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Steven K. Libutti, M.D.
Director, Rutgers Cancer Institute of New Jersey
Vice Chancellor for Cancer Programs, Rutgers Biomedical and Health Services
195 Little Albany Street
New Brunswick, New Jersey 08902

Dear Dr. Libutti:

On September 29, 2022, the External Advisory Board (EAB) of Rutgers Cancer Institute of New Jersey (CINJ) met to review cancer center progress, strategy, and excellence in research that may lead to a reduction in the incidence, morbidity, and mortality attributable to cancer within the state of New Jersey (their catchment area) and beyond. The focus of this meeting was to prepare for their competitive CCSG submission in January and subsequent site visit in the spring. Reviewers supplied comments directly on the written document, with comments here focused on the presentations.

From the Director's Overview, it was apparent that there has been significant progress made over the past year and they have been responsive to the guidance provided through peer review of the last competing NCI Cancer Center Support Grant (CCSG) renewal. Multi-PI grants have continued to increase, the level of science has really improved and it is apparent that significant efforts have been made in Community Outreach and Engagement. Also, a strength is the Consortium with Princeton where the scientific excellence is leveraged to enhance the activities of the Cancer Center.

State and institutional commitment remains strong and the ability of the Center Director to use these funds nimbly to capitalize on unique opportunities and mitigate challenges to achievement of the Center's overall mission is demonstrable. Continuation of this support is critical as the complex responsibilities of a cancer center to drive research that is interwoven with catchment area responsibilities and dedication to diversity and inclusion are persistently demanding.

Most critical for the Director's Overview is to interweave community outreach and engagement, the plan for diversity/equity, and the education programs throughout the Center's research and research decision-making processes and across all program presentations. How are Community/Patient Partners being actively involved? For instance,

CRTEC could start introducing the importance of involving patients/community advocates in research to undergraduate and graduate students. And consider establishing an advocate-researcher co-mentorship program for post-docs to work on their research. A number of funding agencies are encouraging or requiring advocate involvement in their funded grants (e.g., Komen, DOD, V Foundation). These changes require a substantial cultural change so we encourage you to engage patients and the community and to achieve diversity/equity throughout all initiatives so that this is top of mind and heart and not a checkoff or afterthought with valued partners significantly engaged across the center.

Lastly, the slides were too busy and very difficult to read. The slides and visuals should highlight the story and not tell the story, with the presenter and the narrative telling the story. The audience will try to read and understand what's on the slide, first. Then listen to you if there's time and attention to do so and if they cannot read it in the time it is shown...don't show it. A busy (picture dense or word dense) slide detracts from a presentation and the message trying to be shared. Visuals need to be easy to understand and follow. They should strategically highlight what is being shared.

Catchment Area and Community Outreach and Engagement (COE)
The COE efforts are led by Dr. Anita Kinney who brings her considerable public health expertise and experience in NCI-designated cancer centers to her exceptional leadership of the component. The team continues its significant progress in advancing COE efforts across the Center in service to the CINJ's self-described catchment area of New Jersey. In summary, one can hardly imagine a more thoughtful, comprehensive, well-conceived, and well-implemented effort in Community Outreach and Engagement. We anticipate that the COE component would definitely fare well in the next cycle of peer review, perhaps even meriting a score of Exceptional because of its broad and substantial improvements in almost every regard.

Cancer Prevention and Control (CPC) Program
The CPC Program has effective leadership and has been very productive. There has been significant growth in publications and grant funding since the last CCSG review. The Program is very strong in its accomplishments and impact. There is also strong Program leadership with highly qualified co-leaders who have complementary backgrounds and the two co-leader presentation went smoothly – great presentation style. The Program has obtained positive metrics in key areas. The Program has also made great strides in recruitment and addressing concerns from the last review. CPC has excellent stories of translational research activities and partnerships within and outside the Center. However, some areas require additional clarity including: 1) make sure mechanisms for interaction with CHECoE are clear; 2) note any interactions with CRTEC; 3) for clinical informatics, explain how this big effort has been supported by the Center, how the Biomedical Informatics Shared Resource supports the Program, and for future plans, create a cohesive story (with some specificity) of how it will be used; 4) for future plan number 3, explain how recruitments are strategically planned; and 5) note how the Center supports the development of team science grants.

