

SUMMER 2014

Believe

IN A CURE

UF HEALTH CANCER CENTER NEWS



PAGE 6

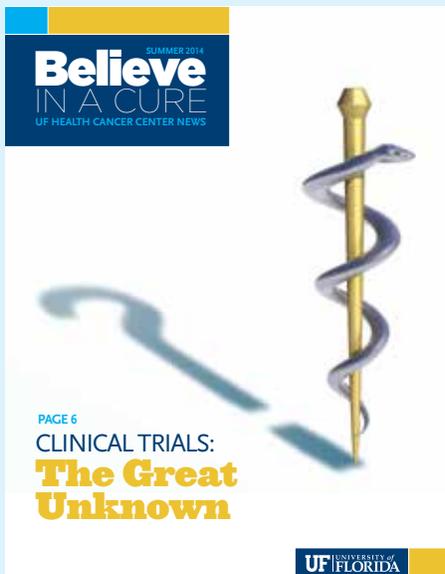
CLINICAL TRIALS:

The Great Unknown

- 3** **From the director's desk**
Clinical trials have helped revolutionize cancer care
- 4** **To kill a tumor**
UF physicians target the genes of lung and colon cancers
- 5** **Clear as a bell**
A new art installation provides a positive ritual for cancer survivors
- 6** **Clinical trials: the great unknown**
An exploration of the UF Health Cancer Center clinical trials network
- 10** **Development dispatch**
A question and an invitation
- 11** **Faculty spotlight**
Nancy Mendenhall, M.D., investigates the effects of proton therapy treatment



About us



Believe in a Cure is the newsletter for the UF Health Cancer Center, home to cancer care and research for the Southeast's most comprehensive academic health center. In each issue, we will bring you stories about the progress and patient-centered care occurring at the center, as well as the partners who help make it happen.

Are you a patient?

For more information about care and services offered at the UF Health Cancer Center, call **352.273.8689**.

To support the work of the UF Health Cancer Center, call the UF Health Cancer Center Development Office at **352.273.8689**, write to P.O. Box 103633, Gainesville, FL 32610, or visit "Make a Gift" at www.cancer.ufl.edu.

To receive or opt out of receiving this newsletter, email Lindy Brounley at brounley@ufl.edu.

ON THE COVER

Clinical trials seek to answer cancer's biggest questions; conversely, many people have questions about clinical trials themselves. This issue hopes to provide some answers while exploring the role trials play at the UF Health Cancer Center. Illustration by Carlos Campos.

PUBLISHED BY UF HEALTH COMMUNICATIONS

Director, UF Health Cancer Center
Paul Okunieff, M.D.

Chief Communications Officer, UF Health
Melanie Fridl Ross, M.S.J., E.L.S.

Communications Director, UF Health Cancer Center
Lindy Brounley

Editor
Marilee Griffin

Designer
J&S Design

From the director's desk

In the decades since the National Cancer Act was signed into law in 1971 to begin our country's War on Cancer, cancer researchers have made great strides in saving lives through improved early detection, development of more effective drugs and advances in diagnostic and therapeutic technologies. New drugs for breast and lung cancers, supportive care for colorectal cancer patients and advances in drug therapies targeted to the genomics of a patient's tumor have revolutionized how we approach cancer care.

Clinical trials are at the heart of every one of these advancements, yet lack of understanding about the benefits, risks and opportunities that trials offer can sometimes prevent patients from taking advantage of the newest drugs and treatments they make available. Clinical trials give enrolled patients the opportunity to be the first to benefit from new treatments, and they advance knowledge and discovery for future patients.

