RUTGERS
Cancer Institute
of New Jersey

Rutgers Cancer Institute of New Jersey
External Advisory Board Meeting

Minutes of the Meeting
July 1, 2020

A meeting of the External Advisory Board (EAB) of Rutgers Cancer Institute of New Jersey (CINJ) was held on Wednesday, July 1, 2020. Due to the COVID-19 pandemic, the meeting was held remotely via the WebEx Events platform.

EAB Members – Present		
Candace Johnson, PhD	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 Debardinis, MD, PhD	Cheryl Jernigan, CPA, FACHE	Marcy B. Waldinger
Eric Fearon, MD, PhD	Thomas Lynch, MD	Danny R. Welch, PhD
Stanton L. Gerson, MD	Benjamin G. Neel, MD, PhD	Theodore J. Yank, MHA

EAB Members – Absent	
I. David Goldman, MD	Jeffrey S. Weber, MD, PhD

Invited Participants - Present		
Wadih Arap, MD, PhD	Bruce Haffty, MD, MS	Paul Novembre
Elisa V. Bandera, MD, PhD	Carolyn Heckman, PhD	Tracie Saunders
Adam Berger, MD, FACS	Howard S. Hochster, MD	Zhiyuan Shen, MD, PhD
Stephen K. Burley, MD, DPhil	Yibin Kang, PhD	Linda Tanzer
Chang Chan, PhD	Anita Y. Kinney, PhD	Eileen White, PhD
Sunita Chaudhary, PhD	Edmund Lattime, PhD	X.F. Steven Zheng, PhD
Cristine Delnevo, PhD, MPH	Steven Libutti, MD, FACS	Wei Xing Zong, PhD
Shridar Ganesan, MD, PhD	Shou-En Lu, PhD	

Call to Order
Dr. Candace Johnson called the meeting to order at 10:30 am. She welcomed the Board and solicited member introductions.

Review and Approval of the Minutes
The minutes of the June 25, 2019 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 and strategic direction. In an effort to condense the duration of the meeting, Developmental Funds; Administration and Planning; and Education and Training were not presented but were provided as Power Point handouts instead. The Shared Resources portion of the presentation was shortened and handouts were provided for discussion.

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, became NCI designated in 1997, and in 2002, under the direction of the former Director Dr. 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. CINJ's partnership with RWJ Barnabas Health System began in 2017 and since then CINJ has leveraged that relationship and expanded its programs significantly across the state.

The Cancer Institute's clinical enterprise is divided into sub-specialty and multi-disciplinary clinics. The clinical enterprise covers common and rare tumors and includes a Phase 1 program. CINJ's research enterprise is comprised of five individual research programs. CINJ also supports Shared Resources that help support the science of the five research programs.

CCSG Senior Leadership has remained relatively stable since the last CCSG. Clinical Leadership has also remained stable with additional leadership recruits of Dr. Adam Berger and Carolyn Hayes. There are also planned leadership recruitments for positions that Dr. Libutti plans to fill over the next twelve months. These positions include: Senior Tumor Immunologist, Chief of Thoracic Oncology, Chief of Thoracic Surgery, Director of Phase I, and Chief of Gynecologic Oncology. The Cancer Center continues to recruit new members. Over the last 24 months membership has increased in the Basic, Clinical, and Population Research Programs, from 233 to 259 members. CINJ's relationship with Princeton University has matured since the last site visit and has aided in creating a stronger Consortium Cancer Center.

The Cancer Institute of New Jersey declared the entire State of New Jersey as their catchment area at the last site visit. It has been CINJ's mission over the last two years to expand their offerings, research, and impact across the state. Under the leadership of Dr. Anita Kinney, the Screen NJ Program has expanded across all of New Jersey's 21 counties with 66 clinical/outreach partners at 163 sites. Colorectal and lung screenings have significantly improved across the state.

