

**Rutgers Cancer Institute of New Jersey  
External Advisory Board Meeting**

**Minutes of the Meeting  
May 19, 2021**

A meeting of the External Advisory Board (EAB) of Rutgers Cancer Institute of New Jersey (CINJ) was held on Wednesday, May 19, 2021. Due to the COVID-19 pandemic, the meeting was held remotely via the WebEx platform.

**EAB Members – Present**

Candace Johnson, PhD (Chair)	Dorothy Hatsukami, PhD	Adekunle Odunsi, MD, PhD
Richard Baer, PhD	Ernest Hawk, MD	Peter J. O’Dwyer, MD
Michael J. Becich, MD, PhD	Chanita Halbert-Hughes, PhD	Andrew F. Olshan, PhD
Melissa Bondy, PhD	Maha Hussain, MD, FACP	Ramon Parsons, MD, PhD
Ralph DeBerardinis, MD, PhD	Cheryl Jernigan, CPA, FACHE	Marcy B. Waldinger
Eric Fearon, MD, PhD	Thomas Lynch, MD	Jeffrey S. Weber, MD, PhD
Stanton L. Gerson, MD	Benjamin G. Neel, MD, PhD	Danny R. Welch, PhD
		Theodore J. Yank, MHA

**Invited Participants - Present**

Wadih Arap, MD, PhD	Bruce Haffty, MD	Gina Londino-Greenberg
Elisa V. Bandera, MD, PhD	Carolyn Heckman, PhD	Renata Pasqualini, PhD
Adam Berger, MD, FACS	Christian Hinrichs, MD	Tracie Saunders
Stephen K. Burley, MD, DPhil	Howard S. Hochster, MD	Zhiyuan Shen, MD, PhD
Chang Chan, PhD	Yibin Kang, PhD	Ioannis Stasinopoulos, PhD
Sunita Chaudhary, PhD	Anita Y. Kinney, PhD	Linda Tanzer
Andy Evens, DO, MSc, FACP	Edmund Lattime, PhD	Eileen White, PhD
David Foran, PhD	Steven Libutti, MD, FACS	X.F. Steven Zheng, PhD
Shridar Ganesan, MD, PhD	Hao Liu, PhD	Wei Xing Zong, PhD

Call to Order

Dr. Candace Johnson called the meeting to order at 8:05 am. She welcomed the Board and solicited member introductions.

Review and Approval of the Minutes

The minutes of the July 1, 2020 meeting were reviewed. Upon motion duly made, seconded, and unanimously carried, the minutes of the meeting were approved.

Director’s Overview - Steven K. Libutti, MD, FACS

Dr. Libutti welcomed the Board and thanked Dr. Johnson for continuing to serve as the External Advisory Board Chair. The EAB was invited to examine Rutgers Cancer Institute of New Jersey’s overall mission, promotion of excellence in research, and strategic direction.

The State of New Jersey is the most densely populated state in the United States. It is the fourth most ethnically diverse and has the fifth highest cancer incidence. The Cancer Institute of New Jersey was established in 1992, it became NCI designated in 1997, and in 2002, under the direction of the former Director William Hait, achieved comprehensive status. In 2013, CINJ was integrated into Rutgers University as an independent unit and, because of the integration, became a member of the Big 10 Cancer Research Consortium. The Cancer Center has grown in terms of membership to 267 members. CINJ’s partnership with RWJ Barnabas Health Systems began in 2017 and became an integrated oncology service line in January of 2017.

CINJ is comprised of five individual research programs; Cancer Metabolism and Growth (CMG); Genomic Instability and Genetics (GIG); Cancer Pharmacology (CP); Clinical Investigations and Precision Therapeutics (CIPT); and Cancer Prevention and Control (CPC). These research programs are supported by Shared Resources and developing Shared Resources.

CINJ is the only NCI designated Cancer Center in New Jersey. CINJ has an impact on the entire State of New Jersey in many ways such as: a consortium partnership with Princeton University to drive forward basic and clinical research; a partnership with the State of New Jersey that is manifested through coordinated oversight between CINJ and the Department of Health (DOH); and the Screen NJ project which is focused on the screening of colon and lung cancer.

The results of the site visit yielded an Impact Score of 28 and an excellent to outstanding rating for the Cancer Institute. There were several notable strengths as well as opportunities to improve their ability to drive discovery forward. These opportunities included: 1) improving the system for identifying and prioritizing translational opportunities; 2) capitalizing on health system partnership through expanding clinical trial accrual; 3) increasing collaborative opportunities (P01) and training grants; and, most importantly, 4) identifying a high-impact Center-defining scientific initiative.

To improve the identification of science in CINJ's Programs that are ready to be translated to the clinic, CINJ created a committee to expedite translational initiatives (CETI). CETI is jointly chaired by Drs. Ganesan and Pasqualini. The CETI Committee meets regularly with Program Leaders to identify science within their Programs to deploy resources provided by the Director. Four REACH Awards have been successfully awarded to members of CINJ. Together with the CETI Committee and the REACH initiative, CINJ is starting to see returns on efforts to bring science from the laboratory to patients through translation and commercialization. A new GMP facility will also be launched in July 2021.

Through the efforts of Dr. Hochster, CINJ has been able to create an integrated Clinical Research Program across the entire health system where all cancer clinical trials are reviewed under CINJ's PRMS (SRB) for scientific strength and integrity. There has been a dramatic increase in the number of therapeutic clinical trial accruals. Despite the pandemic, there was a significant increase in accruals during the 2020 calendar year.

CINJ has many highlights and updates since June 2020 which include new training grants such as an awarded T32, an R25 training grant, and newly developed joint education and mentoring activities with Princeton. Using CINJ's tremendous strengths in Cancer Metabolism as a foundation, the Cancer Institute decided to pursue the nexus between Cancer Immunology and Cancer Metabolism. Through this nexus, the Center of Excellence was formed. The Center of Excellence was selected by Rutgers as a "Big Idea" and a \$25M gift has already been funded. Dr. Hinrichs has been recruited to co-direct the Center of Excellence with Dr. White. In addition, collaboration between Princeton, CINJ, and RWJBH (RWJBarnabas Health) has enabled the launching of the newest Princeton Branch of the Ludwig Institute for Cancer Research.

