



2013 Research Annual Report

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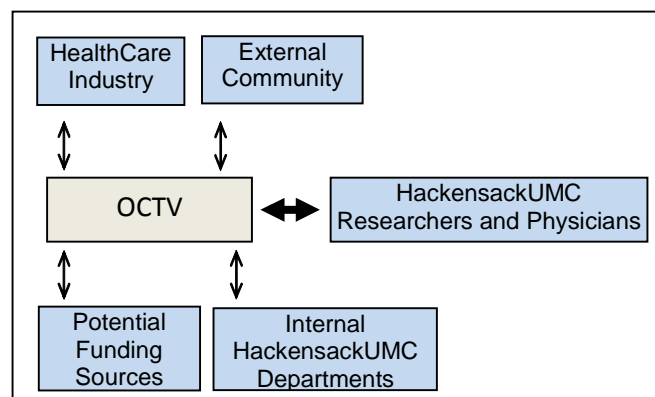
INTRODUCTION

Innovation is often regarded as a core competency of high performance enterprises. In the medical field especially, the presence of an innovative culture that supports the translation of new technology can be viewed as a competitive advantage. The value proposition is compelling. In the face of increasing competition in the healthcare marketplace, consumers of healthcare and related services will seek out providers where innovation thrives. These consumers recognize that research innovation is central to improving overall healthcare care through the introduction of new life-saving therapies and medical devices.

To maintain its regional leadership in providing high quality, state-of the-art healthcare, HackensackUMC has identified the transfer of research innovation into clinical practice as a strategic priority. The strategy includes a goal aimed at enhancing technology transfer endeavors. Towards this goal, the Office of Commercialization and Technology Ventures (OCTV) was formed in February of 2013 to provide leadership in the management of intellectual property and technology commercialization of HackensackUMC research innovation.

Operating as a component of the Department of Research, the OCTV aims to promote a culture where innovation flourishes while focused on professionalizing the technology transfer activity. OCTV is committed to establishing a high performance resource of intellectual property and business development expertise in support of the HackensackUMC research community.

OCTV intends to establish an “**Innovation Ecosystem**”. As illustrated in the figure to the right, this innovation ecosystem may be envisioned as a concentration of participants that include 1) investors and other potential funding sources, 2) internal HackensackUMC departments; 3) the external community including local and regional business leaders together with academic institutions and 4) the healthcare industry which serves as an important



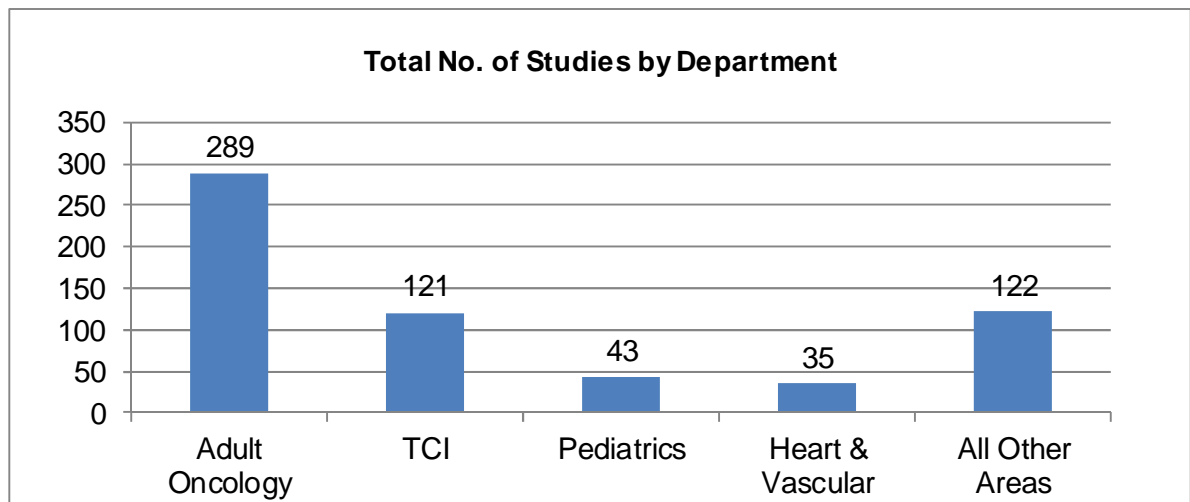
partner for commercialization. These participants collaboratively interact with OCTV to create a network to support the flow of innovation. Paramount to the success of the innovation ecosystem is establishing strong and productive relationships with HackensackUMC researchers and physicians that are based on trust, credibility and a shared sense of teamwork in pursuit of a common goal.

The following 2013 summary of HackensackUMC research activity illustrates what can be achieved from the implementation of an innovative ecosystem where new ideas and collaboration come together to generate potential advances in healthcare as well as accrue benefits to HackensackUMC and its innovators.

DATA and RESEARCH ACTIVITIES

1. Clinical Research Activity by Area/Department

Clinical research studies include chart reviews, industry sponsored clinical trials, registries, investigator initiated studies, cooperative group, and sample collection studies. The chart below shows the distribution of where these studies originate.

