

**Rutgers Cancer Institute of New Jersey  
Internal Advisory Board**

**Minutes of Meeting  
Wednesday, September 5, 2018  
6:00pm – 8:00pm**

<b>Attendees</b>		
Joseph Barone, PharmD	Howard Hochster, MD	Paul Novembre
Kenneth Breslau, PhD	S. David Kimball, PhD	Reynold Panettieri, Jr., MD
Suzie Chen, PhD	Anita Kinney, PhD	Jonathan Potter, DPhil
Karla Ewalt, PhD	Janice Mehnert, MD	Arnold Rabson, MD
Andrew Evens, DO	Edmund Lattime, PhD	Brian Strom, MD
David Foran, PhD	Steven Libutti, MD	Linda Tanzer
Shridar Ganesan, MD	Sharon Manne, PhD	Jay Tischfield, PhD
Robert Goodman, PhD	Christopher Molloy, PhD	Eileen White, PhD
Bruce Haffty, MD	Maral Mouradian, MD	Helmut Zarbl, PhD
<b>Absentees</b>		
Wadiah Arap, MD, PhD	Sherine Gabriel, MD	Robert Johnson, MD
Candace Botnick	John Gantner	Yibin Kang, PhD
Kevin Coyle	Vicente Gracias, MD	Chen Liu, MD, PhD
Thomas Farris, PhD	Perry Halkitis, PhD	Ann Stock

Prior to commencement of the meeting, Dr. Libutti thanked Dr. Molloy for his service as the IAB Chair for the past five years and presented him with a plaque. Dr. Libutti then introduced Dr. Barone as the new IAB chair.

**Call to Order**

The meeting of the Internal Advisory Board (IAB) of the Rutgers Cancer Institute of New Jersey (CINJ) was held on Wednesday, September 5, 2018 and opened at 6:08pm by Dr. Christopher Molloy, Chair.

**Review and Approval of Minutes**

The minutes of the September 6, 2017 IAB meeting were reviewed. Upon motion duly made, seconded and unanimously carried, the minutes were approved.

**Internal Advisory Board Chair**

Dr. Molloy solicited member introductions, then welcomed and turned the floor over to Director Dr. Steven Libutti, who provided an overview of the Rutgers Cancer Institute of New Jersey.

**Director's Overview- Steven Libutti, MD, FACS**

Dr. Libutti welcomed the Board and provided a status report for the Cancer Center. He discussed the success of the recent CCSG site visit and presented a high-level overview of the site visit presentations. He is very pleased with the efforts of the Cancer Center team.

The results of the site visit yielded an Impact Score of twenty-eight and an excellent to outstanding rating for the Cancer Institute. The Cancer Center's Research Programs were one of the highlights of the site visit with Cancer Prevention and Control and Cancer Pharmacology both improving in their NCI scores. The Cancer Institute was recommended by both the site visit team and the parent committee which is essentially the equivalent of the study section. The Cancer Institute was also endorsed by the council for redesignation as a Comprehensive Cancer Center and a consortium relationship with Princeton University for another five years. In October a strategic planning retreat will take place, involving program leaders, shared resource leaders, and Associate Directors. Each

program and shared resource will present a forensic accounting of their evaluation from the site visit and will put forward their four priorities over the next four-year time period.

New Jersey is the most densely populated State in the United States with a population of approximately 8.9M. It is also one of the most ethnically diverse States in the nation. There is a high cancer incidence and mortality rate in New Jersey with 50,000 new cases annually and 16,100 cancer deaths. Through various partnerships with health systems, CINJ has been able to more effectively deliver care and conduct research across the State. Significant disparities across racial distinctions exist in a number of counties throughout New Jersey due to limited access to care. In terms of cancer incidence and mortality, the highest incidence is in the southern part of the State and this is a major focus for the Cancer Institute and Cancer Programs moving forward.

The Center's vision and mission is to become the State's resource for and leader in cancer research, prevention, diagnosis, treatment, surveillance, and survivorship. In 2017 a decision was made that the entire State of New Jersey would be defined as the Cancer Center's catchment area. Rutgers Cancer Institute should: 1) lead in basic science discovery and focus basic science efforts within the programs of the cancer center support grant; 2) translate findings from our laboratories into the clinic leveraging our unique resources (cGMP facility) and location (industry partnerships); 3) enhance access to cutting edge clinical trials; 4) provide exceptional cancer care in a timely fashion with the patient as the focal point; and, 5) educate clinicians and patients, which is a critically important component of the mission.

The Cancer Center was established in 1992 through a P20 planning grant awarded to Dr. Michael Gallo and became New Jersey's first NCI designated cancer center in 1997. In 2002, the Rutgers Cancer Institute achieved Comprehensive Cancer Center designation and integrated into Rutgers University as a result of the New Jersey Medical and Health Science Restructuring Act as an independent unit in 2013. Rutgers Cancer Institute of New Jersey is a member of the Big Ten Cancer Research Consortium and a Consortium Cancer Center with Princeton University made up of 233 members.

