

# Helping Patients Navigate the World of Clinical Trials



**Ms. Merel Grey Nissenberg, a California attorney specializing in medical malpractice cases, is the President of both the American-based National Alliance of State Prostate Cancer Coalitions and the California Prostate Cancer Coalition.**

**Mr. Tom Kirk is the Vice-President of the California Prostate Cancer Coalition and an Invited Guest of the Executive Committee of the National Alliance of State Prostate Cancer Coalitions.**

**Together they form Informed Health Consulting, a group that helps patients of all kinds find clinical trials appropriate for them.**

*Prostatepedia* spoke with them about how, why, and when patients should consider a clinical trial.

*How did each of you become involved in prostate cancer advocacy?*

**Ms. Merel Grey Nissenberg:** In one of the cancer cases I was handling in my medical malpractice law practice, the surgical oncologist recommended that I join the Prostate Cancer Task Force for the California Division of American Cancer Society (ACS). I ended up co-chairing the group the next year.

I have also handled a lot of medical malpractice cases involving prostate cancer, among other cancers—especially inexcusably late diagnoses of prostate cancer. I became an advocate for patients in that way as well.

In 1997, ACS, California Division held a statewide meeting on prostate cancer. During the conference a few of us suggested that California should have its own prostate cancer coalition. People thought it couldn't be done because the state was so big. We're now in our 22nd year!

Along the way, we started the National Alliance of State Prostate Cancer Coalitions in 2004 ([www.nasppc.org](http://www.nasppc.org)) to serve as an umbrella entity over the existing and future state prostate cancer organizations around the country.

**Mr. Tom Kirk:** I got involved in prostate cancer in 2004 when I was recruited to be the President and CEO of Us TOO (<https://www.ustoo.org/>.)

That was about the same time that the National Alliance of State Prostate Cancer Coalitions was formed, so I have known Merel and her work for many years

When I started at Us TOO, one of the strategic plan goals was to increase the amount of educational materials by 100%. For many years, educational material development remained the focus of Us TOO. Of course, we also focused on support groups and support group leader training.

I left Us TOO in 2016 and moved to California where I quickly started work with Merel and the California Prostate Cancer Coalition. I've been the Vice-President of the California Prostate Cancer Coalition for a number of years. I also became involved in the National Alliance of State Prostate Cancer Coalitions as Invited Guest of the Executive Committee, and Chair of its Steering Committee.

Before Us TOO, I was on staff at the National Alzheimer's Association and had an interest in advocacy.

*What is Informed Health Consulting?*

**Ms. Nissenberg:** Informed Health Consulting is our consulting group. Tom and I concentrate in three areas: we set up Patient Ambassador programs; we set up Patient and KOL Roundtables; and most importantly, we do Patient

Accrual for Clinical Trials using a direct patient model.

Informed Health Consulting (IHC) has a very unique methodology. Unlike clinical trial matching services, we work directly with the patients. We know the patients. We're involved in advocacy groups. We are embedded in and between advocacy groups.

IHC does all of its activities across different types of cancer and different disease sites.

For example, we were working for Medivation, which has since been purchased by Pfizer, on a trial that looked for women with advanced or metastatic breast cancer who had a BRCA 1 or BRCA 2 mutation. When we first talked to the company, they said, "We cannot get the last 100 patients. We have tried and tried."

Tom and I identified which patients we needed to approach. We were pretty imaginative, which is what we do. We came up with great ways to meet patients who would be really good candidates for the trial. We went to national and local breast cancer advocacy meetings. Since BRCA 1 and 2 mutations are very frequently seen in Jewish populations, we targeted Jewish university women and big Synagogues on the West Coast.

Long story short, we helped accrue the rest of the patients, the trial closed, and it was a positive trial. The drug, a PARP inhibitor, has already been approved.

It's so exciting because we can really see the fruits of our labors. Hopefully, we have helped to save lives.

*You had a direct impact.*

**Ms. Nissenberg:** IHC is unlike a clinical trial matching service that doesn't really get to know the patient until the patient or their physician contacts them. Companies don't have that personal relationship. Tom and I start out with the personal relationship.

It's been really successful. We hope that we're helping to accrue patients who can benefit from an appropriate trial.

*What might some of the benefit be? Why should patients consider a clinical trial?*

**Mr. Kirk:** Often a clinical trial is the best way to gain some access to new developing interventions.

**Ms. Nissenberg:** First of all, the control group is always going to receive at the very least, standard of care. It's not like you're not going to get care that hasn't already been approved or in practice. But it is an opportunity to see if there is a new therapy or intervention that can benefit patients.