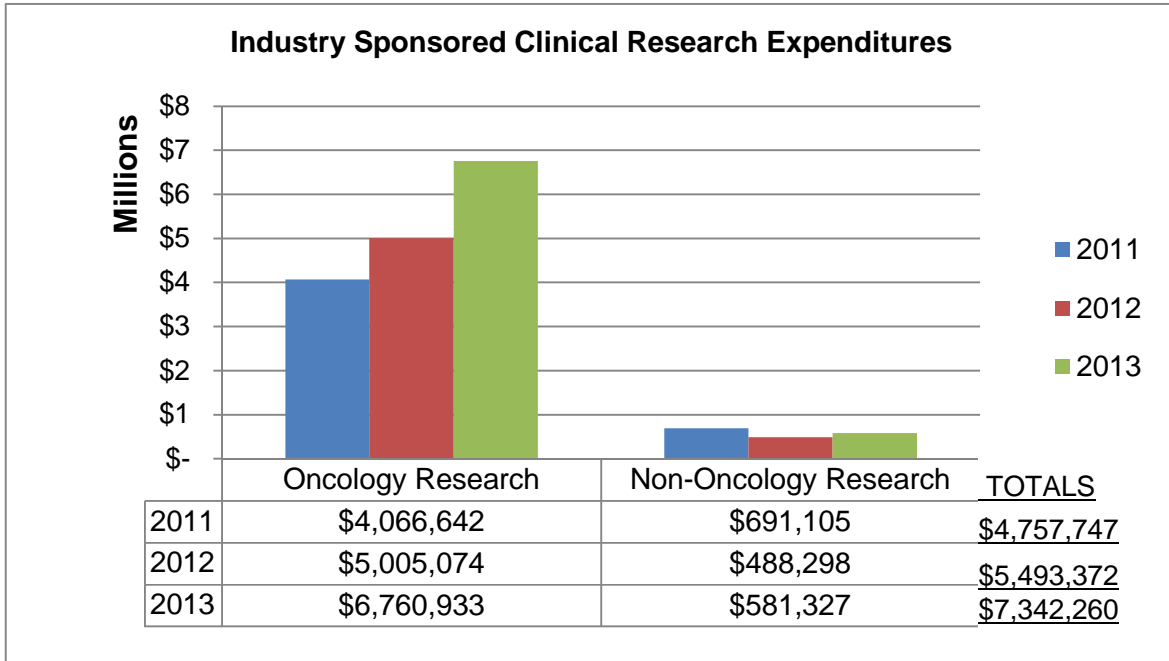


- At the close of 2013, there were a total of 610 active/open research studies at HackensackUMC involving over 355 HackensackUMC research investigators including, scientists, post-docs, principal investigators, sub-investigators, and co-investigators.
- The majority of research studies occurred in the adult oncology area.
- The table below shows the type of Institutional Review Board used for these research studies.

<u>Review Type</u>	<u>Exempt</u>	<u>Expedited</u>	<u>Facilitated</u>	<u>Full IRB Review</u>	<u>Western IRB</u>	<u>Total</u>
No. of Studies	34	124	81	158	213	610

2. Industry Sponsored Clinical Research Expenditures

Expenditures recorded against funds received from industry sponsorship provide a measure of clinical research activity. Over the last three (3) years, HackensackUMC has shown steady increases in clinical research funded by industry.



As shown in the chart above, total industry sponsored clinical research has grown approximately 54% over the past three (3) years primarily due to significant increases in oncology clinical research. Industry sponsorship of non-oncology clinical research reversed its downward trend and increased in 2013 by 19% as compared to the prior year. These data suggests the upward trend of HackensackUMC's attractiveness as site for clinical trials, particularly for the testing of new cancer therapies.

3. Current Research Grant Portfolio

Active HackensackUMC Research grants are illustrated in the table below for the 2013 fiscal year. Active studies reflect both clinical and preclinical research investigations, the vast majority of which are supported by federal funding.

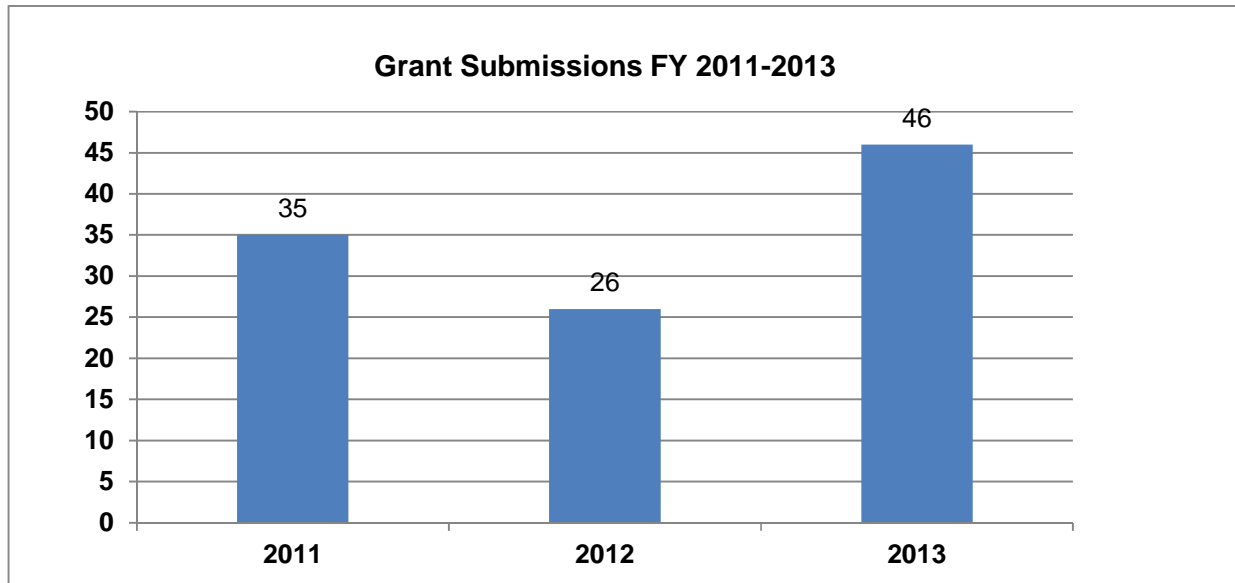
HackensackUMC Active Grants for FY 2013					
PI Name	Department	Grant Title	Funding Source	Grant Type	Amt. Awarded for 2013
Robert Korngold	Cancer Center	T cell repertoire of GVHD and GVTE	NIH/NCI	Basic	\$349,772
Mu Liancai	Research	Anatomical Specializations of Pharynx	NIH/NIDCD	Basic	\$319,454
Daniel Sepkovic	Research	Efficacy of preventive vaccines in an HPV	NIH/NCI	Basic	\$315,742
Sujatha Iyengar	Research	Does HIV Enter Doomed Cell (NCE)	NIH/NIAID	Basic	\$24,844
Sujatha Iyengar	Research	Rock Inhibitor suppression of GVHD	NIH/NIAID	Basic	\$209,442
Stacy Zamudio	OB/GYN	Evolved Placental Response to Hypoxa (NCE)	NIH/NICHHD	Basic	\$243,275
Nick Illsley	OB/GYN	A murine model for placental metabolic	NIH/NICHHD	Basic	\$88,105
Gabriele DiLuozzo	Surgery	Cerebral Function After Hypothermic	NIH/NHLBI	Basic	\$40,663
Jenny Zilberberg	Research	Microfluidic 3D Culture of Osteocytes	NIH_STEVENS	Basic	\$22,893
Herman Morchel	ETD	Development and Evaluation telesonography	DOD_Cipher	Clinical	\$335,100
Joseph Feldman	ETD	Traumatic Brain Injury	DOD_Cipher	Clinical	\$316,256
Joseph Feldman	ETD	Hyperspectral Imaging Technology to evaluate burn wounds	DOD_Cipher	Basic	\$141,312
Liancai Mu	Research	Is Dysphagia in Parkinson's Disease	Michael J. Fox	Basic	\$108,739
Caroline Hu	Pediatrics	Approach to gene discovery in rhabdomyosarcoma	Hyundai Found	Basic	\$125,000
Yukiko Kimura	Pediatrics	Implementing CARRA standardized treatment plans for JIA	Arthritis Found	Clinical	\$100,000
Suzanne Li	Pediatrics	Developing tools for localized scleroderma comparative	Arthritis Found	Clinical	\$100,000
Yukiko Kimura	Pediatrics	Development of Standardized consensus treatment plans	ACR Foundation	Clinical	\$100,000
David Siegel	Cancer Center	Ancillary Tissue Study (Collection of Hematologic Disorders Blood and Bone)	Multiple Myeloma RC	Clinical	\$80,000
Korngold & Zilberberg	Cancer Center	Effect of ONX 0914 and PR-825 on Graft-vs-Host Responses	Onyx Pharma	Basic	\$137,346
Jenny Zilberberg	Cancer Center	Maintaining Human Multiple Myeloma Cells in 3D	HUMC & SIT	Basic	\$161,750
Yong Zhao	Research	Development of novel stem cell educator therapy to treat diabetes	HackensackUMC Foundation	Translational	\$243,400
Rena Feinman	Cancer Center	Multiple Myeloma Research	HackensackUMC Foundation	Basic	\$125,000
Total Awarded Amount for Current Budget Period					\$3,688,093