This issue of Believe in a Cure offers a glimpse into the UF Health Cancer Center clinical trials network — its leading-edge research and medical treatments, its dedicated teams in Gainesville, Jacksonville and Orlando and the partnerships it's

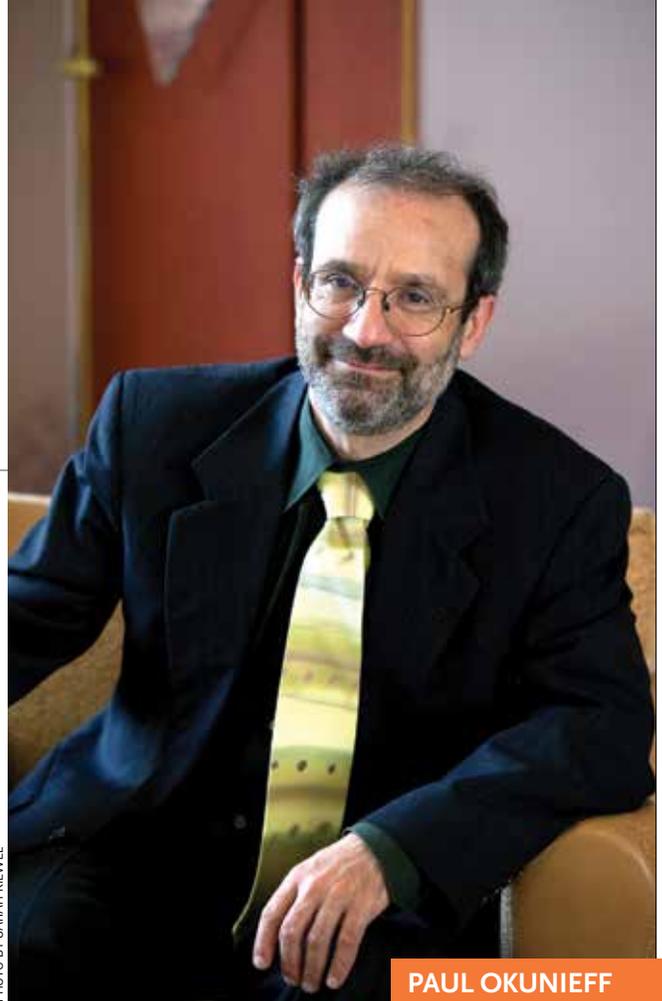


PHOTO BY SARAH KEWEL

PAUL OKUNIEFF

Paul Okunieff, M.D., is the Marshall E. Rinker Sr. Foundation and David B. and Leighan R. Rinker chair and serves as director of the UF Health Cancer Center and chair of the College of Medicine department of radiation oncology.

forging statewide with the aim of doubling clinical trial enrollment within the next five years.

We are also grateful to patients like Pat Theobald, Pg. 9, who participate in clinical trials. They are the brave trailblazers, advancing scientific discovery to benefit themselves and others. Without their involvement, improvements in cancer treatments would be difficult to achieve.

For that, we thank them.

Best regards,

A handwritten signature in black ink that reads "Paul Okunieff". The signature is fluid and cursive.

Paul Okunieff, M.D.
Director, UF Health Cancer Center



UF physicians target the genes of lung, colon cancers

UF physicians and researchers are collaborating to map the genes of different types of cancer, and then deliver medication to attack cancer at its source.

In late January, researchers in the new UF Health Precision Cancer Care Program began identifying the genes of lung and colon cancer tumors, forming the first center in the state to perform this testing for solid tumors. Program members include researchers and physicians from multiple UF departments, encompassing the UF Health Cancer Center and UF Health Pathology Laboratories. By identifying particular gene mutations that drive lung and colon cancers, physicians can deliver better, more targeted treatments to those cancers.

When a patient receives traditional, intravenous chemotherapy, the chemotherapy targets all growing cells. Pinning down what's genetically distinct about a particular type of cancer allows physicians to deliver targeted therapy to the genes causing that cancer instead of targeting all living cells. This can reduce the side effects of what UF researcher Thomas George Jr., M.D., calls "indiscriminate" chemotherapy, such as nausea and hair loss.

