

BIOGRAPHICAL SKETCH

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NAME: Steven Kenneth Libutti, MD

eRA COMMONS USERNAME (credential, e.g., agency login): LIBUTTI

POSITION TITLE: Director

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Harvard College, Harvard University, Cambridge, MA	AB	06/1986	Biology
College of Physicians & Surgeons, Columbia University, New York, NY	MD	05/1990	Medicine
Residency, Presbyterian Hospital, New York, NY		06/1995	Surgery
Fellowship, Surgery Branch, NCI, Bethesda, MD		06/1996	Surgical Oncology

A. Personal Statement

As the Director of the Rutgers Cancer Institute of New Jersey (CINJ), I am fully committed to lead the expansion of its impact throughout the State of New Jersey and lead the Cancer Institute to national prominence as a model for efficient and effective cancer care as well as transformative cancer research. Over the past 5 years despite the challenges of the COVID pandemic and changes in the healthcare landscape we have made significant progress in achieving the major milestones of our strategic plan. We have launched a new Center of Excellence focused on a key scientific priority at CINJ, the intersection of tumor immunology and metabolism. The Duncan and Nancy MacMillan Center for Cancer Immunology and Metabolism was made possible through a generous \$25M gift. CINJ has also increased cancer focused peer reviewed funding, expanded our COE and PED efforts, and succeeded in competing for new multi-project awards from the NCI. Our education and training initiatives have grown, including investment in a new school in our community. We are extremely excited about the impending opening of our new home, the Jack and Sheryl Morris Cancer Center, a 520,000 sf \$750M facility, which will serve as New Jersey's first free standing cancer hospital. Our partnership with the State of New Jersey continues to thrive with additional investment since our last renewal of \$22M per year bringing our total yearly funding from the State to \$53M. With respect to my own efforts clinically and in the laboratory, I have dedicated my career to the advancement of regional and targeted cancer therapy, and I am a recognized expert in endocrine surgery and in the management of neuroendocrine tumors. My clinical practice focuses on the management of malignancies of the liver, pancreas, and gastrointestinal tract. My research focuses on developing novel cancer therapies through an understanding of the tumor microenvironment. My laboratory has focused on studies of the pathogenesis of neuroendocrine tumors and on the familial cancer syndromes MEN1 and vHL. My group has developed some of the first mouse models of these conditions. I am currently a multi-PI on two NCI R01s, an NIH REACH HUB, the PI of a Neuroendocrine Tumor Research Foundation R01 equivalent and the PI of our NCI CCSG P30. I am the author of over 320 peer reviewed journal articles, hold eleven U.S. patents, and serve as Editor-in-Chief Emeritus of Cancer Gene Therapy. I am the recipient of both NCI and National Institutes of Health Director's Awards, and I currently serve on the NCI Board of Scientific Counselors.

Ongoing and recently completed projects that I would like to highlight include:

1R01CA247562-01A1

Zamboni (Contact PI), Chang (MPI) & Libutti (MPI)

04/01/2021-03/31/2026

Minibeam Radiation Therapy Enhanced Delivery of Nanoparticle Anticancer Agents to Pancreatic Cancer Tumors

5R01CA204516-03

Pasqualini (Contact PI), Libutti (MPI) & Arap (MPI)

03/15/2020-02/28/2025

Designing a transcriptome-based, targeted theranostic platform for prostate cancer

5P30CA072720-23
Libutti (PI)
03/07/2019-02/29/2024
Cancer Center Support Grant (CCSG)

3P30CA072720-21S2
Libutti (PI)
03/01/2020-02/28/2023
Cancer Center Support Grant (CCSG) Supplement-Determine patterns of low HPV vaccine uptake, the role of vaccine hesitancy, VHPs' decision-making, and potential acceptability of messaging, information sources, and information delivery channels to reduce hesitancy.

3P30CA072720-21S4
Libutti (PI)
03/01/2020-02/28/2023
Cancer Center Support Grant (CCSG) Supplement-This supplement will 1) expand and integrate TDP's clinical services throughout CINJ. With the ongoing COVID-19 pandemic, this will also include introducing virtual tobacco treatment groups and telehealth visits; 2) develop a uniform tobacco-use identification system and fully integrated electronic referral system into the EMR; 3) recreate our previously successful patient follow-up program; and 4) extend this successful model to our RWJ Barnabas Health System cancer treatment center network through training efforts.