4. Research Grant Submissions for FY 2012-2013

The table below summarizes grant submission from HackensackUMC academic departments and reflects both clinical and basic research endeavors. In most cases, the submissions are potential multiyear grants.

YTD 2012 Submission by Department			YTD 2013 Submission by Department		
DEPARTMENT	No. of Grant Submissions	Annualized Funding	DEPARTMENT	No. of Grant Submissions	Annualized Funding
Research	8	\$1,965,197	Research	16	\$6,962,609
Pediatrics	7	\$1,031,210	Cancer Center	15	\$1,710,405
Cancer Center	8	\$819,835	Emergency Dept.	1	\$823,917
OB/GYN	1	\$88,050	Pediatrics	11	\$295,247
Cardiology	1	\$69,202	Trauma Dept.	1	\$200,000
Surgery	1	\$44,340	Surgery	2	\$240,663
TOTAL SUBMISSIONS	26	\$4,017,834	TOTAL SUBMISSIONS	46	\$10,233,841

- The three (3) year trend of grant submission at Hackensack activity is illustrated in the chart below. Compared to FY 2012, submission activity by HackensackUMC Researchers and Physicians increased nearly 77% in FY 2013, i.e., 46 grants in 2013 compared to 26 grants submitted in fiscal year 2012.



- The increase in grant submission reflects not only increases in research activity, but may also be viewed as hedge against the current difficult funding environment particularly from federal sources.

5. National Institutes of Health Independent Hospital Rankings

The National Institutes of Health compiles a list of grants awarded to independent hospitals located within the United States and ranks the recipients according to the total amount received where No. 1 represents the greatest award dollars received. The table below compares NIH awards to the three (3) top independent hospitals in New Jersey for FY 2013.

FY 2013 New Jersey Independent Hospital Rankings		
Institution	Total Amount Awarded	National Rank
HackensackUMC	\$783,106	42
Cooper University Hospital	\$625,238	49
St Barnabas Medical Center	\$190,653	65

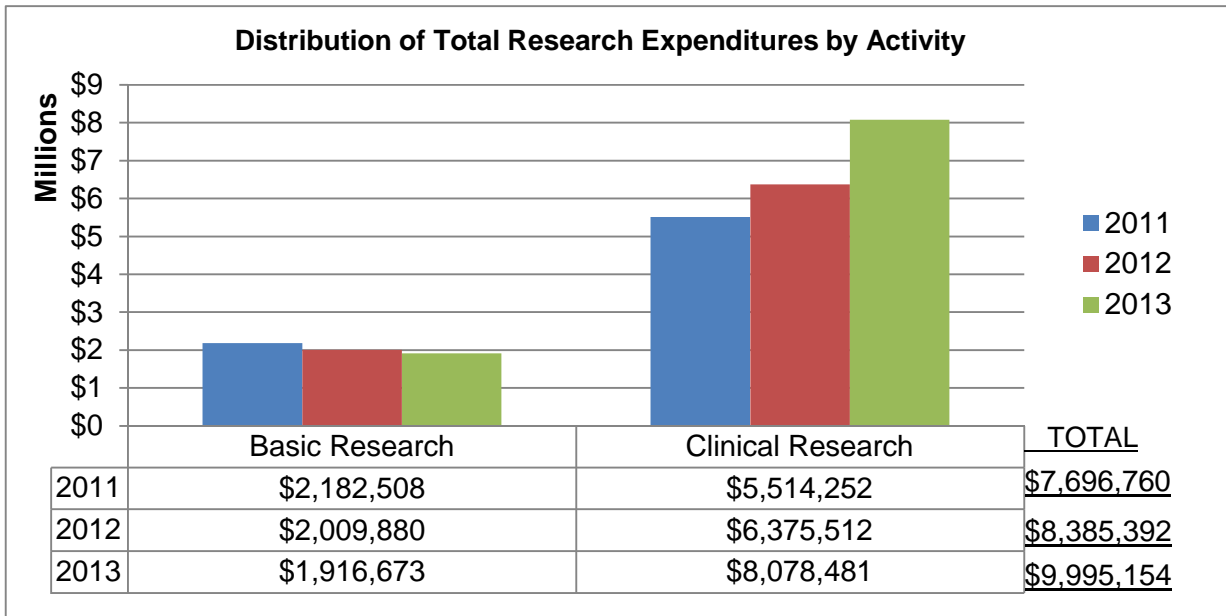
- In FY 2013 HackensackUMC is the top independent hospital recipient of NIH research awards in New Jersey.

FY 2011-2013 US Independent Hospital Ranking for HackensackUMC			
	2011	2012	2013
Amount Awarded	\$2,285,395	\$1,615,057	\$783,106
Total Number No. of Independent Hospitals Reporting	91	91	71
HackensackUMC Ranking	39	46	42

- As the table above shows, in FY 2013 HackensackUMC increased its ranking to 42 out of 71 independent hospitals in terms of the amount of NIH funding received. While this reflects a modest improvement in ranking from the prior year, the chart shows a downward trend in research awards from the NIH which mimics the decrease in federal funding of research nationally.
- Although research funding from NIH is likely to remain problematic for the foreseeable future, the goal of the Department of Research going forward will be to increase federally funded research grants and to rank within the top 25 Independent Hospitals that receive NIH funding.