If the response is really striking, they'll stop the trial midway through after the interim analysis and let patients cross over into the group that is showing great success.

A trial is an opportunity to take advantage of new therapies and new interventions that may ultimately become standard of care.

**Mr. Kirk:** The word you just used, interventions, is essential. Often, clinical trials develop new approaches to treating patients. It's not just access to a drug per se, but also about access to the latest care.

*Frequently at a reduced cost, right? Sometimes trials cover the cost of the drug or procedure.*

**Ms. Nissenberg:** Absolutely.

Some of the numbers people bandy about for clinical trials are not quite accurate. In an issue of the The National Cancer Institute journal that just came out this year, a study shows that the barriers to entering clinical trials are structural, cultural, or clinical for more than three-quarters of cancer patients.

Everyone says that generally 8 percent of patients enter a trial, but only 3 percent of cancer patients. However, this study says that that number is too low.

They performed a meta-analysis. Nearly 56 percent of patients did not have a trial available to them at their institution. Nearly 22 percent were deemed ineligible. [That's what they mean when they talk about structural and clinical barriers.] That low number of 2 - 3 percent is from the 1990s and early 2000s. It was largely based on enrollment in government-sponsored trials. About twice as many patients are enrolled in pharmaceutical-sponsored trials.

The authors of the NCI article believe that an estimate of 8% is likely more reflective of patient involvement in cancer clinical trials, government- or pharmaceutical-sponsored.

*Still, 8% is pretty low when you think about it.*

**Ms. Nissenberg:** Absolutely. However, the authors made an important observation: when patients are offered an available clinical trial, they choose to participate only about 50% of the time. That's shocking. I didn't realize it was that high.

*Why the reluctance in the other 50 percent?*

**Ms. Nissenberg:** I used to be in something called the Summit On



Cancer Clinical Trials. I was part of the dissemination strategy to create a piece for the NCI website to help patients learn what clinical trials are, long before they ever need or consider joining one.

The term clinical trial itself is very foreboding. A lot of people think either of guinea pigs or they think of the boy in Pittsburgh who died after being inappropriately consented for the trial. Or they picture a green-tiled room with a big light hanging down: very stark, very cold. They feel that it's experimental. I think people worry about that. I think that's why they primarily don't join.

*I think a lot of patients think of the clinical trial as a last resort. When your cancer has become so advanced that you're willing to try something experimental. That's not true obviously. Given that, at what stage along the prostate cancer journey should a man consider a clinical trial?*

**Mr. Kirk:** Don't we always say that men should be active in their treatment? We encourage men to be very active, to be the quarterback or CEO of their own care. That would mean he should look for a trial at any stage.

Of course, we would believe the earlier stage is important because men are starting to make decisions about whether to treat or not. Approaches like active surveillance often are developed in clinical trials.

At any stage, it's important for people to explore their clinical trial options. Search early and often.

*Are there many prostate cancer clinical trials available for the newly diagnosed?*

**Ms. Nissenberg:** Just a few. Most of the trials are for advanced prostate cancer. But as you know,

advanced prostate cancer can be non-metastatic. There have been important clinical trials in this space as well. If we can delay, or maybe prevent metastases altogether, then we're going to go a long way to improving overall survival.

Do you think it's in a man's best interest to keep abreast of what kinds of clinical trials are available, even if they're not necessarily for his current disease state?

**Ms. Nissenberg:** That's easier said than done. There are a lot of trials out there. IHC has done a project with a group called Emerging Med. We are helping all prostate cancer groups place a clinical trial finder on their websites. These clinical trial matching finders have computer algorithms that match trials to patients.

*What should a man reading this who is interested in finding a trial do?*

**Ms. Nissenberg:** The first thing is to go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov). That site lists all the NCI-approved cancer clinical trials. It doesn't list all the trials out there, but it lists most of them.

A lot of physicians either don't know about all the applicable trials or they don't really want to send their patient away to a clinical trial unless they're going to get the protocol and do it themselves.

*Why?*

**Ms. Nissenberg:** Some are disincentivized because they're going to lose a patient or lose money. That's just reality. And patients don't always qualify. Sometimes patients will come armed with information about certain trials and the physician hasn't heard of any of them.

Then, the patient could contact a company like Emerging Med and say, "This is my status. Is there a trial that you would recommend?"

**Mr. Kirk:** The National Alliance of State Prostate Cancer Coalitions will be offering this service on our website. We believe these matching services are important. The case management services and individual discussions with a case manager can be very helpful in removing the stress of finding the right kind of clinical trial.