Currently, CINJ has a 225,000 sq. ft. primary clinical and research facility; a 36,000 sq. ft. hematologic malignancies/BMT Program across the street from the main building; 45,000 sq. ft. of leased administration space; and 100 beds in the Radiation Oncology section of Robert Wood Johnson University Hospital. The Cancer Institute plans to build a 515,000 sq. ft. inpatient/outpatient research pavilion. CINJ benefits from the insight and input from their EAB, IAB, and Consortium Steering Committee. CINJ's CCSG (Cancer Center Support Grant) organizational structure has not changed and includes several Associate Directors. A national search is underway for an Associate Director of Diversity and Inclusion. CINJ has remained active in terms of cancer relevance and collaborative publications across the five Programs both intra and inter-programmatic collaborations. CINJ also continues to drive high impact publications and increase multi-PI awards. CINJ is part of the Big 10 Cancer Research Consortium which includes cancer centers across America. There is robust process for determining cancer relevance. NCI funded projects are 100% cancer relevant and non-NCI funded projects are assigned 100%, 75%, 50%, or 25% cancer relevance using standardized guidelines. All assignments are reviewed and approved by the Research Leadership Committee. Overall cancer focused research funding has increased by 12%. And NCI funding has increased by 17%. CINJ continues to benefit from \$111M annual institutional commitment from Princeton University, Rutgers University grant indirects, Rutgers University Foundation-CINJ, State of New Jersey, Rutgers Biomedical Health Sciences, and RWJ Barnabas Health.

Comments/Recommendations:

The EAB felt that the overview was excellent and that CINJ has made significant progress. It is genius to put Cancer Immunotherapy with Cancer Metabolism. Dr. Libutti's role as the SVP at the hospital has worked out beautifully and is a huge strength. CINJ has been very responsive to the critiques of the Cancer Center with many new grants. The progress in the centralization of Clinical Research will be very positive. The Center of Excellence and the Ludwig Princeton Branch are also very impressive accomplishments. In the Director's Overview the State's priority cancers should be spoken about as well as cancer risk factors. It will be useful to think about how CINJ will respond to the new FOI, and how CINJ plans to attract populations of people that have been historically harder to reach. There could be more insight into the Center of Excellence and what the investments will support in terms of faculty and programmatic support. Great job on highlighting the CETI Program. The clinical space is overwhelming and there should be clarification on how the wet labs will be assigned to translational scientists. Organizational capabilities are wonderful being that there is tremendous ability to control resources and workforce across a large enterprise. There should be more focus on accomplishments under transdisciplinary collaborations, etc. The net of funds and ROIs should be included to show how CINJ has invested a large amount of funds. The more you can incorporate regarding planning would be beneficial. CINJ may have overcorrected in the grant process, administration should be able to review grants without involving the Research Leadership Council (RLC).

Catchment Area/Community Outreach and Engagement – Anita Kinney, PhD, RN, FAAN, FABMR

Anita Kinney, Associate Director for Community Outreach and Engagement gave a brief overview. The goals of Community Outreach and Engagement (COE) are to: 1) monitor and evaluate the cancer burden, disparities, and community needs in New Jersey to guide outreach and scientific inquiry; 2) facilitate community stakeholder engagement in cancer prevention, control, care, and research efforts in addressing the cancer burden and reducing disparities; 3) promote the implementation of policies and evidence-based strategies to reduce the cancer burden; and 4) inform and catalyze impactful evidence-based cancer research in NJ and beyond. Equity is a cross-cutting theme.

Community Outreach and Engagement was rated excellent to outstanding in the last review. COE's responses to critiques have been demonstrated through 1) increased outreach across the State; 2) community outreach, engagement, and promotion of research with the health system providers; 3) enhanced structure, strategy, and strategic planning and 4) increased interactions with Princeton. The COE office is led by a 5-member team and a vibrant Community Cancer Action Board (CCAB), as well as an internal advisory committee comprised of catchment area leaders, researchers, and other key leaders. The 35-member CCAB is comprised of different stakeholders that represent a diverse group of members, including survivors. CCAB aligns with the CINJ mission by posturing and understanding the community needs, as well as implementation of strategies to promote cancer control actions, reducing disparities, strategic planning and evaluating impact. The COE team includes 13 staff and coordination with 34 Nurse Navigators throughout the health system. There is strong institutional support with an annual budget of \$5M. Dr. Anita Kinney displayed charts showing the background of funding sources and allocations including committed budget funding and salary versus non-salary.

The COE reports 97% of CINJ patients reside in New Jersey, the most densely populated state in the United States. COE research and outreach efforts extend to all 21 counties. NJ is more urban, educated, racially and ethnically diverse, and foreign-born than the US at large. Although only 5% of residents live in rural areas, many reside in medically underserved areas. New Jersey has the fifth highest incidence of cancer among the 50 states. Southern and western New Jersey carry a disproportionate cancer burden in the state and are priority areas for COE efforts. COE has established prioritization criteria and processes to address breast, lung, colorectal, cervical, prostate, and melanoma cancers. These cancers are associated with significant disparities and risk factors. Projects, research, and outreach activities address the inequities and disparities involving the high cancer burden and low cancer screening rates.

The process for prioritization of catchment area needs was clarified by reference of the center's prioritization criteria and integration of key contributing risk factors with the center's six priority cancers - breast, cervical, colorectal, lung, melanoma, and prostate cancers, presumably selected because of differential incidence and/or mortality compared to national data, and with a stated goal of promoting equity (especially as relates to racial/ethnic equity). The COE conducts many activities which include promoting mutually beneficial partnerships with community organizations

and aligning research with catchment area needs. COE is working to develop and implement strategies to increase the rate of genetic risk assessment. The COE efforts are guided by a Logic Model to assess the impact of activities. The COE has attracted partners on an on-going basis to assess community needs, facilitate cancer control efforts, guide research, and understand gaps. The model includes short-term evaluation metrics of success such as catchment area survey analysis, increased capacity to educate communities through train-the-trainer and bi-directional researcher-community dialogue. The intermediate-term outcomes of the Logic Model include increased use of focused catchment area surveys, increased local CCAB's in priority communities, increased pilot grants and publications, and increased researcher-community interactions in underserved areas. Long-term outcomes of the Logic Model include decreased incidence, mortality, late-stage diagnosis, community participatory research pilot grants and research changes to practice and policy. COE will monitor the cancer burden continuously and conduct catchment surveys within top six priority cancers. COE will focus outreach and research on: 1) catchment area priorities; 2) addressing community concerns and needs; and 3) priority cancers and risk factors. COE will continue to build infrastructure by supporting navigation to clinical-trials and creating data-driven techniques to uphold COE goals.