Cancer Metabolism and Immunology Program (CMI)
The CMI Program, led by Drs. Wei-Xing Zong and Christian Hinrichs, has three themes: 1) cancer cell metabolism (tumor cell-autonomous perspective), 2) nutrient scavenging mechanisms, and 3) tumor-host interactions (non-tumor cell autonomous metabolic, physical, and immunologic relationships with the host). It received a score of Excellent at the last review. Weaknesses noted included: 1) the bulk of the high impact research highlighted was from a few investigators (White and Rabinowitz); 2) there were few/no P01s/SPOREs; 3) there was a lack of a clear plan for the Cancer Immunology Program; 4) there was less connection of aim 3 with the other aims; and 5) there was a paucity of translational clinical connections. Major progress since the last EAB includes the recruitment of Dr. Christian Hinrichs to co-lead the new Cancer Immunology focus within the Program (supported by a major philanthropic gift), the recruitment of new cancer immunology faculty, and the completion of a GMP facility. There has also been a continued increase in multi-PI grants, regular meetings with the Committee to Expand Translational Initiatives (CETI) and the Clinical Investigations and Precision Therapeutics (CIPT) Program, and some evidence of translation.

Genome Instability and Cancer Genetics (GICG)
The GICG leadership should be commended for the superb state of the GICG Program and the remarkable progress made over the recent funding period. As a result, we believe GICG has the potential to improve its ranking from Excellent (2018) to Outstanding and perhaps even Exceptional. However, the presentation undersells the Program and does not adequately highlight its impressive strengths and achievements. Moving GICG's ranking into Outstanding/Exceptional range will require significant effort to re-organize and re-write the narrative, as well as make corresponding changes to the presentation. Nonetheless, the Program is in superb shape and it has improved dramatically over the past funding period. Moreover, all aspects of the Program are strong and there are no fundamental weaknesses that need to be explained, other than providing clarity regarding GICG leadership. The challenge will be to communicate the many strengths of the Program more clearly, in part by describing how they are the intentional outcomes of strategic planning.

Cancer Pharmacology Program (CP)
The Cancer Pharmacology (CP) program is co-led by Drs. Steven Zheng and Stephen Burley, who are senior and highly regarded investigators with complementary scientific expertise. The CP Program received an outstanding to excellent merit assessment in the last CCSG review. The Program has made progress on multiple fronts and has clear potential to receive an improved and potentially substantially improved score in the next review. All-in-all, the slide presentation at the EAB meeting had clearer and sharper focus and more impact than the current write-up. Some suggestions/considerations for the research strategy section write-up are the following: 1) after presenting a high-level overview of the Program and its key metrics and trends since the last renewal, it would likely be best to review the Program co-leader roles/responsibilities and qualifications as well as to describe unique Program co-leader contributions/roles and shared roles in leadership and oversight of the Program; 2) a bit more information about how CETI mechanisms and initiatives have resulted in translation of CP discoveries for translational impact would be helpful, such as via presentation of specific impactful publications and new grant awards

that complement the clinical trials mentioned; and 3) the future plans for the CP Program are brief and too generic. Presentation of more in-depth information that captures the alignment of concrete future plans with each of the three specific aims would likely be helpful, along with information about how the CP Program's future plans are aligned with the overall CINJ center-wide strategic plans as well as selected other institutional initiatives at Rutgers and Princeton.