3P30CA072720-22S2
Libutti (PI)
03/01/2020-02/28/2023
Cancer Center Support Grant (CCSG) Supplement-Develop processes across multiple NCI-supported Cancer Centers and community sites that will facilitate the development of single instances of EHR clinical trial treatment plans that can be deployed at multiple institutions in support of NCI- sponsored network studies.

3P30CA072720-22S3
Libutti (PI)
03/01/2021 – 02/28/2023
Cancer Center Support Grant (CCSG) Supplement-Combine analyses using an orthotopic murine model of breast cancer, in-vitro immune cell analyses and an ongoing clinical trial to identify and validate an Immune Radiation Response Index (i-RRI) with utility in future clinical trials.

3P30CA072720-23S1
Libutti (PI)
03/01/2021-02/29/2024
Cancer Center Support Grant (CCSG) Supplement-Engineered T-Cell Therapy for Human Cancers

Peterson Accelerator Award
Libutti (PI)
01/03/2020–01/02/2024
The role of the B7x pathway in the progression of neuroendocrine tumors

1U01HL150852-01
Panettieri (Contact PI), Libutti (MPI) & Pasqualini (MPI)
09/23/2019-08/31/2023
Rutgers Optimizes Innovation (ROI)

1R01HL141934-04
Lai (Contact PI), Zamboni (MPI) & Libutti (Co-Investigator)
04/01/2021–04/30/2023
Overcoming anti-PEG immunity to restore prolonged circulation and efficacy of PEGylated therapeutics

Citations:

1. Shen HC, He M, Powell A, Adem A, Lorang D, Heller C, Grover AC, Ylaya K, Hewitt SM, Marx SJ, Spiegel AM, **Libutti SK**. Recapitulation of pancreatic neuroendocrine tumors in human multiple endocrine neoplasia type I syndrome via Pdx1-directed inactivation of Men1. *Cancer Res*. 2009 Mar 1;69(5):1858-66. doi: 10.1158/0008-5472.CAN-08-3662. Epub 2009 Feb 10. PubMed Central PMCID: PMC3879686.
2. Quinn TJ, Yuan Z, Adem A, Geha R, Vrikshajanani C, Koba W, Fine E, Hughes DT, Schmid HA, **Libutti SK** (2012). Pasireotide (SOM230) is effective for the treatment of pancreatic neuroendocrine tumors (PNETs) in a multiple endocrine neoplasia type 1 (MEN1) conditional knockout mouse model. *Surgery*. 152(6):1068-77. PMID:23102680 PMCID: PMC3732168.
3. Smith TL, Yuan ZQ, Cardó-Vila M, Claros CS, Adem A, Cui MH, Branch CA, Gelovani JG, **Libutti SK**, Sidman RL, Arap W, Pasqualini R. AAVP displaying octreotide for ligand-directed therapeutic transgene delivery in neuroendocrine tumors of the pancreas. *Proc Natl Acad Sci U S A*. 2016 Mar 1;113(9):2466-71. PMID: 26884209. PMCID: PMC4780640.
4. Yuan Z, Sánchez Claros C, Suzuki M, Maggi EC, Kaner JD, Kinstlinger N, Gorecka J, Quinn TJ, Geha R, Corn A, Pastoriza J, Jing Q, Adem A, Wu H, Alemu G, Du YC, Zheng D, Grealley JM, **Libutti SK**. Loss of MEN1 activates DNMT1 implicating DNA hypermethylation as a driver of MEN1 tumorigenesis. *Oncotarget*. 2016 Mar 15;7(11):12633-50. PubMed PMID: 26871472; PubMed Central PMCID: PMC4914310.