6. Distribution of Total Research Expenditures by Type of Research Activity

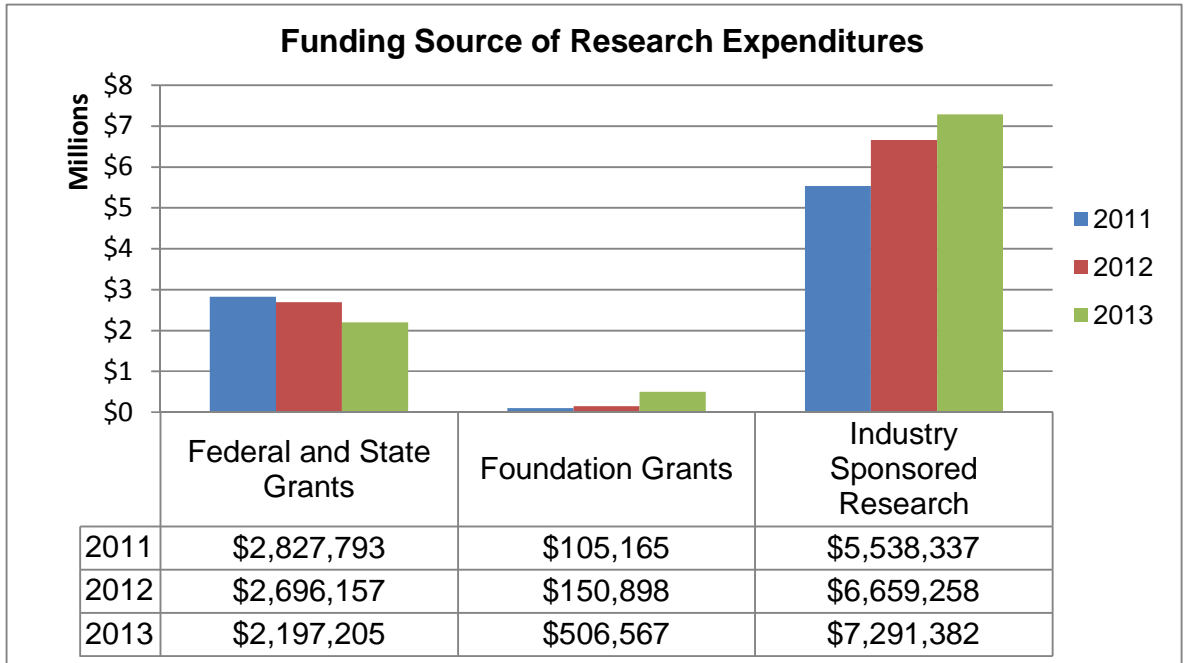
HackensackUMC's research portfolio includes both basic and clinical research activity with support from all major funding sources, including federal (NIH, DOD, CDC), state grants, non-profit and disease focused foundations as well as industry. The following chart illustrates the distribution of funding in support of basic and clinical research activities.



- Over all, total research expenditures related to all research activities have grown significantly in the past three (3) year period. This increase has been due to increases in expenditures related to clinical research.
- The data indicates that investments in oncology research have strengthened HackensackUMC's attractiveness as a site for cancer related clinical research.

7. Total Research Expenditures by Funding Source

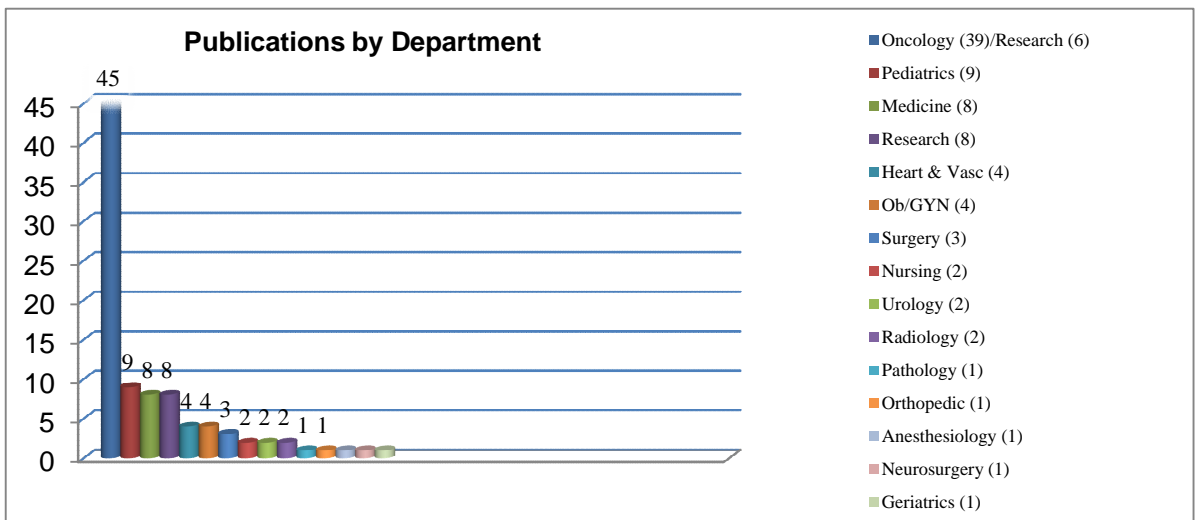
The chart below compares total research expenditures from clinical and basic research activities supported by the three major sources of funding over the past three (3) year period. The funding sources include Federal and state grants (including pass-through subcontracts), non-profit and disease focused Foundation grants (including pass-through subcontracts), and Industry.



- As expected, expenditures from industry funded research activities were overwhelmingly the highest among the reported research funding sources.

8. Publications by Academic Department for FY 2013

Publication output is an important characteristic of an innovative culture and signifies the flow of ideas as potential collaborative opportunities. Over the past year, HackensackUMC scientists and physicians were quite prolific in publishing their research in the scientific literature. As shown by the chart below, there were 92 articles published in peer reviewed journals by the HackensackUMC research community in 2013. The majority of these publications focused on Oncology.