New Jersey has the third highest incidence and second highest mortality from COVID-19. There have been many efforts made in support of the COVID-19 response. The Cancer Center has initiated a randomized trial; vaccine development; a statewide Cancer Program weekly call; surface testing; and clinical trials.

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 including: 1) outstanding science; 2) strong Shared Resources; 3) growth in investigator-initiated trials; and 4) the growing impact on the catchment area across New Jersey. The Cancer Center is focusing on several new strategic planning opportunities such as: 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 4) identifying a high-impact area of research.

Over the last year, CINJ has formally launched its strategic planning process which will be unveiled in 2021. The process involves ongoing strategic planning activities with continuous input from boards and advisors. There is a very strong history of robust cancer metabolism research and it is the basis for the increasing collaborations through the consortium with Princeton University. While cancer immunology has been robust with respect to clinical trial activity, translational research required investment for growth. To meet this need, a Center of Excellence in Cancer Immunology and Metabolism was launched. The Center of Excellence was selected by Rutgers as a "Big Idea" and a $25 million gift has already been secured. The future goals of the Center of Excellence are to recruit leadership and raise an additional $25 million to fully launch the initiative. Currently, a national search is underway for a Center of Excellence Co-Leader, to lead the activities with Dr. White.

CINJ has also introduced a Committee for Expediting Translational Initiatives (CETI) and a REACH Hub. Both initiatives help formalize the process for identifying findings in the laboratory and translating those findings to the clinic.

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 pavilion. Since the last CCSG visit, interventional clinical trial accrual, multi-PI awards, research funding, institutional support, and state support have increased.

In summary, the Cancer Institute of New Jersey derives significant strength from realignment within Rutgers University as an independent unit. The Cancer Institute has increased NCI and overall peer-reviewed funding since the prior grant period. There has been an increase in interventional investigator initiated clinical trial accrual and increased collaborative publications across programs. CINJ has received significant state support and state-wide recognition, authority, and commitment. The Cancer Center is expanding its space and facilities through a new free-standing cancer hospital/research facility which will be the first in the state. Rutgers Cancer Institute has become well positioned to positively impact the catchment area and beyond during the current grant period.

Comments/Recommendations:
The EAB felt that the changes in leadership seemed to be positive, and noted that Dr. Mehnert had served well. They suggested that more time be spent describing CINJ's impactful science and highlighting what distinguishes CINJ as a cancer center. The EAB also noted that there could be more focus on positioning the uniqueness of the Center to take full advantage of the science, location, community outreach efforts, and population. The expansion of the facilities are wonderful and the multi-PI grants are phenomenal. There are several Associate Directors and they all should be justified. A scientific example of transdisciplinary coordination should be given to highlight and distinguish what sets CINJ apart from other cancer centers. More scientific vision on the high-level view of Immunology and Metabolism will be important to understand (i.e., what the strategies will be, what the investments are, and how decisions are being made regarding those investments). Although the upcoming presentations will showcase these questions, it is still important to present how that works in a cross-cutting way across the Center. There needs to be more understanding about what initiatives are being pursued to support the issues in the catchment area. A concern from the prior review mentioned how carefully the Center is addressing the critique elements. The EAB suggests a focus on specific responses that will lead to a better assessment of the Center at its next review. This often takes years in the making and it was less clear how much attention is being paid to each component of the review.

Catchment Area/Community Outreach and Engagement – Anita Kinney, PhD, RN
Anita Kinney, Associate Director for Community Outreach and Engagement gave a brief overview. The goals of Community Outreach and Engagement (COE) are to: 1) assess and monitor the catchment cancer burden and cancer relevant needs to guide outreach and research; 2) conduct and support a wide range of cancer-related community outreach and engagement activities with a particular focus on vulnerable populations; and 3) foster basic, clinical, and population cancer research while focusing on reducing cancer health disparities. COE was rated excellent to outstanding at the prior CCSG review. Community Outreach and Engagement has been responsive to the critiques regarding outreach and engagement across the state. COE's responses to critiques have been demonstrated through: 1) ongoing working plans to increase the use of claims and health systems data; 2) the creation and sustainment of a Community Advisory Board; 3) structure, prioritization, and planning processes; 4) improved integration with community providers; and 4) the expansion of partnerships and reach. There has been some improvement regarding the Princeton Consortium but it remains a challenge to involve Population Science oriented faculty in research and outreach. However, COE has been very successful in mentoring undergraduate interns.