Community Outreach and Engagement has interconnected resources guided by a community provider engagement and participatory research framework aligned with CINJ's mission. Several initiatives have been developed within the past year, such as: 1) BEAT Cancer and other web-based community engagement platforms; 2) improve integration with lung imaging sites to streamline processes; 3) formal research project reviews; and 4) increased involvement of the community health workers, educators, and navigators. COE's future plans focus on priority cancers, behaviors, and community identified needs. COE has been effective in tailoring their efforts at the county level. ScreenNJ is just one example of many statewide efforts; goals are to: 1) improve healthcare system screening navigation, inter-organization coordination; 2) improve screening education and awareness in providers and communities; 3) increase colorectal and lung cancer screening among NJ residents and; 4) tobacco cessation. ScreenNJ has exceeded COE goals since the last site visit to 313 sites at 189 organizations in all 21 counties and over 28,000 patients screened. Community Outreach and Engagement future plans are to: 1) assess, monitor, and evaluate the cancer burden; 2) stakeholder engagement; and 3) disseminate control actions and policy and 4) catalyze catchment area research.

#### Comments/Recommendations:

The presentation was exceptional and deserves many accolades. The clarity of the mission and actions were specific and addressed most critiques from last year's review. A few suggestions to better represent this area include: 1) clarifying CCAB/CINJ leadership interactions and explaining how community advisory board interacts with leadership beyond COE (e.g., frequency of CCAB meetings); 2) further development on how Princeton interactions have been folded into COE efforts to meet community needs; 3) acknowledging denominators and explicitly identify challenges and COE controlled actions (e.g., how racial equity is upheld to meet racial disparities, efforts to reach families); 4) integration of the coming associate director for diversity and inclusion and how it complements COE activities; 5) consider broadening CINJ's partnerships with major employers, insurers, schools and universities/community colleges to provide additional avenues to promote health/wellness and cancer prevention. The EAB also suggests cohesiveness of slides to tell the COE story and incorporating the influence of CINJ. The EAB compliments the robust COE structure/logic model and recommends this be used as a model across CINJ.

#### Overview of Population Science – Anita Kinney, PhD, RN, FAAN, FABMR

Anita Kinney, Associate Director for Population Science and Community Outreach gave a brief overview. Population Science has been successful in recruiting scientists in six academic departments. New developments since the last review include collaboration with the Tobacco Research Center, Survivorship Center, and the Center of Excellence for Cancer Health Equity.

To address the CCSG critiques, Cancer Prevention and Control Program (CPC) and Community Outreach and Engagement (COE) have partnered on a policy analysis of cancer screening utilization. The policy report was approved by New Jersey Medicaid and will be disseminated broadly to legislatives, community partners and other stakeholders. Pilot grants have been awarded to address racial/ethnic disparities prevalent in Medicaid plans data and stimulate cancer projects led in partnership with the Princeton Consortium. Future plans include bolstering research infrastructure for population science and enhancing population science shared resources, expand epidemiology and other research cohorts and strengthen implementation science.

Cancer Prevention and Control Program (CPC) – Elisa V. Bandera, MD, PhD and Carolyn J. Heckman, PhD  
Carolyn J. Heckman, PhD, Co-Leader of the Cancer Prevention and Control Program, gave a brief overview of the Cancer Prevention and Control Program (CPC). The overall goal of the Cancer Prevention and Control Program is to engage in scientific discovery across the cancer control continuum that translates into empirically based interventions, clinical and public health practice, and policy strategies to reduce the cancer burden in New Jersey and beyond. CPC has three specific Program aims: 1) to understand the determinants of cancer risk, treatment and survival, and quality of life outcomes with an emphasis on minorities and underserved populations; 2) to reduce cancer risk behaviors and improve cancer outcomes through individual, family, and system level interventions; and 3) to understand tobacco use and implement effective tobacco control strategies at the individual, system, and population level. Program membership and funding have increased since the last review. Currently, CPC has 42 members with 19 full members and 23 associates. There are 24 R01 equivalent grants, 11 MPI grants, and 1 U54 grant. The Program has a total funding of \$7.9M.

The CPC Program remains high in total publications and has an increased number of intra/inter program collaborations. Regarding the last CCSG review, CPC has been working to improve inter-programmatic collaboration through faculty recruits with translational potential, new initiatives, and a strategic plan (2021-2025) completed. Scientific highlights are: 1) Dr. Bandera and team on Breast cancer research in black women study that has led to major discoveries and 8+ publications; 2) Dr. Delnevo and team on menthol consumption research and social justice implications with 5+ publications and legal analyses regarding FDA ban on menthol; and 3) Dr. Satagopan and team research on melanoma incidence, sun protection behaviors and cancer disparities for black patients. The CPC adds value to CINJ by providing a solid cancer research portfolio, a strong mentoring program of junior investigators beyond CPC, strong research focus on catchment area and active public health policy translation, population science research shared resource, contribution to engaging NJ communities in research and cohort of African American/Black breast cancer survivors as a rich resource for members and an attraction for new faculty. The future plans for CPC include: 1) targeted faculty recruitment to enhance programmatic research in key areas; 2) further increase inter-programmatic collaborations and continue to expand the use of EMR/informatics for CPC research to respond to critiques; 3) enhance epidemiologic cohorts of cancer survivors in minority and underserved populations; 4) move intervention through the translational pipeline to dissemination and implementation R01s; 5) leverage momentum in tobacco control and skin cancer into CINJ and Program grants; and 6) leverage momentum in tobacco control and skin cancer in center and program grants.

Comments/Recommendations:

The presentation was good overall and showed evidence of an outstanding program. The EAB suggests bolstering high-impact scientific manuscripts and multi-project awards (e.g., participation in P01s, P50s, or NCI infrastructures) to push the CPC Program to the very highest tier. The inner programmatic publications are still something that needs work, compelling integration of data, stronger connection to CINJ's strategic plans and addition of a shared resource committee. The EAB felt that there should be a link to inter-programmatic basic research groups to amplify signature programs of CINJ. The EAB commends opportunity with Princeton, however, recommends stimulating activity with the multiple Princeton departments involved, and bidirectionality with COE. The EAB also suggests clarity on membership/recruitment definition and numbers on presentation.

