Rutgers Cancer Institute of New Jersey
Internal Advisory Board

Minutes of Meeting
Thursday, October 1, 2020
5:30pm – 7:30pm

Attendees

Joseph Barone, Pharm D (Chair)	Linda Flynn, PhD, RN, FAAN	Christopher Molloy, PhD
Andy Anderson, MD	David Foran, PhD	Maral Mouradian, MD
Wadih Arap, MD, PhD	Shridar Ganesan, MD	Paul Novembre
Adam Berger, MD	Vicente Gracias, MD	Reynold Panettieri Jr., MD
Martin J. Blaser, MD	Bruce Haffty, MD	Jonathan Potter, DPhil
Suzie Chen, PhD	Christian Hinrichs, MD	Arnold Rabson, MD
Cristine Delnevo, PhD, MPH, FAA	Howard Hochster, MD	Brian Strom, MD, MPH
Andrew Evens, DO, MSc, FACP	S. David Kimball, PhD	Jay Tischfield, PhD
Karla Ewalt, PhD	Anita Kinney, PhD	Linda Tanzer
Thomas Farris, PhD	Edmund Lattime, PhD	Eileen White, PhD
Patricia Fitzgerald-Bocarsly, PhD	Laura Lawson, PhD	
Valerie Fitzhugh, MD	Steve Libutti, MD	

Absent

Candace Botnick	John Gantner	Gwendolyn Mahon, MSc, PhD
Kenneth Breslauer, PhD	Perry Halkitis, PhD	Yibin Kang, PhD
Kevin Coyle	Robert Johnson, MD	Helmut Zarbl, PhD

Call to Order

The meeting of the Internal Advisory Board (IAB) of Rutgers Cancer Institute of New Jersey (CINJ) was held virtually on Thursday, October 1, 2020 and opened at 5:35pm by Dr. Joseph Barone, Chair.

Review and Approval of Minutes

The minutes of the October 17, 2019 IAB meeting were reviewed. Upon motion duly made, seconded and unanimously carried, the minutes were approved.

Internal Advisory Board Chair

Dr. Barone welcomed everyone and solicited member introductions. He turned the floor over to Director, Dr. Steven Libutti, who provided a Director's Report on behalf of Rutgers Cancer Institute of New Jersey.

Director's Report - Steven Libutti, MD, FACS

Dr. Libutti welcomed the members and emphasized the importance of having this Internal Advisory Board (IAB) meeting remotely.

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 significant racial, ethnic, and socio-economic disparities within New Jersey not only impact New Jersey in terms of cancer, but obviously play a major role in terms of the pandemic. The pandemic has accentuated some of those disparities, and put at risk the Cancer Institute's ability to appropriately screen patients. Even at a national level, an increase in cancer incidence over the next five to ten years is expected to occur. CINJ has been preparing their Community Outreach and Engagement Program to make certain that they can stay on top of this projection and ensure patients' safety at screening facilities.

The Cancer Institute of New Jersey was established in 1992, it became NCI designated in 1997, and in 2002 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 Consortia. CINJ's partnership with RWJ Barnabas Health Systems began in 2017. CINJ currently has close to 260 members that represent both Rutgers and Princeton University.

CINJ's subspecialty multidisciplinary clinics focus on a variety of tumor types. These clinics have the capability of treating almost all adult and pediatric cancer diagnoses within the cancer program. CINJ's subspecialty multidisciplinary clinics include a facility in New Brunswick and 12 other sites throughout the health system.

CINJ organizes the research base of the Cancer Center Support Grant (P30 grant) into established research Programs and provides Shared Resources to support the cancer-focused collaborative research of its members. Some Shared Resources operate across the two campuses of Rutgers and Princeton, and some, most notably the Genome Editing Facility, are co-sponsored by the University and by the Cancer Institute.

