.
- Deleted: "Consider requirements to strengthen PI support for resolving ethical dilemmas (when conducting translational research)." (Translation & Dissemination) and replaced it with a "staff request": to review what's included already in the award letter about involvement of IRB requirements. This will not be voted on.
- Deleted: "Consider additional ways to support dissemination of research findings, including but not limited to encouraging PIs to publish their results in Open Access journals or make their work publicly available." (Translation & Dissemination) because it's already mandated in the UC system.
- Find ways to continue to encourage addressing disparities and underserved populations in IDEA and Translational projects. (Disparities & Underserved) (This is not a formal recommendation; the committee is just requesting staff make some changes).

<u>Group C:</u> Arash reported on the committee's revisions to the Overarching Recommendations:

- Change the "Capacity Building' program goal to include "CBCRP priority research." (Capacity Building) Further changes will be clarified during day 2 of the retreat.
- Change: "Define further the program goal of Public Health Outcomes. (Public Health Outcomes)" to "Public Health Outcomes will fund research that will improve public health outcomes that will have a large public health impact."
- Change: "Continue efforts to develop standard evaluation metrics and data collection for all CBCRP grants." by adding "...by setting expectations and asking the researchers specific questions. Arash added that how the program deals with the past and the present might be slightly different. (Innovation)
- Delete: Investigate co-funding between CBCRP and other orgs. (Responsive)
- Deleted: Continue to look for and encourage researchers to focus on CA specific research, including IDEA investigators and researchers from Southern California. (CA Specific)
- Revised: Put efforts toward Continue cultivating research projects among populations that have been historically isolated and/or stigmatized. For example, transgender populations, and migrant workers (e.g. pesticide exposures). (Disparities & Underserved)

- Deleted: Determine whether disparities exist that are unique to populations in California (e.g. Filipinas) and support research into these areas. (CA Specific)
- Revised: "Strengthen advocate-scientist links. (Responsive)" to "Strengthen the advocate-scientist interface, including training and motivating researchers to work with advocates throughout the research process and to better formulate research questions & methods." (Responsive)"
- "In the future, the Program should engage in conversation around promoting and encouraging transdisciplinary collaborations. (Collaboration)" Mhel agreed to have a council discussion about it but it's not a formal recommendation.
- "Ask applicants to explicitly discuss a) how generalizable outcomes of their project are to broader populations; b) how their outcomes might influence the health of larger populations. Ask them to discuss as appropriate. (Public Health Outcomes)." The staff will regroup the public health outcomes into one; put them in the overarching recommendations.

Day One Adjourn: The first day of the retreat adjourned at 5:45pm.

Friday, March 20, 2015: Priority-Setting Retreat (Day 2)

- **I. Call to Order:** Jon called the meeting to order at 9:03 am. Marj reviewed the day's agenda which included outlining the process for the meeting, brief overviews of the upcoming presentations, voting, and approving the recommendations.
- II. Presentation: Senaida gave a presentation on the Program's Approach to Disparities, noting the Program's success with the environment and breast cancer can be carried over to their approach to disparities. The staff provided the disparities subcommittee their perspective on what worked well with the SRI and CBCPI as well as data that included an external expert review of disparities concept papers. The reviewers gave feedback that included the strengths and weaknesses of the proposals as well as providing promising topic areas to consider in the future that helped the subcommittee decide to recommend continuing set-aside funds within Program Initiatives 3. "Disparities" will be more clearly defined and the language will be brought to council at the June meeting.
- III. Large Group Discussion: The group brainstormed topics they wanted to discuss in more detail and then narrowed them down to three areas: models complexity psychosocial, population focus, and chemicals and personal care. The group had a lengthy discussion on the topics and shared their thoughts and concerns. For models complexity, suggestions included increasing the budgets and bringing together researchers with different fields of expertise to improve research making. Mhel added that in the first phase of the SRI, the program funded a successful Survival Consortium Pilot and three projects in the area of developing new statistical models to deal with complexity. The staff will work on strengthening the advocate-scientist interface, including training and motivating researchers to work with advocates throughout the research process and to better formulate research questions & methods. When discussing population focus, the group agreed that applicants should explain why they chose a specific community of people focus on in their research. In regards to chemicals and personal care, Sharima noted that

it's huge p<u>ublic</u> and private policy issue and women should be informed of the chemicals that are in the products they use. The group discussed continuing to refine a shared understanding of higher level policies of individual behavior. The Priority-Setting Committee is tasked with deciding what to do with the topics that were not discussed during this discussion.

