UCI Chao Family Comprehensive Cancer Center

EAB Recommendations 2009 – 2024

External Advisory Board Review, February 8, 2024

Director's Overview

Strategic Plan

- Strategic planning for the next five-year cycle lacks clarity and stakeholder engagement.
- Develop a detailed and well-communicated strategic plan for the next five years.
- More time should be spent on discussing the strategic goals of the center and how they build on unique scientific, institutional, and catchment area strengths and opportunities.
- Little said about continuous planning and evaluation efforts.

Five key areas that require attention.

Community Outreach and Engagement

- Improve organizational structure
- Improve linkage to community
- Focus on its impact
- Improve support of CFCCC research activities

Cancer Control

- Needs additional senior presence
- Needs clearer aims
- Lacking cohesion, needs linkages with other research programs and COE
- Focus cancer control efforts on clear, prioritized aims aligned with catchment area needs.

Catchment Area

- Not clear how the dashboard reports or allows visualization of cancer incidence/mortality patterns, risk-promoting and risk-preventing factors, and other social determinants of health.

Plan to Enhance Diversity: Identify an internal candidate rather than wait for a new recruit.

Clinical Research

- Low clinical trial accrual poses a significant threat to NCI renewal.
- Implement robust strategies to increase clinical trial enrollment, including accountability mechanisms.

Six Essential Characteristics

Physical Space: CFCCC has received an additional 21,000 sf of research space

Organizational Capabilities

- Deliberate positioning of earlier career members into developing leadership roles is laudable
- Need to fill vacated or soon to be vacated leadership positions (e.g., Deputy Director, AD for Shared Resources, AD for DEI, Precision Therapeutics Director)
- Place of Precision Therapeutics Director within CFCCC organizational structure remains vague
- Membership has grown by 19% since 2021
- Funding base continues to rise
- Majority of funding is not from NCI, very important that cancer-related rubrics are rigorous

Transdisciplinary Collaboration and Coordination

- Mechanisms used to foster collaborations and movement along translational continuum need to be better defined
- DOTs do not seem to function effectively and need to be more rigorous in selecting trials
- PRMS needs to close poorly accruing trials more effectively
- Reviewers expect to see actual overall percentage of CFCCC publications that are interprogrammatic (not only at program level)

Institutional Commitment

- Annual institutional support in excess of $40M
- More detail should be provided to specify how these funds are being invested; what percentage of the funds are *sustaining and* being used to support recurring or continued investments and expenses in operations or faculty or staff; and how much of this annual institutional support is *unencumbered* to allow the Director to make new investments in recruitments or program building activities each year.
- Summarize the monetary value of state line FTEs
- Institutional investment in new facilities is impressive

Center Director: Has done a remarkable job and is highly qualified to serve as director.

Developmental Funds: Funds have been well used and generate reasonable ROI.

Community Outreach & Engagement (COE)

COE Liaisons

- Positive that research programs have appointed COE liaisons
- Important to create clear roles and expectations for these liaisons, onboard them, interact with them regularly, and describe the impact they have had on catchment area research integration and bidirectional community engagement.

COE integration and facilitating bidirectional communication/input

- Demonstrate how COE interacts in meaningful ways with all research programs
- Demonstrate COE facilitated bidirectional engagement with researchers
- Demonstrate how community input helped shape research
- 3 to 5 examples: how COE facilitated the science of a peer-reviewed funded project in a Research Program, how that work was published and was responsive to community input that was facilitated by COE, positively impacted a community priority, and how COE transmitted or shared that knowledge back to the community
- Unclear how COE is working with the CTO and DOTs
- Impact and COE's role in facilitating or navigating to screening could be better articulated
- COE activities appeared to be "siloed," and not deeply integrated with center activities or engaging communities back and forth with center components
- Not clear how the activities presented by COE *fostered and facilitated* the scientific activities of the Research Programs or Disease Groups and clinical trial enrollments

Community Equity Board

- Appropriately diverse but small relative to catchment population and diversity
- Not clear how CEB was selected
- Not clear who they represent (in terms of communities, advocates, patients, survivors, community organizations)
- Not clear how they are engaged in communities
- Not clear what impact they have had

Catchment Area Dashboard

- Not clear how the dashboard reports or allows one to also visualize and correlate cancer incidence and mortality patterns and cancer risk-promoting and risk-preventing factors, as well as other social determinants of health, in each unique population and community.

COE informing cancer priorities and strategies

- Careful attention to disparities in cancer mortality rates among different racial/ethnic groups should also be used to develop targeted strategies for community engagement, science, and clinical trial selection and prioritization.

- Cancer priorities were not consistently presented across the Director's Overview, COE, and research programs. This issue warrants immediate attention.
- Essential that COE identify the priority race/ethnic populations, priority cancers

COE scope, strategy, and impact

- A clear strategy for COE with precise targets was not presented
- Strategies presented were too vague and superficial
- Numeric targets and very specific, achievable goals should be set
- Developing pipeline programs for trainees and mentoring is the work of CRTEC

Biotechnology, Imaging & Drug Development (BIDD)

Strengths

- Cohesive leadership. The addition of a highly innovative junior faculty member, Dr. Xiaoyu Shi, further strengthened the leadership team, improved diversity, and created a pipeline for training future leaders.
- Members are collaborative and productive. The team published 170 peer-reviewed papers with 16% in high-impact journals, beyond what is expected for technology-driven programs.
- Highly successful in launching many faculty start-up companies
- Adequately addressed concerns of previous EAB report

Challenges

- Consider future recruitment in nanomedicine, particularly immunomodulation to complement existing immunotherapy efforts
- Encouraged to identify factors that tie the multi-dimensional program together. Specific Aims 1 and 2 are technology-driven, while Specific Aim 3 is chemistry-driven. It may be helpful to show how the systems and methods developed in Aims 1 and 2 facilitated drug discovery.
- intra-programmatic publications, which is very low (8%)
- Capturing the successful launch of many start-up companies as part of Specific Aim 4 could give more significance to this important activity. Consider highlighting the impact of one of them, including the amount raised, number of employees, clinical trial stage, etc.
- Clearly highlighting the role the cancer center played in facilitating the creation of these start-up companies will be important.

Systems, Pathways & Targets (SPT)

Leadership and presentation

- Stories of basic science translation to the clinic and back are important to convey in your vignettes.
- Try and link catchment area priority cancers with those identified by COE.
- Biorepository and molecular profiling need to be quantified as does human relevance for some of the papers cited.
- Some of the grants do not mention cancer in the specific aims – this could be a red flag to CCSG reviewers.
- Future plans slide could benefit from some more specificity.
- Important to carefully justify non-NCI NIH funding as cancer-relevant
- There could have been a stronger emphasis on citing specific examples of how discoveries made by UCI SPT lab researchers were (or are being) translated clinically.

Enhancing clinical trial enrollment

- Work with Alpha clinics to enhance accruals as part of the network
- SPT program is integrated with the DOTs and will be judged on trial enrollment
- Clinical trial accruals could be enhanced with COE partnership and translational working groups to increase manuscripts and thus promotions for clinical trialists

- SPT is likely to be closely scrutinized with respect to enrolling patients onto clinical trials given the many program members who have leadership roles in the DOTs and the overall focus of the program. This area would benefit from focused attention.

Cancer Control (CC)

- Significant vulnerability for the CFCCC
- Needs additional senior presence and clearer aims and linkages with other CFCCC research programs and COE
- Does not appear to function as a cohesive/collaborative program that is well integrated into the cancer center
- *Before competitive renewal* must demonstrate:
    - Program cohesion
    - Clearly articulated directions and priorities that are aligned with catchment priorities
    - Robust interactions with COE and bidirectional engagement with community
    - Alignment with CFCCC's strategic plan
- Aims are not well articulated, too broad and lack specificity and clarity; difficult to distinguish between the two aims. Aims need to be revised to better align with the limited scope of current program strengths and activities.
- Highlight and expand research that focuses on etiology, molecular epidemiology risk factors, and cancer screening.
- Important to focus on the high impact research, provide highlight demonstrating synergy across aims and intra- and inter- programmatic collaborations.
- Priority cancers in the catchment area are not well reflected in program research
- NIH and NCI funding is low. The number of R01 equivalent grants is low and a vulnerability in the competing renewal.
- Cohesiveness is weak. Consider strategically reducing program size to enhance cohesiveness and promote intra-programmatic interactions.
- Interaction and cohesiveness with COE, CRTEC and EDI need improvement. Interactions with COE and how COE-facilitated community engagement helped shape CC science needs to be better described.

Clinical Research

Accomplishments

- CPDM is well-organized and now fully staffed clinical trials office
- Both Chow and Dayyanni are highly qualified to lead this component.
- 30-minute presentation was extremely well done, comprehensive. The extensive presentation was well received, and the program is to be congratulated on several important improvements.
- Joining of ETCTN (U of Pitt) is a great step forward,
- Two flawless FDA audits and numerous internal audits
- Regulatory and staff infrastructure has been fully developed and leadership should be proud of that.
- Successful implementation of the eRegulatory binder system Complion
- Trial activation times have dramatically improved.

Important issues

- Static and low accrual into interventional treatment trials
- Substantial gap between clinical trial accruals and the rising numbers of analytic and clinical cases seen
- Apparent disconnect between the impressive clinician-scientist funds flow support and accrual
- Over $2M in clinical support has been provided to clinicians through this mechanism but with no corresponding increase in clinical accrual activity.
- Despite a recent increase in the number of radiation oncology faculty and clinical trial activations of RT-trials, this has not yet resulted in an increase in accrual.

- Pre-existing group arrangements with OPN Health and the VA have yet to contribute significantly to accrual.

Recommendations

- Radiation oncology efforts were described, need to be developed (with accrual goals) and ready by the next EAB meeting.
- CFCCC has made it clear that it supports a genomics platform and has an EPIC based access to genomics. This is critical and needs to be done ASAP
- CFCCC leaders have proposed using IIT trials to increase accruals. EAB remains concerned that this strategy is not sufficient
- DOTs may not have been sufficiently held accountable for accrual performance and for management of a growing number of activated trials that turn out to be poor accruers (since approximately 47 trials were reported to have accrued only zero to one patients in the past year). Thus, attention to the rigor and quality of DOT oversight over clinical trial endorsements/approvals or activations and their commitment to accrue to already activated trials
- Increase the closure rate for non-accruing trials
- Expand the Phase I operation
- Focus carefully on selected underperforming disease sites
- Increase ClinRoc meeting frequency to monthly until the clinical trial issue is solved.
- COE should be actively engaged in clinical trial accrual (identifying patients for trial).
- Investigators should be incentivized
- Increased funds flow to buy effort and more specific P&T rewards for participating in clinical trials.
- Fellows should be required to screen patients for trial and encouraged to assist in writing IITs with the PI.

Shared Resource Management (SRM)

- Previous critiques include low volume of users for BSR and IVFOI, and the need for timely replacement of SRM management. Adequately addresses at the presentation.
- SR management plan is excellent
- Addition of metabolomic component is timely

Transgenic Mouse Facility (TMF)

To fend off concerns on prioritization of CFCCC users:

- Explain that the TMF is an institutional center of excellence for facilitating mouse-related research across the disease spectrum at UCI and also makes important contributions to NCI-funded cancer research at UCI and other centers.
- Emphasize the subsidy cancer center members now receive
- Focus on the turnaround times for CC members should also help to head off such critiques.

Optical Biology Core (OBC)

- An area of continued concern, albeit minor, is the number of CFCCC users of the core. With such state-of-the-art resources and highly motivated leaders, this core will enrich the research output of many CFCCC members. Before the next NCI review cycle, core leaders may wish to work with CFCCC leadership to identify impediments and how to overcome them.

Genomics Research & Technology Hub (GRT Hub)

- Overall, the GRT Hub SR is currently in solid shape.
- GRT Hub has the potential to score in the outstanding-exceptional range with larger number of high-impact collaborative publications and maximizing usage by CFCCC members.

In Vivo Functional Onco-Imaging (IVFOI)

- A missing instrument in this core is ultrasound. Although incorporating this technology will require significant personnel investment, it will be worth the expenditure.

Experimental Tissue Resource (ETR)

- There appears to be no systematic process for collecting matched normal-tumor specimens, but this can be done on a case-by-case basis.
- Suggest continuing to track increases in the volume of tissues received and distributed year-by-year along with continued assessments to ensure that the personnel, space, and equipment are adequate to keep up with the demand for services.
- Suggest that the process that the CFCCC utilizes to support procuring, archiving and distributing bone marrow and other normal and pathologic hematologic tissues through the ETR be articulated clearly in future presentations.

Biostatistics Shared Resource (BSR)

- Areas for improvement include better tracking and reporting of services, funding sources, cancer focus, and deliverables (e.g., grants and publications) and increased usage among CFCCC members including CC Program members.
- Low usage of the BSR by CFCCC members.
- Low usage in general leads to questions about whether reported usage reflects recharges, total use, or use by CFCCC members and cancer relevant projects.

Biobehavioral Shared Resource (BBSR)

- Practically 100% of the users are in cancer control
- Only a small handful of investigators (maybe 4-5) are using BBSR out of the very large number of total members.
- Hard to argue that this is a valued and critical resource, even for one program
- Depending on what progress has been made in usership, it may be wise to hold off on including the BBSR in the competing renewal and consider listing it as a developing resource.

Cancer Research Training Education & Coordination (CRTEC)

- The development of CRTEC analytics to track outcomes lags behind peer NCI supported cancer centers and should be considered to be a high priority. A robust capacity will be expected at the next competitive renewal. The analytics components are frequently independent Specific Aims at other cancer centers.
- For future presentations, consider showing how CRTEC helped someone get from an idea to a funded project

Plan to Enhance Diversity (PED)

- Appointment of a permanent AD of EDI is urgent. Having CFCCC's AD of CRTEC in this role is a vulnerability.
- Unclear how the center will leverage existing institutional resources in DEI
- PED aims are overlapping with CRTEC and should be revisited.
- Not clear how PED, COE and CRTEC integrate and coordinate, and how they define their swim lanes.
- The discussion warranted more clarity on aligning the PED with institution-wide initiatives. Formation of Steering Committee working groups to address this mandate is a step in the right direction, but the EAB wants to see more specific examples of outcomes.
- Important to be able to demonstrate how CFCCC is able to maximally leverage and put a cancer lens on institution-wide EDI efforts.
- Important to highlight the institution commitment to DEI. A monetary or resource commitment to PED (e.g., EDI office budget, start-up, recruitment, and pilot funding) was not presented, other than a promised 40% FTE for the permanent AD for EDI .

- Pulse Survey is a good idea but would be better represented with national benchmarks –how is CFCCC doing with respect to other centers who have completed the Pulse survey?
- The LEAD program is a great initiative. It is important to incorporate a curriculum and give the LEAD participants actual roles within the Center.
- Diversify the composition of its External Advisory Board, perhaps broadening it to include Hispanic representation.