Senior Leadership has remained relatively stable. CINJ appointed Dr. Adam Berger as the Associate Director for Shared Resources. Given the growth in the numbers and departments of those Shared Resources, CINJ felt it was necessary to create an Associate Director position to focus on the management of those Shared Resources. Dr. Anita Kinney has now taken on the dual role of Associate Director for Population Science and Community Outreach. There is currently an open search for a new Director for the Phase I Program. There have been changes in Program Leadership as well, with the addition of Dr. Carolyn Heckman as the Co-Program Leader for the Cancer Prevention and Control Program. Dr. Christian Hinrichs as the Co-Director of the Duncan and Nancy MacMillan Cancer Immunology and Metabolism Center of Excellence as well as the Co-Program Leader for the Cancer Metabolism and Growth Program. Clinical Leadership has remained relatively stable with the additions of Dr. Aliza Leiser as the Interim Chief of Gynecologic Oncology and Carolyn Hayes as the Chief Nursing Officer. CINJ welcomed CINJ also recruited Dr. James Aikins as the new Chief of Gynecologic Oncology.

CINJ continued to increase the number of Basic Research, Clinical Research, and Population Research Investigators across CINJ's Programs by approximately 60 new investigators. CINJ is a Consortium Cancer Center with Princeton. This consortium relationship is managed through a steering committee that is chaired by Dr. Yibin Kang, who also serves as the Associate Director for Consortium Research. The relationship between Rutgers and Princeton continues to be strengthened through increased membership. This allows for new research opportunities and the cross fertilization between the two universities.

The ScreenNJ Program focuses on cancer screening for both lung and colon cancer. ScreenNJ was launched during the 2018 fiscal year. A new line item from the State of $2M was provided to help CINJ expand cancer screening for lung and colon cancer. ScreenNJ began with only three counties, 17 sites and six clinical outreach partners. Currently, under the leadership of Dr. Anita Kinney, ScreenNJ has expanded to all 21 counties in the State. ScreenNJ has 66 clinical and outreach partners at 163 sites, including five federally qualified health centers at 39 sites. The relationships that ScreenNJ has established across the State has allowed the Program to obtain more information and provide more outreach to at-risk populations regarding cancer and COVID-19. As a result of these initiatives, CINJ now has an MOU with the State Department of Health, allowing a linkage between the Cancer Registry and the COVID-19 Registry. The ability to cross reference between those two registries will create many opportunities for additional research.

The results of the site visit yielded an Impact Score of 28 and an excellent to outstanding rating for the Cancer Institute. Numerous strengths were noted but there were also some areas of opportunity. In late

2019, CINJ launched their 2021 to 2026 Strategic Plan. That process is well underway with a number of planning subcommittees that are already very active. CINJ hopes to unveil their new Strategic Plan at the next EAB and IAB meetings. CINJ has an External Advisory Board, Internal Advisory Board, a Community Advisory Board, and a Consortium Steering Committee. Within CINJ, Dr. Libutti relies on the advice, counsel, and input of CINJ's Associate Directors. CINJ has a Research Leadership Council, which is made up of Program Leaders and Associate Directors. The Research Leadership Council helps to vet new scientific directions, applications for pilot awards, and serves as a standing study section for the evaluation of submissions. There is also an Officers Cabinet which spans not only CINJ CCSG activities, but also the clinical and service line activities for which CINJ is responsible.

CINJ has three Basic Science Programs, a Clinical Translational Research Program, and a Cancer Population Control Program. These Programs are divided into Cancer Metabolism and Growth, Genomic Instability and Cancer Genetics, Cancer Pharmacology, and Cancer Prevention and Control. CINJ's Clinical Investigations and Precision Therapeutics Program, in addition to driving its own science, also serves as a focal point for the translation of ideas into clinical trials. Most of CINJ's clinical investigators are within the CIPT Program. Within CIPT's structure is a newly formed CETI Committee that expedites translational initiatives. This committee helps to vet science from each of research Programs. There are members from each Program that serve on the CETI Committee with the goal to identify science that is ripe for translation into the clinic.

The Cancer Institute's Cancer Metabolism efforts are recognized internationally among the top centers for discovery in this area. These efforts are ably driven by Drs. Eileen White of Rutgers, and Josh Rabinowitz of Princeton. CINJ's new Center of Excellence, which was selected by Rutgers as a "Big Idea" has already raised $25M through a generous gift from Nancy and Duncan MacMillan. The goal is to raise an additional $25M to fully resource the Center of Excellence. A national search is ongoing for additional faculty to populate this new center. This center will focus on the interplay between Cancer Immunology and Cancer Metabolism.