IV. Presentation: Sharima briefly outlined the Approaches and Investment in Breast Cancer Prevention presentation. Ted gave an overview of Population Level Interventions. He provided data showing variable risk factors for cardiovascular disease, BMI statistics in correlation to diabetes, and age specific mortality rates in men as a function of blood pressure to demonstrate his point that most cases of a disease in a population happen in people with an average level of risk exposure rather than a high risk. He also pointed out community intervention is going to go more beneficial than education on an individual level.

Jon presented the pros and cons of Population Level and High Risk Approaches as they apply to clinical breast cancer practice. He provided examples for risk reduction for each approach, including but not limited to living a healthy lifestyle, screening guidelines, and chemoprevention.

Sharima presented Additional Considerations first noting that while both approaches are important, most of the research funds have been put toward individual high risk interventions. The population approach has the potential to have the greatest impact overall, but it makes an impact on health disparities. She presented an article on health inequalities that pointed out that screening and treating high risk individuals might increase inequalities and in general, population level approaches reduces the disparities. Another paper found that neither approach reduced the inequalities, adding that racial/ethnic residential segregation must be eliminated to reduce inequalities. The last article that focused on the vulnerable population approach, a sub group of the high risk populations believed the lack of attention of fundamental causes increases health disparities. This approach can help alleviate inequalities resulting from population approach.

Janna presented data on the investment in breast cancer prevention, providing an analysis of the research funded from International Cancer Research Partners (ICRP), National Cancer Institute (NCI), and CBCRP. The statistics showed that prevention is the smallest investment of the six research categories. The overall conclusions showed that global investment in prevention continues to be weak; there are pros and cons to population level and high risk approaches and supporting population-level interventions impacts public health outcomes.

V. Large Group Discussion: The group discussed the points made in the presentations and asked questions to help in the decision to approve the recommendations put forth from the committee.

During lunch, Mhel presented the revised recommendations from the day before. At that point, Marj guided the group on how to order the recommendations and gave them some time to prioritize. The group began discussing the Program Initiatives Set-Aside & Topics recommendations, changing the language of the Capacity Building goal, Topics for set-aside, and removing Population Level vs High Risk Individual approach to prevention interventions recommendation. The group (Ted, Melanie, Jon and Karuna) asked for clarity and to better define specific language such as vulnerable, underserved, social determinants, and disparities. Marj then suggested moving those requested clarifications to New Projects. The top four bullets in the Public Health Outcomes Committee were combined into one recommendation. The group continued discussing the charge of the committee the language of the goal. Mhel scored the New Projects on their level of difficulty then the council prioritized and selected the ones they wanted to implement. After further reviewing the projects, Mhel returned with the staff's decisions.

VI. New Projects:

- 1. Add a formal step to the programmatic review to ensure the Program is not passing up funding to the strongest proposals to take effect in June 2015.
 - At programmatic review, continue conducting a final review examining the grants with the highest overall score for each award type
 - Conduct a final review examining the grants with the highest component scores for each award type.
 - If there are any grants NOT selected for funding that have the highest overall or relevant component score, consider those grants again.
- 2. Form Ad-hoc Programmatic Review Committee
 - Investigate what it would take to provide specific programmatic feedback to unsuccessful applicants that receive a high scientific score and low programmatic score.
 - Staff to define "underserved" for applicants in the next Call for Applications.
 - Discuss and define "transdisciplinary".
 - If asking for additional information from applicants for Programmatic Review, Council take a critical look at streamlining the application/forms to reduce applicant burden.
 - Melanie, Jon and Naz agreed to be on the committee.
- 3. By the winter of 2016, the Priority-Setting Committee will evaluate the Translational award mechanism after at least 10 projects are completed. Gather consistent data as projects are completed.
- 4. Ensure the council has a conversation about how to promote and encourage, where possible, trans-disciplinary collaborations throughout CBCRP.

- 5. Strengthen the advocate-scientist interface, including training and motivating researchers to work with advocates throughout the research process and to better formulate research questions & methods.
- 6. Request updated publication and grant leverage information from grantees who apply for new grants. Include this request on the application forms.
- 7. Hire fundraising consultant for an assessment and recommendations.
 - Investigate and define models of sustainability for CBCRP, including co-funding between CBCRP and other organizations specific to CBCRP priorities.
- 8. Priority-Setting Committee will take on Public Health Outcomes work.
 - MOTION: Karuna moved (Jon seconded) to accept all of the New Projects. The motion passed unanimously.