"Many of these new targeted therapies are pills and not liquid, intravenous medicines. They tend to be much less toxic or dangerous than traditional chemotherapy and are

"[Targeted therapies] tend to be much less toxic or dangerous than traditional chemotherapy and are used with a much higher degree of certainty that they're working." —Thomas George Jr., M.D.

used with a much higher degree of certainty that they're working," said George, who is research director of the joint oncology program at the UF Health Cancer Center at Orlando Health.

The UF researchers' work builds upon previous discoveries in breast cancer research, George said. Scientists now know that breast cancer is actually composed of at least three genetically different types of cancer. Each type has particular genetic quirks that have changed the way doctors treat patients with one of these certain sub-types of breast cancer.

The UF team wants to apply the same kind of scrutiny to lung and colon cancer tumors. Different types of cancer require different kinds of treatment because each cancer's genetic mutations are unique. These genes are even unique within each individual's cancer, even if he or she has the same type of lung cancer, for example, as another person.

"We realized you can't judge a book by its cover," George said. "We took that principle from breast cancer and we started looking under the hood." —Morgan Sherburne

CLEAR AS A BELL

Patient Care

UF Health cancer patients and their treatment teams rang the Liminal Bell during its unveiling on May 10 at the UF Health Davis Cancer Pavilion. The Liminal Bell is an art installation consisting of a bell created from an oxygen tank that is suspended from an oak beam structure, surrounded by oak benches, surrounded by oak benches.

The word liminal is derived from the Latin word "limen," which means "threshold."

Radiation oncology and medical oncology nurses conceptualized the Liminal Bell project as a way of creating a positive ritual wherein patients can mark the end of cancer treatment by ringing the Liminal Bell in the presence of their family, friends and treatment teams.

"We all have family and really good friends who have been affected by cancer," said Debra Hutchinson, nurse manager at UF Health Radiation Oncology. "We all recognize

the importance of celebrating a milestone in treatment."

The UF Health Shands Arts in Medicine program was instrumental in recruiting local artist Alexis Dold, the owner of Gainesville's Circle Square studio, to create the work of art.

"[The bell] has so much meaning to so many people, and it's going to have so much meaning over time," said Dold, who donated his time to the project. —*Marilee Griffin*



1. Breast cancer survivor Linda McCollum is the second patient to ring the Liminal Bell. 2. L to R: Karen Schroder, R.N., a nurse in the UF department of radiation oncology, Debra Hutchinson, nurse manager at UF Health Radiation Oncology and Alexis Dold, local artist. 3. The Liminal Bell's oak beams and oxygen tank were donations.

The Great Unknown

An exploration into the UF Health Cancer Center clinical trials network

MORGAN SHERBURNE

Each year, more than 1,000 patients take part in clinical trials at the UF Health Cancer Center. Contrary to belief, not all of these patients are testing a new cancer therapy. Some provide genetic information about a particular kind of cancer; others donate samples of their cancer cells. Some patients help clinicians reduce the severity of treatment side effects; others will test new ways of detecting cancer early.

But all are helping UF researchers chip away at the great unknown: what makes each person's cancer tick, and how to stop that ticking without causing harm to the patient over the course of treatment.

For the past three years, John Wingard, M.D., the deputy director for research at the UF Health Cancer Center, has helped oversee clinical trials in its UF Clinical Trials Office. The clinical trials office oversees trials conducted by UF researchers, and also supports UF principal investigators in getting their research to a clinical trial phase.