Consortium Cancer Center - Yibin Kang, PhD

Dr. Yibin Kang, Associate Director for Consortium Research, gave a brief overview of the Princeton/Rutgers Consortium. The Rutgers/Princeton Cancer Research Consortium was formed in 2009 and has successfully completed two grant renewals. The relationship between Princeton and Rutgers has deepened over the years of the Consortium. Princeton makes tangible commitments to the Cancer Institute financially and through the support of Shared Resources. There are 19 Princeton based members that represent 16 R01 equivalent awards and 11 principal investigators.

The Consortium Cancer Center has focused efforts in four main areas which include: 1) strengthening cancer population research collaborations between the CPC Program and Princeton's School of Public and International Affairs; 2) integrating Princeton's research excellence in computational biology and genomics into CINJ's precision oncology initiative; 3) developing cross-institutional program projects and training grants; and 4) using the Cancer Center as a focal point for joint faculty recruitment efforts in both CINJ and Princeton. Recent progress has been made within the Consortium Cancer Center, including: 1) the increase of full members from PU from 19 to 28; 2) 32 cancer-focused and peer-reviewed funded research projects; 3) recruitment of three junior faculty in cancer

immunology/metabolism at Princeton; 4) joint annual symposium to promote collaboration and joint seed grants in computational biology and population science research; 5) multi-institutional/multi-PI program grants; and 6) Funded T32 training grant in CMG and Tumor-Host Interactions. The Consortium Cancer Center has integrated the New Ludwig Princeton Branch of the Ludwig Institute for Cancer Research to promote research between CINJ and Princeton, including fellowships.

Comments/Recommendations:

The EAB is enamored by the engaging collaboration with Princeton University and trajectory since last review. There was not much said regarding activities and promoting the number of collaborations.

Overview of Basic Research – Eileen White, PhD

Dr. Eileen White, Associate Director for Basic Research, and new member of the National Academy of Science, gave an overview of the Basic Research Programs. The role of the Associate Director is to oversee and advocate for the needs of Basic Research Programs; facilitate collaborations and impactful science; and identify new opportunities for scientific and translational impact. Since the last review, there have been several increases in membership and grants, including: P01 - Mechanisms of the BRCA-network in tumorigenesis and therapeutic response; T32 - Postdoctoral Training Program in Cancer Metabolism and Tumor-host Interaction; R25 Rutgers Youth Enjoy Science (RUEYS) program; and a \$25 million philanthropic gift to build on strengths at the Center of Excellence in Cancer Immunology and Metabolism.

The Center of Excellence and the Ludwig Princeton Branch have enabled the newest Princeton Branch of the Ludwig Institute of Cancer Research. To continue building the Center of Excellence in Cancer Immunology and Metabolism and the Ludwig Princeton Branch (led by Joshua D. Rabinowitz [Princeton], Yibin Kang [Princeton] and Eileen White [Rutgers]) a letter of intent was submitted for the CRUK-NCI Grand Challenge in Cancer Cachexia. The center also plans to build diversity and coordination with Population Science in Basic Science Programs. These interactions are facilitated by the Catchment Liaisons, which reside in each of the Basic Science Programs.

Cancer Metabolism and Growth (CMG) Program - Wei-Xing Zong, PhD and Christian Hinrichs, MD

Dr. Wei-Xing Zong, Co-Leader of the Cancer Metabolism and Growth (CMG) program provided an overview. The Cancer Metabolism and Growth Program has three specific aims: 1) to define the mechanisms of tumor cell autonomous metabolism; 2) to define the mechanisms of nutrient scavenging; and 3) to identify the non-tumor cell autonomous metabolic, physical, and immunologic relationship between the tumor and host. The program has 63 members; 49 full and 14 associates. CMG has continued to be highly productive and collaborative which is reflected by the total of CMG's publications and multi-PI grants.

CMG was rated excellent in the last critique and has addressed previous CCSG critiques by: 1) recruiting new members and introducing new research expertise; 2) involvement with the Ludwig Cancer Research Institute and developing P01; 3) recruiting staff/members (including working group, journal clubs and joint recruitments) for the cancer immunology program; 4) increased research on metabolic regulation of tumor-host interaction; and 5) more translational research and clinical connections and recognizing scientific highlights and research relevant to catchment area. Contributions to the translational pipeline include collaboration with CIPT and CETI (metabolism and immunology). The CMG program has benefited from the Cancer Center in several ways including: 1) developmental funds; 2) training programs; 3) shared resources; 4) meetings and retreats; and 5) new program members. CMG has also added value to the Cancer Center as well through: 1) running a cohesive program that increases research collaboration, productivity, and Center funding; 2) continuing coordination with CIPT to promote translational research that benefits Center patients; 3) providing research discoveries that promote Center growth and advance cancer research and treatment; 4) inclusion of T32 Postdoc training award; and 5) metabolomic and immune monitoring shared resource. The future plans of CMG include, submitting a P01 grant application, utilization of the Small Molecule Screening and building cell therapy program.

Comments/Recommendations:

Great progress overall and an exceptional program. Being a signature program for the cancer center, the EAB suggests strategic recruitment and incorporation of a strategic plan (for clinical and administrative processes). The EAB

suggests more oversight into bookkeeping since this was monitored by high level faculty. The fall-off in collaborative publications among programs is also something to strengthen and the process for handing off discoveries within leadership. The EAB also suggests highlighting community collaboration and connections more in the presentation.

Genomic Instability and Cancer Genetics Program (GICG) - Zhiyuan Shen, MD, PhD and Chang Chan, PhD

Dr. Zhiyuan Shen, Co-Leader of the Genomic Instability and Cancer Genetics (GICG) program, provided an overview of the Program. The Genomic Instability and Cancer Genetics Program has three specific aims: 1) to elucidate the core mechanisms that provoke genomic instability, including imprecise repair of DNA damage, DNA replication infidelity, and chromosome segregation errors; 2) to understand the coordination between genome maintenance machineries with the intrinsic cellular homeostasis and environment changes through gene expression and signal transduction networks; 3) to characterize the cancer genome landscape and gene expression signatures to reveal the therapeutic vulnerability. The Program has 46 members; 39 full and 7 associates. Program productivity and collaboration continued to increase since the last CCSG visit.