Community Outreach and Engagement uses a variety of quantitative and qualitive methods to continuously assess and monitor the cancer burden in the catchment area. A Logic Model was developed to assess the impact of COE and CINJ activities. The Model includes short-term metrics of success such as expanded reach to community members, patients, providers, organizations, and catchment area, services provided, disparities

research, and collaborations with community researchers. The intermediate and long-term outcomes of the Logic Model include increased use of cancer prevention services and decreased disparities in late stage of disease diagnosis. Since the last site visit COE has built a formal structure. The organizational unit of the COE provides representation from all catchment area populations. Leadership consists of a Community Cancer Action Board, Directors, and an Internal Catchment Area Advisory Committee. There is strong institutional support with an annual budget of $4.4 million. The COE team includes 10 staff and 36 Oncology Nurse Navigators. The COE office conducts many activities which include promoting mutually beneficial partnerships with community organizations and aligning research with catchment area needs. The COE office connects patients and communities with researchers in CINJ leadership. The Office of Community Outreach and Engagement continuously assesses and monitors the cancer burden; they are currently conducting two statewide catchment surveys.

New Jersey is the most densely populated state in the United States. There are many racial, ethnic, and socioeconomic disparities in cancer incidence, mortality, and access to care. New Jersey has the fifth highest incidence of cancer among the 50 states. Southern and western New Jersey have the highest cancer burden in the state. New Jersey has higher breast, lung, colorectal, uterine, thyroid, kidney, bladder, and non-Hodgkin's lymphoma than the national average. Significant racial disparities, especially in black men and women, are noteworthy. Cancer screening disparities span across the state with mammography screening and colorectal screening below the national average in many counties. Projects, research, and outreach endeavors address the inequities and disparities involving the high cancer burden and low cancer screening rates.

COE has been on an upward trajectory since the last site visit. Overall, COE efforts have reached a considerable number of patients through individual, interpersonal, and organizational level strategies. COE's interactive activities such as the inflatable colon and lung games are very popular. COE's efforts have now grown to include the Asian and LGBTQ community. COE has been effective in tailoring their efforts at the county level. ScreenNJ is just one example of many statewide efforts; it currently focuses on:1) boosting colorectal and lung cancer screening rates; 2) improving smoking cessation; and 3) educating the public about these cancers. ScreenNJ has expanded since the last site visit to 66 clinical and outreach partners at 163 sites in all 21 counties.

Community Engagement is bio-directional and guided by a community participatory research framework. Several initiatives have been developed within the past year, such as: 1) Citizen Scientist program; 2) patient advocate guidance; 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 will monitor the cancer burden continuously and conduct catchment surveys every three years. 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 recruiting a deputy director, Legislative Affairs expert, and a data specialist. COE plans to expand community participatory research implementation science efforts in Botswana and high-risk urban areas in the catchment area. Future plans for ScreenNJ include: 1) enhanced technical support for data capture and impact evaluation; 2) creation of a dissemination and implementation assistance team; 3) expansion of the train the trainer program to develop and continuously support the population health workforce; 4) expansion of efforts beyond colorectal and lung cancers to catchment area priorities such as HPV related cancers, prostate, and breast cancers; and 5) implementation of the genetic risk assessment to guide precision prevention.