CINJ, Rutgers, and RBHS are all involved in efforts to support the COVID-19 response. CINJ launched a randomized trial comparing Hydroxychloroquine with Azithromycin, without Azithromycin, and versus placebo as a means of lowering viral load. Dr. Libutti is hopeful that CINJ will bring this data portion to conclusion over the next month. Drs. Pasqualini and Gennaro have developed a vaccine that expresses the spike protein and some novel antigenic portions of the spike protein. Although, this vaccine is far behind those that are currently in the clinical trials phase, it might ultimately solve a lot of problems that the other vaccinations may present. This is an inhalational vaccine and the vector that carries the gene coding for the spike protein is a bacteria phage that's been modified within adeno associated virus expression cassette. This can provide ease in production and administration. A patent was submitted through the Office of Research and Economic Development (ORED) supporting this vaccine platform. CINJ has also been looking at Cytokine response profiling for cancer patients versus COVID-19 patients that have received checkpoint inhibitors. A biorepository for those samples has been established and CINJ has started the profiling process. CINJ launched a Statewide Cancer Program Call which takes place every Friday morning. This call is attended by all the Cancer Programs across the State and has evolved into talks about collaborative clinical research projects, best practices for surface testing, and the best standards of procedure.

Dr. Libutti went on to discuss the six essential characteristics and CINJ's strengths in those areas. Physical space, which is under the direction and responsibility of the Cancer Center's Director, is managed and allocated towards the mission of CINJ. Currently, CINJ is a 225,000 square foot primary clinical and research facility. This does not count the numerous outpatient and inpatient facilities across the health system which come under the management of CINJ. There is also an additional 36,000 square feet of space in the East Tower of Robert Wood Johnson University Hospital dedicated to hematologic malignancies and CINJ's Bone Marrow Transplant Program. There is 45,000 square feet of leased administrative space across New Brunswick mostly located on Albany Street. Located in the Robert

Wood Johnson University Hospital, there are approximately 100 cancer dedicated beds in the North Tower and CINJ's Radiation Oncology Facility is also within the hospital. There is a planned 515,000 square foot inpatient/outpatient Cancer Pavilion which will also be located in New Brunswick. 195 Little Albany Street will be converted into a primary research and administrative facility, allowing CINJ to move the 45,000 square feet of leased administrative space into this primary CINJ building. CINJ's 36,000 square feet at the East Tower and the Robert Wood Johnson University Hospital space will move into this new freestanding Cancer Pavilion. By the time of CINJ's next site visit, CINJ will have over 700,000 square feet of clinical and research space under the responsibility of the Cancer Institute Director. Outpatient care at the Cancer Pavilion will include 84 infusion bays, 74 exam rooms, advanced radiology with linear accelerators, CT equipment, MRI equipment, mammogram equipment, core laboratory facilities, pharmacy facilities, and an outpatient urgent care. The inpatient care area of the Cancer Pavilion will include 96 inpatient beds, surgical/procedure rooms, a central sterile processing area, and inpatient support spaces. The research area of the Cancer Pavilion will include wet lab facilities, research equipment, clinical trial offices, and faculty offices. This will be the first freestanding Cancer Hospital in the State.

Organizational capabilities encompass several committees and boards that are important to the day-to-day functions of the Cancer Institute. These include the External Advisory Board, the Research Leadership Council, the Officer's Cabinet, the Internal Advisory Board, and the Consortium Steering Committee. The Director of the Cancer Institute reports to the highest levels of both the University and the health system. This is incredibly important in terms of both receiving strategic direction from the highest levels but also playing a role in advising and giving counsel to those leaders in terms of implementing the Cancer Program more broadly. CINJ has a very nimble administrative structure with authority dispersed to various levels.