Translational Research

Oversight to enhance translational interaction is promoted at multiple levels. This is guided by the "Committee to Expand Translational Initiatives" (CETI) which includes Program Leaders in addition to Cancer Center Associate Directors. The committee meets quarterly. Program Leaders nominate scientific projects that are ready for translation. Those that are promising based on the committee SOP criteria for prioritization taking into account several critical elements are invited to present at the CETI translational meeting. Pilot funding of $100K/year is available for 1-3 projects. Several examples were presented from funded projects. To date, the ROI is impressive with several successful examples, including the launch of six Biotech Startups based on institutional translational science. Several future directions were presented that are very important. Since interaction across the bench/bedside is critical for translation, it is not clear if and how the clinical researchers of the different clinical disease teams are engaged in the process. This needs to be clearly mentioned in the write-up and presentation.

Clinical Investigations and Precision Therapeutics Program (CIPT)

The Clinical Investigations and Precision Therapeutics (CIPT) Program's overall goals are to: translate outstanding science into early phase trials and to new diagnostic, prevention, and therapeutic strategies, and to foster inter-programmatic collaborations with the other CCSG Research Programs. Since the last site visit 22 new members were added. Overall, the membership has been relatively stable relative to that at the time of the last site visit. At the last CCSG review, the Program was rated Excellent to Outstanding. At this year's EAB, Dr. Ganesan's presentation highlighted the progress to date including increase in overall Program funding to $5.6 million, particularly with a 50% increase in NCI funding compared to prior cycle. The number of R01s and multi-PI grants has also significantly increased. The total publications have also increased by 27% over the past five years; 17% were in high impact factor journals (IF ≥ 10) with increase in collaborative intra- and inter-institutional publications. The program has clearly improved since the last review, with increased metrics in almost all areas; the $3.9 million in NCI funding is good.

Precision Medicine efforts were also expanded through the Molecular Tumor Board which is now regularly attended by Partner institutions (RWJBH, Newark, Livingston, Atlantic Health) and trainees across the Consortium (Princeton) leading to: 1) multiple high impact translational discoveries leading to grants and publications; 2) multi-project grants with CIPT members successfully obtained, including a P01 grant in DNA repair in collaboration with GICG; 3) CIPT members collaboratively working with CPC and CP to submit U grants; and 4) a CIPT member is project leader on an inter-institutional NET SPORE. Several major discoveries as they relate to the respective aims were presented and some of the emerging scientific data has led to four IITs led by CIPT clinical researchers. The idea of a COE-CA

liaison is excellent and should be featured earlier in the presentation. Slide 15 on the catchment area impact is a very good one but should go earlier in the presentation. The Program and its leaders are to be congratulated on the impressive progress. Overall, there has been clear growth and upward trajectory in funding and productivity. The examples provided at the presentations for the aims are excellent.

Clearly, the ultimate goal is bidirectional scientific interaction and growth of impactful scientific discoveries and translating those into the clinical setting and *vice versa*. Critical to that is an interactive program that involves clinical investigators. What continues to be unclear is where do the clinical investigators from different disease teams fit and what does it take for clinical researchers to be included as a member of this Program, which is technically the best fit for them. What are the forums to enhance bidirectional translation and interaction? Clearly there continues to be the need to increase the integration of disease team members into this Program and interaction with the other programs. This should be reflected in the write up and presentation.

The Molecular Tumor Board (MTB) was featured multiple times, however, it was not clear why it was featured multiple times and until we asked it was clarified that it is not technically a conventional tumor board (i.e., where cases are discussed) but rather a forum to enhance research. This is something that has to be clarified in the write-up and presentation. It would be good to provide examples of collaborative efforts emerging from the MTB. The P01 is a major Program accomplishment and should be better highlighted in the write-up and in the presentation. For example, how the Program facilitated the P01, the overarching theme of the grant, and potential future impact. As stated at the two prior EAB reviews, there continue to be no examples of hematologic malignancies research, which is a limitation. We would also recommend creating a table providing examples of translation/clinical trials based on institutional science including the scientist, funding, clinical researcher, and the clinical trials. Not much is mentioned or included with regard to research in gynecologic and pediatric oncology. Another area to address is how the disease teams interact across the state, and specific examples of system-hospital trial PIs would be useful to reinforce the integration.