"We're ensuring that we're meeting the rigorous standards that protect patient safety,

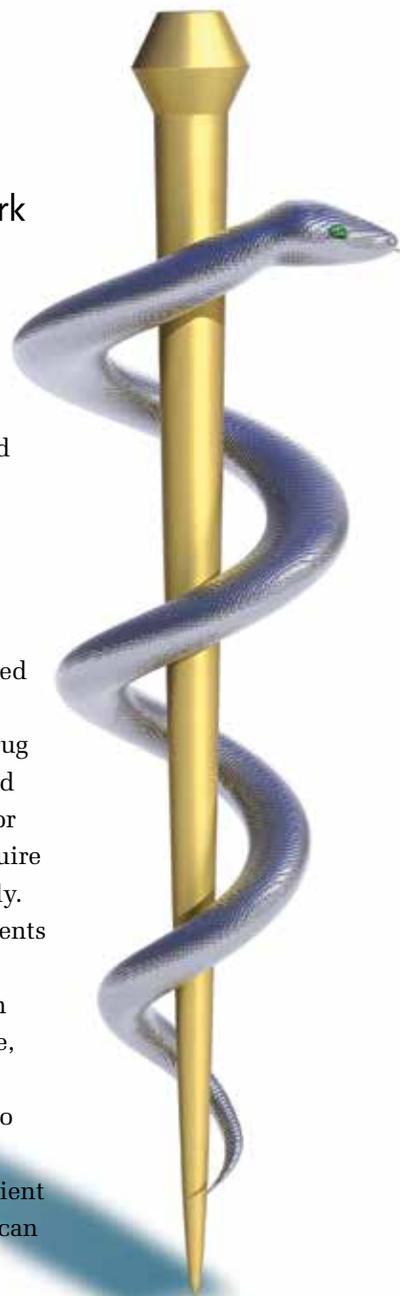
but also contributing to the knowledge of cancer care," Wingard said.

With each of the 130 trials currently ongoing within the clinical trials office and 20 trials within the Pediatric Oncology Clinical Trials Office, UF clinicians and researchers are hoping to do just that.

Clinical trials are research studies in which physicians test a drug that has not been used before — or test a previously used drug in a new way. Depending on the type of clinical trial, patients can receive the drug by itself or in combination with established drugs, said Nam Dang, M.D., Ph.D., director of the clinical trials office. Other trials require patients to not have been treated previously. And some clinical trials are offered to patients whose traditional therapy has failed.

According to a 2014 study published in the *Journal of the National Cancer Institute*, patients who participated in clinical trials had a better survival rate than patients who didn't.

"Many times, it's the only time the patient might get a drug that is the only drug that can help him or her," Dang said.



TO LEARN MORE ABOUT UF HEALTH CANCER CENTER CLINICAL TRIALS, VISIT [HTTP://CANCER.UFL.EDU/CLINICAL-TRIALS](http://cancer.ufl.edu/clinical-trials).

“In my 25 years of experience working in clinical trials, I have seen this multiple times: a patient’s only shot at life, at living longer, is if they get that drug.”

CLINICAL RESEARCH RIGHT AT HOME

Wingard is also working to support UF investigators.

“As a research university, UF is trying to contribute new knowledge and improve on cancer treatment outcomes — to not just perform the status quo, but recognize we need to improve it,” Wingard said. “It’s

important we allow discoveries in the lab either at UF or elsewhere, and to put those in the hands of practicing clinicians,”

One of these investigators is Christopher Cogle, M.D., an associate professor of medicine.

Cogle’s current research involves finding leukemia cells hiding within patients’ bodies. These cancer cells survive initial doses of chemotherapy by hunkering down in blood vessels. After the chemotherapy coast is clear, the leukemia cells can re-emerge, putting the patient into relapse.

One of the aims of Cogle’s study is to use a drug to attack the safety sites that the leukemia cells create for



John R. Wingard, M.D.



Nam Dang, M.D., Ph.D., director of the UF Health Clinical Trials Office, in the lab. Dang’s research involves finding novel treatment strategies for patients with lymphoma.

Cancer Clinical Trials Myth-Busted

MYTH: Clinical trial participants are just human guinea pigs

FACT: Clinical trial patients are partners with their research teams in the process of discovery. They receive some of the best therapies and treatments currently available and receive ongoing updates throughout the process. According to the American Cancer Society, patients overwhelmingly rate their clinical trial experiences as positive, saying they were treated with dignity and respect.

