

Montefiore
Inspired Medicine

**Pioneering Treatments.
Extraordinary Possibilities.**



Dear Colleague,

Now is a time of extraordinary possibility in the field of cancer research and treatment. And I'm honored to take a moment to share with you some of the remarkable advancements we're making in this respect at the Montefiore Einstein Center for Cancer Care.

The partnership between the Montefiore Einstein Center for Cancer Care and the Albert Einstein Cancer Center has created fertile ground for advancing cancer care. We have a wide range of programs treating patients with both common and rare cancers. Additionally, we have robust research programs across all tumor types and treatment modalities. For example, we are pleased to be the only academic medical center in the United States utilizing in clinical trials an implantable, biodegradable device that shields healthy tissue from radiation delivered to the prostate.

Likewise, we are among a handful of hospitals developing New York City's first center for proton-beam radiation therapy, a technique that dramatically reduces radiation toxicity. And we continue to be a pioneer in the development of the latest chemotherapeutic and targeted agents.

We are excited about our studies in nanomedicines. We look forward to beginning a Phase II clinical study of a nanomedicine that delivers tumor necrosis factor (TNF) via colloidal gold to solid tumors. Phase I studies conducted at the National Institutes of Health demonstrated the ability of this agent to dramatically reduce the toxicity of TNF.

These are just a few examples of ongoing research at the Montefiore Einstein Center for Cancer Care, made possible by the superb leadership of researcher-clinicians, including Shalom Kalnicki, MD, and Roman Perez-Soler, MD. Their skills are surpassed only by their dedication to improving the quality and length of life for patients with cancer.

This brochure will provide you with an overview of our program, as well as insight into our pioneering research and outstanding care provided to our patients. We hope you find this information useful. We look forward to collaborating with you as we work to advance cancer care.

Sincerely,



A handwritten signature in black ink, appearing to read "Steven Libutti". The signature is fluid and cursive.

Steven Libutti, MD, FACS

Director, Montefiore Einstein Center for Cancer Care
Vice-Chairman, Department of Surgery, Montefiore Medical Center
Professor, Departments of Surgery and Genetics
Albert Einstein College of Medicine

Extraordinary Research & Results

At the Montefiore Einstein Center for Cancer Care, we have a deep and lasting commitment to combining research with clinical practice to yield breakthroughs that change the way cancer is diagnosed and treated.

It is here that researchers, physicians and caregivers are united in providing groundbreaking, leading-edge patient care, while seeking new knowledge and educating the next generation of physicians about cancer.

At the center of this paradigm is a partnership between the Montefiore Einstein Center for Cancer Care and the Albert Einstein Cancer Center. Among the 66 National Cancer Institute (NCI)-designated cancer centers in this country, the Albert Einstein Cancer Center is one of the nation's most respected research centers and is recognized globally for developing innovative approaches for the diagnosis, treatment and prevention of cancer. At the Montefiore Einstein Center for Cancer Care, these research findings are translated into advanced patient-care protocols.

Supported by state-of-the-art diagnostic technologies and innovative basic and clinical research, the Montefiore Einstein Center for Cancer Care provides new treatments for patients with common and rare cancers and creates a new framework for predicting, preventing, diagnosing and treating cancer.

Montefiore Einstein Center for Cancer Care provides advanced care for both rare and common types of cancer, including:

- Breast cancer
- Colorectal cancer
- Endocrine and neuroendocrine cancers
- Gynecologic cancers
- Head and neck cancers
- Hepatobiliary cancers
- Lung cancer
- Melanoma
- Neurological cancers
- Sarcoma
- Pancreas and upper gastrointestinal cancers
- Urologic cancers

Inspired Leadership

The Montefiore Einstein Center for Cancer Care is led by Steven Libutti, MD, FACS, Shalom Kalnicki, MD, and Roman Perez-Soler, MD. All three physicians are internationally recognized for their work in developing innovative strategies for cancer detection and treatment.