Dr. Libutti went on to discuss the reporting lines, influence of the Cancer Institute Director, and the leadership structure. The Director reports directly to the President of the University and has very a close working relationship with the Chancellor of RBHS; serves as the Vice-Chancellor for Cancer Programs and is the Senior Vice President of Oncology Services; and is now responsible operationally and fiscally for the entire cancer service line across all eleven adult hospitals and two children's hospitals throughout the RWJ Barnabas Health System.

Rutgers Cancer Institute has a number of subspecialty, multidisciplinary clinics that are responsible for clinical care on the New Brunswick campus and other campuses throughout the health system. CINJ's Research Programs are divided into five areas of focus: Cancer Metabolism and Growth; Genomic Instability and Cancer Genetics; Cancer Pharmacology; Clinical Investigations and Precision Therapeutics; and Cancer Prevention and Control. The Cancer Institute of New Jersey also has eight shared resources: Biomedical Informatics; Biometrics; Biorepository and Histopathology; Comprehensive Genomics; Flow Cytometry; Genome Editing; Metabolomics Service; and Research Pharmacy. There are currently two developing shared resources. Having a statewide focus, affords CINJ significant opportunities due to its consortium relationship with Princeton University in terms of driving research across the State. CINJ has twelve partner hospitals. Through RWJBarnabas Health it also has additional statewide partners across New Jersey with who they collaborated in cancer screening, prevention and clinical trial activity. Rutgers Cancer Institute of New Jersey is not only a cancer center for a single health system, it is the State's cancer center.

The consortium with Princeton University is a formalized relationship that promises strength in cancer research in New Jersey. CINJ's steering Committee with Princeton helps to oversee the relationship. The Committee represents individuals at the highest level of both institutions. All members have access

to the shared resources. Dr. Libutti, as the Director, has oversight of all shared resources whether they are located at Rutgers or Princeton. There are currently ongoing discussions with Princeton University's Dean of Research, the Chancellor of New Brunswick, and the Chancellor of RBHS for opportunities to explore co-appointments and co-recruitments between Rutgers and Princeton.

The Screen NJ initiative is a cancer prevention, education, and detection program, focused on four counties across the State. Health systems, federally qualified health centers and other cancer centers have been brought on as partners across the State of New Jersey to facilitate in navigating, educating, and closing the loop for patients and cancer screening. Screen NJ will ultimately span the entire State and eventually include screening for other types of cancer.

CINJ has a very vigorous strategic planning process and the IAB is an important component of this plan. The current strategic plan that the Cancer Institute is operating under is the 2015-2020 plan but it will begin this fall with October's retreat. The strategic planning process is an ongoing activity with significant interaction with very involved External and Internal Advisory Boards and the Consortium Steering Committee.

There have been key leadership recruitments in medical oncology (Dr. Howard Hochster, Dr. Wadih Arap, Dr. Renata Pasqualini) and surgical oncology (Dr. Richard Alexander, Dr. Andrew Evans, Dr. Peter Cole, and Dr. Anita Kinney). Additional faculty recruitment has also taken place over the past 24 months with eighteen Basic, eight Clinical, and six Population Research positions being filled. Newly launched initiatives for the next grant period within the Cancer Institute include the Center for Immune Oncology, Precision Medicine, Center for Neuroendocrine Tumors, and enhancing scientific partnerships. Dr. David August has been appointed Associate Director for Faculty Affairs for CINJ.

The Cancer Institute of New Jersey's six essential characteristics, including organizational capabilities, transdisciplinary collaboration/coordination, cancer focus, institutional commitment, center director, and physical facilities scored outstanding to exceptional by the NCI. The Cancer Institute's physical space was commended for its facilities. At the New Brunswick Campus, the primary facility is a 225,000 sq. ft., there is an additional 30,000 sq. ft. facility in the East Tower of the Robert Wood Johnson Hospital for the bone marrow transplant program and hem-malignancies program, 14,000 sq. ft. for the neuro-oncology program on Plum Street, and administrative offices 30,000 sq. ft. on Albany Street; CINJ has now been approved for a new 300,000 sq. ft. facility. At the Newark Campus, CINJ has a 200,000 sq. ft. facility that has both outpatient clinics and research laboratories. CINJ's physical footprint, interventional clinical trial accrual, cancer relevant collaborative publications, number of multi-PI NIH awards, cancer research funding, and NCI funding have all increased.

**Comments/Recommendations:**

- The relationship with Princeton has evolved in a very positive way and there needs to be more discussion about how more collaborations in a variety of areas can be facilitated. The research output of Rutgers and Princeton together is over \$1 billion.
- Dr. David Kimball should be involved in all Novartis meetings going forward.
- There should be more focus on the joint MD/PhD program between Rutgers and Princeton.
- The marketing of Rutgers University has been insufficient for a very long time and there needs to be a coordinated effort in order to make sure it happens.
- The Universities need to talk about the joint effort with Princeton, the positives of CINJ, and what can be done in a pipeline for physicians in the State.
- Drs. Kang and Rabinowitz along with other faculty at CINJ have been the core that keeps the consortium relationship strong and very much valued at Princeton University.
- Princeton and Rutgers are both on the right track but better marketing needs to become a main focus.