9. List of Research Publications for FY 2013

1. **Subepithelial corneal immunoglobulin deposition as a manifestation of multiple myeloma: a case report and literature review.** Wang TP, Safran SG, Richter JR, Siegel DS, Vesole DH. Clin Lymphoma Myeloma Leuk. **2013** Oct 1. [Epub ahead of print]
2. **Phase Ib study of panobinostat and bortezomib in relapsed or relapsed and refractory multiple myeloma.** San-Miguel JF, Richardson PG, Günther A, Sezer O, Siegel D, Bladé J, LeBlanc R, Sutherland H, Sopala M, Mishra KK, Mu S, Bourquelot PM, Victoria Mateos M, Anderson KC. J Clin Oncol. **2013** Oct 10;31(29):3696-703.
3. **From clinical trials to clinical practice: single-agent carfilzomib adverse events and their management in patients with relapsed and/or refractory multiple myeloma.** Siegel DS. Ther Adv Hematol. **2013** Dec;4(6):354-365.
4. **Association between molecular monitoring and long-term outcomes in chronic myelogenous leukemia patients treated with first line imatinib.** Goldberg SL, Chen L, Guerin A, Macalalad AR, Liu N, Kaminsky M, Ericson SG, Wu EQ. Curr Med Res Opin. **2013** Sep;29(9):1075-82.
5. **Correlations between cytogenetic and molecular monitoring among patients with newly diagnosed chronic myeloid leukemia in chronic phase: post hoc analyses of the rationale and insight for gleevec high-dose therapy study.** Akard LP, Cortes JE, Albitar M, Goldberg SL, Warsi G, Wetzler M, Ericson SG, Radich JP. Arch Pathol Lab Med. **2013** Dec 5. [Epub ahead of print].
6. **The palatability and tolerability of deferasirox taken with different beverages or foods.** Goldberg SL, Giardina PJ, Chirnomas D, Esposito J, Paley C, Vichinsky E. Pediatr Blood Cancer. **2013** Sep;60(9):1507-12.
7. **Historical perspective on the progress of chemotherapy-induced nausea and vomiting treatment in oncology nursing forum.** Flaherty AM. Oncol Nurs Forum. **2013** May 1;40(3):205-7.
8. **Safe handling of chemotherapeutic agents in the treatment of nonmalignant diseases.** Menonna-Quinn D. J Infus Nurs. **2013** May-Jun;36(3):198-204.
9. **Carfilzomib: a next-generation proteasome inhibitor for multiple myeloma treatment.** Bilotti E. Clin J Oncol Nurs. **2013** Apr;17(2):E35-44.
10. **Single-agent lenalidomide in patients with mantle-cell lymphoma who relapsed or progressed after or were refractory to bortezomib: phase II MCL-001 (EMERGE) study.** Goy A, Sinha R, Williams ME, Kalayoglu Besisik S, Drach J, Ramchandren R, Zhang L, Cicero S, Fu T, Witzig TE. J Clin Oncol. **2013** Oct 10;31(29):3688-95.

11. **Update in the management of mantle cell lymphoma.** Goy A. Clin Adv Hematol Oncol. **2013** May;11(5):297-9.
12. **Osteomyelitis of the patella caused by Legionella anisa.** Sanchez MC, Sebti R, Hassoun P, Mannion C, Goy AH, Feldman T, Mato A, Hong T. J Clin Microbiol. **2013** Aug;51(8):2791-3.
13. **Rituximab, cyclophosphamide-fractionated, vincristine, doxorubicin and dexamethasone alternating with rituximab, methotrexate and cytarabine overcomes risk features associated with inferior outcomes in treatment of newly diagnosed, high-risk diffuse large B-cell lymphoma.** Mato A, Feldman T, Zielonka T, Singavi A, Gadaletta G, Waksmundzki K, Bhattacharyya P, Chow KF, Yang X, Panush D, Agress H, Rosario M, Howlett C, Pecora A, Goy A. Leuk Lymphoma. **2013** Dec;54(12):2606-12.
14. **Genomic imbalance defines three prognostic groups for risk stratification of patients with chronic lymphocytic leukemia.** Houldsworth J, Guttapalli A, Thodima V, Yan XJ, Mendiratta G, Zielonka T, Nanjangud G, Chen W, Patil S, Mato A, Brown JR, Rai K, Chiorazzi N, Chaganti RS. Leuk Lymphoma. **2013** Nov 12. [Epub ahead of print].
15. **Donor-derived CD19-targeted T cells cause regression of malignancy persisting after allogeneic hematopoietic stem cell transplantation.** Kochenderfer JN, Dudley ME, Carpenter RO, Kassim SH, Rose JJ, Telford WG, Hakim FT, Halverson DC, Fowler DH, Hardy NM, Mato AR, Hickstein DD, Gea-Banacloche JC, Pavletic SZ, Sportes C, Maric I, Feldman SA, Hansen BG, Wilder JS, Blacklock-Schuver B, Jena B, Bishop MR, Gress RE, Rosenberg SA. Blood. **2013** Dec 12;122(25):4129-39.
16. **Combined lenalidomide, low-dose dexamethasone, and rituximab achieves durable responses in rituximab-resistant indolent and mantle cell lymphomas.** Ahmadi T, Chong EA, Gordon A, Aquí NA, Nasta SD, Svoboda J, Mato AR, Schuster SJ. Cancer. **2013** Oct 7. [Epub ahead of print].
17. **Long term results of a phase 2 study of vincristine sulfate liposome injection (Marqibo®) substituted for non-liposomal vincristine in cyclophosphamide, doxorubicin, vincristine, prednisone with or without rituximab for patients with untreated aggressive non-Hodgkin lymphomas.** Hagemester F, Rodriguez MA, Deitcher SR, Younes A, Fayad L, Goy A, Dang NH, Forman A, McLaughlin P, Medeiros LJ, Pro B, Romaguera J, Samaniego F, Silverman JA, Sarris A, Cabanillas F. Br J Haematol. **2013** Sep;162(5):631-8.
18. **Targeting BTK with ibrutinib in relapsed or refractory mantle-cell lymphoma.** Wang ML, Rule S, Martin P, Goy A, Auer R, Kahl BS, Jurczak W, Advani RH, Romaguera JE, Williams ME, Barrientos JC, Chmielowska E, Radford J, Stilgenbauer S, Dreyling M, Jedrzejczak WW, Johnson P, Spurgeon SE, Li L, Zhang L, Newberry K, Ou Z, Cheng N, Fang B, McGreivy J, Clow F, Buggy JJ, Chang BY, Beaupre DM, Kunkel LA, Blum KA. N Engl J Med. **2013** Aug 8;369(6):507-16.