Comments/Recommendations:
The presentation was very thorough and had a comprehensive approach. An assessment of socioeconomic status was not discussed and should be included in future presentations. The EAB would like COE to further explain the process in which a person, after being identified by Screen NJ, is monitored, referred, and navigated to care. The EAB felt that identifying nine priority cancers was a concern and that the amount of priority cancers should be narrowed. The success of research related to the catchment area in any way across the Programs should be demonstrated to show the impact of COE. Examples of work done in the community such as early detection

programs, counseling, and addressing the disparities in terms of access to care should be showcased. A few criticisms from last year's review have not been addressed including creating greater clarity for the CINJ's priorities, bolstering interactions with Princeton, and creating more integration with community providers.

Cancer Prevention and Control Program (CPC) – Elisa Bandera, MD, PhD
Elisa Bandera, 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 through epidemiologic investigations 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 39 members with 19 full members. There are 21 R01 equivalent grants, 13 MPI grants, and 1 U54 grant. The Program has a total funding of $8.4MM.

The CPC Program was rated outstanding in the last review. A three-year plan was implemented to address the Program's modest level of inter-programmatic collaborations and the relatively limited application of clinical informatics into research. Throughout the Program there is a strong focus on disparities and breast cancer risk of survival. This leads to multiple intra/inter program collaborations. CPC benefits from CINJ through the facilitation of member recruitment, and the provision of resources such as the New Jersey State Cancer Registry, Shared Resources and developmental funds. The Program adds value to CINJ by providing a solid cancer research portfolio, a strong mentoring program, and help in attracting new faculty. The future plans for CPC include: 1) faculty recruitment to enhance programmatic research in key areas; 2) increase in inter-programmatic collaborations; 3) continuing expansion of the use of EMR/informatics for CPC research to respond to critiques; 4) enhancement of epidemiologic cohorts of cancer survivors in minority and underserved populations; 5) movement of intervention through the translational pipeline to dissemination and implementation R01s; 6) leveraging momentum in tobacco control and skin cancer into CINJ and Program grants; and 7) enhancement of the Population Science Research Support Shared Resource.

Comments/Recommendations:
The presentation was very good and showed evidence of much progress. The inter-programmatic grant level is still something that needs work and high impact publications need to be bolstered. Participation in P01s, P50s, or NCI infrastructures like NCORP would also be helpful in order to push the CPC Program to the very highest tier. The EAB felt that there should be a link to CINJ's nine prioritized cancers. A strategic plan should be created that would incorporate and promote some of the inter/intra programmatic collaborations. There should be demonstration that faculty recruitment was part of a strategic planning process. The significant increase in Associate Members can be showcased, but be clear about the definition of an Associate Member and how they contribute. Clinical Informatics is a priority but recruitment, outcomes, researchers, and the focus to help leverage the informatics data was not clear. There was nothing mentioned regarding COE and its role in CPC's projects.

Consortium Cancer Center - Yibin Kang, PhD
Dr. Yibin Kang, Associate Director for Consortium Research, gave an overview of the Princeton/Rutgers Consortium. The Princeton Cancer Research Consortium was formed in 2009 and has successfully completed two grant renewals. The relationship between Princeton and Rutgers has been strengthened over the years of the Consortium. Princeton makes tangible commitments to the Cancer Institute financially and through the support of Shared Resources. We have 19 Princeton based members that represent 16 R01 equivalent awards and 11 principal investigators. There were a few areas identified that needed to be improved at the last CCSG visit: 1) better integration of Princeton research leaders into the Consortium with more details on how research and resources are being integrated across the Consortium; 2) significant opportunities remain to be pursued for CINJ

to capitalize fully on the unique strengths of Princeton in population science/policy and computational biology; 3) the need to enhance Consortium interactions including consortium-wide participation in multi-Pl research awards and CINJ program-level leadership; and 4) the continued development of the Small Molecule Screening Shared Resource to a mature shared resource.