Administration

- Staffing falls short of what is seen at cancer centers of comparable size. Pursue additional staffing opportunities to address voids in Communications, Human Resources, and Planning and Evaluation activities as these are expectations outlined in the CCSG guidelines.
- Hire full-time Managers and Coordinators for PED, CRTEC, and COE instead of relying on partial staffing for all three of these components.
- Strategic plan refresh – goal to complete a new plan at least 1 year before CCSG submission
- Review all SOPs (cancer relevance, membership)
- Add Trainee Associate Membership
- Think about Administrations impact and how this can be better communicated
- Perform a deep dive on membership
- Better incorporation for EVAL and iLab (e.g., are they being fully utilized? are there opportunities for data mgmt.)

External Advisory Board Review, February 28, 2023

Overall Recommendations

- A defined role for the Director in long-term plan for effectively marketing the CFCCC to highlight its matrix strength, as well as a formalized budget to support its implementation, would be important.
- A transparent and sustainable funds flow formula that provides discretionary resources under the authority of the director is recommended to ensure continued progress.
- Creative solutions, such as linking precision medicine initiatives with proactive identification of potentially eligible patients should be considered.
- Inconsistent linkage of catchment area priorities should be rectified and processes should be in place
- Persistent investment will be required for Cancer Control program to achieve it's potential
    - Highlight the comprehensive clinical services or expertise only available at a major matrix academic medical center.
    - Develop organizational excellence around cancer care delivery and best-in-class access to care.
    - An "all hands-on deck" approach by UCI senior leadership, working in conjunction with the CFCCC, to aggressively counter inevitable efforts by City of Hope to expand its clinical care footprint in Orange County.
    - Emphasize and articulate nationally known UCI strengths in biotechnology and bioengineering, and how these strengths are being leveraged by the CFCCC in delivering state-of-the-art diagnosis and therapy for people with cancer.
    - CFCCC is a critical element in the overall health system but more importantly cancer care specific to this area.
    - Continue to pursue aggressive recruitment and retention efforts for UCI/CFCCC faculty and staff.
    - Use CFCCC's Community Outreach and Engagement infrastructure and community partnerships to serve as ambassadors to the catchment area.

Director's Overview, Six Essential Characteristics, Leadership, Planning & Evaluation (LPE)

Six Essential Characteristics

- It will be imperative that the 25,000 SF research space be provided to the CFCCC under the Director's authority, ideally as part of the new Falling Leaves Foundation Medical Innovation building on the Irvine campus planned to be open in 2025.
- The CFCCC continues to have relatively modest inter- and intra-programmatic metrics. This remains a work in progress. Specific measures to promote and facilitate inter- and intra-programmatic interactions, catalyzed by the Center, and supported by robust institutional resources, have not yet come to fruition.
- A few exciting CAR-T IITs are in the works, but given their cost and uncertainty, CFCCC might consider emphasizing small molecule and antibody based translational avenues as well. The imaging initiatives are intriguing and should be pursued, particularly if they create differentiated clinical and clinical research offerings. The new cancer metabolism initiative is exciting, and a mass spectrometry based shared resource will support and accelerate this work.
- The CFCCC is encouraged to continue pre-award administrative support (grant writing, budgeting, etc.) for the development and submission of grants from the NCI, other NIH, or federal agencies.
- The current clinical funds flow model provides about $3.5M to support clinical investigator's effort, and another $2-3M yearly to support the clinical trial office. This is essential and will need to be appropriately scaled as the clinical research operation expands.
- A clear, transparent, and sustainable funds flow formula (perhaps linked to clinical revenues from the cancer service line) that provides discretionary resources to the Director for investments in the cancer program should be considered.

Leadership, Planning & Evaluation (LPE)

- Dr. Nelson also serves interim AD DEI pending a critically important search for a permanent AD.
- A Strategic Plan is in place, but the Overview presentation to the EAB was not directly linked to the Strategic Plan.

Administration

- Continued concern about the broad criteria for membership which Administration reported that they had not yet changed their membership criteria.
- The issue of tightening the application of the cancer relevancy policy was stated that an opportunity still exists. Administration is encouraged to review application of the cancer relevancy policy with center leadership.

Community Outreach & Engagement (COE)

- The catchment area priorities need to be more clearly articulated. These priorities could better guide research efforts within all the research programs and disease groups as well as outreach activities.
- Further develop the COE logic model with clear strategies, quantifiable evaluation metrics for short-, intermediate- and long-term outcomes that are aligned with the COE aims and catchment area priorities.
- Ensure that that the size, structure, organization, and support of the COE Office are sufficient to address CFCCC's needs and opportunities and aligned with the logic model, including evaluation metrics. This is critical for ensuring the Center's continued overall success and success in COE, especially as it relates to the delivery of evidence-based interventions beyond the walls of the UCI health system and its two FQHCs, and toward conducting impactful research that is relevant and responsive to catchment area needs in concert with the CFCCC's Research Programs.
- The catchment area includes a much larger proportion of residents that do not access care through these systems (two FQHCS). Clear plans for how to reach these populations would be helpful.
- There have been increases in cancer screening in the catchment area, but it is not entirely clear how COE helped accomplish this and what the strategy is for improving primary and secondary prevention in screening in African Americans and other population subgroups.

Biotechnology, Imaging & Drug Development (BIDD)

- The next target for the BIDD program is to achieve an "exceptional" rating in the next NCI review cycle. This lofty but achievable goal requires consolidating current projects and services and anticipating future needs in cancer research.
- The ability to translate new cancer imaging and therapeutic agents to the clinic will require clinician-investigators with interest in molecular imaging and drug evaluation. Active participation of these clinicians in the early stages of BIDD project initiation will be key to enhancing CFCCC's status as a translational cancer imaging and new therapeutics development center of excellence.
- Another potential area for further strategic development is imaging informatics and analytics. Radiomics and other forms of data mining seem to be an especially opportune area for further development.
- Small molecule drug candidates have not emerged from BIDD. Leveraging the expertise from the well-known Chemistry Department of UCI may be able to correct this deficiency. It will be important for the program, and more generally the CFCCC as a whole, to clearly describe the process used to identify and support projects moving along the translational pipeline.

Systems, Pathways & Targets (SPT)

- Identifying the reasons for the relatively low percentages of inter- and intra-programmatic publication rate and implementing efforts to improve them.
- The relationship between the scientific programs (SPT, BIDD) and the DOTS was unclear. The relatively low number of accruals to clinical trials is a related concern.
- There was relatively little presented to the EAB about how SPT members are utilizing molecular profiling to inform precision cancer therapeutic trials. Efforts in this area might be developed in collaboration with the DOTs.

Cancer Control (CC)

- NIH and NCI funding is relatively low and will need to be improved. The number of R01 equivalent grants, to qualify for program status, is low and will need to go up.
- Overall accrual to trials is low, particularly for a cancer control program with very broad aims, and accruals come primarily from a small handful of members.
- Program aims are very broad and cover the entire cancer control continuum from etiology to primary prevention, cancer detection, and survivorship. However, active research is lacking in some of these areas. Consider revising program aims to better align with program strengths.
- Alignment of research in the program with catchment area priorities is not well described. Interactions with COE and how COE-facilitated community engagement helped shape programmatic science could be better described.

Clinical Research

- The impact of the COVID pandemic on Stern Center staffing has affected several key CCSG metrics such as accrual and time-to-activation. The impact of the "Great Resignation" is not unique to CFCCC but is an area of concern in that it has contributed to low accrual numbers to interventional treatment trials relative to DT3 analytic cases. The Stern Center has almost restaffed its vacant positions, but newly recruited staff requires training and on-boarding that often burdens remaining staff.
- There is a clear mismatch between the available clinical trials and the demographic make-up of cancer patients walking through the door at CFCCC. Efforts to establish a more balanced portfolio of available trials that matches patient demographics with DT3 numbers would be required. This would naturally involve the active engagement of the DOTs so that their members can identify and endorse qualifying trials that would support strong accrual aligned with catchment area demographics.
- It was stated that OPN Healthcare was being re-engaged by UCI to enhance external referrals to CFCCC for clinical trial participation; it is unclear whether this engagement will in fact result in a substantial increase in the accrual metrics, particularly in light of City of Hope's encroachment into the CFCCC's catchment area.

- High level UCI leadership is encouraged to strongly communicate to all faculty that clinical trial participation is an expectation of employment in the academic health system. Clinical trials of novel therapeutic or diagnostic approaches that originate from UCI science would serve as a competitive advantage that differentiates CFCCC from other health care systems. Incentives to promote the development of investigator initiated clinical trials that match the demographic make-up of CFCCC patients, such as seed funds for pilot or early phase trials, should be considered.
- The 270K marketing campaign, while appropriate, is not nearly sufficient. The commitment needs to be much larger, especially concerning the threat that COH imposes. A much larger marketing budget along with a systemic plan led by the Director would be the appropriate plan. This approach should specifically emphasize the clinical trial portfolio that CFCCC has and will be expanding. The portfolio should address the catchment area needs as defined by COE.
- Given the challenge of COH and the flat clinical trial accrual, make sure COE is intimately involved in the clinical trial structure and patient accrual.
- Time to activation, although improved from 170 days to 133 days in the past year, is still far from the stated target of 90 days. Several initiatives to improve time to activation were outlined but it remains unclear whether these strategies will be successful.

Cancer Research Training and Education Coordination (CRTEC)

- The CFCCC might consider applying for an NCI R25 to support its laudable summer oncology training program for high school students.
- It remains important to directly engage with minority institutions to diversify participation in the diverse education activities described. The relationship with CSU-Fullerton again described at the EAB meeting is an excellent initiative that is relevant to diversity and inclusion in cancer research. The CRTEC might leverage similar relationships between UCI and OC community colleges in the area of STEM to enhance cancer research career and training opportunities.
- Recommend that CRTEC consider adding new junior faculty mentoring activities in collaboration with CFCCC program leaders to fill in any existing gaps. Senior mentorship should be leveraged to identify non-NIH sources of support for young cancer researchers and for outlining expectations for competing for an independent faculty position at UCI or other leading institutions.
- CRTEC could do a better job of tracking outcomes of undergraduates through junior faculty as they move along in their careers. It is expected that CRTEC utilize a central database to track the outcomes of all trainees, ranging from high school through mentored faculty. In addition, track how many T32 trainees are doing cancer research projects.

Plan to Enhance Diversity (PED)

- Recruitment for a permanent Associate Director of Diversity, Equity, and Inclusion is ongoing.
- PED should describe the institutional initiatives that are currently in place and how a cancer center lens is being applied to those initiatives.
- A concrete or cohesive plan to diversify CFCCC leadership or membership to reflect national demographics was not presented.
- Recommend that PED consider developing more targeted programs to enhance the diversity of its membership and programs to develop its members to become leaders. In addition, PED is encouraged to explore “special opportunities” relevant to unique populations within Orange County that can be exploited or leveraged to further advance DEI efforts within the CFCCC. These opportunities can involve unique populations (e.g., other under-represented or marginally represented groups) that are not typically reflected by national demographics.
- It is also an expectation that PED establish clearly defined metrics for monitoring and evaluating the progress of its efforts.

Shared Resource Management (SRM)

- Low volume users for BSR and IVFOI is a concern. Expansion of services by BSR to include bioinformatics and machine learning will help. Fostering new collaborative projects that use imaging equipment of IVFOI will increase the number of users.
- A timely replacement of the Deputy Director, a critical position, will be important for the success of CFCCC and the SRs.

Transgenic Mouse Facility (TMF)

- The TMF is currently launching a new website that will include video tutorials on popular methods for genetic engineering of mice. This is an excellent approach and will greatly facilitate the outreach efforts of the TMF with both faculty as well as trainees. This should be completed as soon as possible so that by the time of renewal, good examples of the impact will be available.
- Prioritization of Cancer Center users by the shared resource. It will be important to explain that the TMF is an institutional center of excellence for facilitating mouse-related research across the disease spectrum at UCI and also makes important contributions to NCI-funded cancer research at UCI and other centers.
- Highlighting the prioritization of cancer center members when cancellations arise is worthwhile, particularly if the overall turn-around times are excellent.
- Emphasizing the subsidy cancer center members now receive will also aid in heading off such critiques.

Optical Biology Core (OBC)

- Future plans were articulated as installation of the new Zeiss confocal, completion of the renovations for new OBC space, and acquisition of a BD spectral 6-way sorter. It will be important to get the new instrument up and running over the next year as well as complete the renovations and move into the new space over the next year. Given the acquisition of new equipment, CFCC may consider offering its researchers a grace period to test the instruments and generate pilot data for grant proposals and publications.
- Another area for consideration is the number of users.

Genomics Research & Technology Hub (GRT Hub)

- The use of this core by clinical investigators appears to be rather limited and could be used to fuel new correlative study grants for investigator initiated clinical trials and to inform biomarker development. This core could benefit from further integration within a precision medicine tumor board that aligns with the disease-oriented teams (DOTs).

In Vivo Functional Onco-Imaging (IVFOI)

- IVFOI acquired a new high-end instrument. Granting small pilot awards to test this system will help generate preliminary data for extramural funding and expand CFCCC member usage of the core's resources.
- IVFOI also initiates and implements new research directions. While this activity positively impacts the overall CFCCC mission, it also overlaps with other basic and clinical programs. Coordinating these activities with relevant research programs will enhance programmatic integration.
- It is reasonable to expect high usage from BIDD members, the IVFOI leaders are encouraged to create new opportunities for collaboration with other programs.

Experimental Tissue Resource (ETR)

- It is noted that hospital-wide prospective consenting for biospecimen collection (Goal 2) will require assistance of the hospital administration.
- It will be important to initiate random RNA/DNA QC of fresh tissues to document specimen integrity.

Biostatistics Shared Resource (BSR)

- We encourage the CFCCC leadership to make investments in resources and new personnel to ensure that the BSR serves the biostatistical needs of CFCCC members in a timely and effective manner.
- To engage the leaders of the programs and DOTs regarding how the BSR can broadly enhance clinical, translational, population sciences, and basic research in the CFCCC. These discussions should include identifying ways the BSR can improve services and the resources required to do this.
- Establishing processes for tracking when the BSR receives a request for biostatistical support and when these analyses are completed with the results returned to investigators.
- Suggest a process to ensure that the contributions of the BSR are appropriately acknowledged in research publications.