The program was rated excellent and in response to prior critiques, there have been changes to translational studies, team science, and collaboration with consortium investigators. The GICG program has benefited from the Cancer Center in several ways, including: 1) developmental funds; 2) shared resources; 3) meetings and retreats; and 4) member recruitment. GICG has also added value to the Cancer Center through: 1) providing foundation for team sciences; 2) fueling forward and reverse translation and supporting clinical projects; 3) addressing multiple catchment priorities; and 4) providing mentorship to trainees in R25, T32, and residency programs. GICG's future plans include promoting synergistic team science and facilitating translational science.

Comments/Recommendations:

The presentation was great, particularly in terms of the progress that has been made in the past year and addressing opportunities from the last critique. Going forward with P01 and T32 is the next big goal. There were questions about institutional commitment to help this application. The EAB suggests using these ventures as momentum for new innovations. Questions arose about the projection on human disease within GICG being exceptionally ranked/funded and assumptions about community data. It will be important to incorporate a slide into the presentation that will show leadership contributions to the program and a slide showing program components of P01 (how it was put together, etc.). Being much more explicit in how P01 was built is important to serve as a model. Also, it is important to highlight how the new strategic focus of the cancer center will be addressed.

Cancer Pharmacology Program (CP) - Stephen K. Burley, MD, DPhil and X.F. Steven Zheng, PhD

Dr. Stephen Burley, Co-Leader of the Cancer Pharmacology program, gave a brief overview of the Program. The overarching goal of the Cancer Pharmacology Program is to discover and develop more effective cancer treatments through pharmacology-based preclinical research. The Program has three aims: 1) to understand the biology of key molecular targets in cancer that drive cell growth, proliferation, and survival so that they can be effectively targeted for cancer therapy; 2) to determine the modes of action and mechanisms of resistance to anticancer agents; and 3) to discover and develop novel therapeutics and drug delivery technologies for more effective cancer treatment. In response to the last CCSG, CP increased Princeton representation and added a member from the New Jersey Institute of Technology. The CP program has 55 members: 42 full and 13 associate. Despite the pandemic, program members continue to be highly productive and collaborative. The total number of publications remains high with approximately 60% of the papers being generated from collaborations with other institutions and 25% in high impact journals.

The CP program received a score of outstanding to excellent in the most recent renewal. Progress in addressing critiques has been made and includes increases in multi-PI grants, progress in translation projects and discovery of SHMT inhibitors for leukemia. The Cancer Center and the Cancer Pharmacology Program have a symbiotic relationship. Cancer Pharmacology benefits from CINJ through: 1) developmental funds; 2) training programs; 3) shared resources; 4) center meetings/retreats; and 5) recruitment of key new members. In turn, the Cancer Pharmacology Program benefits CINJ with its: 1) translational activities and progress; 2) drug discovery infrastructure; 3) program-focused meetings; 4) program-focused training; 5) recruiting; and 6) mentoring. Cancer Pharmacology's future plans include: 1) a multi-disciplinary approach to promote collaborative publications and

funding; 2) enhancing translational efforts; 3) focusing on effective drug discovery resource utilization; 4) developing the protein databank as a global resource for oncology research; 5) emphasizing the catchment area priorities and racial disparities; and 6) program-focused recruitment in collaboration with Rutgers and Princeton.

Comments/Recommendations:

The presentation was very succent in highlighting work for all three of CP's aims. The overall funding for program versus members is modest; this may be worth looking at member assignments moving forward. The EAB suggests highlighting what the overarching strategic themes are connected to CP. Senior leadership could also develop some new opportunities for multi-PI grants in various catchment areas. Metrics and contributions to education are important to feature (e.g., successes in mentoring faculty, K awards, cross-program bridges gapped, industrial partnerships, etc.). It is important to address down numbers in publications. Figures and schematics could also be simplified in the presentation to aid in cohesion of information.

Associate Director for Translational Research - Shridar Ganesan, MD, PhD

Dr. Shridar Ganesan, Associate Director for Translational Research, provided an overview of Translational Research and introduced the Clinical Investigations and Precision Therapeutics Program. As Associate Director of Translational Research, Dr. Ganesan's role is to 1) promote the transition of basic science discoveries across the consortium into clinical and translational studies; and 2) promote the reverse translation of important clinical findings into novel basic research programs. Together with the Program's fellow associate directors, Dr. Ganesan helps to foster inter-programmatic collaborations, provide mentorship/support to junior faculty, and aids in the expansion of the research infrastructure. Translational Research has a variety of tools to prioritize research findings including the Committee for Expediting Translational Initiatives (CETI), the REACH Award, and the Precision Oncology platform. The CETI Committee, which is led by Drs. Pasqualini and Ganesan, includes Associate Directors and Program Leaders. The committee meets quarterly, and program leaders nominate scientific projects within their program that they feel are most promising for translation to clinical trials. The most promising projects are invited to give talks at the CIPT translational meetings and apply for pilot funding. The criteria for prioritizing translational initiatives include: 1) a concept generated by peer-reviewed funded research by a program member; 2) stage of development of therapeutic intervention (new compound/IND, novel use for approved drug, novel use of drug in early phase clinical trial) or diagnostic/correlative assay; 3) addressing cancer burden in catchment area; 4) availability of appropriate patient population, specimens; 5) potential for clinical impact; and 6) potential for peer-reviewed funding for trial or correlatives.

Rutgers is very supportive in translational grants with biotech startups. Currently, funded pilot projects focused on supporting clinical trial development are underway. Translational Research continues to explore ways to consolidate tumor sequencing protocols across the health system and is currently generating preclinical data to support IIT for various awards. Future plans include: 1) prioritization and funding of translational pilot projects from programs via CETI; 2) identify and promote projects ripe for REACH awards; 3) work with the COE and Ludwig center to translate key findings; 3) expand precision oncology/MTB to partner hospitals; 4) organize joint retreats between CIPT and others research programs at Princeton and Rutgers Universities; 5) conduct workshops on genomic and bioinformatics tools for clinical, population, and basic scientists; and 6) conduct workshops on clinical/translational approaches for basic scientists.