The Consortium Cancer Center has made investments into four main areas which include: 1) strengthening cancer population research collaborations between the CPC Program and Princeton's Woodrow Wilson School of Public and International Affairs; 2) integrating Princeton's research excellence in computational biology and genomics into CINJ's precision oncology efforts; 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) the increase from 16 projects to 28 cancer-focused and peer-reviewed funded research projects; 3) the development/seed grants and joint annual symposium to promote collaboration; 4) new multi-institutional/multi-Pl program grants; and 5) the successful submission of a T32 training grant for translational research in CMG and Tumor-Host Interactions. In terms of leadership, the Consortium Cancer Center has integrated additional members to the Consortium Steering Committee to emphasize the cross-campus collaboration.

Comments/Recommendations:
The EAB is enamored by the engaging collaboration with Princeton University. There was not much said regarding the relationship with public and international affairs. Policy research in the cancer space and the potential for global health should also be addressed. Given the maturity of the relationship between Rutgers and Princeton, it is now time to showcase how Rutgers is of value to Princeton.

Overview of Basic Research – Eileen White, PhD
Dr. Eileen White, Associate Director for Basic Research, 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. The Basic Research Programs provide a collaborative environment that encompasses: 1) meetings and retreats; 2) shared resource development; 3) pilot and new investigator awards; and 4) training. There are three Basic Science Programs: Cancer Metabolism and Growth; Genomic Instability and Cancer Genetics; and Cancer Pharmacology. The three Basic Science Programs interface with the Clinical Investigations and Precision Therapeutics Program to facilitate bi-directional translation of bench-to-beside. This is facilitated by the CETI initiative and the REACH Grant. The Basic Science Programs also interact with the Cancer Prevention and Control Program; these interactions are facilitated by the Catchment Liaisons which reside in each of the Basic Science Programs.

There has been considerable progress toward strategic goals, such as: 1) enhanced relationship with Princeton University; 2) new grants; 3) new members; 4) a submitted P01 (GICG), a P01 in development (CMG), a U grant submitted (CP), and a T32 submitted (CMG); investment in members through developmental funds that resulted in new peer-reviewed funding; 5) established and developing shared resources; and 6) a Center of Excellence in Cancer Immunology and Metabolism, established with a $25MM philanthropic gift. The Immune Monitoring Core shared resource was expanded to support the science within the Center of Excellence. Two junior faculty have been recruited in the past year, both with a focus in Cancer Immunology. Similar efforts at Princeton University regarding Cancer Immunology and Metabolism recruitment are being coordinated. The plans for the Center of Excellence include recruitment of a Co-Director and additional faculty and operationalization of the GMP facility to enable cellular therapy development.

Comments/Recommendations:
The EAB would like to congratulate the group for putting together the Center of Excellence in Cancer Immunology and Metabolism. More information needs to be presented regarding the $25MM gift and how it will be incorporated into the Center of Excellence’s budget. It was suggested that Dr. White explain how the

Center of Excellence is unique and distinct from other centers of immunotherapy around the country. The connection between the Basic Science Programs, the Center of Excellence, and the catchment area should be discussed. The process and efforts to foster program grants and SPOREs should be further examined.

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

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 56 members – 44 full and 12 associate. CMG has continued to be highly productive and collaborative, as evidenced by the increase in publications and multi-PI grants. CMG has addressed previous CCSG critiques by: 1) increased member productivity; 2) refined and focused membership based on cancer relevance of grants and publications; 3) new research areas/technologies/members; 4) increased consortium collaborations; 5) appointment of Dr. Edmund Lattime as Interim Co-Leader; and 6) a developing P01 application. The CMG program has benefited from the Cancer Center in various ways, including: 1) developmental funds; 2) training programs; 3) shared resources; 4) meetings and retreats; and 5) new program members. CMG has added value to the Cancer Center, through: 1) running a cohesive Program that increases research collaboration, productivity and funding; 2) continuing coordination with CIPT to promote translational research that benefits patients; and 3) providing research discoveries that promote Center growth and advance cancer research and treatment. Future plans include submitting the P01 grant, continuing to establish the Center of Excellence, recruiting a Program Co-Leader, and boosting translational research through utilization of the Small Molecule Screening facility.