Biobehavioral Shared Resource (BBSR) – in development

No EAB recommendations provided for Biobehavioral Shared Resource

External Advisory Board Review, April 1, 2022

Overall Recommendations

- The apparent funding gap to support these components will therefore require enhanced or new institutional resources beyond what was previously committed.
- Future plans to expand stem cell transplant and cellular therapy are sensible, though the competition from City of Hope is likely to be stiff. Immunotherapy initiatives are timely, though the CFCCC will be playing catch up, and will need to find an appropriate niche for these efforts.
- The new cancer metabolism initiative is exciting, and a mass spectrometry-based shared resource will support and accelerate this work. Given that this is a newly proposed Shared Resource, it will likely require continued institutional support to become fully established.
- The most critical issue facing the CFCCC at this time is the encroachment of City of Hope's clinical cancer operations into Orange County. This is an existential threat that, if not addressed aggressively, could degrade the growing clinical and clinical research operation. Even more robust institutional commitment is now required of UCI leadership to address this issue.
    - Highlight the comprehensive clinical services or expertise only available at a major matrix academic medical center such as UCI Health and CFCCC. These include faculty with expertise in surgical sub-specialties, intensive care, emergency medicine, cardiology, pulmonology, and integrative oncology among others.
    - Develop organizational excellence around cancer care delivery and best-in-class access to care. The EAB suggested that CFCCC should continue to engage with the community to gain goodwill and to improve relationships with points-of-access (e.g., referring physicians, PMDs, and surgeons) who are often the "first touch" for newly diagnosed cancer patients in order to build and sustain a patient pipeline into UCI and CFCCC. Many more such patient-centered efforts will be necessary to counter COH's market encroachment.
    - Establish coordinated and consistent messaging and marketing, both within the institution and across the catchment area. These advantages should be comprehensively prioritized and publicized and would benefit from an "all hands on deck" approach by UCI senior leadership working in conjunction with the CFCCC, perhaps with the development of a "Command Center" tasked to oversee this effort.
    - Emphasize and articulate nationally known UCI strengths in biotechnology and bioengineering, and how these strengths are being leveraged by the CFCCC in delivering state-of-the-art diagnosis and therapy for people with cancer.
    - Pursue aggressive recruitment and retention efforts for UCI/CFCCC faculty and staff. It is anticipated that UCI may not be able to offer compensation on par with that of COH. However, creative approaches should be considered in order to attract and retain the best talent, including the provision of support for protected time to pursue creative work.
    - Use CFCCC's Community Outreach and Engagement infrastructure and community partnerships to serve as ambassadors to the catchment area. For example, community navigators can be deployed to

develop a pipeline of patients with cancer or at risk of developing cancer that would preferentially select CFCCC for their clinical care rather than COH due to an established trusting relationship with UCI.

Director's Overview, Six Essential Characteristics, Leadership, Planning & Evaluation

Six Essential Characteristics

- It will be imperative that the 25,000 SF research space be provided to the CFCCC, ideally in the new building on the Irvine campus.
- It is strongly recommended that the IAB be leveraged to maximize the CFCCC's matrix structure, particularly regarding the advancement of new research initiatives and the recruitment of diverse faculty members with a focus on cancer research. **For example, the IAB can be instrumental in the** development and advancement of interdisciplinary **cluster hiring** practices that crosscuts departments, schools, and colleges, with an emphasis on recruiting URM faculty.
- The CFCCC must continue addressing its relatively modest inter- and intra-programmatic metrics. This remains a work in progress. Specific measures to promote and facilitate inter- and intra-programmatic interactions, catalyzed by the Center and supported by robust institutional resources, should be enacted.
- CFCCC-directed seed funding rounds for the development of new teams focused on the center's strategic initiatives should be considered, with the expectation that these team develop and submit MPI team science grant applications (P-, U-, or MPI R-type grants) within a reasonable period of time following receipt of seed funds.
- Immunotherapy initiatives are timely, though the CFCCC will be playing catch up, and will need to find an appropriate niche for these efforts.
- CFCCC is encouraged to continue pre-award administrative support (grant writing, budgeting, etc.) for the development and submission of grants from the NCI, other NIH or federal agencies (in which case "cancer" ought to be highlighted in the grant abstract/specific aims), or cancer-focused sponsors (e.g., ASCO, AACR, ACS, others).
- More concrete articulation of how FTE, space, and start-up resources for new cancer-focused recruits will be sustainably provided to the Center Director over the foreseeable future would be important to reassure future site visitors of the institution's already robust commitment to the CFCCC. This will be essential to fill gaps in CCSG support of COE, CRTEC and Plans to Enhance Diversity (PED).
- The current clinical funds flow model provides about $2M to support clinical investigator's effort, and another $2-3M yearly to support the clinical trial office. This is essential and will need to be appropriately scaled as the clinical research operation expands.

Leadership, Planning & Evaluation

- The Summary Statement noted the 5% effort allotted for the senior leaders was modest. We recommend increasing this (a minimum of 10% support) would more accurately reflect the level of engagement described in the application and during the EAB meeting
- It would be worth considering even more (at least 20% effort) for the inaugural AD of PED to launch a new, important initiative in such a short timeframe.

Community Outreach & Engagement (COE)

- Given the recent events involving the City of Hope Cancer Center, it will be important to consider a marketing budget for COE efforts to further develop its community brand.
- A suggestion is to consider revising the aims to better call out COE's role in fostering research that addresses the catchment burden, besides clinical trials and community engaged research, that is relevant and responsive to the catchment's particular needs and addresses cancer disparities.
- Careful strategic planning over the next year should consider further development of the logic model with quantifiable evaluation metrics and ongoing evaluation to demonstrate success for the specific metrics, including outreach efforts (Aim 2).

- Although COE appears to be well integrated in the cancer center, it will be important to better articulate how COE works with the research programs in both the COE and Research Program presentations.
- Several weaknesses were noted, including: 1) undeveloped description of how community engagement informed the COE strategic plan and activities; 2) unclear metrics linked to COE strategic plan; 3) underdeveloped processes for stakeholder engagement in research; and 3) lack of clarity how COE supports catchment area research activities.
- It will be important to describe processes for catalyzing catchment burden and disparities research across all the research programs and with the clinical trials office.
- The EAB encourages leadership to consider refining aim 3. While COE facilitates minority engagement and accrual to trials, CPDM is held accountable for minority accrual rates.
- FOA guidelines suggest that centers describe their reach beyond the catchment area. More information about these activities is needed.

Administration

- Administration has not addressed the Summary Statement's concern to better define its oversight of COE administrative activities. It is recommended that the (administrative) director at least have a dotted line reporting relationship into Ms. Hui and in anticipation of the PED infrastructure, a similar relationship.
- Site visitor concerns about the broad membership criteria were raised in Administration, which should be examined with the rest of the center leadership, as well as the application of the center's cancer relevancy policy for grants. Opportunities exist for tightening each of these protocols.

Biotechnology, Imaging & Drug Development (BIDD)

- A number of the comments made by the reviewers fall under the rubric of the translational pipeline, including concerns about the Phase 1 program, PK/PD capabilities, and precision oncology. It will be important going forward to develop a process for monitoring and facilitating the progress of projects moving along the translational pipeline.
- A more robust approach for SPT projects, providing validated targets moving to BIDD, needs to be implemented both to facilitate their development as well as to bolster the translational impact of the SPT program. Clear examples of success stories in this regard will be highly effective.
- It will be important to demonstrate success in the translation of projects to the clinic. Facilitating IND approval in whatever way possible of two of the three products described in the proposal would be a very effective metric to achieve in this regard.
- Highlighting the clinical applications of the fluorescence lifetime imaging approaches being developed at UCI would also contribute very effectively. The X-ray acoustic tomography capability is innovative and if successfully translated, will have high impact in cancer screening. We would also recommend exploring the use of exploratory IND (eIND) as a mechanism to enhance the number of clinical translational projects.
- A possible effective mechanism for the program to engage with COE would be to explore ways the program supports cancer screening in the catchment area.
- In terms of training impact, the pursuit of a T32 grant in imaging would be an effective demonstration of impact in this realm.

Systems, Pathways & Targets (SPT)

- Identifying a second leader to replace Dr. Becker is a high priority for the Center – an accomplished, R01-funded physician/scientist with a translationally-focused research program would seem ideal for this role.
- The U54 Systems Biology grant is a key component of the SPT Program and is a signature accomplishment. Continued success in obtaining such quality multi-investigator grants will be critical moving forward and a solid plan to do so is in place.
- Additional concrete examples of clinical translation that is informed by laboratory-based research and preclinical studies conducted by Program members would underscore the value of the SPT program. The

Program would benefit from additional recruitments that might advance this goal.

Cancer Control (CC)

- While the program was praised for its strong cancer focus, attention to catchment area priorities and disparities, a rise in the number of publications, and its mature streams of research, reviewers pointed out the low NCI funding base, modest inter- and intra-programmatic interactions, low clinical trial activity, and the unevenness of the aims and gaps in behavioral science and risk behaviors, among other concerns. Most of those reviewer concerns persist; however, the program's dynamic and energetic leadership team have outlined reasonable plans to address most these issues.
- The modest number of intra-programmatic collaborations and limited evidence of synergy across the aims suggests that CC has not fully matured into a cohesive program.
- The EAB encourages the program leaders to re-assess programmatic priorities to overcome the impression that CC lacks centeredness wherein the program is perceived as a collection of disparate individual projects rather than a unified CCSG program that addresses and/or complements the stated aims.
- Concrete steps to promote centeredness and cohesion need to be clearly articulated, including the development of new forums for inter- and intra-programmatic interactions. These steps might include formal strategic planning involving program members and CFCCC leadership, and the provision of targeted seed funds to support collaborative interactions that would ultimately result in team science awards (NCI MPI P-, U-, or R-type awards).
- The relatively low NCI funding base also calls attention to the rather limited critical mass of cancer control-focused faculty at UCI. Additional recruits, other than the new biostatisticians, are needed to increase depth and breadth of programmatic research.
- There appears to be persistent conflation of cancer prevention with cancer detection in Specific Aim 1; perhaps this aim can be better articulated or fine-tuned to distinguish these separate albeit complementary themes. This issue can be addressed through the strategic planning process.

Clinical Research

Clinical Research/Clinical Protocol and Data Management (CPDM)

- It will be critical for CFCCC to recruit a permanent Administrative Director for CPDM/Stern Center to solidify and maintain their clinical leadership team.
- It will be important to note that the Stern Center is fully within and under the authority of the Cancer Center (and is not a separate institutional entity), assuring that CFCCC and its parent institution honor the NCI expectation that all institutional cancer clinical trials fall under the auspices of the Cancer Center.
- It is not clear if the CFCCC has Cancer Center members who are engaged on committees and within leadership roles of the NCTN Cooperative Groups; this would be helpful.
- Close examination of accrual to therapeutic interventional trials in 2021 is only 8% (346 interventional therapeutic accruals relative to an analytic case number (Data Table 3) of 4192). This is of significant concern and therapeutic trial accrual needs to improve markedly during the next project period.
- it is imperative that the new CPDM leadership team re-focus its efforts into stimulating the development and activation of clinical trials – preferably IITs through the DOTs and NCTN trials – that align with the most common tumor types seen at the CFCCC as summarized in DT3 and develop specific strategies to improve accrual to therapeutic trials.
- The leaders should empower and hold each of the tumor-focused Disease Oriented Teams (DOT) group leaders accountable for developing a trial menu that reflects the nature of the patients in the catchment area and entering CFCCC for care which is balanced among NCI, IIT, and pharma trials and each DOT should be held accountable for specific accrual targets.
- The development and use of a Feasibility Committee, functioning between the Disease Groups and PRMC can review utilization of resources and likelihood of timely accrual providing feedback to the Disease Groups. Most NCI Centers have now established such committees. Thus, each Disease Group should be held to specific performance metrics.

- With more intentional clinical trials portfolio balancing – including an effort to support and open more NCI trials – a fractional increase in the activation of NCTN/ETCTN trials could help improve the TTA metric. CFCCC should also demonstrate TTA separately for NCI, pharma, and IIT trials, which is customary in most NCI Centers.
- The strategic plans presented to increase trial accruals are more scientifically oriented than plans to drive minority accrual, and while they may yield minority accrual to interventional trials, it is not clear that these strategies will increase accrual, and particularly minority accrual to therapeutic interventional trials.
- In most NCI Centers now, each DOT and each Research Program identifies a member to be a formal liaison to COE to assure community engagement and minority and catchment area concerns are addressed in trial menu development and research program strategies. Similarly, members of COE should be formal members of the PRMC.
- Since a new clinical leadership team is in place, it is important for Dr. Chow to concretely articulate his vision for clinical science in the new funding period, including the team's specific strategies to increase accrual (particularly to therapeutic interventional trials) and to catalyze/facilitate the development of IITs that draw their rationale from UCI/CFCCC science.
- There are also opportunities to link Dr. Van Etten's goal to further develop Integrative Oncology by aligning center-wide resources and priorities related to integrative oncology with CPDM and the Stern Center via interventional trials.
- It is essential for CFCCC to implement a cancer precision medicine program to facilitate trial accrual and drive center science, as they are planning. CFCCC may want to consider use of companies that provide CAP/CLIA approved comprehensive sequencing (whole exome, unbiased RNA seq) rather than implement more limited cancer panels, particularly considered the diverse populations served by CFCCC.
- A clearer articulation of plans to enhance clinical trial accruals at the Laguna Hills site would be important, as would along with plans to enhance accruals to early phase clinical trials.

Shared Resource Management (SRM)

No EAB recommendations provided for Shared Resource Management

Transgenic Mouse Facility (TMF)

- It will be important to explain that the TMF is an institutional center of excellence for facilitating mouse-related research across the disease spectrum at UCI and also makes important contributions to NCI-funded cancer research at UCI and other centers.
- Highlighting the prioritization of cancer center members when cancellations arise is also worthwhile, particularly if the overall turn-around times are excellent.

Optical Biology Core (OBC)

- Report the total funds expended on rebates for citing OBC.
- Illustrate usage with projects that used more than one instrument (e.g., confocal microscope and flow cytometer) to further strengthen the intra-core integration.
- Leverage OBC's success to apply for a high-end instrumentation grant before the next renewal to demonstrate the Core's resourcefulness.
- Specify the number of CFCC users (currently shown as 41%) if the total number is impressive.
- Partner with industry to customize any one of the instruments.

Genomics High Throughput Facility (GHTF) (now Genomics Research & Technology Hub, GRT Hub)

- NCI reviewers were also looking for innovation in tool development from GHTF. The team responded that the goal was to really provide excellent access to state-of-the-art genomic technologies rather than methods development. This criticism might be addressed by broadly sharing analytic pipelines as they are developed with core users who have bioinformatic expertise in their labs.

In Vivo Functional Onco-Imaging (IVFOI)

- With >90% BIDD usage, the Core serves only one Program. It would have been helpful to see the number and names of users. More usage by SPT Program members should be encouraged.
- It is not clear why the score was not at least Outstanding given the expertise and technologies available and clinical impact of this Shared Resource. Many Comprehensive Cancer Centers have a small animal imaging core, so perhaps it was unclear to the reviewers whether IVFOI is the equivalent to similar preclinical cores elsewhere or a hybrid preclinical and translational core.

Experimental Tissue Resource (ETR)

- It is imperative to gain CAP/CLIA certification of the Tissue Resource as this is an expectation by the NCI for NCI Cancer Centers.
- The reviewers noted a slight decrease in publications in 2021 compared to 2015.
- An increasing emphasis on analysis of liquid biospecimens is likely over the coming funding period and additional resources may be needed if the volume of such biospecimens is high.

Biostatistics Shared Resource (BSR)

- The NCI site visit team rated BSR as "Excellent to Outstanding". One major critique noted by the site visit team was the lack of bioinformatics expertise and the lack of a permanent director for BSR. The planned recruitment of a new BSR Director with expertise in bioinformatics and leadership skills to expand cancer center support for emerging areas such as statistical methods for next-gen sequencing or single-cell sequencing data analysis and early phase clinical design will adequately address this critique.

Biobehavioral Shared Resource (BBSR)

- Center Leadership will need to determine the overall value of this Shared Resource and whether there is sufficient demand for it.