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

- 2017-Present Director, Rutgers Cancer Institute of New Jersey, Rutgers, The State University of New Jersey, New Brunswick, NJ
- 2017-Present Vice Chancellor for Cancer Programs, Rutgers Biomedical and Health Sciences, Rutgers, The State University of New Jersey, New Brunswick, NJ
- 2017-Present Senior Vice President, Oncology Services, RWJBarnabas Health, New Brunswick, NJ
- 2017-Present Professor (Tenured), Department of Surgery, Rutgers Robert Wood Johnson Medical School, Rutgers, The State University of New Jersey, New Brunswick, NJ
- 2017-Present Affiliated Distinguished Professor in Genetics, School of Arts and Sciences Department of Genetics, Rutgers, The State University of New Jersey, New Brunswick, NJ
- 2009-2017 *The Marvin L. Gliedman, M.D. Distinguished Surgeon*
- 2009-2017 Professor (Tenured) and Vice-Chairman, Department of Surgery, Professor, Department of Genetics, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY
- 2009-2017 Director, Montefiore-Einstein Center for Cancer Care, Associate Director for Clinical Services, Albert Einstein Cancer Center, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY
- 2006-2009 Senior Investigator (Tenured), Section Chief, Tumor Angiogenesis Section, Surgery Branch, National Cancer Institute, Bethesda, MD
- 2001-2006 Investigator (Tenure Track), Surgery Branch, National Cancer Institute, Bethesda, MD
- 2000-2001 Staff Physician, Surgery Branch, National Cancer Institute, Bethesda, MD
- 1996-Present Professor of Surgery, USUHS, F. Edward Hebert Sch of Med, Bethesda, MD
- 1999-2000 Senior Clinical Investigator, Surgery Branch, NCI, Bethesda, MD
- 1996-1999 Clinical Investigator, Surgery Branch, NCI, Bethesda, MD

Other Experience and Professional Memberships

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| Association of American Physicians | Society of University Surgeons |
| NCI Board of Scientific Counselors | American Association for Cancer Research |
| American Surgical Association | American Society of Clinical Oncology |
| Fellow of the Society of Surgical Oncology | American Joint Committee on Cancer |
| Fellow of the American College of Surgeons | Institutional Review Board, National Cancer Institute, Chairman |
| American Association of Endocrine Surgeons, | |
| President 2015-2016 | |

Honors

- 2022 New Jersey Health Foundation Excellence in Research Award
- 2022 Roy A. Bowers Award for Leadership and Contributions to the Advancement of Patient Care
- 2022 NJ Biz Health Care Power 50 (top 10)
- 2021 NJ Biz Healthcare Heroes Healthcare Professional of the Year

2021	Edward J. III Excellence in Medicine Outstanding Healthcare Executive Award
2020	Dr. Randy Siegel Pediatric Cancer Medical Humanitarian of the Year Award
2019	SDHB Pheo-Para Coalition Science Award
2018	Neuroendocrine Cancer Awareness Network Above and Beyond Award
2014	Federal Technology Transfer Award
2007	NCI Director's Intramural Innovation Award
2006	NIH Director's Award
2006	NCI Director's Gold Star Award
2003, 2004	NCI Technology Transfer Award
1995	Blakemore Prize for Outstanding Body of Research by a Graduating Chief Resident
1993	U.S. Congressional Citation for Outstanding Contributions to Medicine

Editorial Boards

Cancer Gene Therapy, Editor-in-Chief Emeritus	Surgery (Society Editor)
Endocrine Related Cancer	Annals of Surgical Oncology (Section Editor)
Journal of Immunotherapy	Journal of Surgical Oncology
Journal of Translational Medicine	