Clinical Protocol and Data Management (CPDM)
The unified trials program is a major strength and will be well received by reviewers and is a major strength of the overall CCSG; the same applies to the 80 treatment trials open in the overall system. The idea of having a small committee that comprises an external DSMC is also strong, as is the presence of the patient advocate on the peer review committee. The increase in minority accrual is quite impressive and the improvement in activation time from 160 to 112 days is excellent but a decreasing trend would be even better. The approximately 2.5% "not approved" rate by the PRMC was quite low, and there should be some indication of what proportion of trials are considered at the disease group meetings and rejected.

Cancer Research Training and Education Coordination (CRTEC)
Generally speaking, the CRTEC section has improved significantly since the last site visit and the last EAB meeting. In response to prior critiques, Drs. Lattime and Chaudhary have successfully led efforts to expand the training grant portfolio. The educational and mentoring activities have been well described and there are distinct CINJ-led activities on both

campuses. CRTEC is coordinating a large number of activities on both campuses and has plans in place for outcomes tracking. While the activities of CRTEC are presented, there were missed opportunities to highlight. Also, overlapping CRTEC, COE, and PED components' responsibilities should be introduced in each section to describe how they work together and how each CCSG component is responsible for specific aspects of education and workforce development.

Plan to Enhance Diversity (PED)
Dr. In is new to this role and also new to the institution, and this is a new CCSG component with a lack of clarity regarding how PEDs will be reviewed and assessed. CINJ has developed and established some critically important pieces: you have an Office of DEI, you have started to assemble some key metrics, and you have collected relevant data through surveys and focus groups and have engaged an external consultant. The specific aims were not as crisp as they could be and, in some places, felt overlapping – it was difficult to fully understand how the aims were distinct and this should be presented more clearly and cleanly for the reviewers. NCI has set forth an ambitious goal of having the diversity of the nation's cancer centers in terms of their membership and leadership reflect the diversity of the nation. PEDs will be primarily evaluated on how compelling the plan is toward outlining a clear path to achieving this goal. What was presented does not clearly provide a description of the current state of CINJ and what your goals are, what specific strategies and actions will be taken to address shortcomings and achieve goals, what the timelines will be, and finally what metrics or other assessments will be used to define progress/success. For example, two key metrics are the compositional diversity of the members (faculty) and leadership. Like almost all centers, CINJ has a long way to go to realize the vision of these two groups reflecting the diversity of the nation, but what I find missing are clear plans/strategies for addressing both of these. Another thing that was largely absent is a description of the relationship between PED and the other components of the CCSG (COE, CRTEC, and research programs). You could consider a liaison-type model plus regular meetings with COE and CRTEC leadership to identify and pursue points of synergy. The PED work came across as a bit siloed, particularly since each program had separate slides talking about their engagement with COE and CRTEC, but none talked about engagement with PED beyond a brief footnote. It also isn't clear how you are supporting your URM faculty. This was mentioned briefly in the presentation and should be expanded to issues like isolation, imposter syndrome, stereotype threat, etc. There needs to be more specifity about what metrics you consider to be important and how you will track them. Also, you should be more focused in what metrics you track since some are things that are really the responsibility of others to track (COE, clinical trials, etc.). There was no mention of "special opportunities" as called out in the PAR. Are there local MSIs/HBCUs with which you could partner with or have existing partnerships?

Lastly, a couple of comments that apply to all the presentations include a more definitive strategic plan with the appropriate metrics for the program or section presented, future plans that are more specific with metrics rather than a generic statement at the end of each presentation and finally, when discussing the COE, relate it to actual examples that tell a story across diversity, education, and other aspects of the Center.

Thank you for inviting us to review the Rutgers Cancer Institute of New Jersey. The future of your cancer center is especially exciting and we look forward to seeing what wonderful things you accomplish in the coming year. As always, we are here to serve you and help you in your role as the Cancer Center Director. Please let us know if you need anything else.

Sincerely yours,

Candace S. Johnson, PhD
President & CEO
Roswell Park Cancer Institute
Chair, Rutgers CINJ External Advisory Board