Cancer Research Training & Education Coordination (CRTEC)

- In response to the site visit reviewer's criticism that *"the CRTEC's role is not clearly defined in the governance of some programs with respect to cancer",* it might be useful to emphasize how the CFCCC members make key contributions to "umbrella" graduate programs and the MSTP by serving on admissions committees, governing councils, and at PhD thesis advisors.
- The EAB suggests including a biomedical engineer as a member of the CRTEC Steering Committee and/or emphasize the engineering expertise of one or more existing members.
- The CFCCC might consider applying for a T-32 imaging grant to align with BIDD, OBC, and IVFOI components of the CFCCC.
- It would be ideal to directly engage with minority institutions to diversify participation in the diverse education activities described. The relationship with CSU-Fullerton described at the EAB meeting is an excellent initiative that is relevant to diversity and inclusion in cancer research. This might be further enhanced by engaging the local community college system. The CRTEC might leverage similar relationships between UCI and OC community colleges in the area of STEM to enhance cancer research career and training opportunities.
- The CRTEC might consider adding new junior faculty mentoring activities in collaboration with CFCCC program leaders to fill in any existing gaps. The NIH grant writing Boot Camp includes reviewing grant proposals before submission. We endorse the plan to develop a similar CFCCC program targeted to physician investigators.
- Senior mentorship might be helpful for identifying non-NIH sources of support for young cancer researchers and for outlining expectations for competing an independent faculty position at UCI or other leading institutions.

Plans to Enhance Diversity (PED)

- Moving forward it will be important to develop and articulate CFCCC-based mechanisms to increase diversity in hiring and in trainee and faculty development.
- It would be appropriate to recruit a new AD of DEI who could devote at least 20% effort to overseeing the PED. As well, CFCCC will need to establish an infrastructure to support the AD. At minimum, this would involve a program coordinator who could also have a dotted line to Administration to leverage their resources in human resources, events management, and fiscal support.
- It was noted that the recruitment of an AD for DEI was a year out. Until a permanent recruitment is made, it would be prudent to appoint a current cancer center member as interim AD of DEI so CFCCC does not fall further behind in formalizing a plan, which must be integrated in all CFCCC missions: leadership, training and education, clinical trial accrual, research, outreach and engagement.
- CFCCC should immediately convene a DEI Council to begin developing programs and initiatives that would more directly benefit the CFCCC workforce such as a program to mentor its diverse members into leadership positions.

External Advisory Board Review, March 19, 2021 (Site Visit Rehearsal #2)

Note: 2021 EAB Meeting was Site Visit Rehearsal #2 in preparation for NCI Site Visit (which was virtual due to the pandemic). Recommendations were mostly advice on Site Visit presentations. EAB letter doesn't list specific recommendations; summary below generated by Administration. Specific recommendations on slide formatting have been excluded.

Overall Recommendations

- Provide additional detail on the funds flow model to support clinical research
- Further highlight 'centerness'; ways in which the work and impact could not have been possible without the existence of the Cancer Center
- Population Science remains an area of development. Emphasize the science in the Cancer Control Program.
- Create/provide simple comparison tables for data for 2015 vs. 2021
- Remaining concern regarding cancer relatedness of some publications/grants
- Shared Resource strength should be emphasized in Overview and within Programs
- All Research Programs should indicate how the CRTEC and COE components interface with, or are woven within, the Program
- Consider adding sections on immunotherapy efforts to each Research Program
- For each Program, provide info on total usage of Shared Resources by members
- Provide specific information about how the Programs interact with the Disease-Oriented Teams
- Concern regarding large number of members in comparison to funding base (in all the Programs)
- Consider reducing the number of UCI leader presentations
- Have UCI leaders speak directly to *what institution is doing to support* CC rather than what the CC has done.

Director's Overview, Six Essential Characteristics, Leadership, Planning & Evaluation

- Recommend increase in clinical trial data be added to slides
- Provide information regarding the impact of Covid-19 on clinical trial accrual
- Describe how the ramping up of clinical trial accruals will move forward
- Provide clear information on how clinical investigator time is protected
- Provide information on how CFCCC has fostered initiatives with other CCs outside of California
- Briefly describe the process for determining cancer relevance of grants/publications and specify that CFCCC is following that process precisely.
- Prepare response for potential questions regarding expansion of City of Hope into Orange County
- Provide a slide introducing catchment area priorities before presenting the science

- Provide information on the broader Phase I initiative including how tissues/patient samples are to be collected and annotated, how they will be run thru the Disease-Oriented Teams, etc.
- Outline how the spin-off products ended up back in CFCCC clinical trial development
- Recommend not using the grants dashboard to avoid optics of uneven funding

Community Outreach & Engagement (COE)

- Provide an example of how a study changed as a result of community feedback
- Provide a vignette showing how COE provided meaningful input into a research project (where COE influenced the study design or data collection methods, or patients/participants recruited, etc.)
- "Hub-and-spoke" model with FQHCs is impressive but, given ~ 4M people in catchment area, should provide additional activities
- Provide information on how COE informs senior leadership about research priorities given statistics within catchment area
- Provide information on how COE assesses/evaluates its impact

Administration

- Be prepared for questions regarding:
  - Cancer relevancy of grants
  - Formula-based return on clinical revenue
  - Clinical investigators compensation plan
  - Who oversees the billing/invoicing of services for the Shared Resources
  - How many (and what) endowed chairs there are under the Director's authority
  - The difference in membership privileges between members and associate members
- Provide table summarizing breakdown of space, under the authority of the Director, categorized by administration, research (SR in your space, CTO), and clinical space
- Make sure any data presented in Administration is consistent with data presented elsewhere (ex: Director's Overview)

Biotechnology, Imaging & Drug Development (BIDD)

- Elaborate on increase in membership
- Provide information regarding the future plan for the GMP facility

Systems, Pathways & Targets (SPT)

- Highlight work of physician-scientists
- Provide information about meetings/retreats/working groups
- Provide more detail about impact based on research in the Program

Cancer Control (CC)

- Provide detail on how the Program is fostering inter- and intra-programmatic collaborations
- Emphasize how the Program is working with COE in communities
- Emphasize the value and effectiveness of team science
- Programmatic science examples should be unique (i.e., not represented in any other presentation such as COE)
- Provide information on how CRTEC integrates with the Program
- Provide information on how the Shared Resources are being employed to impact Program research
- Provide concrete examples of impact of research in the catchment are
- Use team science and team science awards as a lever to highlight program strengths

Clinical Research

- Provide specific examples of the "culture of research"

- Provide information describing -what is the accountability of the PIs (in terms of accrual pace) since they don't report up to the Cancer Center
- Provide information on how CFCCC provides support them when they are struggling with accrual
- Provide information (if any) regarding any sponsor closure of trials (due to Covid-19)
- Describe how the Stern Center plans to incorporate new technologies (including AI) to assist with accrual
- Provide the denominator of active trials and number which were audited
- Recommend showing data resulting from QA
- Provide information on the increase in analytic cases without a commensurate increase in accrual and outline what's being done to address that disparity
- Provide information on how many FTEs work on IND development/regulatory reporting
- Provide information on how the Stern Center is working with the UCI alpha stem cell clinic

Shared Resource Management (SRM)

Note: Shared Resources "presented" by slides only (as is the new NCI Site Visit requirement)

- Be prepared to answer questions regarding what happens when a Shared Resource reaches capacity how the CFCCC makes decisions regarding the requirement for new equipment
- Be prepared to answer questions about the process in place to determine which Shared Resources will be sunsetted in the future

Transgenic Mouse Facility (TMF)

No EAB recommendations provided

Optical Biology Core (OBC)

No EAB recommendations provided

Genomics High Throughput Facility (GHTF)

No EAB recommendations provided

In Vivo Functional Onco-Imaging (IVFOI)

No EAB recommendations provided

Experimental Tissue Resource (ETR)

No EAB recommendations provided

Biostatistics Shared Resource (BSR)

- Provide information on how BSR is supporting the clinical trials office

Biobehavioral Shared Resource (BBSR)

- Provide detail on number of investigators supported and number who are CC members
- Take ownership of (and show value of) resourcing provided to others in country

Cancer Research Training & Education Coordination (CRTEC)

- Provide information on how CRTEC interfaces with the Research Programs and Shared Resources
- Prepare for questions on the details of the CRTEC outcomes tracking database including duration of tracking and management structure
- Consider adding Population Science leaders to CRTEC committee
- Prepare for questions on how CFCCC educates trainees about catchment burden/disparities and how CRTEC interacts with COE

Developmental Funds

- Highlight additional positive information regarding new recruits
- Consider specifying the funding sources for the new faculty recruitments

- Provide specific examples to put some granularity to the ROI statistics

Community Outreach & Engagement (COE) ad hoc **EAB Review, September 29, 2020**

Catchment Area Description

- Prepare to answer questions that only 74% of the patient population comes from the catchment area and where the rest of the population goes for clinical care
- Describe the neighboring counties (i.e., Los Angeles, San Bernardino, Riverside) to justify the catchment area assignment, given there are three Cancer Centers in Los Angeles. Discuss the patient population outside of the county as justification for future expansion.
- Establish reason for using term "Latinx"; alternatively, use "Latino"
- Provide information on proportion of population that is Black, and provide socio-demographic data, as well as cancer burden, even if data are not available for all items.

Data and Metrics

- When discussing population in the catchment area, must include African-Americans (despite small number in the catchment area).
- Use data sources as up-to-date as possible and/or data for neighboring counties, for comparison (if Orange County-specific data is unavailable)
- There was a difference of opinion among EAB members regarding using OMB categories that separate race and ethnicity versus using the categorization that is most common in California in which all Latinos, regardless of race are grouped into one category given the demographic composition of the state. It was noted that the California Cancer Registry (SEER and State) only reports data per the latter. However, it may be prudent to report OMB categories where available given FOA instructions and the reporting form in the PHS 398 form.
- Use more commonly-used cancer screening metrics of 'not up to date' (rather than 'never had mammo' or 'never had PAP')
- Some of the data presented (e.g., for risk factors) are very dated and likely do not represent the current state of risk factors/behaviors in the catchment area

Specific Aims

- Ensure that the Aims are consistent throughout all materials (i.e., grant write-up, presentations)
- Address how COE fosters clinical trial accrual: minorities, gender and across the lifespan (per new FOA requirements). Clearly define interactions with the clinical trials office and provide information on processes (e.g., implementation of best practices) that are in place to evaluate and help with minority, age, gender enrollment with trials. Also how COE interacts with the DSRGs.
- Specify details on contributions made to policies

  Aim 1:
  - Include a statement of how "CFCCC priority cancers and risk behaviors are determined based on the data and discussions with the community and leadership."
  - Include comparisons with the National and California averages

  Aim 2:
  - Highlight impact (e.g., policies, COVID19 grants)
  - Include logic model and longer term impact with SMART goals

  Aim 3:
  - Tie priority cancers (and risk factors, community-identified) to research programs
  - Consider choosing different phrase than "bi-directional community engagement" since reviewers may have a different set of expectations for examples. Consider "engage with community stakeholders" as an alternative.
  - Conduct strategic planning and evaluation under guidance of logic model

Engaging with Research within Programs

- Choose research examples outlining where COE provided input in the research within programs
- Provide more research examples outside of Dr. Tanjasiri's own research
- Involve COE with basic science research on prostate cancer to facilitate engagement with the community
- Outline examples of how COE catalyzed catchment area research in all Programs; not just the Population Science program (Cancer Control) program. Examples should fall across the full continuum of research (i.e., population, basic, and clinical sciences)

COVID-19 Impact on Communities and COE

- COE activities can be done remotely. However, consider underserved population who do not have internet access and work with the CEB and FQHC to address outreach to that population (e.g., provide cancer screening and contact information at food banks).
- Consider having one slide about how COE activities are being handled during COVID-19.
- Consider responding to the overall needs of the community and not limited to addressing cancer screening and prevention during COVID-19.

Future Plans

- Provide plan for having COE staff that can serve the different communities
- Provide information on funding sources for COE office. Include future plans when BMS funding ends.
- Leverage training current FQHC staff to showcase continuity in work in the community when Bristol Myers Squibb Foundation grant ends

Other Recommendations

- Emphasize Dr. Tanjasiri's extensive involvement with Orange County community but only claim activities for UCI.
- Discuss maintaining relationship with California State University, Fullerton, (a minority serving institution)
- Provide examples/tell stories about community engagement (including bidirectional) including basic and translational science
- Address global issues (per new FOA requirement)
- Use organizational chart in slide deck, rather than the chart currently in write-up.
- Ensure all documentation outlines that COE is present in all activities in the Cancer Center (not just about the work in which the COE is directly engaged)
- Be brief in response to Site Visit reviewer questions

External Advisory Board Review, February 26, 2020

Overall Recommendations

- Frame strategic planning & presentations around strengths in chemistry, physics and imaging. Faculty recruitment in these areas is essential. Demonstrate clear cancer relevance in cancer systems biology.
- Continue to develop strategic plan aligned with overall UC Irvine objectives
- Letters of Institutional Support (for inclusion with CCSG submission) must be explicit regarding space, recruitment lines, funds flow and discretionary financial resources under the authority of the Director
- Delegate authority of committee overseeing cancer clinical and clinical research enterprise to Center Director
- Clinical Trials: Aggressively recruit to IITs and demonstrate improvement in IIT design/execution. Strengthen translation of Center's science into clinic via therapeutic IITs. Strengthen culture of clinical research. Demonstrate connection of industry-sponsored trials to Center and programmatic science.
- COE/Population Science: Generate more detailed geospatially mapped data that better defines cancer burden of Center's catchment area, identification of highest research priorities based on cancer burden, and dissemination of these priorities across center and its stake holders (i.e., Programs and membership).

- Consolidate and 're-fashion' OIB and MDT Programs to increase the cancer-focused technologies and their translational applications
- Establish process for supporting protected time for clinical investigators. Needs to be finalized, adopted and operationalized well in advance of the CCSG competing renewal submission (Jan 2021)
- Establish formal funds flow model (documented in a MOU), well in advance of January 2021 CCSG submission, per new NCI mandate.

Director's Overview & Six Essential Characteristics

- *Space*: Spend less time on this element during the Site Visit presentation; spend more time describing Center's science
- *Organizational Capabilities:* UCI must develop a transparent, fair and reproducible funds flow model that will help sustain the center beyond the Director's startup package and fully leverage cancer service line's contribution to UCI Health's margin. Develop a true cancer service line.
- *Cancer Focus*: Develop more robust algorithm for assessing cancer-relevance. Consolidate MDT and OIB Programs into a single Program with reformulated aims that leverage strong science & technology platforms. Urgently focus on new grant funding and new recruitments of funded investigators into Cancer Control Program and establish dynamic future plans for Program.
- Demonstrate detailed understanding of the catchment area composition, cancer burden, COE activities etc. Outline how the COE informed some of the overall research (*as written in 'Community Outreach & Education' section of EAB Report*)
- Include research examples from the Cancer Control Program, particularly those that are well-aligned with overall Center strategic priorities and those that are highly relevant to catchment area needs (*as written in "Cancer Control Program" section of EAB report*).