Clinical Investigations and Precision Therapeutics (CIPT) Program - Shridar Ganesan, MD, PhD and Wadih Arap, MD, PhD

Dr. Shridar Ganesan, Co-Leader, Clinical Investigations and Precision Therapeutics Program, gave a brief overview of the main critiques, the program leaders' plans to address these critiques, and the future goals of the Program. The overall goal of the Clinical Investigations and Precision Therapeutics (CIPT) Program is to: 1) translate outstanding science into early phase trials, new diagnostic, prevention, and therapeutic strategies; and 2) foster inter-programmatic collaborations with the other CCSG Research Programs. The four specific aims of this Program are: 1) targeting cell death and survival pathways in cancer (collaboration with CMG); 2) targeting DNA repair and cell cycle checkpoint abnormalities in cancer (collaboration with GICG and CP); 3) the development of rational immuno-oncology



approaches (collaboration with CMG and CP); and 4) investigating markers of response and resistance to cancer therapy (collaboration with CMG and GICG).

In terms of the program membership profile, CIPT has 63 members: 25 full members and 38 associate members. Total cancer relevant funding and peer-reviewed grant support has continued to increase since last year's record. Program productivity and collaborations have also continued to increase and inter/intra publications remain strong. The Program scored excellent to outstanding in the previous CCSG review, however, certain critiques were highlighted. The Program's response to these critiques include the following: 1) funding has increased significantly since year of record driven by increased R01 and MPI R01s; 2) multiple other "reverse translation" findings have arisen from the Molecular Tumor Board in the past two years and these findings have resulted in publications, independent grant funding, and clinical impact; 3) CIPT members are involved in P01 submission (with GICG), P20 Disparities SPORE Planning grants (with CPC), and multi-PI U grants (with CPC and CP); 4) now highlight an example of research in heme-malignancies; and 5) more examples of research now shown in the presentation to emphasize the catchment area.

In terms of selected investigator-initiated trials, CIPT includes a variety of clinical investigators that are organized into disease specific groups and PI (Principal Investigator) activity status. This shows that investigators in these disease groups are involved in research projects aligned with at least two of the aims of the Program. CIPT adds value to CINJ by: 1) providing translational opportunities; 2) opportunities for national validation of early phase trials through ETCTN and Big Ten Collaborations; 3) educational seminars; and 4) enhancing inter-programmatic interactions. CIPT benefits from CINJ through: 1) developmental funds; 2) shared resources; 3) center meetings/retreats; and 4) recruitment of key new members. The future plans for CIPT include the expansion of: 1) Phase I Program; 2) MTB (Molecular Tumor Board)/ clinical trials to partner hospitals in the Barnabas Health System; 3) CINJ science into clinical trials and correlative assays; 4) molecularly targeted trials; 5) relationships within the industry; and 6) molecular characterization of cancers.

#### Comments/Recommendations:

Overall, great presentation on CIPT and clinical trials research. The presentation showed that goals are intentional, deliberate, and address priorities of CINJ strategic plan. The EAB suggested more clarity among CIPT members enrollment metrics based on area of specialty and discussing direct forums for translation. The EAB suggests showing a report on accruals and keeping an eye on this during the program. Great examples used but the EAB suggests including how the DSG's contribute to the program and impact members.

#### Clinical Trial Infrastructure, CPDM, PRMS, DSMC - Howard S. Hochster, MD

Howard S. Hochster, Associate Director for Clinical Research gave an overview on clinical trials infrastructure and the protocol review systems for CINJ. The overall mission of Clinical Trial Infrastructure is to: 1) conduct the latest state-of-the-art trials; 2) train new generations of clinical investigators; and 3) deliver these state-of-the-art trials to the people of New Jersey. The specific Clinical Trial Infrastructure aims are to: 1) foster interventional accruals working with COE for underrepresented populations; 2) unify clinical trials operations between Rutgers and RWJBH; 3) increase accrual and engagement at RWJBH sites; and 4) integrate Cancer Center committees (SRB, HROC, Audits) globally. The Clinical Research Leadership agenda includes: 1) providing infrastructure for unified and broad clinical research operation throughout the RWJBH system; 2) facilitating the development and implementation of translational research through Investigator-Initiated Trials (IIT); 3) organize and support CINJ science-based trials from the bedside and back; 4) organizing inter-programmatic meetings in support of this goal; 5) facilitating inter- and intra-programmatic collaborations; and 6) mentoring junior faculty and fellows in clinical trial conduct and culture.

In support of Aim 1, Dr. Hochster shows current clinical trial portfolio highlighting total open interventional protocols and interventional treatment protocols. Overall accrual progress for 2019-2020 was discussed and prioritization of clinical trial efforts throughout the pandemic. Interventional treatment trials and non-interventional trials discussed with attention to race, ethnicity, gender, and age characteristics. There is also a broad portfolio of Investigator-Initiated trials through CINJ and partners. Community Outreach and Engagement is a major aim and a major source of collaboration, especially with Disease Study Groups (DSG). The DSG meet monthly to discuss accruals and updates to each respective group. Regarding scientific review and data safety monitoring efforts, Scientific Review Board (SRB) protocol flow is utilized for all hospitals throughout the RWJBH system. The 2020

review contained a total of 280 protocols submitted and reviewed of which 176 (63% approved as submitted). The data safety monitoring (DSM) process is embodied in Human Research Oversight Committee (HROC) that meets weekly and accrual for each DSG is reviewed each quarter; IRB (Internal Review Board) safety concerns are submitted to SRB in this process.

In support of Aim 2, a goal is to have a unified clinical trials infrastructure across Rutgers Cancer Institute and RWJBH. Clinical trials infrastructure participates in the Community Cancer Action Board (CCAB). They are members of the CCAB, their work with the CCAB helps to review options in extending clinical trials and outreach to communities. To aid in creating a single research operation, the statewide research office increased staffing (89 FTE); monthly meetings are administered with physician and research nurses from system sites; the OnCore application, which is the clinical trials management system, is at the center of their effort; investigational pharmacy has evaluated infrastructure and capabilities in each of the sites and extended their Stego software for managing the investigational drug products at each site; partner sites were added to CTSU and consolidated trails under a systemwide PI; revised SOP's to include partner sites (posted on central website); and system website executed. DSM protocol is also in place for regulatory and quality assurance.

In support of Aim 3, the program plans to improve subject recruitment and retention through expansion to multiple sites across the state affiliated with RWJBH, 11,000+ new analytic cases across the system and clinical trials open and actively accruing at health sites. Accruals increased despite the COVID-19 pandemic. This expansion also includes mandatory investigator training, a fundamentals of oncology clinical trial basic research course, and fundamentals of oncology course for nursing education.