19. **CYP3A-mediated drug-drug interaction potential and excretion of brentuximab vedotin, an antibody-drug conjugate, in patients with CD30-positive hematologic malignancies.** Han TH, Gopal AK, Ramchandren R, Goy A, Chen R, Matous JV, Cooper M, Grove LE, Alley SC, Lynch CM, O'Connor OA. *J Clin Pharmacol.* **2013** Aug;53(8):866-77.
20. **Phase 2 clinical trial of rapamycin-resistant donor CD4+ Th2/Th1 (T-Rapa) cells after low-intensity allogeneic hematopoietic cell transplantation.** Fowler DH, Mossoba ME, Steinberg SM, Halverson DC, Stroncek D, Khuu HM, Hakim FT, Castiello L, Sabatino M, Leitman SF, Mariotti J, Gea-Banacloche JC, Sportes C, Hardy NM, Hickstein DD, Pavletic SZ, Rowley S, Goy A, Donato M, Korngold R, Pecora A, Levine BL, June CH, Gress RE, Bishop MR. *Blood.* **2013** Apr 11;121(15):2864-74.
21. **Herpes zoster complicating bortezomib therapy of relapsed/refractory indolent B-cell and mantle cell lymphoma: an analysis of two phase II trials.** Solh M, Fisher RI, Goy A, de Vos S, Bernstein SH, Esseltine DL, Neuwirth R, Morrison VA. *Leuk Lymphoma.* **2013** Oct;54(10):2185-9.
22. **A multicenter phase II trial to determine the safety and efficacy of combination therapy with denileukin diftitox and cyclophosphamide, doxorubicin, vincristine and prednisone in untreated peripheral T-cell lymphoma: the CONCEPT study.** Foss FM, Sjak-Shie N, Goy A, Jacobsen E, Advani R, Smith MR, Komrokji R, Pendergrass K, Bolejack V. *Leuk Lymphoma.* **2013** Jul;54(7):1373-9.
23. **Vorinostat or placebo in combination with bortezomib in patients with multiple myeloma (VANTAGE 088): a multicentre, randomised, double-blind study.** Dimopoulos M, Siegel DS, Lonial S, Qi J, Hajek R, Facon T, Rosinol L, Williams C, Blacklock H, Goldschmidt H, Hungria V, Spencer A, Palumbo A, Graef T, Eid JE, Houp J, Sun L, Vuocolo S, Anderson KC. *Lancet Oncol.* **2013** Oct;14(11):1129-40.
24. **Phase 2 dose-expansion study (PX-171-006) of carfilzomib, lenalidomide, and low-dose dexamethasone in relapsed or progressive multiple myeloma.** Wang M, Martin T, Bensinger W, Alsina M, Siegel DS, Kavalchik E, Huang M, Orlowski RZ, Niesvizky R. *Blood.* **2013** Oct 31;122(18):3122-8.
25. **Treatment outcomes in patients with relapsed and refractory multiple myeloma and high-risk cytogenetics receiving single-agent carfilzomib in the PX-171-003-A1 study.** Jakubowiak AJ, Siegel DS, Martin T, Wang M, Vij R, Lonial S, Trudel S, Kukreti V, Bahlis N, Alsina M, Chanan-Khan A, Buadi F, Reu FJ, Somlo G, Zonder J, Song K, Stewart AK, Stadtmauer E, Harrison BL, Wong AF, Orlowski RZ, Jagannath S. *Leukemia.* **2013** May 14.
26. **Preclinical data and early clinical experience supporting the use of histone deacetylase inhibitors in multiple myeloma.** Richardson PG, Mitsiades CS, Laubach JP, Hajek R, Spicka I, Dimopoulos MA, Moreau P, Siegel DS, Jagannath S, Anderson KC. *Leuk Res.* **2013** Jul;37(7):829-37.

27. **Second transplants for multiple myeloma relapsing after a previous autotransplant-reduced-intensity allogeneic vs autologous transplantation.** Freytes CO, Vesole DH, Lerademacher J, Zhong X, Gale RP, Kyle RA, Reece DE, Gibson J, Schouten HC, McCarthy PL, Lonial S, Krishnan AY, Dispenzieri A, Hari PN. *Bone Marrow Transplant.* **2013** Nov 25.
28. **Trends in utilization and outcomes of autologous transplantation as early therapy for multiple myeloma.** Costa LJ, Zhang MJ, Zhong X, Dispenzieri A, Lonial S, Krishnan A, Freytes C, Vesole D, Gale RP, Anderson K, Wirk B, Savani BN, Waller EK, Schouten H, Lazarus H, Meehan K, Sharma M, Kamble R, Vij R, Kumar S, Nishihori T, Kindwall-Keller T, Saber W, Hari PN. *Biol Blood Marrow Transplant.* **2013** Nov;19(11):1615-24.
29. **Intermittent zoledronic Acid prevents bone loss in adults after allogeneic hematopoietic cell transplantation.** Hari P, DeFor TE, Vesole DH, Bredeson CN, Burns LJ. *Biol Blood Marrow Transplant.* **2013** Sep;19(9):1361-7.
30. **Uncovering the biology of multiple myeloma among African Americans: a comprehensive genomics approach.** Baker A, Braggio E, Jacobus S, Jung S, Larson D, Therneau T, Dispenzieri A, Van Wier SA, Ahmann G, Levy J, Perkins L, Kim S, Henderson K, Vesole D, Rajkumar SV, Jelinek DF, Carpten J, Fonseca R. *Blood.* **2013** Apr 18;121(16):3147-52.
31. **Salvage second hematopoietic cell transplantation in myeloma.** Michaelis LC, Saad A, Zhong X, Le-Rademacher J, Freytes CO, Marks DI, Lazarus HM, Bird JM, Holmberg L, Kamble RT, Kumar S, Lill M, Meehan KR, Saber W, Schriber J, Tay J, Vogl DT, Wirk B, Savani BN, Gale RP, Vesole DH, Schiller GJ, Abidi M, Anderson KC, Nishihori T, Kalaycio ME, Vose JM, Moreb JS, Drobyski W, Munker R, Roy V, Ghobadi A, Holland HK, Nath R, To LB, Maiolino A, Kassim AA, Giralt SA, Landau H, Schouten HC, Maziarz RT, Michael J, Kindwall-Keller T, Stiff PJ, Gibson J, Lonial S, Krishnan A, Dispenzieri A, Hari P; Plasma Cell Disorders Working Committee of the Center for International Blood and Marrow Transplant Research. *Biol Blood Marrow Transplant.* **2013** May;19(5):760-6.
32. **Plasma cell leukemia: consensus statement on diagnostic requirements, response criteria and treatment recommendations by the International Myeloma Working Group.** Fernández de Larrea C, Kyle RA, Durie BG, Ludwig H, Usmani S, Vesole DH, Hajek R, San Miguel JF, Sezer O, Sonneveld P, Kumar SK, Mahindra A, Comenzo R, Palumbo A, Mazumber A, Anderson KC, Richardson PG, Badros AZ, Caers J, Cavo M, LeLeu X, Dimopoulos MA, Chim CS, Schots R, Noeul A, Fantl D, Mellqvist UH, Landgren O, Chanan-Khan A, Moreau P, Fonseca R, Merlini G, Lahuerta JJ, Bladé J, Orlowski RZ, Shah JJ; International Myeloma Working Group. *Leukemia.* **2013** Apr;27(4):780-91.
33. **Economic benefits of adequate molecular monitoring in patients with chronic myelogenous leukemia.** Guérin A, Chen L, Dea K, Wu EQ, Goldberg SL. *J Med Econ.* **2013** Nov 5. [Epub ahead of print]