C. Contributions to Science

1. I have had a longstanding interest in studies of the familial cancer syndromes MEN1 and vHL (von Hippel-Lindau). Specifically, I have focused my efforts on an understanding of the pancreatic lesions associated with these diseases especially pancreatic neuroendocrine tumors. My group described the first clinical criteria for the management of these tumors in vHL, we developed some of the first directed imaging approaches and created the first mouse model of the tissue specific deletion of vHL and MEN1 in the pancreas.
 - a. Lonser RR, Glenn GM, Walther M, Chew EY, **Libutti SK**, Linehan WM, Oldfield EH. von Hippel-Lindau disease. *Lancet*. 2003 Jun 14;361(9374):2059-67. Review. PubMed PMID: 12814730.
 - b. Blansfield JA, Choyke L, Morita SY, Choyke PL, Pingpank JF, Alexander HR, Seidel G, Shutack Y, Yuldasheva N, Eugeni M, Bartlett DL, Glenn GM, Middleton L, Linehan WM, **Libutti SK**. Clinical, genetic and radiographic analysis of 108 patients with von Hippel-Lindau disease (VHL) manifested by pancreatic neuroendocrine neoplasms (PNETs). *Surgery*. 2007 Dec;142(6):814-8; discussion 818.e1-2. doi: 10.1016/j.surg.2007.09.012. Erratum in: *Surgery*. 2008 Feb;143(2):302. PMID: 18063061; PMCID: PMC6771023.
 - c. Shen HC, Adem A, Ylaya K, Wilson A, He M, Lorang D, Hewitt SM, Pechhold K, Harlan DM, Lubensky IA, Schmidt LS, Linehan WM, **Libutti SK**. Deciphering von Hippel-Lindau (VHL/Vhl)-associated pancreatic manifestations by inactivating Vhl in specific pancreatic cell populations. *PLoS One*. 2009;4(4):e4897. PubMed PMID: 19340311; PubMed Central PMCID: PMC2660574.
 - d. Keutgen XM, Hammel P, Choyke PL, **Libutti SK**, Jonasch E, Kebebew E. Evaluation and management of pancreatic lesions in patients with von Hippel-Lindau disease. *Nat Rev Clin Oncol*. 2016 Sep;13(9):537-49. doi: 10.1038/nrclinonc.2016.37. Review. PubMed PMID: 27030075.
2. A major limitation to effective cancer therapy is off target toxicity. I have spent a great deal of effort developing strategies and novel therapies that are targeted to tumor tissue in order to avoid dose limiting toxicity. Efforts have been directed at the tissue specific delivery of anticancer cytokines using targeted gene therapy and targeted nanomedicines. In addition to developing these strategies in the laboratory, my group performed some of the first clinical trials of cancer-targeted nanomedicines in patients.
 - a. Paoloni MC, Tandle A, Mazcko C, Hanna E, Kachala S, Leblanc A, Newman S, Vail D, Henry C, Thamm D, Sorenmo K, Hajitou A, Pasqualini R, Arap W, Khanna C, **Libutti SK**. Launching a novel preclinical infrastructure: comparative oncology trials consortium directed therapeutic targeting of TNFalpha to cancer vasculature. *PLoS One*. 2009;4(3):e4972. PubMed PMID: 19330034; PubMed Central PMCID: PMC2659423.
 - b. **Libutti SK**, Paciotti GF, Byrnes AA, Alexander HR Jr, Gannon WE, Walker M, Seidel GD, Yuldasheva N, Tamarkin L. Phase I and pharmacokinetic studies of CYT-6091, a novel PEGylated colloidal gold-rhTNF nanomedicine. *Clin Cancer Res*. 2010 Dec 15;16(24):6139-49. PubMed PMID: 20876255; PubMed PMCID: PMC3004980.