Voted one of the top cancer doctors in the United States, Dr. Steven Libutti, Director of the Montefiore Einstein Center for Cancer Care, Vice Chairman of the Department of Surgery, Montefiore, and a professor with the Departments of Surgery and Genetics, Albert Einstein College of Medicine, began his research career at the National Cancer Institute (NCI). His work on the study of tumor angiogenesis and the tumor microenvironment has led to novel approaches for the treatment of cancer. He is also one of the pioneers of regional and targeted cancer therapy.

Dr. Shalom Kalnicki, Professor and Chairman of Radiation Oncology, Montefiore and Albert Einstein College of Medicine, is an internationally recognized leader in radiation oncology, with extraordinary expertise in the development of innovative radiation delivery methods critical to improving survival rates and quality of life for patients with cancer. He is currently working with positron emission and computed tomography fusion advanced technologies.

Dr. Roman Perez-Soler, Chairman and Chief, Department of Oncology, Montefiore, Gutman Professor of Medicine, Associate Director for Clinical Research and Co-Leader of the Experimental Therapeutics Program, Albert Einstein Cancer Center, is internationally recognized for his research contributions in applying molecular-based approaches to the prevention and treatment of lung cancer. He has played a pivotal role in the preclinical and clinical development of novel targeted drug regimens that are now standard-of-care in the treatment of lung cancer, including the EGFR and the topoisomerase I inhibitors. His research has been continuously funded by the National Cancer Institute since 1989 and has resulted in the introduction into the clinic of several new therapeutic agents and 17 patents.

The provision of exceptional cancer care requires a group effort, and the integration of hospital and research laboratories offers unique opportunities for collaboration and innovation. Montefiore Einstein Center for Cancer Care leadership has eliminated traditional boundaries to care in favor of multispecialty teams of physicians with subspecialty expertise, composed of medical oncologists, radiation oncologists, plastic surgeons, surgical oncologists, pathologists and other medical specialists. Nurses and other specialists educate and assist in genetic counseling and provide nutritional and rehabilitation support. The teams conduct onsite pathology reviews of each patient's cancer. A comprehensive, highly individualized treatment protocol is designed to ensure accurate diagnosis and achieve the best possible outcome using the least invasive approaches. Whenever possible, patients are invited to participate in clinical trials that offer the most advanced therapies.

The National Cancer Institute-designated Albert Einstein Cancer Center is a major research institute dedicated to basic investigations on the causes of cancer and the translation of fundamental discoveries into new approaches to the prevention, diagnosis and treatment of cancer. Clinical trials that are conducted at the Montefiore Einstein Center for Cancer Care, in partnership with the Albert Einstein Cancer Center, offer Montefiore patients access to the most advanced cancer treatments under the care of a highly specialized cadre of academic physicians.

Advanced Technological Support

The Montefiore Einstein Center for Cancer Care and its research partner, the National Cancer Institute-designated Albert Einstein Cancer Center, work together to advance the standard of cancer care. This work is supported by cutting-edge technologies such as PET/CT scanners, the latest robotic surgical equipment, Image Guided Radiation and other minimally invasive and nonsurgical procedures. There have been major investments in infrastructure to support these technologies. These include a new Center for Radiation Therapy offering the most comprehensive and innovative array of technologies and services in the region and a major outpatient facility for multidisciplinary cancer care.

Montefiore is committed to taking cancer care to the next level and has made significant investments in technologies that place the Montefiore Einstein Center for Cancer Care at the forefront of advanced treatments in surgical, medical, gynecological and radiation oncology.