Leadership, Planning and Evaluation

- Specify how frequently senior leaders meet and how they have worked together to support the Center's initiatives
- Clarify the roles of the Associate Directors in directing/facilitating the science of specific programs
- Prioritize completion of new strategic plan

Administration

- Develop more rigorous procedure for assessing cancer-relevance and recalculate Data Tables (*as also written in "Cancer Focus" and outlined in the "Molecular Diagnostics & Therapeutics Program" section of the EAB report*)
- Prepare general budget for the projected CCSG 5-year cycle in which sources of funding are clearly noted. Budget should identify the clinical funds flow amount, any pass-through of UCI's F&A, philanthropy, institutional support, technology transfer revenues, etc.
- Review of Administrative organizational chart displays a thin infrastructure. Recommend:
  - Hire at least one additional fully-dedicated FTE to provide administrative oversight of the Shared Resources and Cancer Research Training and Education Coordination;
  - Hire a fully dedicated FTE in the area of advanced administrative informatics
  - Expedite replacement hire for Assistant Director of Administrative Programs

Community Outreach & Engagement

- Establish rapid and significant progress in overall COE
- Clarify, and provide consistency, in data on demographic characteristics and cancer-related burden in catchment area
- Areas singled out as important (ex: obesity, tobacco use, high melanoma rates) must be consistently addressed with, at a minimum, evidence of outreach and engagement activities addressing these areas
- Focus on how COE helps to catalyze catchment relevant research across all of the CFCCC Research Programs. Include specific examples of this in both narrative and presentation.

- Clarify roles of faculty members listed under “catchment area research”
- Clarify roles of clinical care coordinators in COE unit. Provide information on funding for positions including sustainability of funding support
- Include cancer survivors on Community Equity Board
- Clarify strategic priorities for COE
- Establish clear processes for informing Center leaders and membership about catchment area needs. Demonstrate effectiveness in catalyzing catchment area research.
- Establish, and review measurable metrics at regular intervals to ensure COE is meeting its strategic goals
- Clarify strategic priorities of COE, and provide indication of how plans are synergistic with the overall CFCCC strategic priorities
- Apply more careful consideration to research vignettes included in presentation. Coordinate with Cancer Control Program in selection of vignettes.

Cancer Research Training & Education Coordination

- Provide robust metrics in all levels of training, including faculty mentoring.
- Provide clarification on staffing and monetary commitment to support training and mentoring activities
- Focus on detailed presentation of formal mentoring process for the Cancer Center (rather than details on pilot project recipients)
- Establish more concrete plan to augment training grant opportunities for Cancer Control Program and population sciences
- Outline how this effort would have happened without a NCI-designated Cancer Center

Clinical Research

(Note: Separate sections in EAB Report entitled “CPDM”, “Clinical Research”, “Research Portfolio/Protocol Review/Clinical Trial Accrual/IITs” and “Stern Center Enhancements” have been consolidated under this heading of “Clinical Research”)

- Recommend that all federated cancer clinical trial components be centralized under the single Cancer Center clinical trials office prior to site visit in 2021
- Continue efforts to achieve a 90-day activation timeline
- For NCTN trials, more aggressive time to activation benchmarks can be set
- Task the administrative leadership to conduct a protocol-specific (IIT vs. Cooperative Group vs. Pharmaceutical; interventional-treatment vs observational vs. interventional-non-treatment) work-flow study from evaluate points of inefficiencies in protocol trafficking.
- Consider recruiting, or contracting with, a project manager to monitor and track activation timelines and anticipate any delays so that team can intervene early with solutions
- Link the relevance and selection of industry trials to Program science
- Clarify level of rigor that is applied by the DOT to protocol review and whether there is full engagement of stakeholders
- Recommend that review criteria be revised to include consideration of whether UCI science is being translated into the protocol under review and whether academic credit is available for investigators participating in proposed study
- Develop incentives to evolve investigator culture by developing a compensation model that allows for physician-investigator protected time and buy-down of work RVU requirements from clinical research activities
- Incentivize investigators that develop and activate clinical trials that are based on UCI science
- Provide data on accrual of individuals across the lifespan (a new CCSG requirement)
- Develop SOPs for review of the metrics by which trials are assessed and targeted for closure
- Add senior level positions but they must be tasked with appropriate staffing models to support growth
- Invest in brand recognition

Programs

All Programs

- Describe how each Program is addressing catchment area priorities and how Program interacts with COE (*as written in 'Community Outreach & Education' section of EAB Report*)

Molecular Diagnostics & Therapeutics Program (MDT)

- Specify specific programmatic and administrative roles for each Program Co-Leader
- Program Co-Leaders should review/curate publications attributed to the Program, eliminating those that have minimal-to-no cancer relevance
- Describe impact of research discoveries on national or global cancer research and/or impact of clinical activities on altering standard of care
- Program Co-Leaders should formulate specific plan for advancing projects down translational pipeline and highlighting relevance to catchment area (emphasizing link to COE component)
- Activities without a strong track record should be moved from Specific Aims into Future Plans
- Recommend merging MDT with OIB Program

Onco-Imaging & Biotechnology Program (OIB)

- Hold program member retreat to envision a new future for the program that identifies new areas of research
- Recommend merging OIB with MDT Program

Systems, Pathways & Targets Program (SPT)

- Stronger interactions with more clinical translational results will strengthen the Program
- Outline how COE activities identified needs and stimulated Program research addressing those needs
- Provide tighter focus, in 'Future Plans', related to Center strategic initiatives
- More rigorous delineation of cancer relevance of grants needs to be applied (*see "Administration" section of summary*)
- Carefully review publication list, removing less cancer-relevant publications
- Select highly impactful scientific examples with demonstrable metrics (papers, grants, grant applications)
- Further delineate the actual catchment area relevance of the work on the specific PDX models

Cancer Control Program (CC)

- Include brief discussion of how Program transition was accomplished and how Program Co-Leaders interact and provide direction to the Program, including bolstering intra-and inter-programmatic collaborations
- Further increase depth in survivorship research with more peer-reviewed funding and more high-impact publications
- Highlight research with peer-reviewed grants and high impact journal publications in the field
- Highlight research examples linked to catchment area and how Program interacts with the COE
- Emphasize interactions of Cancer Control members with Disease-Oriented Teams
- Demonstrate successful inter-programmatic collaborations
- Service-oriented outreach activities should be presented by COE (rather than the Program)
- Recommend removing behavioral medicine as a Future Aim

Shared Resources Management

- Further clarify the Shared Resource management role of each Associate Director in Basic Science, Clinical Science, and Population Science & Cancer Control
- Provide examples of how Internal Advisory Board advice has shaped decision-making at the Shared Resource level

Shared Resources (Poster Session Only)

Transgenic Mouse Facility (TMF)
- Include (in write-up) scientific example from other institutions (as was in the poster)

Optical Biology Core (OBC)
- *No specific recommendations*

Genomics High-Throughput Facility (GHTF)
- Increase usage by CFCCC members to further strengthen the Shared Resource
- Acquisition of additional equipment & expertise for spatial transcriptomic and proteomic analysis will further improve the Shared Resource

In Vivo Functional Onco-Imaging Shared Resource (IVFOI)
- Center leadership should consider a pilot project RFA for high-field MRI use that would support use by Center members
- Eliminate barriers to access to the large-bore MRI

Experimental Tissue Resource (ETR)
- Develop specialized forms of tissue analysis including immunohistochemistry, microdissection, and other forms of modern tissue-based genomic or biologic or imaging analysis
- Initiate the collection of paired normal specimens (buccal mucosa, blood) that would facilitate future genomic analysis of collected biospecimens and next generation sequencing
- Consider initiating the process to become certified by CAP/CLIA
- Work with CFCCC Administration, Senior Leadership and Research Programs to set future goals and strategies that will enhance the value of the shared resource

Biostatistics Shared Resource (BSR)
- Consider establishing a 'walk-in' service with broadcasted, fixed hours so that answers to quick questions (e.g., sample size/power calculations, design considerations, etc.) could be addressed
- Recommend presenting results from the highest impact publications with different methodologies (statistical genetics, genomics, epidemiology, and/or clinical trials)
- Provide clear examples of evaluation and application of novel statistical methods
- As the Phase I program develops, a member of BSR should be in attendance at protocol construction to optimize dose-finding/efficacy endpoints
- Provide more strongly-developed future plans and clearer articulation of a vision for the next five years

Biobehavioral Shared Resource (BBSR)
- Recommend that narrative and poster highlight high-impact published and highly innovative research, clearly describe the role that BBSR played in this work, and present research findings
- Include examples of work by others than the Shared Resource Director
- Include examples of work conducted in programs other than the Cancer Control Program
- Provide a clear listing and description of the services offered
- Consider the addition of a research assistant

External Advisory Board Review, February 25, 2019

Overall Recommendations
- Increase NCI-qualifying funding base
- Continue developing compelling vision/narrative emphasizing distinctive attributes of CFCCC & leveraging UCI strengths (i.e., computation, physical sciences, engineering, chemistry, optical imaging)
- Develop/execute CFCCC strategic plan that is aligned with overall UC Irvine objectives
- Letters of Institutional Support (in CCSG) should be explicit (i.e., space, recruitment lines, discretionary funds under Director's control) outlining ability of Director to execute plan

- Request one-year no-cost extension from NCI (to focus on key recruitments & strengthen funding portfolio)
- Director should be provided (by University) with an academic title reflecting responsibilities of committee role overseeing cancer clinical operations and clinical research enterprise
- Clinical Research: Focus on aggressive recruitment & improvement in IIT design/execution
- Onco-Imaging & Biotechnology (OIB) Program: Consider consolidating OIB and Molecular Diagnostics & Therapeutics (MDT) programs if OIB is not strengthened enough prior to CCSG submission
- Community Outreach & Engagement (COE): Ramp up staffing
- CFCCC Leadership: Focus on recruitments for AD for Administration & Finance and Program Co-Leaders for Cancer Control (CC) and OIB as one the highest priorities

Director's Overview & Six Essential Characteristics

- *Organizational Capabilities*: Develop true cancer service line. Unique opportunity for UCI to develop a "funds flow model" that will sustain the Director's start-up package and leverage the cancer service line's contribution to UCI Health's margin.
- *Cancer Focus*: Develop process that defines the proportion of cancer relevance of grants & publications. Focus on meeting minimum requirements for Programs; consider consolidating OIB & MDT *[Note: See above in "Overall Recommendations"]*. Identify/articulate key scientific themes that leverage unique strengths of UCI and differentiate it from other NCI centers in region.
- Provide greater detail on the interactions of SPT & the Disease-Oriented Teams (DOTs). Provide criteria for an organized DOT and provide additional details with respect to how these are related to the Center & how they interact with the Programs *[Note: Recommendation made in SPT Program section]*
- Further highlight impact of B-ALL on Hispanics relevant to the U54 grant in Catchment Area presentation *[Note: Recommendation made in SPT Program section]*
- Consider providing pilot project funding to MDT and CC *[Note: Recommendation made in MDT & CC Program sections]*

Clinical Research

- UCI Leadership must take more proactive role to establish the **expectation** that all clinical faculty should accrue patients to trials. Expectation should be tied to academic advancement.
- Increase clinical trial accrual, particularly to IITs
- Increase number of IITs
- Associate Director (AD) should take immediate & direct role in portfolio management within the DOTs
- Consider hiring trial eligibility support personnel to reduce required enrollment activities for faculty
- Establish priority for clinical trial development/implementation that follows clear understanding of cancer-specific prevalence seen at Center
- Task clinicians who manage the most common solid tumors to develop/find/open trials. Hold DOT leads accountable for poor accrual & provide them with resources required for turn around.
- Quickly establish concrete plans to bring UCI-originated science into clinical translation. Consider prioritizing 1-2 therapeutic trials from UCI that will bring robust accrual prior to site visit.
- Phase I Program: Prioritize developing a full Phase I Program

Administration

- Continue coordinating/documenting governance activities
- Adopt formal charters for each leadership committee and include minutes for Associate Directors meetings
- Improve consistency in frequency of Shared Resource (SR) advisory meetings & document how SRs prioritize user demands
- Develop specific criteria for defining cancer relevance of grants [*Note: Recommendation made in Overall Recommendations & MDT Program sections*]
- Perform careful review & curation of publications and appropriate reallocation of resources/members across Programs [*Note: Recommendation made in MDT Program section*]

- Remind Shared Resource users, on a regular basis, to cite Shared Resource(s) in publications [*Note: Recommendation made in IVFOI Shared Resource section*]

Cancer Health Disparities & Community Engagement

- Broaden focus within catchment area to focus on cancers of highest prevalence, not only on high incidence (i.e., number of occurrences) and mortality in Orange County as compared to rates in State of California
- Continue plans for partnering with CalOptima and Federally Qualified Health Centers. Provide details on research component of initiative.
- Provide evidence of very specific achievements in the area of community engagement
- Establish a healthy portfolio of funded research that directly addresses the cancer needs of the catchment area population
- COE needs to engage in conducting several on-the-ground engagement activities
- Provide staffing support for COE leader (S. Tanjasiri)
- Aggressively recruit for 4-5 additional funded mid/senior level investigators in cancer control

Cancer Research Career Enhancement & Related Activities

- Distinguish between training & career development programs that are UCI-wide (in which CFCCC is a participant) vs. those that are unique to/led by CFCCC and/or CFCCC members
- Focus on examples of innovation & successful outcomes
- Provide description of what types of trainees are supported by the T32 program, whether any of the grants are NCI-funded & how many of the PIs are members
- Showcase students from underserved minority groups and efforts to recruit them
- Include examples of success in developing careers of young investigators in cancer control/population science

Programs

All Programs

- Strategically map out future recruitments aligned with the CFCCC's strategic scientific priorities [*Note: Recommendation made in Cancer Control Program section*]

Molecular Diagnostics & Therapeutics Program (MDT)

- Efforts to develop a Mass Spectrometry Shared Resource are to be commended
- CFCCC could foster collaborative efforts with UCI's outstanding chemistry department by providing pilot fund support
- Develop specific aims that reflect the strong cancer research in this program
- Provide better justification of the cancer relevance of non-NCI grants attributed to the Program (via explicit cancer center criteria for defining cancer relevance of grants). These grants should be highlighted in the CCSG & at the Site Visit
- Improve publication rates and both inter- and intra-programmatic metrics
- More strongly develop relevance of MDT's research in catchment area
- Improve clinical trial accrual

Onco-Imaging & Biotechnology Program (OIB)

- CFCCC Director is strongly encouraged to use his influence, as much as possible, to have UCI leadership select a Beckman Director (replacing B. Tromberg) with strong & direct ties to, and interests in, cancer research

Systems, Pathways & Targets Program (SPT)

- Explain in greater detail the interactions of SPT & the DOTs
- Further highlight impact of B-ALL on Hispanics relevant to the U54 grant

- Further highlight PDX model
- Consider redesigning SPT as 'Systems, Pathways, Targets & Therapeutics (SPTT)" if the decision is made to consolidate MDT & OIB
- More strongly emphasize pre-clinical assessment of multi-agent target therapy