Transdisciplinary collaboration is shown through the various opportunities that stimulate activities across the translational spectrum, disease specific groups, and programs. The CETI Committee is instrumental in the promotion of collaboration. The greatest metric CINJ has for measuring the success of translation is the conduct of interventional clinical trials, especially investigator initiated interventional clinical trials. Under the leadership of Dr. Howard Hochster, CINJ has substantially increased interventional accrual totals and investigator initiated interventional accrual totals. Another measure of collaboration is cancer relevant collaborative publications. CINJ's various programs have grown with respect to intra- and inter-programmatic collaborations. CINJ has also seen a dramatic increase in the number of Multi-PI awards.

Cancer focus is measured by how concentrated on cancer CINJ's Programs are in relation to the grants support that they receive from their members and the science that their members are driving forward. Every year CINJ Program Leaders review their individual programs and the members of their programs to determine what percentage of the grants held by those members are cancer relevant. After their review, they assign a metric to the cancer relevance. If a grant is funded by the National Cancer Institute, by the National Cancer Institute's metrics, it is considered 100% cancer relevant. Each Program needs to provide brief justifications, in writing, for each of the grants to which they assign a percentage. Those assignments are reviewed and approved by CINJ's Research Leadership Council.

Institutional commitment has been provided through the RBHS Chancellor's Office, grant indirects, CINJ Rutgers Foundation support, the State of New Jersey, and RWJBarnabas Health. In total, there has been approximately $72M in annual institutional support. In addition to that support, there has also been a commitment of $750M for construction of a new Cancer Pavilion and renovations to the existing building. Annual commitment has increased and continues to be sustained. Dr. Libutti went on to thank the Chancellor, the Chancellor's Office and the Government Affairs team at the University for making certain that the commitment of the State was kept intact during the COVID-19 pandemic.

The Cancer Center Director, Dr. Steve Libutti is a surgical oncologist, who spent time at the NCI and at the Albert Einstein College of Medicine before joining CINJ. He continues to have an active research laboratory that is currently funded by a Multi-PI R01 grant and a Peterson Accelerator Award from the Neuroendocrine Tumor Research Foundation. Dr. Libutti is the Emeritus Editor-in-Chief for the Cancer Gene Therapy Springer-Nature Journal. He is also a member of the Board of Directors for Alliance, a member of the Eastern Cooperative Oncology Group, a member of the American Joint Committee on Cancer, a member of the NCI Board of Scientific Counselors, and the Chair of the Society of Surgical Oncology Education Council. As Senior VP for Oncology Services, Dr. Libutti is responsible for the budgeting of cancer services at all of CINJ's facilities.

CINJ has derived significant strength from the realignment as an independent unit within the University. The Cancer Center has increased their NCI and overall peer reviewed funding. They have also increased interventional investigator initiated clinical trial accrual and continue to maintain significant support from the State of New Jersey. CINJ will be expanding their physical plant into a brand-new, freestanding cancer hospital and research facility. Dr. Libutti believes CINJ will continue to positively impact the catchment area as CINJ moves towards the next grant period.

Questions/Comments/Recommendations/Answers:

Q: What is the impact of COVID-19 on clinical operations? What kind of reserves does CINJ have in place? What is the plan to deal with the shortfalls of the last six months and the projected shortfalls in the future?

A: Dr. Libutti: CINJ does not know what will happen in October, November, December, but at least to date, CINJ will likely finish the calendar year 2020 either at the same productivity as in 2019, or just shy of it. While a lot of other clinical programs went entirely to telemedicine, CINJ continued treating cancer patients throughout the pandemic. CINJ's infusion units and radiation therapy units were open. CINJ saw new patients, in person and by telemedicine. This year has been one of the better years for CINJ with clinical trial accrual. Clinical trials were never shut down although most of the peer cancer centers went into shelter-in-place mode. This led patients searching for clinical protocols to enroll at CINJ. CINJ has weathered the storm better than most especially given the fact that CINJ is in the heart of New Jersey and in the epicenter of that first wave of COVID. CINJ was highlighted as one of the centers that kept pushing the mission forward. CINJ has kept moving throughout the pandemic. Beginning in May, CINJ started testing all patients and staff. CINJ has created a safe environment for patients. The new building will not be completed in time to help the pandemic but having a cancer-only hospital for the system will allow CINJ to concentrate on cancer patients and continue to perform surgery.