Clinical Trials Infrastructure's future plans include: 1) new recruitment office to evaluate new trials and match patients with existing trails (Fall 2023) within one EMR system; 2) finalizing contractual and regulatory relationships; 3) expanding the Protocol Activation office and centralizing start-up activities for the system; 4) evaluate current trial portfolio; 5) continue to evaluate current staffing matrix at each site; and 7) continuing to expand trial accruals (>550 in 2022).

#### Comments/Recommendations:

Overall, the presentation highlights tremendous accomplishment and organizational effort despite various challenges (legal, educational, COVID, etc.). There were improvements to clinical trials complementary to other programs, which have come together in a constructive way. Diversity presents as an opportunity. The number of IITs is very high and shows productivity of faculty; however, there may be an opportunity to encourage faculty to apply for more funding (e.g., R01, cross-collaboration). The EAB suggests clarity on master agreements with pharma. The EAB suggests incorporation of Princeton interactions/correlative studies, activation times, and analytic case numbers (per site). The EAB also suggests data highlighting institution/center support for DSG groups, CTSU size/management and data on IIT strategy for growth.

Cancer Research, Career Enhancement and Related Activities – Edmund C. Lattime, PhD and Sunita Chaudhary, PhD  
Dr. Edmund C. Lattime, co-leader of the program and Associate Director for Education and Training, provided an overview of the Cancer Research, Career Enhancement and Related Activities program. The program has three aims: 1) to develop and implement programs to train the next generation of basic, clinical, and population researchers and the broad-based student population; 2) provide cancer center supported seminars, conferences, and retreats to impart the most up-to-date information for the education of trainees, faculty, and the community; and 3) provide state-of-the-art career enhancement opportunities to Rutgers Cancer Institute junior faculty.

During the previous CCSG review, the CRCERA scored very good to good with critiques involving the number of peer-reviewed training grants, the description of Rutgers Cancer Institute educational/mentoring activities at Princeton, and clarity on how the cancer center training and seminar activities differ from university activities of Rutgers and Princeton. Since then, there has been a number of additions to strengthen the program including: 1) Rutgers Youth Enjoy Science (RUYES) program supported by NCI grant to provide training and professional development support to teachers and students (high school and undergraduate) of underrepresented groups; 2) NCI T32 post-doctoral training program in cancer metabolism and tumor host interactions; 3) education and mentoring activities with Princeton University including annual cancer research symposium at Princeton, joint seminars/chalk talks, molecular tumor boards, CINJ faculty lecture at Princeton courses and summer research internships. Regarding CINJ and University programs, CINJ faculty contribute as mentors to both programs and support several fellowships.

CINJ faculty are also supported by individual training awards (NIH and foundation). Collaborative initiatives are continued to be built with community outreach and engagement with goals to: 1) educate adolescents about the importance of cancer research for cancer risk education; and 2) conduct outreach activities to increase science and health education in the community.

Future plans of the program include 1) submitting a T32 training grant on *Integrated Training in Genetic, Genomics, and Targeted Therapy*; 2) develop additional consortium-wide initiatives, and; 3) develop additional collaborative initiatives with community outreach and engagement.

Comments/Recommendations:

The EAB suggests attention on tracking of metrics (e.g., success of post-docs; outcome of efforts; high school students and faculty development). The plan for the upcoming T32 grant and recruitment of members could be outlined better in the presentation. The EAB suggests emphasizing clinical training of residents and fellows through Rutgers Cancer Institute. There needs to be a stronger link to COE since this can be a major red flag.

Shared Resources – Adam Berger, MD, FACS and Ioannis Stasinopoulos, PhD

Dr. Adam Berger, co-leader, and Associate Director of Shared Resources, provided a brief overview of Shared Resources and provided examples of quality work generated. To expand upon established CCSG shared resources, developing resources include: 1) immune monitoring and advanced genomics; 2) small molecule screening (located at both consortium institutions); and 3) population sciences research support. Changes to shared resources include: 1) the comprehensive genomics and flow cytometry core have been administratively merged into immune monitoring core; and 2) national search finalized for biostatistics shared resource. The shared resources program is supported by pillars managed through 1) review of policies discussing scientific, operational and financial principles annually guided by SR (Shared Resources) advisory for each resource; 2) reporting outreach metrics (survey findings) to members annually and dissemination with advisory directors; 3) reporting to Rutgers Cancer Institute leaders (Research Leadership Council); and 4) planning and evaluation with external advisory board and ad hoc expert committees. The focus this year has been on outreach as a shared resource with Rutgers, Princeton, other academic institutions, and industry. Chargebacks have been managed in coordination with SR leadership that develops a system of chargebacks and SKU's that reflect reasonable value when compared with NCI designated cancer centers of similar size and membership. All new rates and rate changes are reviewed by the SR Advisory Committee at the annual meeting and on an ad hoc basis. Chargeback goals in prior CCSG site visit and most recent 12 months have increased, but improvements will be made to address reduced activity due to COVID-19. Implementation has begun for iLab for Genome Editing and Immune Monitoring, with expectations to move to implementation with Biostatistics and Metabolomics in the next few months.

Key scientific accomplishments highlighting shared resources include: 1) Homology modeling for a publication in Biomedical informatics in collaboration with multiple programs (CIPT, CP and GICG); 2) CIPT collaboration within Biorepository and Histopathology shared resource where over 1000 prostate surgical cases will be retrieved from RWJBH archives and used to augment and enrich SEER registry data with high-quality population-based biospecimen data; 3) collaboration with multiple programs (CMG and GICG) with assistance from metabolomics shared resource: showing for the renewal of intestinal stem cells acetate replenishes TCA cycle intermediates in HNF4 double-KO organoids; and 4) collaboration with Rutgers Cancer Institute and Princeton with help from the small molecule screening shared resource consultation.

Comments/Recommendations:

The EAB is impressed with examples of work supported by shared resources and applauds focus on chargebacks. The slides showed some inconsistencies in how decisions are made based on a variety of inputs (eliminate, add, or consolidate share resources); also, from user surveys there was not a clear sense on data asked or how leaders use data to make decisions. The EAB would like an explanation on the investment in resources and collaboration with institutional grants. The amount of institutional support and how decisions are made is something to consider adding.