These include:

- The latest da Vinci Si surgical system
- Radiofrequency ablation
- Respiratory gating for radiation therapy
- Hyperthermic Intraperitoneal Chemotherapy (HIPEC)
- Calypso® Localization System™, GPS for the Body®
- Varian TrueBeam™ System
- High-energy focused ultrasound for radio-recurrent cancer
- Video-assisted thoracoscopic surgery (VATS)
- Stereotactic radiation therapy
- Transarterial chemoembolization





“Montefiore has always been linked to basic science at Einstein. There are many unanswered questions in cancer, and when you bring clinical and basic research together with patient care, you have a winning combination.”

— Steven Libutti, MD, FACS

*Director, Montefiore Einstein Center for Cancer Care, Vice-Chairman, Department of Surgery, Montefiore Medical Center, Professor Departments of Surgery and Genetics
Albert Einstein College of Medicine*

Solid Ground for Advancing Care

The long-standing relationship between Montefiore and the Albert Einstein Cancer Center has led to important contributions in cancer prevention and treatment. These include:

- Clinical trials for molecular-based analyses of breast tumors to facilitate development of individualized cancer treatments
- Leadership of national cooperative clinical trials among academic medical centers that have advanced the treatment of breast and other cancers
- The development of Taxol for the treatment of cancer
- Identification of new targets in cancer cells that have led to the development of novel cancer treatments
- Identification of the human papilloma viruses that are the targets for cervical screening and for current, and planned, vaccines for the prevention of cervical cancer
- Development of genetically engineered animal models of colon and rectal cancer for the study of new approaches to cancer prevention and treatment
- Radiofrequency ablation for the treatment of radiation-resistant prostate cancer

This long tradition of research achievements is recognized by major grants from the National Cancer Institute and other national cancer funding agencies.

A major recent grant enables practicing clinicians to devote substantial time to clinical research so that patients treated at the Montefiore Einstein Center for Cancer Care have increased access to the most advanced clinical trials available. The NCI-funded Calabresi program supports Center physician-investigators who focus their efforts on the development and clinical evaluation of new approaches to the treatment of neoplastic diseases in collaboration with laboratory scientists at the Albert Einstein Cancer Center. This program was implemented in 2009 and has already resulted in the introduction into the clinic of new viral therapies for colorectal carcinoma (funded additionally by the American Society of Clinical Oncology), new immunotoxin approaches for patients with hematological malignancies, first clinical trials with agents that kill cancer cells by a new mechanism called autophagy, combinations of novel blockers of pathways that support the growth of breast cancer cells, and new approaches for the treatment of malignancies associated with HIV infection and hepatocellular carcinoma.

“This is an important time in cancer research. We are poised at the threshold of revolutionary discoveries in the laboratory that will translate into remarkable new treatments in the clinic.”

— Roman Perez-Soler, MD
*Chairman and Chief, Department of Oncology
Montefiore Medical Center, Gutman Professor of
Medicine, Albert Einstein College of Medicine
Associate Director for Clinical Research and
Co-Leader of the Experimental Therapeutics
Program, Albert Einstein
Cancer Center*

The Direction of Research Today

Montefiore Einstein Center for Cancer Care clinical researchers are developing novel drug treatments and delivery systems with the primary goal of reducing toxicity while increasing effectiveness. These include orally administered drugs, inhaled drugs for the prevention and treatment of lung cancer, and molecularly targeted and genetically driven therapies.

Preparations are underway for a Phase II study of a nanomedicine that delivers tumor necrosis factor (TNF) via colloidal gold to solid tumors. Phase I studies led by Dr. Steven Libutti while he was at the National Institutes of Health demonstrated the ability of this nanoparticle to dramatically reduce TNF toxicity. Funded by the National Cancer Institute, the nanomedicine initiative blends the expertise of five research institutions to focus an array of innovative nanotechnologies on improving the outcome of patients with ovarian or pancreatic cancers. Researchers are also developing stem cell-based approaches to the prevention of the intestinal toxicity associated with radiation therapy of abdominal cancers.

The Montefiore Einstein Center for Cancer Care is a participant in a consortium of major academic hospitals that will develop New York City's first proton-beam cancer treatment center. There are only eight such centers in the United States.