Comments/Recommendations:

There was not much discussion about projects that were created in the laboratory and now are in the clinic. The EAB suggested that the Program be clearer regarding the specific cancers on which they will focus. The process in which preclinical candidates move forward towards the clinic needs to be clearly articulated. The EAB felt that there needs to be an example provided during the presentation of a specific way in which the Program has facilitated particular interactions. Anything that the Program can do to partner with surgical colleagues to get primary samples for metabolic profiling would add value to the Program.

Genomic Instability and Cancer Genetics Program (GICG) - Zhiyuan Shen, MD, 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; and 3) to characterize the cancer genome landscape and gene expression signatures to reveal the therapeutic vulnerability. The Program has 45 members; 36 full and 9 associate. Program productivity and collaboration continued to increase since the last CCSG visit. 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's been made in the past year. The Program must address the lack of cancer focused publications. The Program should acknowledge the very important links between genome stability and the immune response, particularly the response patients have to the immune checkpoint blockade. There was a concern with the African American lung cancer component of the presentation because there was no etiology to that single pathway. GICG's new discoveries should be discussed with the Community Advisory Board for further input. A close eye should be kept on intra- and inter-programmatic publication numbers. It will be important to incorporate a slide into the presentation that shows how the Center of Excellence will be integrated into multiple programs but also be part of a whole. The highlighted portion of the presentation should instead focus on something that a younger faculty member or recruit has accomplished.

Cancer Pharmacology Program (CP) - Stephen K. Burley, MD, DPhil
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. At the last CCSG review, the Program scored outstanding to excellent. Areas for improvement included the lack of P01 equivalent grants, paucity in translational success, and the need for a better interface with Princeton. The Program consists of 48 members who are highly productive and broadly collaborative. The total number of publications remains high with approximately two thirds of the papers being generated from collaborations with other institutions. The Program's research that is relevant to the catchment area addresses African American breast cancer disparities and the high prostate cancer rate in New Jersey.

The Cancer Center and the Cancer Pharmacology Program have a symbiotic relationship. Cancer Pharmacology benefits from CINJ through development funds, training programs, shared resources, meetings/retreats, and recruitment of key new members. In turn, the Cancer Pharmacology Program benefits CINJ with its translational activities, drug discovery, infrastructure meetings, recruiting and 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 and racial disparities; and 6) focusing on recruitment in collaboration with Rutgers and Princeton.

Comments/Recommendations:
The presentation highlighted well the work in all three aims, each of which is highly significant. The range and depth of the publications cited for each of the examples is very impressive. The Program has been very responsive to critiques about increasing translational impact and some of the other issues. Only cancer relevant grants should be highlighted during the presentation. The presentation should indicate how non-cancer pharmacologist, non-drug discovery, and non-structural biology investigators from CMG/GICG are incorporated into the Program. It would also be helpful to show how Cancer Pharmacology works with clinical investigators to provide target data and early preclinical data in defined processes through monthly meetings or quarterly retreats. There should be some thought given to collaboration with the education team and possibly serving on their mentoring committee. The commercialization and licensing of molecules needs to be emphasized.

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 for Translational Research, Dr. Ganesan's role is to promote 1) transition of basic science discoveries across the consortium into clinical and translational studies; and 2) reverse translation of important clinical findings into novel basic research. Together with the other associate directors, Dr. Ganesan helps to foster inter-programmatic collaborations, provide mentorship/support to junior faculty and aid in the expansion of the research infrastructure. There are a variety of tools to prioritize translational research findings, including the Committee for Expediting Translational Initiatives (CETI), the REACH Award, and the Precision Oncology platform.

The CETI Committee, led by Drs. Pasqualini and Ganesan, includes Associate Directors and Program Leaders. The committee meets quarterly and there is a top down approach for each Program. 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. Invited applications for pilot projects will be reviewed by CETI Committee members/external reviewers annually and top scoring applications will be nominated for funding.