**Ms. Nissenberg:** This is in contrast to other sites that only have a couple of sponsors' trials. They're not getting all the trials out there. They're only getting the ones that those sponsors are enrolling and that don't necessarily apply to that patient or his condition. You have to be really careful that you're looking at a completely objective, non-commercial source for clinical trial listing.

*A man can look for trials from a variety of sources: online, through his doctor, through one of these clinical trial matching services and then come up with a short list of trials that he may be interested in?*

**Mr. Kirk:** Yes.

*Are there any other considerations men should keep in mind as they evaluate appropriate trials?*

**Ms. Nissenberg:** Be realistic. See if a trial is geographically appropriate or determine if your own physician can run the protocol. Look at quality of life issues—are there known side effects that you're not going to want to deal with? But then look at the positive side too. The control arm should never be less than standard-of-care treatment. But keep in mind that if it is truly a randomized control

trial, which is the kind that we really need to set new standards of care, you're not going to be able to choose the arm of treatment. You have to be willing to go into the trial knowing that you could just get standard of care and not the new therapy or intervention. The trials are blinded; you don't know what you're getting.

*Isn't it true that even men on the control group tend to do better because they're being monitored more closely?*

**Ms. Nissenberg:** That's true. They have much better care. They've usually got an oncology nurse assigned to them. Sometimes those getting standard of care or placebo end up getting some of the benefits, especially the psychological benefits, because they think they're being treated with the new treatment. The placebo effect is very interesting.

*The placebo effect can be positive.*

**Mr. Kirk:** Right.

*Any final thoughts for men as they start to look for clinical trials or consider clinical trials, any final advice?*

**Mr. Kirk:** Remain active. Know that your contribution is about more than just yourself. Share with others your experience of being in a clinical trial to help other men deal with their hesitancy.

*One way might be to join IHC's Patient Ambassador Program. Can you talk a bit about that program?*

**Ms. Nissenberg:** We develop groups of Patient Ambassadors. Let's say a company has a genomic test, for example. We identify a group of diverse patients—diverse in terms of geography, socioeconomics, and race.

We bring together about 15 or 16 men who have had this genomic test and want to share their experiences with other men. We bring them in for a weekend. We bring them to the company. They have a tour of the facilities. They meet everybody. They completely bond. We train them on how to go out to support groups and to civic groups like Rotary Club to talk about the test and what it meant to them.

We then maintain a call list. If a patient wants to talk to another patient who has had this test, we set up a phone call. We've had patients go to other states to talk about whatever the product is. (It could be a therapy or a test.)

**Mr. Kirk:** This is personal advocacy based on experience.

*You mentioned genomics as one grouping but how many of these patient ambassador groups do you have?*

**Ms. Nissenberg:** It depends. We have to be careful because we're not marketing anything for anybody. These Patient Ambassadors aren't marketing people and we're not selling a product. We're just sharing patient experiences.

Another thing Informed Health Consulting is doing are Patient Roundtables. For example, in October of last year, we had a Roundtable on bone health and access to bone-targeted therapy. Access to care is a hot-button topic.

**Mr. Kirk:** For not only prostate cancer, but also for breast cancer.

**Ms. Nissenberg:** Right. We brought in prostate, breast cancer and lung cancer patients. These were people who were dealing with bone mets, osteoporosis, or osteopenia.

We brought in physicians to talk to them and to help them with access issues.

We're going to be doing another Roundtable on step-therapy in the Fall.

The Roundtables are great because we can bring people in from anywhere in the country. We teach them. We can find out from them what they're hearing in their local communities. For example, if there is an access issue, what are they hearing? Where is their pushback? It could be on a therapy. It could be on access to different tests. It could be coverage issues.

*You mentioned that these patient roundtables are not prostate cancer-specific. Is the Patient Ambassador Program also not prostate cancer-specific?*

**Ms. Nissenberg:** Correct. We develop Patient Ambassador groups for any disease. It's the same modality. The most time-consuming and challenging parts are not the planning for the meetings or trainings. The hardest part is identifying the right patients for both programs. [PP](#)

### *If you're interested...*

...in participating in Informed Health Consulting's Patient Ambassador or Patient Roundtable programs, contact Merel at [merel@informedhealthconsulting.com](mailto:merel@informedhealthconsulting.com) or Tom at [tom@informedhealthconsulting.com](mailto:tom@informedhealthconsulting.com).

Both can also be reached by calling [424-253-1169](tel:424-253-1169).