Q: How will CINJ integrate the Newark operations into the story of the Cancer Institute at the next renewal?

A: Dr. Libutti: Newark plays an incredibly important role for CINJ's program; not only the Clinical Care Program, but the Clinical Research and Population Research Programs. The unique populations that exist in Newark and the challenges that those populations face in terms of access to care are critical. Dr. Kinney has been expanding CINJ's Community Outreach and Engagement Program on the ground in Newark. CINJ has been growing the clinical research footprint in Newark. One of the challenges CINJ faces in Newark is that University Hospital is a separate clinical entity from RWJ Barnabas Health. The way in which CINJ has constructed the service line is that University Hospital's Cancer Program, for which CINJ is responsible, is competing with Newark Beth Israel's Cancer Program. This has been a very clumsy structure and CINJ has made tremendous progress in actuating a new relationship with University Hospital that will bring the clinical activities under the umbrella of the service line. This will help CINJ to integrate the clinical research activity and the Community Outreach and Engagement activities that take place on that campus. CINJ is hoping to have that new relationship in place early in

2021. Hopefully, this will tell a more robust story about CINJ's presence in Newark.

Q: The RBHS Strategic Plan Clinical Subcommittee would like to know what needs to be done to achieve open access to information, research, programs, and hospital services provided by the major academic centers.

A: Dr. Libutti: It is still in evolution and the most important thing is trust. Every single hospital in the Health System originated as an independent hospital at one point. As recently as 2016, RWJ Health System and Barnabas Health System were two completely different systems that were competing. The systems coming together as an integrated system has significant benefits. The first thing that is important is that each of the individual hospitals, and the programs that existed in those hospitals, be respected for what they have to offer to their communities and what they can accomplish in their communities. No patient likes to travel great distances to get care if they can get it close to home. One of the reasons why CINJ has been successful in getting referrals from the hospitals for things like bone marrow transplant, radiation therapy, and some of the other specialty activities is that these treatments are unique to the New Brunswick campus. CINJ has developed trust across the other hospitals. The second important component is integration and communication. CINJ has built a unified service line across the hospitals. Communication aids the individual practitioners, referring doctors, and cancer providers, in knowing who is where and what is where. The Call Center and the Cancer Navigator Program has been able to help with certain problems and acquiring referrals. Clinical Navigators deployed throughout the Health System help navigate patients to the level of the care they need at different facilities. This has been embraced by the local hospitals and cancer programs across the system. The challenge right now is that every patient has a different medical record number; the transition to EPIC will greatly enable and enhance the exchange of information between the EMR and EHR system. Once all systems are on one platform, *intra*-campus and *inter*-campus referrals will be more streamlined. It all starts with trust; different facilities must have the belief that there is value in sending their patients to a different campus. They must trust that they won't be punished financially and that their patients will return to them even after they've gone to that other level of care.

Q: What do you think about incorporating an accessible link, where all investigators can mine data?
A: Dr. Libutti: This is something to start working on immediately. It will be helpful to have common platforms. It is beneficial that CTSA has embraced Oncore as its platform for doing clinical trial management and work. This will aid in the cross fertilization between the Cancer Programs and the CTSA with respect to clinical research activities. Already, any investigator at Princeton or Rutgers, whether they're in the cancer program or not, can access any one of CINJ's Shared Resources for support of their science. In fact, CINJ would love to have more investigators leveraging those core facilities. CINJ is certainly not looking to duplicate resources. This is the reasoning for jointly managing the Genome Editing Facility with ORED. Every five years, CINJ must justify the Shared Resources as a component of the P30. There are many opportunities to leverage already established Shared Resources and to prevent duplicating Shared Resources moving forward. Drs. Adam Berger, Eileen White, and Ned Lattime would be very willing and open to have conversations to explore how CINJ can operationalize some of that.

Meeting Adjourned at 7:20 pm.

Respectfully submitted by,
Jazmun Dotts
Secretary for the meeting