Cancer Control Program (CC)
- Recruitment for AD for Population Sciences and CC Program Co-Leader should be a top priority and must provide very competitive recruitment packages
- Further revise CC's overall scientific mission statement and improve themes so they reflect the mission with regard to discovery & intervention research
- Improve presentation of integration of programmatic research within the themes and highlight how disparities is a cross-cutting theme. Improve synergy across themes.
- Bolster behavioral/community intervention & cancer care delivery research
- Improve presentation of peer-reviewed funded & published disparities research
- Increase both intra- and inter-programmatic collaboration
- Strengthen description of CC's integration within the CFCCC & actions by leadership to improve this
- Consider providing pilot funds/seed money to Program leadership to develop collaborative grant applications
- Aggressively recruit 3 additional funded investigators whose research aligns with program themes/aims
- Take advantage of formation of UCI integrative medicine program and focus on recruitment of integrative oncology clinician scientists with expertise in intervention, outcomes & survivorship
- Integrate CC members into new melanoma projects

Shared Resources

Transgenic Mouse Facility (TMF)
- Tabulate and present all cancer usage (including usage by any NCI-designated Cancer Center) to further highlight how TMF enhances cancer research, both at UCI and at other institutions
- Emphasize the following in the CCSG & at the Site Visit: projects for NCI-funded grants (UCI and external), projects where TMF-made mouse strains resulted in R01 awards, high-impact publications and/or contributions to advancing cancer research and those that illustrate cutting-edge technology of TMF.
- Provide TMF presentations at CFCCC scientific program meetings
- Core Director (G. MacGregor) could meet with PIs of T32 grants

Optical Biology Core (OBC)
[no specific recommendations]

Genomics High-Throughput Facility (GHTF)
- Increase usage by CFCCC members

In Vivo Functional Onco-Imaging Shared Resource (IVFOI)
- Expand usage by CFCCC members in programs other than OIB
- Bring planned new high-field MRI unit online as soon as possible

Experimental Tissue Resource (ETR)
- Highlight collaboration with Champions to develop PDXs from Asians & Hispanics with liver/gastric cancer leveraging U54 Minority PDXNet project (M. Waterman) since this addresses key need in catchment area
- Operationalize fully functional database as soon as possible
- Enhance fresh tissue banking during this upcoming year

Biostatistics Shared Resource (BSR)

- Complete recruitment of permanent Core Director as high priority for CFCCC
- Increase usage by CFCCC members in other programs than Cancer Control
- Provide data emphasizing that BSR is utilized by a large majority of CFCCC investigators (rather than presenting data stating that 82% of users are in the Cancer Control Program)
- Re-balance Shared Resource funding balance from other sources rather than the CCSG (which provides 87% of current funding)
- Highlight high impact publications that BSR supported & delineate BSR's role in the project
- Highlight projects that have clear relevance for cancer burden in the catchment area

Biobehavioral Shared Resource (BBSR)
- Attempt to have BBSR support projects outlined in high impact journals
- Increase service support to CFCCC members

External Advisory Board Review, February 7, 2018

Overall
- Space: Need clarity on both location and Cancer Center Director's requisite authority over space mandated by CCSG regulations
- Status of Director: Recommend Director have direct report to Vice Chancellor with status as an Associate Dean or Associate Vice Chancellor
- Financial Resources: Commitments for access to resources to support future recruitments, developmental funds & equipment are necessary (concern that there are no provisions for future funds flows after depletion of Director's original recruitment package). Strong recommendation that Cancer Research Institute is renewed as an ORU.
- Clinical Oversight: Recommendation that Director have oversight of cancer clinical operations
- Clinical Research Support: Strong recommendation that all decisions regarding CC involvement in centralization process are delayed until after competitive renewal

Clinical Research
- Shorten clinical trial activation timeline
- Take more proactive control of the portfolio
- Concern regarding low level of institutional support for CTO (half of average provided at other NCI centers)
- Identify clinical investigators in each of the DOTs to lead efforts with better support from CTO
- Connect clinical investigators w/translational scientist to better leverage translational research endpoints or support developmental concepts
- Focus seed funding on these initiatives
- Establish master agreements under alliances w/small biotech or asset leads for big pharma

Administration
- Develop long-term (five-year) budget forecast (including institutional commitments) be secured and presented at future EAB meetings. Administration should be heavily involved in the process.
- Provide Data Tables & program meeting documentation at EAB meetings
- Correct minor issues in DT2 including high amounts of annual direct costs from trials based on low level of accrual

Cancer Health Disparities & Community Engagement
- Primarily emphasizing cancers with higher incidence rates in Orange County compared to the state as a whole provides opportunities for UCI to distinguish itself by targeting understudied cancers in distinct ethnic populations but this approach is also unduly narrow in its prioritization of relatively uncommon cancers and does not reflect the overall cancer burden in the county in terms of the

actual number of individuals affected (incident cases, survivors, and cancer deaths)
- Provide explanation for why focus is on Asians (18% of population) and not Latinos (35% of population)
- Concern regarding lack of progress in implementation plan to hire nurse educators & patient navigators
- Implement meaningful and substantial community engagement activities in the two year time frame until competing renewal.
- Substantial institutional investment in providing staffing support for Dr. Bristow (e.g., master's level community program coordinator, public health nurse, nurse navigator) required. Delivering funded research addressing catchment area needs will be an uphill task given the current state of the Cancer Control program.
- Very aggressive recruitment of an additional 4-5 funded mid/senior level investigators in Cancer Control (disparities, community research focused) and a visionary leader to anchor the program are urgently need to meet the research related expectations for COE.

Cancer Research Career Enhancement & Related Activities
- Present with create a clear sense of excitement about the more innovative, important, and effective initiatives
- Select and highlight a few key elements for the future site visit.
- Be cautious when referencing "joint initiatives of: the CFCCC and the CRI; could draw reviewer questions about why CRI is distinct from the CFCCC
- Simplify presented bar graph
- Site specific examples of successful trainees (T32 grants in Cancer Biology & Therapeutics and Gyn Oncology, the ACS IRG and the NIH Bootcamp) who went on the obtain subsequent NCI funding (K23/K08/R01)
- Emphasize how the CFCCC adds value to the R25 program for Complex Biological Systems and the UCI MSTP
- Provide specific examples of "value added" to the CFCCC with respect to organizing and supporting successful training grant applications

Programs

Chemical & Structural Biology Program
- Emphasize cancer relevance (i.e., which specific cancer problem is being addressed?)
- Develop mass spectrometry shared resource, as presented
- Although the program identifies itself as a basic science program, the strength of the chemistry faculty facilitates a high degree of expectation for translational science. This is evident in at least two examples for which early phase clinical trials are anticipated prior to the next site visit. Such translational activities should be highlighted in conjunction with the Molecules to the Clinic seminar program.
- Need an infusion of new members with NCI funding is needed. This can result from new targeted recruitment of senior faculty with NCI funding or shifting currently funded members from other programs into CSB. The latter is probably more feasible given the resources available the relatively short timeline to the next CCSG review.
- Consider rebranding Program. The idea of transitioning this program to an Experimental Therapeutics Program should be contemplated.
- The other consideration is adding a nano-medicine/particle component to CSB assuming that there is enough cancer relevance and funding to support such an expansion.

Onco-Imaging & Biotechnology Program
- Monitor peer-reviewed funding given 2018 end-dates
- Try to find/develop specific examples in which P41 research resources were used to obtain preliminary data that led to R- series grants within OIB's funding portfolio (since new guidelines

prohibit affiliating P41s with Programs)

Systems, Pathways & Targets Program

- Perform membership review with attention to criteria for Associate Member status
- Continue to monitor the grant portfolio to ensure it meets the new "5 investigators with 7 R0I awards" metric
- Clearly explain and justify cancer relevance
- Work on improving the intra-programmatic co-publication rate
- Highlight how program adds value to the Educational activities of the UCI Cancer Center
- Find ways to interact more meaningfully with the CSB program

Cancer Control Program

- Need to increase grant base and intra-programmatic publications
- Increase member participation in Disease-Oriented Teams
- Need increased evidence of members reaching out to other programs
- The emphasis on disparities is well justified but the total burden of cancer in the catchment area also deserves consideration.
- Increase intervention research in the program
- Increase emphasis on factors that affect treatment outcome
- Since the CFCCC has linkages to major care providers, it might be possible to disentangle factors-such as delay, failure to recognize symptoms, inability to find a care provider, lack of transportation-that lead to diagnosis of more advanced cancer. This emphasis would also link well with the theme of survivorship.
- If Disparities is listed as a program theme, must have projects focused on or addressing disparities. No clear plans were provided for how this mismatch between themes and actual research portfolio will be addressed.
- The research on the willingness of people to participate in genetic studies touches on an important issue. It will be important, as the Cancer Control Program proceeds, to identify how this information might facilitate interventions to decrease the burden of cancer in the catchment area and at large.

- If Survivorship is featured prominently as a theme, this research portfolio must be increased
- Program must improve clear focus and energy. Institution must make the necessary investments to re-vitalize the program with new and dynamic leadership. The program will need at least 4-5 new mid-senior level, R01-funded faculty as well as a visionary leader who can build a robust and focused program

Shared Resources

Transgenic Mouse Facility

- Emphasize demonstrating the broad cancer research impact of the TMF by collecting data on utilization by extramural scientists who hold NCI grants and subsequently published work that benefitted from collaborating with the TMF.
- Continue ongoing efforts to develop a UC regional facility in collaboration with the Cancer Centers at UCSD and UCLA. Consider including outreach to engage and serve researchers at UCSB, UC Riverside, and UC Merced.
- Underscore that the percentage of TMF utilization for cancer-focused projects (particularly by intramural and extramural NCI-funded investigators) is commensurate with the 20% budgetary contribution from the CCSG Core grant.
- Create a small collection of online tutorials available through the TMF website that address the most common issues they are asked to consult on.

Optical Biology Core
- Important for core to be proactive in describing education/training

Genomics/High-Throughput Facility
- Clarify information on access to high performance computing

In-Vivo Functional Onco-Imaging
- Expanded use into other programs aside from OIB (particularly SPT) is encouraged
- IVFOI leadership is encouraged to leverage Dr. Van Etten's stature within the institution to push for/prioritize facilities completion (for the small bore, high field MRI) sooner rather than later, if necessary

Experimental Tissue Resource
- Imperative that a working database be operational by the renewal submission. Having the database searchable by investigators would be excellent but given the relatively short time timeframe, limited budget and HIPAA-related issues this is probably not realistic in the short term.
- It is important that all biobanking takes place under the umbrella of the Experimental Tissue Resource. Even if a sub-biobank is relatively independent, using common standard operation procedures, consents and/or databases shows a unity of effort and insures high quality. If external reviewers see multiple independent banking efforts within the Cancer Center, this is perceived as a significant weakness.
- College of American Pathology (CAP) biorepository accreditation would be a plus but is not essential, so long as robust standard operating procedures are in place and can be documented.
- To date the collaboration with Champions has not yielded significant scientific benefit to the Cancer Center. If this does not mature in the next year it should not be emphasized in the renewal.

Biostatistics Shared Resource
- Clarify the over one-third of effort listed as "other/administration"

Biobehavioral Shared Resource
- Focus on service to CC members (i.e., heavy orientation toward service of non-members may be a detriment in future CCSG reviews)
- Differentiate between BBSR and BSR
- Focus more on community-based trials
- Introduce quality of life measures for electronic health record studies

External Advisory Board Review, April 13, 2017

Overview and Essential Characteristics
- Critical need for stronger institutional commitment that includes a need for both wet and dry laboratory space (minimum of additional 50,000 sq. ft. under the control of the director)to enhance recruitment of NCI-funded basic, translational, clinical and population cancer researchers
- Need institutional resources of $15 million yearly to support new recruitments
- In presentation, emphasize the overall scientific directions of the Cancer Center, its strategic scientific priorities and its unique distinctions, both in its catchment area, and within the national cancer movement.
- Identify plans to sponsor/encourage multi-investigator grants
- Important to quantify that the DOTs need to become the foundational infrastructure to substantially improve investigator-initiated, therapeutic clinical trial accrual
- Put forth concerted effort to increase therapeutic accruals to at least 250 per year by the time of the next CCSG submission

Administration

- Provide examples of how CFCCC Administration has contributed to one or more key scientific priorities of the Center
- Conduct an extensive gap analysis to determine the current portfolio and quantify incremental needs for investment now to fulfill new guidelines requirements for peer-reviewed funding for Research Education and Training

Clinical Research

- Mandate all cancer center clinical trial accruals to be registered in central clinical trials management system (OnCore)
- Closely follow timelines from concept to first patient in
- Name a research leadership team to start the EPIC conversion process
- Secure funding for proposed expansion of both research personnel, regulatory personnel and a cancer center dedicated or in house budget/legal team – will need substantial year-over-year investment
- House resources dealing with CCC trials under the Cancer Center research operations team
- Institute central institutional auditing with PI and research staff education
- Establish, expand and incentivize translational pilot projects. Need to identify clinical PIs to match with preclinical PI's, as well as, a junior PI mentorship strategy – particularly in solid tumors
- Develop a global strategic plan for clinical research aligned with patient population and a fiscally viable expansion plan (both solid and liquid tumors)
- Consider hiring a clinical accrual specialist/RDC person to identify potential clinical trial candidates

Community Outreach and Engagement (COE)

New CCSG requirement; unclear how reviewers will interpret and rate

- Find linkages with other areas in the cancer center
- Add focus on the most common cancers in each ethnic group (without comparisons to other geographies)
- Establish more thoughtful and broader approach to defining "disparities" is encouraged (ex: examining disparities in access to care, uptake of cancer screening, tobacco use, patient reported outcomes, receipt of appropriate care, etc.)
- Synergies with CPOS (Program) should be emphasized and efforts should be made to find links to other cancer center programs and the clinical trials enterprise
- Unclear why a molecular epidemiologist or a health economist would be good investments. It may be more important to recruit in the area of health disparities intervention research, outcomes intervention research, prevention/risk reduction research (e.g., tobacco, vaccines, obesity, cancer screening, cancer outcomes, survivorship).