The Center has developed a biospecimen repository that makes possible research into the genetic changes inherent in cancer that facilitates new approaches to the prevention and treatment of these diseases.



Clinical Trials Hold Exciting Promise

“Our goal is to reduce the burden of cancer in our lifetimes. The challenge is great, but important progress is being made through a combination of basic research discoveries and the development of new technologies, anticancer drugs and surgical approaches.”

— Shalom Kalnicki, MD
*Chairman and Professor of Radiation Oncology
Montefiore Medical Center and
Albert Einstein College of Medicine*

More than 100 clinical trials are offered at the Montefiore Einstein Center for Cancer Care. These include Phase I clinical trials designed to identify safe ways to administer new anticancer drugs, Phase II clinical trials to evaluate the effectiveness of new drugs and drug combinations for the treatment of specific cancers, and Phase III clinical trials that compare standard-of-care treatment regimens with advanced regimens designed to be more effective.

Innovative clinical trials designed by Montefiore Einstein Center for Cancer Care physicians provide patients with access to new technologies and treatments before they are available elsewhere. Clinical trials sponsored by the National Institutes of Health (NIH), the Eastern Cooperative Oncology Group (ECOG), the Gynecologic Oncology Group (GOG), the Children's Oncology Group (COG), the American College of Surgeons Oncology Group (ACoSOG) and the Radiation Therapy Oncology Group (RTOG) are also conducted.

The Albert Einstein Cancer Center is the lead institution for the New York Cancer Consortium, a multicenter clinical trials group funded by the National Cancer Institute, with clinical studies conducted at the Montefiore Einstein Center for Cancer Care. Implemented in 2000, the Consortium is the premier cooperative group in the New York area for early Phase II studies of the most promising new agents provided by the NCI for the treatment of a wide variety of neoplastic diseases.

A major grant was recently awarded by the National Cancer Institute to evaluate the effectiveness of Carraguard®, an antiviral agent, against the human papilloma virus, which causes cervical cancer.



Disease-Specific Research

Lung and Thoracic Cancers

Montefiore Einstein Center for Cancer Care lung cancer experts are recognized for their innovative research on targeted therapies that attack molecular changes unique to cancer cells. They have pioneered the development of the newest chemotherapeutic and targeted agents, including the taxanes, topoisomerase I inhibitors, EGFR inhibitors and antiangiogenesis agents.

In particular, novel efforts are focused on the development of inhaled drugs for the prevention and treatment of the early defects that occur during the development of lung cancer.

Breast Cancer

Montefiore Einstein Center for Cancer Care breast cancer physicians initiate a range of research studies and participate in many national clinical trials with the goal of improving survivorship and quality of life for patients with breast cancer. Current clinical trials include:

- Examinations of the genetic composition of tumors to determine the likelihood that a patient with early-stage breast cancer will develop recurrent disease (TAILORx)
- Exploration of PARP inhibitor therapy in patients with triple-negative breast cancer
- Gene expression profiling as a predictor of response to drugs in breast cancer
- Studies of ovarian function suppression in operable breast cancer

Colorectal Cancer

Hyperthermic peritoneal perfusion is available for patients with colorectal cancers that have spread to the abdominal cavity. This treatment, being refined at the Montefiore Einstein Center for Cancer Care, bathes the abdomen with chemotherapeutic agents to eradicate rogue cells, while sparing the patient the side effects of systemic chemotherapy.

Geneticists now conduct risk assessments to determine a subject's probability of having an inherited type of colorectal cancer and to guide preventive and early treatment measures.

Endocrine and Neuroendocrine Cancers

The Montefiore Einstein Center for Cancer Care has one of the few endocrine and neuroendocrine cancer programs in the country and the first in the New York metropolitan area. The program is supported by basic research on tumor angiogenesis, and on normal components of the tumor microenvironment that influence tumor growth, invasion and spread. One objective of the studies is to identify genes that predict for tumor aggressiveness and the risk of metastasis.