The goals for Translational Research are to: 1) use CETI to prioritize and fund translational pilot projects that arise from programs; 2) identify and prioritize projects for REACH awards; 3) expand Precision Oncology to partner hospitals; 4) establish joint retreats between CIPT, basic science programs, and population science programs; 5) introduce formal workshops on genomic and bioinformatic tools for clinicians, population, and basic scientists; and 6) provide workshops on clinical/translational approaches for basic scientists. Currently, initial pilot projects focused on supporting clinical trial development are underway. The AD for Translational Research continues to explore ways to consolidate tumor sequencing protocols across the health system, expand the Molecular Tumor Board, and schedule retreats/workshops.

Comments/Recommendations:
The presentation gave a nice overview and great examples of translation, but a slide showing CETI's current investment, which programs benefited, return on investment, and impact should be included in the presentation.

Clinical Investigations and Precision Therapeutics (CIPT) Program - Shridar Ganesan, 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) developing 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 is a relatively large program because it includes clinical investigators. CIPT has 26 full members and 41 associate members. Total cancer relevant funding and peer-reviewed grant support has continued to increase since 2017. Program productivity and collaborations have also continued to increase. The Program scored excellent to outstanding in the previous CCSG review; however, certain critiques were raised. The Program's response to these critiques include the following: 1) funding has increased significantly since year of record driven by increased R0l and MPI R0ls; 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; and 3) CIPT members are involved in P0l submission (with GICG), P20 Disparities SPORE Planning grants (with CPC), and multi-Pl U grants (with CPC and CP). In terms of translational research, CIPT includes a variety of clinical investigators that are organized into disease specific groups. 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 is very involved in disparities and catchment focused projects. CINJ adds value to the Clinical Investigations and Precision Therapeutics Program by supporting recruitment, developmental funds, meetings, and shared resources. CIPT adds value to CINJ as well by providing translational opportunities; opportunities for national validation of early phase trials through ET-CTN and Big Ten Collaborations; and conducting educational seminars. CIPT serves as a translational hub and enhances programmatic interactions throughout the Consortium. The future plans for CIPT include the expansion of: 1) the Phase I Program; 2) Molecular Tumor Board and clinical trials to partner hospitals in the RWJBarnabas Health System; 3) CINJ science into clinical trials and correlative assays; 4) molecularly targeted trials; 5) relationships with industry; and 6) molecular characterization of cancers.

Comments/Recommendations:
The EAB felt that there was a lack of focus on hematology; the presentation failed to show research in leukemia or transplant myeloma. The program is on an upward trajectory because of the focus on clinical trials. The process in which a concept or a discovery moves from one Program to another should also be explained. More examples of research should be highlighted in the presentation to emphasize the catchment area. Examples of the types of translational tools provided to Population Science should be present.

Clinical Trial Infrastructure, CPDM, PRMS, DSMC - Howard S. Hochster, MD
Howard S. Hochster, Associate Director for Clinical Research addressed clinical trials infrastructure and the protocol review systems for CINJ. The overall mission of Clinical Trial Infrastructure is to conduct the latest state-of-the-art trials, to train new generations of clinical investigators, and to deliver these state-of-the-art trials to the people of New Jersey. There are four specific Clinical Trial Infrastructure aims: 1) foster interventional accruals; 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, Audit) globally. The Clinical Leadership agenda includes:1) providing infrastructure for unified and broad clinical research operations; 2) facilitating the development and implementation of translational research through Investigator-Initiated Trials (IITs); 3) organizing and supporting 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. Throughout the COVID-19 pandemic, clinical trials at CINJ remained steady. Dr. Hochster commented that rotating staff and alternating day teams helped in continuing the enrollment of patients.