MYTH: Clinical trials are dangerous

FACT: All treatments must first undergo pre-clinical testing in laboratories. Once treatments are identified as being effective and as not having intolerable side effects, they move into clinical trials. In addition, patients must read and sign an informed consent document, which details potential risks and benefits, before participating in a

trial. Patients are closely monitored by physicians throughout and can choose not to participate at any time.

MYTH: Clinical trial participants receive sugar pills

Fact: The use of placebos is rare in cancer clinical trials. Study participants receive either the best standard treatment for their condition or the new treatment.

MYTH: Clinical trials are only for people whose other treatment has failed

FACT: Cancer clinical trials differ according to their purpose. They exist for all types and all stages of cancer treatment, as well as for cancer prevention. There are also trials that focus on quality of life factors, as well as diagnostic tests or procedures. —Marilee Griffin

themselves, said Joe Stokes, R.N., nurse manager of the clinical trials office's malignant hematology division.

"Cancer treatment is moving to look at target therapies that really get to the root of the cancer and eradicate it by not allowing it to replicate rather than just killing everything and hoping it doesn't come back," Stokes said.

Brian Sevier, Ph.D., associate director of the clinical trials office, says it's the role of physicians and researchers to explore these new therapies.

"Cogle had an original idea, and he's gone and put that into practice," Sevier said.

GIVING BIG ATTENTION TO SMALL PATIENTS

Alongside the UF Clinical Trials Office is the Pediatric Oncology Clinical Trials Office in the UF College of Medicine. The pediatrics office operates separately because the biology of cancers that affect children is so different from cancers that adults have, said Giselle Moore-Higgs, A.R.N.P., Ph.D., assistant director of the office.

The pediatrics office is affiliated with a national organization called the Children's Oncology Group, a National Cancer Institute-designated research program. Being a part of that organization allows UF Health to tap into a network of children's cancer research.

"Because most children's cancers are rare, being affiliated with the Children's Oncology Group allows you to focus your attention in a particular direction for the management of a particular cancer," Moore-Higgs said. "That way, you don't have lots of sites with multiple trials open, but only accruing one patient every five years. Instead, you have 150 sites accruing patients to a particular trial that many people think is the right direction to go."

The 150 sites are spread across the United States and Canada.



Christopher Cogle, M.D.

Moore-Higgs also focuses on helping UF investigators apply for grants and get their own clinical trials established.

"If we didn't have a clinical trials office, we wouldn't have clinical research," she said. "There are too many things that have to be done that physicians cannot do without having a clinical trials staff to do it — the data collection, the data management, the UF Internal Review Board management and regulatory support all has to be there."

EXTENDING OUR REACH

Drawing on a broad range of clinical research is partly why UF is developing its network further than just the Gainesville area. The UF Health Cancer Center announced its partnership with Orlando Health in December 2013, and has already begun collaborating with physicians there to enroll patients in clinical trials.

Additionally, the clinical trials office in Gainesville is an enrolling member for NRG Oncology, a nonprofit research organization within the National Cancer Institute. The organization conducts clinical cancer research and uses the study results to inform clinical research decisions and health care policy, said Alison Ivey, R.N., senior registered nurse supervisor for the clinical trials office.

Even when patients are ineligible for a clinical trial or choose to not enroll, their experience with UF Health can benefit them, Wingard said.



Left to right: Gigi Moore-Higgs, ARNP, Ph.D., assistant director of the pediatric oncology research office, Brian Sevier, Ph.D., associate director of the clinical trials office and Allison Ivey, R.N., senior registered nurse supervisor, regularly meet to discuss current clinical trial protocols, future research and clinical trial needs.



Joe Stokes, R.N., M.S.A., manager of the clinical trials office's malignant hematology division and study coordinator Leslie Pettiford, R.N., review a patient chart at the UF Health Shands Cancer Hospital.

“Cancer treatment is moving to look at **target therapies** that really get to the root of the cancer and eradicate it by not allowing it to replicate. —Joe Stokes, R.N.