- Due to the Barnabas partnership there are now more opportunities to retain doctors in the MD/PhD program instead of sending them out to other hospitals. This should definitely be highlighted and used in marketing the program.
- Marketing has increased following the Master Affiliation Agreement with RWJBarnabas.
- This Fall a much larger campaign will be presented and implemented.

### **Overview of Clinical Research and Clinical Trials Infrastructure – Howard S. Hochster, MD**

Dr. Hochster gave an overview of the Clinical Research Program and the relationship across the RWJBarnabas Health System. The mission of Clinical Research is to conduct the latest state-of-the-art trials based on the Cancer Center's science and translation; to train new generations of clinical investigators; and to deliver state-of-the-art trials to the people of New Jersey. The Clinical Research Leadership Team includes the Associate Director for Clinical Research, Howard Hochster, MD; Associate Director for Translational Research, Shridar Ganesan, MD; Phase 1 Director, Janice Mehnert, MD; OHRS Director, Tracie Saunders, RN, MS; Scientific Review Board, Joseph Aisner, MD and Rajat Bannerji, MD; Human Research Oversight Committee, Dirk Moore, PhD and Anne Silk, MD; and Disease Specific Group Leaders.

The Clinical Research leadership agenda is to provide infrastructure for a unified and broad clinical research operation while facilitating the development and implementation of translational research through investigator-initiated trials. Leadership continues to organize and support CINJ science-based trials and organizes inter-programmatic meetings. The leadership agenda extends to the development of mechanisms for seed/pilot support, the facilitation of inter- and intra-programmatic collaborations, and mentoring.

Working groups such as Phase 1, Precision Medicine, and Immunotherapy support Clinical Translational Research. The Clinical Research network has many opportunities to expand its research through the program's collaborative relationship with many other hospitals within the State. A new organizational structure based on the memorandum of understanding between Rutgers Biomedical Health Sciences and RWJBarnabas Health has led to a new oncology service line, clinical trial leadership, consolidation of research services, a partner physician research working group, and LAPS submission.

Clinical Trial Operations' flow of review begins with concept development and approval. Protocols are then submitted to the Scientific Review Board/Protocol Review and Monitoring System for review, then passed on to the IRB. The IRB accepts applications for cancer studies only after the Scientific Review Board has reviewed and approved them. An IRB representative attends the Scientific Review Board and HROC meetings ad-hoc. The Scientific Review Board meets twice monthly and there is a primary and secondary reviewer. During the review process, there is a statistical review, an exempt process and an administrative approval of all NCTN, ETC, and externally reviewed trials. The possible outcomes of the Scientific Review Board's review include approved, approved with conditions, deferred, or disapproved. Any amendments that vary from the protocol must first be reviewed by the Scientific Review Board and usually go into administrative review by the co-chairs. The Protocol Review and Monitoring System review activities show that the majority of the trials submitted within the past few years have been predominately investigator initiated or national trials, with industry trials representing a small percentage. Reviews are taken seriously with a percentage of the trials being either conditionally approved or outright disapproved. Protocols are being opened within three to six months, which is close to the industry's standard time frame.

Reviews by the Scientific Review Committee, and all the other operational aspects are all central

functions that can be performed at CINJ/RWJBarnabas New Brunswick, even if the trials are being conducted elsewhere. The goal is to do most of the back-office infrastructure at the Cancer Institute and have the patients receive care at the other RWJBarnabas offices. OnCore is used for protocol lifecycle management and is able to track all aspects of the protocol lifecycle. Every subject of a clinical trial is enrolled into the system in order to track the number of patients and every aspect of the patient's treatment. OnCore also allows research billing to be done versus standard billing. Within a year, the entire oncology service line will be able to track all of the clinical trial enrollment at all RWJBarnabas sites. There has been a significant increase in clinical trial accruals over the past few years.

Going forward, the Clinical Research Program will continue to develop a community based clinical trial network; hire new research personnel and faculty; and open new trials at both campuses. The goal of the Clinical Research Program is to develop the program's own science; expand through the RWJBarnabas System; develop research tools and structure for clinical trials; expand staff centrally and in network; and develop new types of training, retention, and oversight methods to insure high quality research will continue to be done.

***Comments/Recommendations:***

- In terms of 50% accruals, is that the right kind of ratio to have?
- Collaborations with Novartis and BMS have been mentioned but what about J&J and Merck?
- Is there a research pharmacy with the capabilities to perform new compound drug formulations?
- Pharma is very interested in funding training programs, so that they can bring in physicians to train who ultimately might become investigators and research leaders.
- It is the right time to start developing some fairly exciting training programs and research programs.
- With the new building coming on board, is the new space going to be mixed usage?

**Meeting Adjourned at 7:52pm.**

Respectfully submitted by,  
Jazmun Dotts  
Secretary for the meeting