Community Outreach and Engagement is a major aim and source of collaboration. Clinical Trials Infrastructure participates in the Community Action and Advisory Board (CAB). They are members of the CAB, helping to review options in extending clinical trials and outreach to communities. They meet monthly with the CAB staff to review accrual of various populations. A statewide research office has been established with increased staffing to coordinate research activities at different sites. The OnCore clinical trials management system is at the center of their efforts. Clinical Trials Infrastructure plans to move towards a cloud-based enterprise system. The 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. Clinical trials are open in Newark (New Jersey Medical School / University Hospital and Newark Beth Israel), Livingston, Hamilton, Somerset, and Monmouth. A site management plan has been instituted with Pl oversight, investigational agent management, biospecimen activities, and monitoring. The clinical trial finance office has been reorganized under OHRS and the OnCore Finance module is being implemented across the system. Training (including onboarding programs, mandatory investigator training, fundamentals of oncology clinical trial basic research, and fundamentals of oncology for nursing education courses) is expanding and a universal system-wide research competency program is being developed. Future plans include: 1) signing final IRB reliance agreements; 2) finalizing contractual relationships; 3) strengthening the Protocol Activation office and centralizing activity through statewide recall; 4) continuing protocol entry and enrollment data using the OnCore system; 5) continuing to work with sites to evaluate the best trial portfolio fit for each of their hospitals; 6) evaluating current staffing matrix at each site; and 7) continuing to expand trial accruals.

Comments/Recommendations:
There was concern regarding therapeutic accruals only being around 300 to 350 a year, but the EAB was confident that the target goal of 500 accruals will be accomplished. It would be a good idea to see the accrual breakdowns by disease site to show that there is a representative number of trials in each. Accrual figures should also be broken down by phase I, II, or III. The improvement in quality indicators is impressive. With many major drug companies headquartered in New Jersey, there should be an opportunity to create stable arrangements that would yield funding to the institution.

Shared Resources – Adam Berger, MD, FACS
Dr. Adam Berger, Associate Director of Shared Resources, provided highlights of impact from some of the

Shared Resources.

During the COVID-19 pandemic, the Genome Editing Shared Resource (GESR) was able to create and genotype new ACE2 + mice for use in multiple COVID-19 related projects across the Rutgers campus in less than eight weeks. Additionally, they generated seven other mouse lines for use in COVID-19 related research. The Biospecimen Repository and Histopathology Service assisted in the Rutgers/CINJ COVID-19 drug trial by assisting both with sample collections from enrolled patients as well as the processing of samples. The Biometrics Shared Resource was involved in the design of the trial and is now interpreting interim findings. The Immune Monitoring Core has been involved in processing samples from patients on the COVID-19 drug trial.

An important finding was just published in *Nature Chemical Biology*, with contributions from the Small Molecule Screening Facility as well as the Metabolomic Core - investigators were able to identify a novel small molecule inhibitor of the G6PD pathway and to show that this inhibitor suppresses T cell cytokine production and the neutrophil oxidative burst. A second manuscript using the same molecule inhibitor has now been accepted in *Cancer Research* which concerns K-Ras mediated tumor growth and metastasis.

Dr. Khiabanian was awarded an R01 award to support his study "Evolution and Clinical Impact of Clonal Hematopoiesis of Indeterminate Potential (CHIP) in Breast Tumor Microenvironment." This study has accrued 16 patients to date and relies on support from both the Bioinformatics and Biospecimen Repository Shared Resources. Dr. Anita Kinney is conducting the R01 "The H.E.R.O. Study" that focuses on the biologic and behavioral impact of Tai Chi in senior fatigued prostate cancer survivors.

Comments/Recommendations:
The EAB would like an explanation of the investment in resources. The EAB asked that Shared Resources shed some light on the plans to have Core Facilities interact between these two very important institutional grants which both include Rutgers and Princeton.

Next Meeting
The next meeting of the External Advisory Board is anticipated to take place in the first half of 2021.

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

Respectfully submitted by,
Jazmun Dotts
Secretary for the Meeting