Continued Current Efforts:

- 1. Program Directed Initiatives
 - Continue SRI/CBCPI set-aside focusing on disparities, environmental links to breast cancer, and prevention. (Sources: CA Specific, Responsive, Disparities & Underserved, Collaboration, Non-Duplicative, Translation & Dissemination)
 - Continue Program Directed set-aside at a minimum of 50% that does not require a minimum dollar amount per year. (Source: Non-Duplicative)
 - Implement a Rapid Response Health Policy Initiative with the guidance of the Council's policy committee. (Source: Policy)
- 2. Collaboration
- Continue the CRC Mechanism, as currently structured. (Sources: Disparities & Underserved, CA Specific, Translation & Dissemination, Collaboration, Responsive, Public Health Outcomes)
- Continue supporting outreach and training opportunities for CRC awards with special emphasis on increasing applications in the disparities, environment, and prevention areas. (Sources: CA Specific, Capacity Building)
- Continue with the current collaboration mechanisms, including JFCA. (Source: Collaboration)
- 3. IDEA

- Continue funding IDEAs for \$100K or \$150K (animal and human participants) with an18-month duration. (Source: Innovation)
- Continue identifying junior investigators during the application process for IDEA awards and reviewing them differently than established researchers. (Source: Capacity Building)

4. Translation

- Continue funding the Translational Research awards. (Sources: Translation & Dissemination, Public Health Outcomes)
- 5. Overarching
- Continue training efforts (e.g. QuickStart). (Sources: Capacity Building, Disparities & Underserved)
- Continue efforts to develop standard evaluation metrics and data collection for all CBCRP grants, past and present. (Source: Innovation)
- Continue cultivating research projects among unique California populations and those that have been historically isolated and/or stigmatized. (Source: Disparities & Underserved)
- MOTION: Karuna moved (Jon seconded) to accept all of the Continued Current Efforts. The motion passed unanimously.
- VII. SRI & CBCPI Presentation: Mhel presented a proposal for how to move forward on the Program Initiatives. She gave an overview of the SRI and CBCPI including the goals, topics, set-aside amounts, implementation, and evaluation. She also provided a summary of the Evaluation of the CBCPI, including its structure, methods to identify topics, the various challenges faced, and the recommendations for the future. Mhel then presented the Program Initiatives 3 proposal and provided the supporting data including suggested topics such as environment, disparities, and prevention, the structure for funding mechanisms for the planning process and the benefits of the plan. She also presented the idea and benefits of a competitive prize/challenge to get research concepts. She presented the elements, timeline, and benefits of the initiative. The proposed plan will combine the greatest components of the SRI and CBCPI, adding a new emerging mechanism and increase community engagement. Having a strategy team rather than advisors will ensure a more thoughtful group process and will ideally provide them a transdisciplinary learning opportunity.
- VIII. **Large Group Discussion:** The group discussed the idea of collaborating with other groups that are doing the same work and the feasibility of the prize challenge. Ted

expressed his concern that the topics that include physical environmental agents are a step away from embracing the complexity model and added that the health inequalities are extremely complex and focusing disparities on breast cancer will be challenging. Mhel suggested they change the topics. Melanie suggested adding "identification of interactions among environment causes and health disparities in breast cancer". The group further discussed clarifying and combining the language of the PI-3 topics.

Program Initiatives Set-Aside & Topics

- Topics for set-aside: Environment, Disparities, and Prevention
 - Identification and elimination of **environmental contributors** to breast cancer.
 - Identification and elimination of fundamental causes of **health disparities**, with a focus on breast cancer in California.
 - Development and testing of **population-level interventions intended to prevent breast cancer** incorporating a vulnerable population approach.
- Staff to structure next phase of set-aside to identify higher impact disparities initiatives. (Source: Non-duplicative)
- Change the "Capacity Building" program goal to say: "Fund research that helps recruit, retain, and develop high-quality California-based investigators who engage in research that advances CBCRP initiatives."

Program Initiatives 3 Package:

- RFQ for Convener
- Steering Committee Leadership
- Strategy Team
- Science Reviews
- Idea generation: Prize Competition
- Timeline
- On-going Evaluation
- Costs

IX. Vote:

- MOTION: Jon moved (Alice seconded) to approve the Program Initiatives 3 Set-Aside & Topics as amended by the Council. The motion passed unanimously.
- MOTION: Jon moved (Alice seconded) to approve the Program Initiatives 3 Package. The motion passed unanimously.
- X. Jon adjourned Day 2 of the Priority-Setting Retreat at 4:25pm.