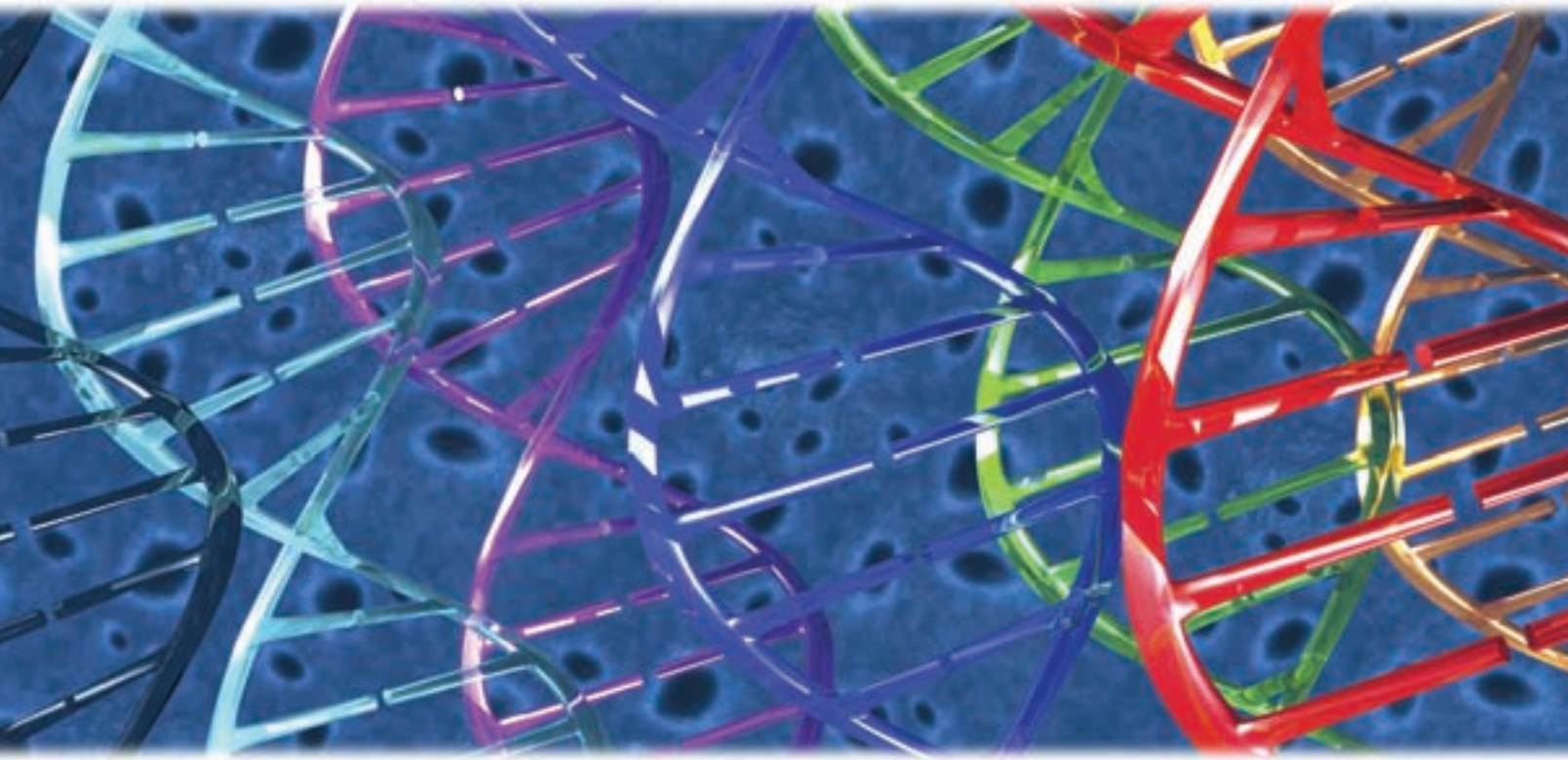

A Research Professional
Learns First-hand What Matters Most to Patients

In New Orleans, where Alicia Pouncey lives, most folks describe life in one of two ways. There's "before the storm" and there's "after the storm."

Hurricane Katrina was Alicia's temporal landmark too, until January, when she was diagnosed with breast cancer. Three months later, her father was diagnosed with pancreatic cancer. Suddenly, life fell into two new categories: "before the diagnosis" and "after the diagnosis."

A site monitor with years of experience in the clinical research industry, Alicia says her personal experience with cancer now enables her to see her field through a different lens. She has an even greater appreciation for the importance of medical research and a new sense of empathy for research volunteers.

"I won't say I'd wish this upon my best friend or that I'd have wished when I was 10 that I would get cancer at 44," says Alicia, managing director of Aureus Research Consultants and a member of the DIA faculty. "But at least from my father and me going through this, I've gained a different perspective. It's reinforced what I believed before and helped me to see the bigger picture."