- c. Yuan Z, Syrkin G, Adem A, Geha R, Pastoriza J, Vrikshajanani C, Smith T, Quinn TJ, Alemu G, Cho H, Barrett CJ, Arap W, Pasqualini R, **Libutti SK**. Blockade of inhibitors of apoptosis (IAPs) in combination with tumor-targeted delivery of tumor necrosis factor- α leads to synergistic antitumor activity. *Cancer Gene Ther*. 2013 Jan;20(1):46-56. PubMed PMID: 23154431; PubMed Central PMCID: PMC3534156.
 - d. Gabizon A, Bradbury M, Prabhakar U, Zamboni W, **Libutti SK**, Grodzinski P. Cancer nanomedicines: closing the translational gap. *Lancet*. 2014 Dec 20;384(9961):2175-6. PubMed PMID: 25625382. PMCID: PMC6615547.
3. The mechanisms controlling tumor invasion and metastasis are complex and involve the interplay of a variety of pathways. My group identified filamin A interacting protein 1-like (FILIP1L) as an important protein regulation tumor cell invasion via modulation of the WNT signaling pathway. We further described the association of FILIP1L with invasive forms of breast, ovarian, colon, lung and pancreatic cancer and identified promoter methylation as an important regulator of FILIP1L expression.
 - a. Kwon M, Hanna E, Lorang D, He M, Quick JS, Adem A, Stevenson C, Chung JY, Hewitt SM, Zudaire E, Esposito D, Cuttitta F, **Libutti SK**. Functional characterization of filamin A interacting protein 1-like, a novel candidate for antivasular cancer therapy. *Cancer Res*. 2008 Sep 15;68(18):7332-41. PubMed PMID: 18794120; PubMed Central PMCID: PMC2614293.
 - b. Kwon M, Lee SJ, Reddy S, Rybak Y, Adem A, **Libutti SK**. Down-regulation of Filamin A interacting protein 1-like is associated with promoter methylation and an invasive phenotype in breast, colon, lung and pancreatic cancers [corrected]. *PLoS One*. 2013 Dec 5;8(12):e82620. doi: 10.1371/journal.pone.0082620. eCollection 2013. Erratum in: *PLoS One*. 2013;8(12). PubMed PMID: 24340050; PubMed Central PMCID: PMC3855469.
 - c. Kwon M, Lee SJ, Wang Y, Rybak Y, Luna A, Reddy S, Adem A, Beaty BT, Condeelis JS, **Libutti SK**. Filamin A interacting protein 1-like inhibits WNT signaling and MMP expression to suppress cancer cell invasion and metastasis. *Int J Cancer*. 2014 Jul 1;135(1):48-60. PubMed PMID: 24327474; PubMed Central PMCID: PMC3991758.
 - d. Kwon M, Kim JH, Rybak Y, Luna A, Choi CH, Chung JY, Hewitt SM, Adem A, Tubridy E, Lin J, **Libutti SK**. Reduced expression of FILIP1L, a novel WNT pathway inhibitor, is associated with poor survival, progression and chemoresistance in ovarian cancer. *Oncotarget*. 2016 Nov 22;7(47):77052-77070. PubMed PMID: 27776341 PMCID: PMC5340232.
 4. The use of gene expression signatures for the diagnosis of cancer and for establishing prognosis has gained significant acceptance among cancer clinicians. Our group developed some of the first gene expression based predictive models for thyroid and breast cancer. These signatures have been validated and are useful in distinguishing benign from malignant tissue and can be used to predict risk of tumor recurrence thus informing adjuvant therapy selection.
 - a. Sotiriou C, Powles TJ, Dowsett M, Jazaeri AA, Feldman AL, Assersohn L, Gadisetti C, **Libutti SK**, Liu ET. Gene expression profiles derived from fine needle aspiration correlate with response to systemic chemotherapy in breast cancer. *Breast Cancer Res*. 2002;4(3):R3. Epub 2002 Mar 20. PubMed PMID: 12052255; PubMed Central PMCID: PMC111028.
 - b. Mazzanti C, Zeiger MA, Costouros NG, Umbricht C, Westra WH, Smith D, Somervell H, Bevilacqua G, Alexander HR, **Libutti SK**. Using gene expression profiling to differentiate benign versus malignant thyroid tumors. *Cancer Res*. 2004 Apr 15;64(8):2898-903. Erratum in: *Cancer Res*. 2004 Jul 15;64(14):5028. PubMed PMID: 15087409.
 - c. Rosen J, He M, Umbricht C, Alexander HR, Dackiw AP, Zeiger MA, **Libutti SK**. A six-gene model for differentiating benign from malignant thyroid tumors on the basis of gene expression. *Surgery*. 2005 Dec;138(6):1050-6; discussion 1056-7. PubMed PMID: 16360390.
 - d. He M, Mangiameli DP, Kachala S, Hunter K, Gillespie J, Bian X, Shen HC, **Libutti SK**. Expression signature developed from a complex series of mouse models accurately predicts human breast cancer survival. *Clin Cancer Res*. 2010 Jan 1;16(1):249-59. PubMed PMID: 20028755; PubMed Central PMCID: PMC2866744.

Complete List of Published Work in MyBibliography: <https://www.ncbi.nlm.nih.gov/pubmed/?term=Libutti+s>