Prostate Cancer

Patients with prostate cancer are offered the opportunity to participate in an international clinical trial of BioProtect's SpaceGuard Balloon™, an implantable, biodegradable device that shields surrounding healthy tissue during radiation to the prostate. Montefiore is the only academic medical center in the United States participating in this trial.

Additionally, high-energy focused ultrasound will be made available for the treatment of prostate cancers that are resistant to radiation therapy.



Pancreas and Upper Gastrointestinal Cancers

Because the optimal treatment for pancreatic and upper gastrointestinal cancers has not been established, physicians that specialize in the management of these diseases have developed clinical trials to assess new approaches to the treatment of these cancers. These include:

- Combinations of chemotherapy and surgery for gastric cancer
- Chemotherapy prior to surgery for pancreatic cancer
- Hyperthermic perfusion therapy for abdominal malignancies (peritoneal disease)
- Isolated liver perfusion for intrahepatic malignancies

The physicians are studying various screening modalities with the objective of finding a method for the very early diagnosis of pancreatic cancer. The goal is to develop a protocol for screening patients and families at high risk for the development of pancreatic cancer that will allow curative surgical resections very early in the evolution of the disease.

Gynecologic Cancer

The Montefiore Einstein Center for Cancer Care offers a broad spectrum of treatment options, guided by clinical trials for patients with cervical, endometrial and ovarian cancer. The Center is currently the lead site for gynecologic cancer prevention and treatment trials, many of which are funded by the National Cancer Institute.

Melanoma

The Montefiore Einstein Center for Cancer Care is one of a select number of medical centers offering high-dose interleukin-2 (IL-2) therapy. This highly complex therapy, administered on a dedicated hospital floor, can achieve complete remissions in some patients with far advanced disease. The melanoma physicians are currently conducting clinical trials of a promising group of targeted agents known as B-Raf inhibitors, as well as immunotherapy with anti-CTLA-4.

Head and Neck Cancers

Members of the Head and Neck Cancer Program at the Montefiore Einstein Center for Cancer Care helped pioneer the use of transoral robotic surgery to remove tumors of the head and neck. The team was the first to perform transoral total laryngectomy, and has since used this approach to perform a free-tissue transfer for reconstruction.

Sarcoma

At the Montefiore Einstein Center for Cancer Care, clinical trials provide access to new, potentially more effective agents, including trabectedin (Yondelis), a marine-derived anti-tumor agent, and insulin-like growth factor 1 receptor (IGF-1R) blockers, which counteract the ability of IGF-1 to resist chemotherapy and promote metastasis.

Pediatric Oncology

The Pediatric Oncology Program is a member of the National Cancer Institute-funded Pediatric Preclinical Testing Program that systematically evaluates new treatments for childhood cancers. The program also coordinates the world's largest tumor research repository for osteosarcoma, the most common bone tumor in children. With this translational research and over 50 active clinical trials, the Pediatric Oncology Program offers comprehensive clinical care.



A Partnership for Progress

Montefiore Einstein Center for Cancer Care is committed to translating academic research findings into breakthrough treatments and therapies.

The partnership that unites the clinical expertise of Montefiore cancer specialists with the research excellence of National Cancer Institute-designated Albert Einstein Cancer Center scientists results in the most advanced and innovative approaches to the prevention, diagnosis and treatment of cancer. We can't promise a cure for every patient with cancer, but we promise to keep working to improve the outcome of our cancer treatments and the quality of life of our patients with cancer.

How to Reach Us

To refer a patient or speak with one of our physicians, please contact us at **718-862-8840**.

Visit www.montefiore.org/cancer for more information.

Montefiore Einstein
Center for Cancer Care

Montefiore Medical Center
111 East 210th Street
Bronx, New York 10467

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