“We may find ourselves able to offer advice of additional treatment options to the practitioner in the patient’s local community,” Wingard said. “Other patients may choose to remain in UF Health to get their care. So it improves communication with our community oncologists, and also gives our patients more options, even if they’re not eligible to enter a trial.”

THE REAL HEROES

In the UF Health Cancer Center, the clinical trials office revolves around the patient, Dang said. After all, it’s these patients who help researchers push the standard of care for cancer today, and create a new standard of care tomorrow.

“It’s an honor and a privilege to take care of this type of patient,” Dang said. “We make a huge effort to minimize risk when we conduct clinical trials. But there is a risk involved — a risk of the unknown. These patients hope the drug will work for them. Without them, there would be no new drugs, and no patients to be helped down the line. I tell my patients that in my mind, they are heroes.”



True colors

It’s a routine. Every two weeks, Pat Theobald and one of her family members stop for bagels — then make the hour-long trip from their home in Dunnellon, Florida to the UF Health Davis Cancer Pavilion in Gainesville, where she receives chemotherapy.

When Theobald, 63, was first diagnosed with pancreatic cancer in March 2013, she was told she had at most a year to live. It’s been 16 months this July.

Because her mother died from the same disease six years ago, Theobald knew what she wanted to do with her remaining time: enjoy her family, and help future pancreatic cancer patients. To that end, she became an advocate for pancreatic cancer awareness and joined a Phase II clinical trial through the UF Health Cancer Center.

First, an oncologist reviewed her options regarding the trial, and Theobald discussed it with her two daughters — a cancer researcher and a nurse practitioner who, after asking many questions, encouraged their mother to participate. Asking questions is crucial, Theobald says.

“There’s lots of misinformation out there,” she says. “Go ahead and educate yourself, but don’t be afraid of the trial itself. I went into it wholeheartedly, and it turned out to be even better than I anticipated.”

In her experience, participation in the clinical trial has meant more professionals watching over her treatment and giving her individual attention, Theobald said. The clinical trial staff also value patient feedback as a high priority, she said.

“For me, this translates into decreased anxiety and increased security. This is so important to a patient who is in a tough battle.”

This March, Theobald celebrated the one-year mark at a steakhouse with friends, family — and a pineapple martini.

“I feel that being in this clinical trial has helped me to beat my initial prognosis, and has given me the greatest gift: more quality time to spend with family and friends, and I am very grateful.” —Marilee Griffin



Partners

Development dispatch

What will it take to cure cancer? At the UF Health Cancer Center, this question defines our daily work and commitment to improving the lives of all who are battling this disease. I have had the honor and privilege of meeting many of our patients and their families and am deeply grateful for their willingness to share their stories and their passion for helping us solve one of the most pressing health issues of our time.

Every one of us has unique reasons for our choices of what we support through philanthropic gifts. At our center, contributions from our patients, families and community members have had an extraordinary impact upon the research and patient-care initiatives that are making a real difference in our search for a cure. These gifts represent their trust and faith in our work, and they pave the way for tomorrow's breakthroughs.

To learn more about how your gift to the UF Health Cancer Center directly supports promising research and quality, patient-centered care, please contact Marcela Brandao at 352.273.8689 or mbrandao@ufl.edu.

As a development officer, I am charged with uniting purpose and passion on behalf of those willing to support the UF Health Cancer Center. It is the most fulfilling job I could have imagined, made better every day by the opportunity to meet and speak with people like you.

I would welcome your phone call, email or personal visit to my office, which is located on the

Contributions from our patients, families and community members have had an extraordinary impact upon research and patient-care initiatives. —Carol Nimitz

first floor of the UF Health Davis Cancer Pavilion by the elevators, or at a location convenient to you. Working together, we can answer the question, “What will it take to cure cancer?” Thank you for your continued confidence in, and support of, our work.