Research Education and Training

New CCSG requirement; unclear how reviewers will interpret and rate
See note in 'Administration' about recommendation to perform gap analysis

Programs

Onco-Imaging & Biotechnology Program

- Increases in total peer-reviewed funding and NCI fraction will go a long way towards eliminating any continued concerns at the next competitive renewal
- Reducing the number of program members might be helpful

Chemical and Structural Biology Program

- Take pro-active approach to delineate the cancer relevance of some of the work by pointing out the cancer relevance and laying out how the projects can contribute to the cancer problem, albeit sometimes with a more long-term outcome
- Highlight those projects with translational significance that are clearly moving to clinical applications
- Recruit new NCI-funded investigators to CSB
- Consider moving members from the nanomaterials group in the OIB to CSB to bolster funding
- Create a shared resource for mass spectrometry, as proposed

Systems, Pathways and Targets

- Think of three emerging or aspirational program project grants and make them the scientific themes around which the program can be organized
- In the absence of a disease-oriented program in the UCI CFCCC, connections amongst basic scientists in this program with the various DOTs is critical for the overall success of the Center

- Provide examples of ongoing trials within one or more of the DOTs that were informed by NCI-funded basic science research within the program and/or have a strong laboratory component.
- Review SPT membership and perhaps clinical members can be specifically identified if their funding is limited
- Strive to recruit one or more established cancer scientists into the program
- Additional collaborative applications like the pending U54 proposal and other efforts to increase the percentages of inter- and intra-programmatic publications by SPT program members is encouraged

Cancer Prevention, Outcomes and Survivorship (CPOS) Program

- Consider strategic re-conceptualizing CPOS Program themes from three to two to improve focus and minimize potential misconceptions
- Take better advantage of institutional research opportunities in catchment area
- Recruit 2 to 4 R01-funded researchers
- Focus on translational, transdisciplinary research efforts; eliminate historical contributions of chemoprevention and epidemiology as research is > four years old and with modest impact
- Increase university support and investment in this highly visible and high impact UCI program
- Change Program title to emphasize cancer *risk*, rather than cancer *prevention*
- Establish Program Co-Leaders who are R01 funded
- Must show evidence that work is cumulative, that there is collaboration and interaction—synergy—within this program
- Planned recruitments in the Community Outreach and Engagement (COE) component should be allocated to CPOS, because the program is critical for maintaining CFCCC comprehensive status.

Shared Resources

Transgenic Mouse Facility (TMF)

- Capture the true cancer research impact of the TMF by tabulating utilization by extramural scientists and including these data as a separate category in future progress reports and renewal applications
- Emphasize that Membership usage is commensurate with the percent of the operating budget from the CCSG core grant.
- Remain attentive to education and training; conduct a survey of CFCCC members regarding educational tools and activities that might be beneficial to them and to then respond accordingly; and/or develop one or more on-line tutorials the explain specific technologies for engineering mouse strains and address frequently asked questions that could be accessed through the TMF and CFCCC web-sites.
- If the UCI CFCCC considers appointing an Associate Director to oversee Shared Resources, Dr. MacGregor would be an exceptional candidate for such a role.

Optical Biology Core (OBC)

- Information on how budgetary and charge-back resources are sourced/deployed was not presented but would be helpful, since OBC has a significant non-member clientele, and demonstrating that the CC carries a financial burden commensurate with member use is important.
- More and/or other education/training/advertising interventions might be considered (i.e., looking at all of OBCs facilities in terms of time-charting of use in light of education/training events is encouraged and is likely to be informative).

Genomics High-Throughput Facility

- More effectively communication information on training and education
- Consider developing liquid biopsy and enhancing single cell analysis
- Critical that the CFCCC maintains the necessary support and organizational structure of GHTF and bioinformatics to maximize capabilities. To achieve an outstanding rating, greater usage of CFCCC members are required and more high impact publications are needed highlight the use of this core in basic and translational research.

In Vivo Functional Onco-Imaging (IVFOI) Core

- CC-member use beyond OIB would strengthen the core
- Consider better accounting or promotion of clinical systems use (MRI, PET/CT which are listed among the core instruments/services provided) in CC-member clinical studies being conducted through the DOTs.
- Encourage cancer-related clinical studies to incorporate imaging whenever possible and appropriate
- It may be possible to increase usage by the SBT program, given the excellent animal imaging resources which could be used by investigators in this program.
- Consider marketing “engineering design and fabrication services” to the broader CC community as available through IVFOI and then account for these research development activities as purchased services, not unlike biostatistics services when consultation and study design are required (i.e., services/interactions beyond pure statistical computation/number-crunching).

Experimental Tissue Resource (ETR)

- Imperative that the linking of tissue data with patient-specific data is operational by next review; consider adding additional resources to accomplish this.

Biostatistics Shared Resource (BSR)

- Biostatistics requires a recalibration with a new UCI-wide plan for integrating statistical consulting services.
- Expand BSR usage to other Programs aside from CPOS
- Launch search for new Shared Resource Director (since incumbent is only ‘interim’); it may be advantageous to recruit a director who has a peer-reviewed program of population sciences research that could count towards the CPOS program metrics

Biobehavioral Shared Service

- Expand BBSR usage to other Programs aside from CPOS

Mass Spectrometry ad hoc **Advisory Board Review, April 6, 2017**

- Immediately poll all researchers to ascertain: 1) the currently-unmet mass spectrometry needs; 2) what grants are likely to be supported by the proposed facility; 3) how needs are currently served; and 4) required services for current and future research projects.
- If ‘matrix’ MS facility is established, recommend hiring an independent director. Key responsibility of director needs to be clearly defining the roles and services provided by each group to prevent competition

and redundancy within the facility and to present clear organizational vision to the UCI community. Initial salary investment will need to come from Cancer Center
- If proteomics is to be included in core, LUMOS instrument should be acquired as soon as possible. If funds for this purchase cannot be secured in reasonable timeframe before CCSG competing renewal submission, recommend leaving proteomics out of the 'matrix' MS facility
- Clearly delineate MS approaches; chemistry facility should focus on small molecules and develop metabolomics capabilities.
- Re-evaluate the situation in one year to assess current state of instruments and personnel and advancements with changes in mindset of the multiple groups.

Population Science External ad hoc **Advisory Board Review, March 6, 2017**

- Consider strategically re-conceptualizing CPOS Program themes from three to two to improve focus and minimize potential perceptions of overlap between themes
- Take advantage of multitude of research opportunities given our ethnic and socio-economic diversity within our catchment area
- Consider altering program title to better reflect narrowed focus of program
- Must recruit 2-4 NCI-funded investigators to the program
- Trim membership of program to those with peer-review funded projects or essential research contributions (e.g., clinical investigators with high rates of study accrual)
- Consider eliminating focus on historical contributions of chemoprevention and epidemiology since the research is 4 or more years and appeared in relatively modest-impact journals
- Increase focus on translational, trans-disciplinary research efforts that build on one another, demonstrating linkages across program's themes, potentially fruitful interactions with other programs and driving toward impactful clinical or public health actions
- Given prior NCI comments regarding lack of R01-type funding held by program co-leaders, consider various leadership scenarios
- Greatly increased university support and investment of this highly visible, high-impact UCI asset is critically needed

External Scientific Advisory Board Review, April 12, 2016

Overall

- Critical that Director is provided with necessary resources and space to transform the Center. Center must have recurrent revenue stream.
- Center needs institutional resources of $15 million/year to support recruitments
- Need institutional resources to support strong strategic planning
- Recommend guarantee of proportional share of clinical revenues to Center as cancer center service line grows
- CC Director should have responsibility for cancer service line at UCIMC with formal input and authority over the cancer clinical operations
- Institution needs to double the current high quality laboratory and "dry" space under direct & full
- authority of the Director
- Need aggressive recruitment of talented, NCI-funded investigators
- Need targeted investment to build population sciences (including institutional commitment to support recruitment of geneticists, epidemiologists, health services researches, behavioral scientists)
- Clarify Robert Bristow's roles & responsibilities on senior leadership team

Clinical Research

- Mandate use of OnCore (Clinical Trials Management System) for all oncology studies

- Closely follow study activation timelines & understand Fair Market Value for trial budgeting (esp. in comparison to local competition)
- Secure funding for expansion of Clinical Trials Office (including regulatory, study management, Center-dedicated budget/legal team)
- Institute central institutional auditing with PI & research staff education
- Establish/expand/incentivize translational pilot projects. Match clinical PIs to preclinical PIs.
- Develop junior PI mentorship strategy
- Develop global strategic plan for clinical research aligned with patient population (including fiscally viable expansion plan)
- Consider hiring clinical accrual specialist or creating Research Development Core to identify potential trial candidates

Programs

Cancer Prevention, Outcomes and Survivorship (CPOS)

- Capitalize on opportunities for inter-programmatic collaborations (with CPOS)
- Institution must support targeted external recruitments for mid-level & senior population scientists (ideally with attention to specific cancer burdens in catchment area and with focus on vision of differentiating UCI)
- Launch programmatic strategic planning effort to focus on reorganizing program to be more cohesive & robust. Must consider funding status of program leaders.

Onco-Imaging and Biotechnology (OIB)

- Work to engage investigators in data science on technology-oriented studies with goal of increasing intra/inter-programmatic publications (with goal of doubling current percentage)
- Engage clinical specialists earlier in technology development
- Ensure that new co-habituating centers/initiatives contribute to demonstrable increases in cancer-focused, NCI-funded initiatives

Systems, Pathways and Targets (SPT)

- Review how specific lab research programs might link to specific DOTs and develop milestones & timelines for overcoming obstacles and moving most promising projects toward 'bench to bedside' therapeutic translation
- Review membership criteria and roster of Program members
- Develop contingency plans if U54 proposal is not successful
- Consider launching national search for 1-3 physician/investigators with current R01 funding who are performing state-of-the-art preclinical or translational lab research that would be synergistic with ongoing research in Program and in one of the DOTs

Chemical and Structural Biology (CSB)

- Current chemists should segue from writing methods- or technology-oriented grants to writing NCI-friendly collaborative programs in conjunction with cancer biologists
- Consider recruiting basic science-oriented, senior and NCI-funded investigators to Program

Shared Resources

Experimental Tissue Resource (ETR)

- Perform banking of fresh tissue under single umbrella
- Use uniform standard operating procedures for tissue collection and single database to maintain consistent ability to retrieve critical information
- DOTs should help develop databases of clinical annotations that fit their ongoing scientific/clinical needs using IRB-approved protocols

Genomic High-Throughput Facility (GHTF)
- Perform targeted outreach to specific members of CPOS, CSB, OIB
- Include latest technologies in future GHTF services

Optical Biology Core (OBC)
- Consider forming Executive Committee for OBC
- Establish greater visibility of OBC training in future renewals. Obtain feedback from trainees on effectiveness of training and subsequent use of OBC instrumentation
- As Flow Cytometry is reorganized, ensure that it is servicing the needs of Center membership and that there is clear oversight of its activities by the OBC Director

In-Vivo Functional Onco-Imaging (IVFOI)
- Promote services via presentations, seminars, workshops, etc. within translational and clinical sciences
- Consider CFCCC call for proposals utilizing Onco-Imaging (to potentially generate more R-series proposals)

Transgenic Mouse Facility (TMF)
- Identify and focus on achievements by other Programs than SPT that directly benefitted from TMF usage
- Consider targeted pilot grants program focusing on funding proposals to generate novel mouse cancer models for compelling projects, particularly for fostering preclinical therapeutic studies

Biostatistics Shared Resource (BSR)
- Launch outreach efforts to basic and clinical scientists within Center to boost usage further

Biobehavioral Shared Resource (BBSR)
- Articulate more clearly the separate areas of expertise between this Core and BSR

Note: No administrative reviewer present so Administration was not reviewed. No separate reviews for Planning & Evaluation or Developmental Funds.

External Scientific Advisory Board Review, March 17, 2015 (Site Visit Rehearsal #2)

Note: 2015 ESAB Meeting was Site Visit Rehearsal #2 in preparation for NCI Site Visit. Recommendations were largely advice on Site Visit presentations. No formal letter was produced/provided.

Overview, Sr. Leadership, 6 Essential Characteristics
- Emphasize significant achievements since new leadership including strong institutional support (including Director's discretionary funds), key new recruits
- Suggest graphic displaying strong integration of Programs with Disease-Oriented Teams (DOTs)
- Consider providing document displaying link of new Strategic Plan to future activities including use of recruitment dollars via Developmental Funds
- Outline strong authority of Director including Van Etten's involvement in key campus committees

Programs

Chemical & Structural Biology Program
- Emphasize even more recent scientific examples
- Consider inviting Nobel Laureate program members to Site Visit

Onco-Imaging & Biotechnology Program

- Add PI photos to graphically illustrate strong teamwork in Program

Systems, Pathways & Targets Program
- Provide information on how we prioritize translational projects
- Emphasize examples where seed funding to Program supported research

Cancer Prevention, Outcomes & Survivorship
- Organize slide examples by programmatic themes
- Emphasize strong examples of diversity research
- Consider mentioning inter-programmatic research with Chemical & Structural Biology (CSB) Program as outlined in CSB presentation

Planning & Evaluation and Developmental Funds
- Recommendation: Consolidate Director's presentations of both Planning & Evaluation and Development Funds into Overall presentation. Easier for NCI reviewers to obtain information
- Outline process of launching and finalizing new Strategic Plan including information on key stakeholders

Protocol Review & Monitoring System
- Emphasize positive changes since new leadership and processes
- Outline successful metrics
- Consider creating new resource committee if required moving forward
- Consider reducing time limit for PI response to letters from PRMC

Clinical Protocol & Data Management
- CRC performance - establish SOPs/FTE requirement for portfolio

Administration
- Identify all positive outcomes/measurables and emphasize (ex: speeding up of protocol activation timeline)
- Administrative re-organization - emphasize positive changes resulting from re-organization.
- Outline administrative specific aims very clearly
- Space policy - be prepared to outline and provide numbers/data. Emphasize details in prepared Administration book.
- Concern that Associate Director for Administration & Finance is not lateral to clinical operations administrator. Recommend removing dotted line reporting.
- Link use of Developmental Funds to Strategic planning
- Dispel and potential concerns that CC funds are used for clinical purpose (based on concerns in the past)
- Emphasize improvements resulting from use of OnCore CTMS (ex: improved analytics, etc.)
- Concern regarding inclusion of CHOC studies in Data Table 4
- Shared Resource Mgmt. - be prepared for questions. If run out of depts., how do we oversee? Member access? Evaluation process?
- Catchment Area - focus on how we establish catchment area. Who minds the store? Tie catchment area to cancers emphasized in Strategic Plan
- More clearly define the 'Associate Member' category. Appears throughout grant but is not clear. Be prepared to answer questions.
- Data Table 4: How are trials assigned to Programs? What is the process?
- Program Leaders - how are new leaders brought in/mentored/etc.?
- Membership Policy - be prepared to defend
- Describe the impact as a result of the satellite clinics

External Scientific Advisory Board Review, May 11-12, 2014

Overview and Administration

- Obtain monthly guidance from seasoned leader (Cancer Center Director) to address limited amount of experience in scientific leadership
- Be clear and concrete in presentation of the Director's vision (including in Program sections)
- Be candid about past problems and future plans/solutions
- Take credit for achievements (ex: Director's recruitment package, financial commitment for future research space) and show how they are aligned with Director's future plans
- Clearly delineate between research-focused space vs. clinical space
- Clearly outline responsibilities and decision-making roles for the Committees
- Begin to undertake Strategic Plan process (possible goal of completion: time of site visit)
- Must make changes to Administrative unit structure including re-titling of positions to more accurately reflect structure and possible turnover
- Clearly delineate responsibilities/accountabilities of senior leaders
- Take credit for successes and camaraderie of senior leadership

Essential Characteristics

- Outline plans to address challenges: "We heard you, we internalized it, we are responding"
- Outline progress quantitatively whenever possible

Physical Space

- Delineate clinical vs. basic science space but draw link to how all contributes to CC success

Organizational Capabilities

- Eliminate 'co-Director' title; replace with more nationally recognized "Deputy Director". Avoid explanation of CRI title in grant (to avoid confusion)
- Simplify organizational chart lines of Associate Directors to provide more clarity of oversight/authority
- Demonstrate advantages of two-campus system
- Undertake a Strategic Plan, possibly prior to grant submission

Transdisciplinary Collaboration and Coordination

- Indicate how DOTs are integrated into Programs
- Provide quantitative evidence of improvement in trial accrual and clinical publications (resulting from DOT structure)
- Highlight how transdisciplinary collaboration results in new knowledge, publications, grants. Provide strong examples.