Overview of the Center Administration and Planning (Admin Core): Linda L. Tanzer

Linda L. Tanzer, Associate Director of Administration and Planning, presents on center administration. Center Administration and Planning includes a well experienced team dedicated to the CCSG application process, data, and

reporting, membership, developmental funds, and meeting coordination and documentation. The team is currently implementing new data management and reporting tools including publication curation, and developmental funds curation and tracking. Administration is instrumental in space and facilities management including design and operational guidance; new space acquisition; policies for space allocation; and workspace assignments. Administration provides support for strategic planning and works closely with leadership to maintain synergy and alignment with Rutgers Cancer Institute. Administration also provides support for shared resources including support from center administration and new shared resources administrative infrastructure. Administration oversees developmental funds processes and business planning/budgeting to aid in the launch of new initiatives and support for the center. Support is also provided for researchers to enhance collaboration potential; complete submissions for grant, protocol, and scientific presentations; and administrative support (Administrative Research Associates) to streamline mechanisms for collaboration between consortium universities. Faculty recruitment and retention is also supported by administration.

Leadership, Planning and Evaluation: Linda L. Tanzer

Leadership dedicated to fostering discovery and advancing scientific findings including experienced CCSG leadership. New CCSG leadership was added since the 2018 competing renewal. Outstanding clinical leadership has also remained stable and is integrated into implementation of research missions. Leadership has been added since the last review in Melanoma, Gynecologic-oncology, and Thoracic Medical Oncology. There is an effective internal (IAB) and external (EAB) advisory and evaluation committees including leadership from Rutgers, Princeton, and the whole system. The IAB meets annually, advises on, and supports progressive organizational/institutional support and aid the development of collaborative cancer center activities across the matrix and consortium. The EAB meets annually. The EAB is composed of national leaders whose expertise aligns with the centers' scientific and administrative needs. The Community Cancer Action board (CCAB) provides critical input from community leaders and patient advocates to ensure COE and research activities are informed, promote health equity, and strengthen local capacity, and are responsive to community needs. The Consortium Steering Committee provides a venue to check and regularly assess opportunities to promote a cancer focus. An important process is oversight of the CCSG application, which includes the Research Leadership Council (RLC) and associate directors who meet monthly and plan, develop, and review/evaluate all aspects of the CCSG process. Senior leaders have worked with the center director to establish a research focus for Rutgers Cancer Institute that will be implemented through management of the new five-year strategic plan through partnership between Rutgers Cancer Institute and RWJBH system. The development of the 2021-2025 strategic plan involved consultation with a steering committee, focus groups, CCAB, Consortium Steering Committee and other topic-specific groups. The strategic plan was provided to EAB for review/comments.

Comments/Recommendations:

The EAB suggests including the impact of leadership groups and outcomes of meetings. The governance boards should be connected to outcomes. A theme that comes through in other programs is metrics, and this is not as clear in the administration presentation. It would be helpful to add the number of faculty supported. The EAB suggests tailoring strategic plans around 4-5 pillars opposed to using goals to frame strategy.

Developmental Funds- May 2018 to Present: Steven K. Libutti, MD, FACS

An overview of developmental funds was presented by Steven K. Libutti, Director and Vice Chancellor of Rutgers Cancer Institute. Developmental funds are used mainly to seed new science brought forward with respective pilot projects, investigator awards, and shared resources. There is a rigorous peer-review process following NIH procedures and new investigator awards are assessed by the RLC. In support of research priorities, developmental funds were used to: 1) support new investigators in areas of programmatic importance; 2) stimulate collaborations across the consortium and support development of large multi-PI grant applications (e.g., P01s); 3) promote translational research projects to further evaluate basic research discoveries through clinical research, identify clinical observations to be studied in laboratories, or generate preliminary data for investigator-initiated trials through CTEP; 4) foster collaborations to yield interventions/solutions to reduce cancer burden, address cancer disparities and advance health equity; and 5) produce innovative research and intervention in cancer survivorship. Return on Investment to date (measured over last 2 years) includes 150% on new investigator and pilot project awards. The success of new investigators is demonstrated by their high-impact publications as well as NCI and other peer-reviewed funding.

Future goals for CCSG support include: 1) recruitment of investigators in areas of strategic research priorities; 2) as a goal under shared resources, continued development of immune monitoring and small molecule screening; and 3) pilot awards to support strategic priorities and catchment areas.

Comments/Recommendations:

Overall, the prestatation was outstanding and clear. The EAB suggests including the processes for pilot awards at various stages, prioritization for clinical trials and overlap of developmental funds with internal grants programs. Investment is unclear; the EAB suggests including approaches to invest in presentation. Finally, it would be helpful to highlight funds that go back to the community, like efforts to raise clinical trial enrollments.

Closing Remarks (Director's Summary): Steven K. Libutti, MD, FACS

The Director's summary was provided by Steven K. Libutti. To become an exceptional cancer center across the state, the following was accomplished: 1) strength from Rutgers Cancer Institute realignment as an independent unit within Rutgers University equivalent to the medical schools; 2) increased NCI and overall peer-reviewed funding since the prior grant period including program and training grant; 3) defined a high impact scientific initiative through the establishment of a new Center of Excellence and alignment with the Ludwig Cancer Research Institute – Princeton Branch; 4) increased therapeutic clinical trial accrual since last renewal; 5) significant State support (\$36 million annually); 6) expansion through new free-standing cancer hospital and research facility; 7) statewide recognition, authority, and reach through our integration with RWJ Barnabas Health; and 8) well positioned to continue positively impacting our catchment area.

Future plans include to: 1) Continue investment and growth in the Center of Excellence for Immunology and Metabolism and build on the collaboration with the Ludwig Cancer Research Institute – Princeton Branch; 2) continue to invest in and grow collaborative program project and training grants. New P01s from CPC and CMG are in the planning stages, as is a T32 from GICG; 3) prepare for the opening of the new Cancer Pavilion; 4) continue expansion of clinical trial activities across RWJBH sites; 5) increase support to COE through increased ScreenNJ funding; 6) increase the translation of Rutgers Cancer Institute science into the clinic and ultimately commercialization by leveraging our REACH program and CETI; and 4) execute new strategic plan in cooperation with our community partners and continue to positively impact New Jersey and beyond.

Next Meeting

The next meeting of the External Advisory Board is anticipated to take place in the first half of 2022.

Adjournment

Motion to adjourn was made by Dr. Johnson and was passed unanimously.

Respectfully submitted by,  
Dominique Graham  
Secretary for the meeting