34. **Randomized, dose-escalation study of the p38 α MAPK inhibitor SCIO-469 in patients with myelodysplastic syndrome.** Sokol L, Cripe L, Kantarjian H, Sekeres MA, Parmar S, Greenberg P, Goldberg SL, Bhushan V, Shammo J, Hohl R, Verma A, Garcia-Manero G, Li YP, Lowe A, Zhu J, List AF. *Leukemia*. **2013** Apr;27(4):977-80.
35. **Health-related quality of life of bone marrow versus peripheral blood stem cell donors: a prespecified subgroup analysis from a phase III RCT-BMTCTN protocol 0201.** Switzer GE, Bruce JG, Harrington D, Haagenson M, Drexler R, Foley A, Confer D, Bishop M, Anderlini P, Rowley S, Leitman SF, Anasetti C, Wingard JR. *Biol Blood Marrow Transplant*. **2013** Nov 1. [Epub ahead of print]
36. **CMX001 to prevent cytomegalovirus disease in hematopoietic-cell transplantation.** Marty FM, Winston DJ, Rowley SD, Vance E, Papanicolaou GA, Mullane KM, Brundage TM, Robertson AT, Godkin S, Momméja-Marin H, Boeckh M; CMX001-201 Clinical Study Group. *N Engl J Med*. **2013** Sep 26;369(13):1227-36.
37. **Multicenter study of banked third-party virus-specific T cells to treat severe viral infections after hematopoietic stem cell transplantation.** Leen AM, Bollard CM, Mendizabal AM, Shpall EJ, Szabolcs P, Antin JH, Kapoor N, Pai SY, Rowley SD, Kebriaei P, Dey BR, Grilley BJ, Gee AP, Brenner MK, Rooney CM, Heslop HE. *Blood*. **2013** Jun 27;121(26):5113-23.
38. **Economic survivorship stress is associated with poor health-related quality of life among distressed survivors of hematopoietic stem cell transplantation.** Hamilton JG, Wu LM, Austin JE, Valdimarsdottir H, Basmajian K, Vu A, Rowley SD, Isola L, Redd WH, Rini C. *Psychooncology*. **2013** Apr;22(4):911-21.
39. **Unraveling graft-versus-host disease and graft-versus-leukemia responses using TCR V β spectratype analysis in a murine bone marrow transplantation model.** Fanning SL, Zilberberg J, Stein J, Vazzana K, Berger SA, Korngold R, Friedman TM. *J Immunol*. **2013** Jan 1;190(1):447-57.
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10. Innovation Transfer Activity:

The primary goal of the Office of Commercialization and Technology Ventures (OCTV) in its first year of operation has been to provide leadership in the area of technology transfer in support of the HackensackUMC research community. Towards this goal, OCTV has endeavored to develop the concept of an “innovation ecosystem” as described in the Introduction section of this report. This effort, consistent with the strategic priorities of the

medical center, is intended to promote a culture that supports collaboration and the flow of technology into clinical practice. In the past year, OCTV has pursued the following objectives:

a) **Professionalized Technology Transfer Operations.** OCTV has focused a significant effort on implementing technology transfer best practices, refining existing policies and procedures and mentoring of staff to ensure the productive and efficient management of innovation. Notable accomplishments in 2013 included:

- Initiated the design and build of a intellectual property and technology transfer database.
- Reviewed and refined the HackensackUMC IP policy
- Participated for the first time in the AUTM technology transfer national survey.
- Established technology transfer agreement templates including, invention disclosure form, material transfer agreements, research collaboration and confidentiality agreements.

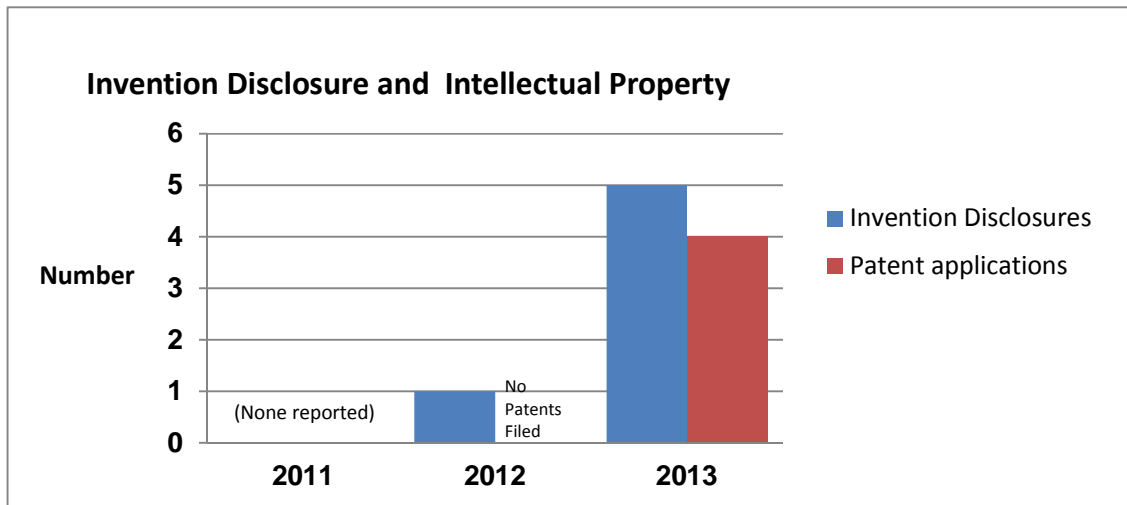
b) **Enhanced awareness of OCTV to internal/external communities.** Relative to other national academic centers, formalized technology transfer is a relatively new activity at HackensackUMC. OCTV has endeavored to promote the awareness of the office to HackensackUMC faculty and staff as well as to external academic/commercial communities. Notable 2013 accomplishments included :