Alicia's experience with cancer began last winter. She was playing with her dogs when one of them jumped up on her. As she pushed the dog off her chest, she felt a lump in her left breast. Hoping the lump was merely a mass of fibrous tissue that would go away; she waited a few weeks to visit the doctor. Unfortunately, a biopsy showed otherwise. Alicia was diagnosed with Stage 1 breast cancer and underwent a lumpectomy.

During her initial evaluation for her follow-up radiation treatment, the radiologist described a clinical trial he thought might interest Alicia. Rather than receiving six weeks of targeted radiation, the trial was investigating the efficacy of five weeks of radiation delivered via an implanted device. Although she was interested, Alicia was unable to qualify for the study because the cavity where her tumor had been was located too close to the surface of her skin. Without a trial to consider, Alicia moved forward with targeted radiation therapy. Three days into her treatment, her 71-year-old father was diagnosed with early stage pancreatic cancer.

"They don't do trials where he was diagnosed in Mississippi," Alicia explains, "and my parents were coming down to visit me a lot anyway, so he came to New Orleans to have his tumor removed. It kept both of us from wallowing in our own self pity," she says.

Like Alicia, her father was approached about a trial. During their initial meeting, the surgeon described a trial that was testing the effectiveness of treating prostate cancer patients with four weeks of chemotherapy prior to surgery.

Alicia remembers sitting on the couch with her father and walking through the voluminous informed consent form. She drew on the back of the document, trying to explain the trial to her father. She defined terms like "clear margins" and explained arcane industry acronyms. "I can't imagine someone going through that document with a family member and not knowing at least something about the industry," she says.

While her father asked a lot of excellent questions, ultimately what he wanted to know from the researchers was, "what would you do?"

"The informed consent process runs counter to the way many people are socialized," Alicia says. "It is so inconsistent with how we are normally treated when we visit a doctor." People are accustomed to hearing a physician advise them on the best course of treatment. They see doctors as individuals dedicated to improving the patient's health and well-being. "It illuminates the need for some other way to do this informed consent process. We need to move the person who plays the dual role out of the process and get a neutral third party in."

In the end, Alicia's father decided the trial was worth pursuing. He signed the consent form, but was disqualified from the trial because his albumin levels did not meet the study criteria.

Today, Alicia and her father are recovering. Alicia's father underwent surgery on April 13 and will not be undergoing chemotherapy treatments until late this year. Alicia completed her radiation in mid-April. Her lymph nodes are cancer free. She takes Tamoxifen to help prevent a recurrence of her cancer, but decided to forego chemotherapy.

A decade ago a combination of radiation and chemotherapy would have been standard for a tumor like Alicia's. But doctors now know that "with my type of tumor and stage, undergoing chemo would only reduce my risk of recurrence in 10 years from 8 percent to 6 percent," Alicia says. "I owe the fact that chemotherapy was an 'option' for me to all the researchers and all the women who volunteered to participate in a clinical trial five years ago."

Although she's still regaining her strength, Alicia is back at work with a fresh perspective. "With a serious illness you feel like crap and you're forced to lie down and stare at the ceiling," she says. "You have to stop the pace that your life usually moves at and reflect."

She's had time to reflect on the fact that most researchers have never walked a mile in the trial volunteer's shoes.

"I teach a lot of classes for research professionals and always ask, 'How many of you have ever participated in any type of study?' It's always less than 5 percent of the people in the room and these are people in the industry!" she says.

Not only are researchers failing to set an example and make a statement about the importance of clinical research, they're missing an opportunity to understand what volunteers go through. She notes how easily researchers use words like "nausea" and "vomiting" and quips, "there should be a way to simulate nausea and vomiting for them" so they can better understand what patients experience.

She's thought about the fact that less than 5 percent of oncology patients participate in clinical trials. "We don't have a cure for pancreatic cancer," she says. "Why wouldn't a person consider a trial? We haven't talked about research in our culture in our everyday discussions."

Most of all, she's thought about the heroes: the professionals who push the scientific envelope, the volunteers who step forward to help them do it, and the people who support them throughout the process.

As a patient and the family member of a patient, she knows what it feels like to be suddenly inundated in information; to drown in facts.

"I didn't think there was a point where one could be too informed. Now I think there is a plateau. There really are limits to the information that one can convey. To say to someone who has just learned they have pancreatic cancer, 'Now let me talk to you about a study,' and to think that all that can take place in one setting is a little short sighted." What's more, she says, voluminous informed consent forms further complicate the matter. "I don't think a 25-page document necessarily makes a more informed patient than a 5-page document," she says.

Thoroughness, education, patient confidentiality, it's all important, Alicia says, but in the end, it's humanity and the human touch that must prevail.

"Patients want to be treated," she says. "As a patient you really don't care that someone didn't dot an 'i.' You care that they sat and listened and cared. Patients don't care about the paperwork. They don't care about database locks. They care about the interaction." ■

Ken Pouncey and his daughter, Alicia Pouncey.

This story is from a series of articles created by CISCRP as part of their educational awareness campaign to increase public understanding that those who volunteer to participate in clinical trials are genuine "Medical Heroes."