Sincerely,

Carol Nimitz

Senior Director of Development
cnimitz@ufl.edu, 352-273-8689

Invisible Connections

She'd never admit it, but 11-year-old Eva Okunieff was proud of her father.

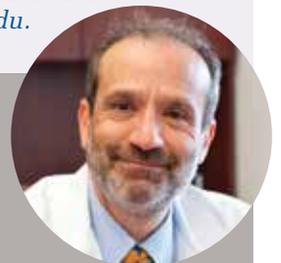
“You could tell she was,” said Paul Okunieff, M.D., director of the UF Health Cancer Center.

It was April, and Okunieff was returning home from visiting his father for Passover. He was in Chicago, on an airplane that was getting ready to taxi away from the terminal, when the flight attendant asked over the PA system if there was a doctor on the plane.

Eva immediately volunteered her father. He helped stabilize a passenger who was having a heart attack until the man could be offloaded by EMTs.

After Okunieff returned to his seat, the flight attendant came up to him with a copy of “Delta Sky” magazine, opened to a UF Health ad that features Okunieff sitting next to a patient in a diner. The ad highlights the “invisible connections” between patients and researchers.

“You have a fan who would like your autograph,” she said.
—Paige Parrinelli



Paul Okunieff, M.D.

Proton power

Faculty Spotlight

Nancy Mendenhall, M.D.

UF radiation oncologist targets tumors with precision

As medical director of the University of Florida Proton Therapy Institute in Jacksonville, Nancy Mendenhall, M.D., not only helps heal cancer patients, but also researches innovative cancer treatments.

A UF College of Medicine faculty member since 1985, Mendenhall served as the chair of the department of radiation oncology for 13 years. Now the associate chair of the department of radiation oncology at UF Health Jacksonville, she helped inspire the development of the UF Proton Therapy Institute, which is affiliated with the UF Health Cancer Center. Currently, Mendenhall is responsible for the day-to-day clinical operations of the institute.

More than 5,000 patients have been treated at the institute since it opened in 2006. Of those, 97 percent have been involved in some kind of clinical study investigating the effects of proton therapy treatment.

Proton therapy employs targeted doses of radiation to treat cancer. Using focused beams of accelerated protons is of particular benefit when a tumor is located in sensitive areas like the lung, brain, head and neck, eye, liver, prostate or pancreas. Most of the energy from proton therapy is deposited in the tumor target, resulting in less damage to healthy tissues surrounding the tumor than

conventional radiation therapy. This means that patients may have fewer negative side effects because of treatment.

“We’ll be more successful at treating cancers because we won’t have to worry as much about normal tissues,” Mendenhall said.

In addition to working with pediatric and Hodgkin’s disease patients, Mendenhall and her colleagues have conducted numerous clinical trials involving a variety of cancer types. A follow-up study with the institute’s first group of prostate cancer patients showed that 76 percent of the high-risk participants remained disease-free after five years. The number was 99 percent for participants who had low or intermediate risk.

Mendenhall and her colleagues have also studied the use of protons to treat left breast cancer as it relates to heart damage. Breast cancer patients treated with certain conventional radiation techniques may experience heart disease later in life, Mendenhall said. Comparative studies done on proton radiation and X-rays showed that proton therapy exposes patients to much less radiation.

“The impact of protons is quite significant for breast cancer, because there will be both less toxicity and better coverage of the cancer target,” Mendenhall said.
—Paige Parrinelli



Nancy Mendenhall, M.D.



Greetings from the Gov.

In May, Gov. Rick Scott visited the UF Health Shands Cancer Hospital to talk with patients and speak with UF Health physicians. The visit was conducted in part to raise awareness for his initiative to fund the Florida Consortium of National Cancer Institute Centers. In March, Scott and leaders from UF Health and Orlando Health held a press conference announcing a drive to help Florida's academic cancer centers achieve National Cancer Institute designation.



P.O. Box 103633
Gainesville, FL 32610-3633