- Multiple presentations at HackensackUMC clinical and administrative leadership meetings.
- Invited speaker at the Internal Medicine Grand Rounds. Presentation entitled "*The Transfer of Academic Innovation: Is it still relevant in Today's Healthcare Environment?*"
- Participated in meetings of the NJ/NYC academic technology transfer offices. HackensackUMC will host of a meeting of the regional technology transfer offices in Q2 of 2014.
- Featured in an article in the NJ Business Journal.
- Featured in an article in Becker Hospital Review.
- Established OCTV as the "go to" resource for expertise in matters related to the research administration, technology transfer, industry collaborations and IP related transactions.

c) **Development of HackensackUMC owned intellectual property** Key to the efficient flow of innovation is the establishment of a productive working relationship with faculty

and staff. Over the past year, departments across HackensackUMC have accessed OCTV for guidance with respect to IP and commercialization matters. These interactions encourage invention disclosure and promote collaboration. Notable 2013 accomplishments included:

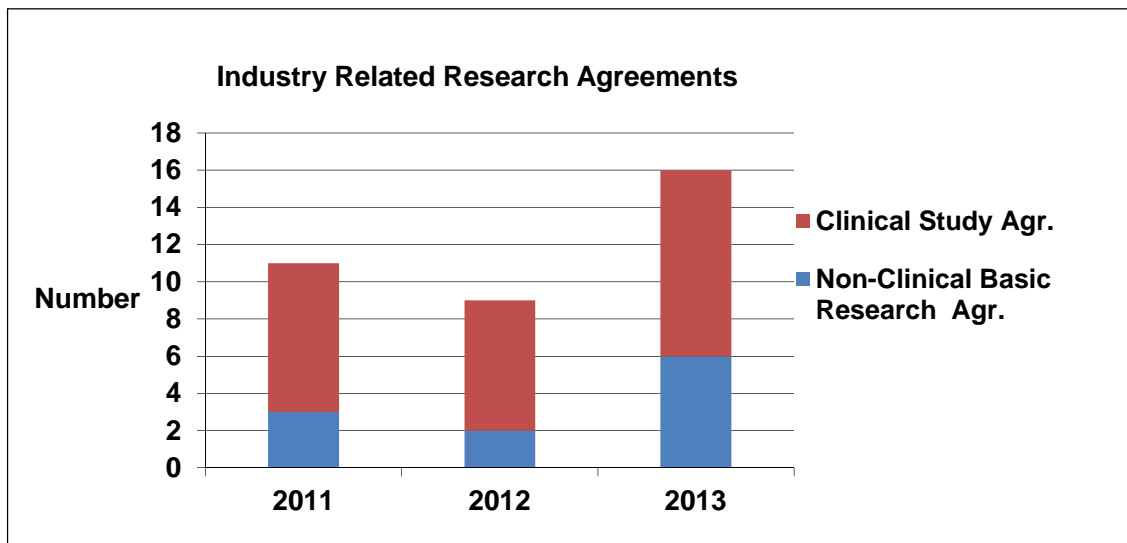
- Activity of invention disclosure and patent filing has significantly increased over prior years as shown in the figure below.



- To date, five (5) invention disclosures from faculty have been received and evaluated by OCTV in conjunction with external patent counsel. From these, four (4) inventions have been found to be worthy of filing patent applications.
- The growing portfolio of HackensackUMC owned intellectual property provides the basis for future licensing opportunities.

d) Cultivated opportunities to collaborate with industry and other external parties. In 2013, OCTV played a leadership role in cultivating important collaborations on behalf of HackensackUMC faculty and staff including the partnerships with the Stevens Institute and Georgetown University. Notable 2013 accomplishments included:

- Significantly increased the number of industry related research collaboration agreements compared to the prior two (2) years. As shown in the following figure, a total of sixteen (16) research agreements have been executed in 2013, nearly a 78% increase over 2012. Six (6) of these agreements were related to non-clinical research reflecting an increase in basic research studies as compared to prior years.



- Provided assisted to the HackensackUMC Emergency and Trauma Department and scientists at Stevens Institute in preparing a jointly submitted \$1.5M grant to the DoD focused on the use of Hyperspectral Imaging to assess Burn Severity.
- Provided assistance to HackensackUMC physicians within the Trauma Surgery department and scientists from the Stevens Institute in negotiating a clinical trial collaboration agreement with Harman International that focused on the impact of sound in the clinical environment.
- Negotiated a Patent & Intellectual Property Agreement with the Leukemia & Lymphoma Society on behalf of HackensackUMC investigators.
- Negotiated a Interinstitutional Invention Administration Agreement with the Stevens Institute in connection with a jointly held patent application.
- Negotiated a Patent & Intellectual Property Agreement in connection with a jointly submitted grant to the DoD by HackensackUMC Department of Research and Georgetown University investigators.
- Negotiated a Material Transfer Agreement as an amendment to the HackensackUMC/Georgetown University Affiliation Agreement to provide easy transfer of research material between the two institutions.
- Negotiated a funding agreement with the Stevens Institute in connection with a joint research project between the parties.
- Negotiated a Letter of Understanding with Meadowlands Commission on behalf of the Deirdre Imus Environmental Health Center.

- Assisted the HackensackUMC Tissue Repository in amending its SOP.

FINAL THOUGHTS

Budgets cuts and the general slowing of federal spending on research, especially from the National Institutes of Health have impacted research programs at academic centers across the country. So too at HackensackUMC, 2013 has been a challenging year for the funding of basic research activities. That said, sponsored clinical research at HackensackUMC, especially in oncology, showed robust growth in 2013 while its researchers demonstrated a strong record of publication in the medical and scientific literature. These achievements reflect the continued strength of HackensackUMC as a regional leader in providing innovative medical care. Going forward, we believe the formation of OCTV, as a provider of technology transfer and business development efforts, will strengthen the research program by encouraging collaboration and enhancing the flow of innovation. The entire team in the Department of Research looks forward to working with HackensackUMC physicians and scientists in implementing a culture where *Medicine Meets Innovation*.