Cancer Focus

- Clearly outline membership criteria and make sure all members are cancer-focused
- If NCI funding is down, outline plan for improvement

Institutional Commitment

- Quantify changes (monies, space, FTEs, organizational restructuring); section requires particular attention based on prior score

Director

- Outline and quantify any improvements in Director's authority (including space)
- Outline succession plan re: Deputy Director

Planning and Evaluation
- Consider seeking planning advice from an experienced CC Director
- Need to outline strong support from Dean of Medical School and CEO of Medical Center
- Assemble a strategic plan committee or working group
- Cancer Prevention and Prognosis Program - Need to more clearly articulate linkage of risk diagnosis to prevention
- Cancer Prevention and Prognosis Program - Clearly explain dynamics of research in this program and onco-imaging needs

Developmental Funds
- Show clear alignment with strategic goals (even if new Plan is still being developed)
- Detail selection process for usage of Developmental Funds
- Demonstrate active role of Senior Leadership in taking actions to foster translation and collaboration

Mentorship, Education & Training (MET)
- Incorporate MET description/work into Overview or Essential Characteristics (in CCSG application)

Catchment Area
- Establish clearer definition of catchment area
- Identify characteristics of cancer burden in identified catchment area; then map research in Programs to this

Chemical & Structural Biology (CSB)
- Carefully assess program membership; focus on well-funded, cancer-focused PIs is critical
- Program must become more engaged in translational activities (including integration with SPT Program); dedicated resources will be required

Onco-Imaging & Biotechnology (OIB)
- Expand and more clearly define translational work (in coordination with DOTs); need sustainable integration and communication
- New treatment paradigms will be important
- Address potential concerns regarding physical separation of technology from patients being treated

Systems, Pathways & Targets (SPT)
- Significantly downsize membership via restructuring of membership criteria ('full' member vs. 'associate' member which would not be included in CCSG)
- Remove any grants without significant cancer focus (and alter member status accordingly)
- Continue to strengthen and demonstrate connection between its basic research and clinical activities
- Develop biomarker work and synergy with medicinal chemists, structural biology, pharmacology and the animal core
- Consider establishing a clinician co-leader

Cancer Prevention & Prognosis (CPP)
- Need to improve overall vision and goals of Program as it integrates with those of the CC
- Reconsider current organization of research into bins of etiology, prevention and prognosis; consider thematic area focused on behavioral science and survivorship
- Recruitment of 1-2 mid-level cancer population science investigators is imperative; consider recruitment of new Program Leaders
- Reactivate and revitalize Community Advisory Board; provide financial support
- Identify and support member/leader to oversee CAB activities and provide link to CPP research

- Provide details on how research evolved with support from CC and shared resources

Personalized & Genomic Medicine
- Place in Director's Overview
- Demonstrate a more refined research structure and integration with Programs
- Demonstration of strong connection to pathology and clinical informatics is critical
- Development of clinical genetics counseling may be desirable

Biostatistics Shared Resource (BSR)
- Continue to expand interactions with basic and clinical Programs
- Clarify how BSR works with other Cores
- Provide examples of value added with respect to biomedical informatics and/or bioinformatics infrastructure

Biobehavioral Shared Resource (BBSR)
- Continue to expand services supporting community-based trials
- Include additional examples of value added by BBSR (supporting studies belong to other PIs than the Core Directors and supporting use of quality-of-life measures through the electronic health record)
- Clarify interaction of BBSR with BSR; coordinated effort could enhance value of both
- Provide quantitative metrics showing increase in new funded CC members using BBSR over last 3 years

In-vivo Functional Onco-imaging
No recommendations

Experimental Tissue Resource
- Provide clarity on what information and procedures can be done with tissues under the waver-of-consent protocol. If no restrictions, this should be stated.
- Provide clarity on how many FFPE tissues are potentially available
- Change process so that on-site personnel collect fresh tissue
- Provide tissue quality metrics if fresh tissue is being collected
- State procedures for monitoring freezers and safe-guarding tissues.
- Establish Resource Allocation Committee

Clinical Protocol & Data Management
- Make sure numbers match in grant document and site visit presentations
- Reference this area as "CPDM" rather than "Stern Center" (internal name) for CCSG to avoid confusion
- Quantify specific actions/successes or, at least, outline clear plans to address issues
- Provide correction action plan for accruing underrepresented and special populations
- Develop multi-site trials and Investigational New Drug (IND) studies
- Finalize implementation of the Clinical Trials Management System
- Quickly address data from previous years that requires correction
- Engage faculty leaders in developing policy for how study data is handled
- Address issue of large number of studies approved and not activated
- Provide clarity on mechanisms for study prioritization and closure. Document authority and ensure a uniform process
- Take immediate action on improvements

Early Phase Clinical Trial Support, Inclusion of Minorities & Women, Inclusion of Children
- EPCTS: Need to make sure EPCTS funds are only applied to qualifying studies (agent/device for diagnosis, prevention, detection or treatment within a 1-2 year timeframe for complete accrual

- Minorities/Women: Analyze all clinical trials to be sure there is no differential consenting processes for patients of different genders
- Children: Increase clinical care and research at both UCI and CHOC to attempt to increase number of patients on clinical trials from CHOC

Administrative External Advisory Board Review, March 20, 2013

Organizational Structure

- Establish an administrative senior leader role/position covering more strategic, direction-setting activities
- Focus on leadership/strategy rather than tactical matters

Director Search

- Recruit new CC Director with strong leadership, administrative, fundraising and scientific skills
- Provide significant start-up package including ongoing support, space, 5-10 state-funded faculty FTEs

Philanthropy

- Establish dedicated, achievement-oriented development professionals to secure funds (restricted, unrestricted, expendable & endowment)
- New CC Director needs absolute authority overseeing development activities

Clinical Research

- Re-establish Phase I Program
- Create culture that encourages high-impact investigator-initiated studies
- Director needs to ensure there is appropriate academic & administrative leadership with the skills to drive this area

Finance

- Need consistency between budgets/actuals
- Invest in clinical trials management system to enhance functionality
- Add clinical research positions that will enhance clinical trials finance management
- Identify currently overlooked billable events for which CC could collect revenue
- Eliminate current standard of holding residuals from clinical trials accounts in the CC that should be transferred to the PIs within the departments

External Scientific Advisory Board Review, May 28-29, 2012

Overall

- Need to hire new CC Director very quickly given CCSG timeline
- Request NCI approval for postponement of CCSG submission and request a cost extension on the CCSG for a minimum of 18 months
- Establish firm commitment from University leadership to a focused philanthropic effort to directly support CC
- Establish interim CC Director starting 10/1/12

Programs & Disease-Oriented Teams (DOTs)

- *Cancer Prevention Program* - Recruit additional senior-level NCI-funded investigators
- *Cancer Prevention Program* - Consider change in emphasis in the Program
- Consider adding Pediatric Oncology, under the leadership of Dr. Sender, as an additional DOT

External Scientific Advisory Board Review, May 5-6, 2011

Overall

- Streamline CCSG Programs to 3-4 in total to emphasize remaining strengths based on NCI funding and cancer focus
- Solidify numbers displaying grant funding, therapeutic accrual to clinical trials, and interventional clinical trials (i.e., presented numbers were questionable)
- Develop a realistic long-term strategic plan to rebuild and grow the CC in a stepwise fashion
- Continue focused efforts on accrual and recruitment of at least one NCI-funded PI
- Emphasize growing affiliation with CHOC in the CCSG
- Integrate Center for Personalized Medicine into existing program or core
- Provost is encouraged to align his current commitment with the deficiencies noted in comments from the NCI review
- Count investment into the CTSA as investment into clinical research for cancer-relevant components
- Strongly consider when to compete the CCSG
- Complete all senior leadership and other key faculty recruitments by time of submission

Strategic Plan
- Recruit NCI-funded senior PIs, preferably a nationally recognized Deputy Director
- Recruit a Director of Population Sciences

Developmental Funds
- Establish strategic investment into initiatives for which there is strong return on investment (do not overstate ROI)
- *Recruitments* - provide clarity on whether or not recruitments represent a net gain of faculty for the CC
- *Pilot funding* – provide better documentation of stringency of review
- *Pilot funding* – demonstrate ROI
- *Pilot funding* – present bridge funding as an example of institutional commitment rather than a CC competitive award

Programs

Systems & Developmental Biology
- recommend two co-leaders rather than three

Chemical Structural Biology
- Must show solid grants and publications for CCSG
- Work to increase numbers of Epi/Obs and therapeutic trials over the last three years
- Consider removing translational component of program and moving trial accrual into other programs

Carcinogenesis
- Further integrate with Center of Personalized Medicine
- Increase trial accrual and intra-programmatic collaborations and publications
- Consider modification of themes

Onco-Imaging and Spectroscopy
- Consider opportunities for placing new members in program

Growth Factors and Signaling
- *No specific recommendations*

Population Sciences & Prevention
- Need to increase qualifying grants (only 42% of members have qualifying grants)

- Recommend recruitment of additional tenure-track faculty
- Clarify goals of Program
- Clarify intra- and inter-programmatic interactions
- Evaluate activities such as seminar series, TWGs and pilot funds
- Provide clear presentation of catchment area and how population science research and outreach programs have addressed cancer burden within the diverse population
- Increase critical mass of funded mid-level or senior investigators
- Establish co-leader in population sciences
- Suggest making members not funded by NCI-eligible grants Associate Members for purposes of the CCSG renewal

Cores

Overall (administrative issues)

- Shared resource leadership take credit for services provided and supported to effort funded on grants rather than lumping it under 'other'
- Clarify productivity of shared resources by providing number of users and specific publications citations

Transgenic Mouse

- *No specific recommendations*

Biostatistics

- Pay more attention to linking the past to the current for the BSC

Clinical Research Office

- Establish faculty leader who can fully engage with the CRO
- Increase meetings to a weekly schedule and relocate leader's office to the CRO
- Correct and validate therapeutic clinical trial accrual numbers
- Carefully review PSRS

Genomics and High-Throughput Facility

- Define fee structure for ChIP-seq and RNA-seq; should be comparable to, if not better than, other Centers

Biobehavioral

- Further clarify provided services
- Perform further reviews to identify what the BBS are added to studies
- Counseling role needs to be more clearly described
- Clarify that director's usage is part of chargeback
- Administratively address issue that she CCSG support (93%) is larger than use by all members

Experimental Tissue

- Establish a protocol -riven tissue banking infrastructure

Administration

- Immediately address issues of data integrity, integration, and overall process (including Shared Resources, grants and clinical trials data)
- Stringently review reports with an eye toward complete accuracy for use in decision-making and reporting
- Closely review CCSG summary guidelines
- Immediately resolve issues regarding structure of the administrative unit

External Scientific Advisory Board Review, April 7, 2010

Overall

- Work toward improvement in areas of cancer focus for some programs and an increase in intra- and inter-programmatic joint publications
- Assign a formal mentor to each unfunded junior investigator; provide a table illustrating such mentoring and each scientific program
- Avoid changing speakers during presentation

Programs

Cancer Prevention & Control

- Illustrate distribution of funded research across all members
- Emphasize inter-programmatic collaborations with Developmental Biology with CHOC
- Pay attention to accrual numbers reported for Epi studies; don't count 'controls' in these totals
- Priority: recruit new faculty with FTE-equivalent packages

Carcinogenesis

- Reduce and integrate the seven stated themes
- Highlight the most impactful papers and discoveries

Chemical and Structural Biology

- Increase number of faculty with external grant support, intra-programmatic publications and Core usage
- Define distinct strength of program by putting in place new metrics of success

Developmental Biology

- Establish recruitment or restructuring to broaden the base of cancer related funding and activities

Growth Factors & Signaling

- *No specific recommendations*

Shared Resources (limited number were fully reviewed)

Clinical Research Office

- Perform careful reviews of Summary 4 reports to make sure that new CTMS is working and data is accurate

Experimental Tissue

- Eliminate developing tissue banking service component of the Core (not funded by the CCSG)

Optical Biopsy Core

- *No specific recommendations*

Administration

- Avoid use of abbreviations in presentations; provide consistent presentations

Planning & Evaluation

- Consider reorganizing program members in Developmental Biology given concerns over NCI funding and cancer focus
- Outline CHOC affiliation and TWG mechanism in this section in the future

Planning and Evaluation

- Keep Translational Working Groups in planning and evaluation but don't force them into a formal administrative structure; consolidate number of programs and incorporate translational/clinical research into existing programs

CHOC (administrative issues)

- Add investigator-initiated studies to Summary 4
- Establish single Clinical Trials Protocol Review and Monitoring Committee

Clinical Research Office

- Clarify accrual numbers and classification of accruals
- Give focused attention to what is being reported, how it is being reported and making sure numbers are properly and consistently reported across all written and verbal reports
- Carefully generate review and consider the women and minority accrual information to identify areas for targeted recruitment and potential catchment areas issues

External Scientific Advisory Board Review, May 13, 2009

Overall

- Hold leadership meetings every 2 weeks with a tracking plan; conference call should be in place
- Dissolve Translational Oncology Program and integrate cancer-focused members into remaining 4 Programs
- Schedule full-day individual program meetings; repeat these meetings every 6 months for the next 36 months
- Remove members from any program who are not active or who distract from cancer focus; add members who may have cancer-relevant research
- Provide seed funding for any new initiative that will demonstrate both cancer focus and new collaboration
- Submit one NCI Program Project Grant within the next 24 months
- Participate in submission of one SPORE with another Center
- Revisit Shared Resources to address issues of administrative leadership, member usage, effectiveness of chargebacks, equipment, and publications that benefited from usage
- Develop communication plan to enhance accrual to clinical trials
- Commit to implementation of new CTMS and have data corrected by next renewal
- Assist junior faculty and developing investigator-initiated clinical trials
- Encourage Dean’s active search to recruit leader for GynOnc
- Re-establish authority of Director and streamline currently complex and uneven process of annual budget allocation to the CC
- Restore 4 faculty slots in Hematology/Oncology over the next 24 months
- Work with Dean to make sure all chairs of clinical departments understand and embrace mission of the CC
- Continue dialogue with institutional leaders and office of development to obtain funds to cover reduction imposed by the NCI
- Directors, Associate Director, and other senior leaders should meet weekly with head of development to establish fundraising timeline and plan to meet funding needs outlined in strategic plan
- Prioritize and complete buildout of Sprague Hall and 7th floor of new hospital (oncology) as soon as possible
- Work with Dean and CEO of the hospital to develop new model of revenue-sharing in oncology
- Once 2-year strategic plan is established, Director, Dean, CEO of hospital and Chancellor should visit NCI to gauge level of enthusiasm for plan and agree on metrics of institutional commitment