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MJFF: Welcome to a recap of our latest third Thursday webinar. Hear directly from expert panelists as they discuss Parkinson's research and answer your questions about living with the disease. Join us live next time by registering for an upcoming webinar at michaeljfox.org.

Dr. María L. De León: Hi, good morning or afternoon, depending on where you're joining us from. My name is Maria De León and I'm a movement disorder specialist, and I am also Michael J. Fox Patient Council member as well as be your moderator this morning for the webinar. So today we're going to discuss different types of clinical research and how to find the best study for you. So we'll cover potential benefits and risk of participation and how volunteering for research can become a critical part of your Parkinson's journey. We've got a lot to discuss this morning, so let's get started. So I would like to start by introducing our panelists this morning or afternoon, John Humphreys was diagnosed with Parkinson's Disease in 2008. He is an active Michael J. Fox Foundation public policy advocate, and he just got an award, so congratulations, and has participated in over 300 clinical research studies.

Dr. María L. De León: Karen Williams is joining us from Northwestern in Chicago, right? In Illinois. She is a clinical research manager at Northwestern Medicine and a study coordinator for many studies, including the Foundation's landmark, the PPMI Parkinson's Progression Markers Initiative. And we're going to talk about them more later. And finally, but not least we have Dr. Stuart Isaacson, who is the director of the Parkinson's Disease and Movement Disorder Center, at Boca Raton. At this center, Dr. Isaacson has been the principal investigator for many PD clinical studies, including the PPMI, and also has treated many patients with PD. So we will be learning a lot from him today. Let's get started. First, we're going to talk about the types of research studies we have. We have both the interventional trials and the observational trials. So Dr. Isaacson, can you talk to us more about what the differences between those two types of studies?

Dr. Stuart Isaacson: Sure. We're always... We are all in this together, trying to find better ways to evaluate and diagnose Parkinson's, better ways to figure out how to treat Parkinson's, both from the beginning and throughout the multi-decade course and we do a lot of research trying to find better treatments, better ideas, better knowledge. There are some trials that we can do in research that don't involve medication, but just involve, watching, and learning, and asking questions. We call these observational studies. They don't require any type of medication. We may monitor movement by wearing a watch or carrying a phone around. We may monitor things in the blood or the spinal fluid or in brain scans by doing these types of tests.

Dr. Stuart Isaacson: And we might ask lots of different questions and scales and keep track over time to see how things change over time and perhaps to compare how things change

in some people compared to how things change in other people. And indeed, we'll talk about a program today, a research program that The Michael J. Fox Foundation is sponsoring, called PPMI, that looks for biomarkers and understandings of how Parkinson's begins and how it changes over the years.

Dr. Stuart Isaacson: You're also probably aware of how new medicines are needed for Parkinson's and how we've had a lot of new medicines in the past four or five years. And we try to understand these medicines before they can be prescribed, or either had gotten at the pharmacy, and we do this in research programs that begin in early phase, what we call phase one, where we check them and make sure they're safe. And then in phase two, we try to find the right dose. Then in phase three, we try to test the right dose against a placebo dose to make sure that a medication has a good effect and has tolerability and is safe before it becomes available to be prescribed by doctors and nurses, to people who have Parkinson's. So different types of programs... We can have interventional with medications or surgeries, but we can just observe and try to understand better about the disease.

Dr. María L. De León: Great. Thank you very much. John, you're an expert in participation in clinical research. How have you decided... What motivated you to start participating? Because I know, also, that most of your research studies have included non-medication... Only about seven, you said. So could you tell us about what motivates you and how do you decide to do the observational versus interventional trials?

John Humphreys: Thank you for asking me to be in this panel today, first of all, Maria and Christina. But 13 years ago when I was diagnosed with Parkinson's I knew I wanted to get involved. And I thought... I was told about advocacy. I was told about clinical trials on soul, about fundraising. And I really wasn't crazy about fundraising because I was in sales. I always say I was in sales all my life and everything I sold I had to go back collect for about 60 days later. So I got involved with clinical trials because I had lost my job and I didn't have insurance. So I talked to a social worker who is now retired from Emory, Lynn Ross, and she suggested to do clinical because you could get more exams from a movement disorder specialist at a teaching hospital than you could ever imagine.

John Humphreys: So I kind of got involved and my movement disorders specialist at Emory gives you the business and said they'd lose money on me because they never get to file anything for insurance because all my visits are for free. So I got involved with clinical trials and it's just... I do it mainly because it keeps you really abreast of what's going on. And then also to be honest, we live with hope when we have Parkinson's and this gives me hope every day.

Dr. María L. De León: Great. Thank you. But how do you decide between doing an observational, where you don't take medication, how do you decide between one or another?

John Humphreys: Well, it's just what it comes about because I don't do a lot of studying on the like Fox Trial Finder. I actually just get all of my references basically from my

movement disorder specialists, and I know all the clinical trial coordinators, so whatever's available. It's 300, but there are anywhere from... I've had one that lasted... Couple of them lasted for three years and I've had some that were 15 minutes. It just depends on what they have available.

Dr. María L. De León: Okay. Wonderful. Thank you very much. So, Karen, how do you recommend one or another to patients?

Karen Williams: Okay, we ask... We look at the patient's medical history to see what other conditions that they have that would come to get some of the inclusion, exclusion criteria of studies. We also check and confirm with the doctors and the participants, whether they have early PD or medic... Or make that at stages where they require medication. And then we ask them about their availability. If they're early PD, maybe they are still working. We ask about transportation issues. And so we ask patients a lot of questions and then we also will... Most medical centers, academic centers are just like a restaurant, and I'm sure they have a menu of studies that they hand down to patients, describing the inclusion and exclusion criteria, where patients can look over that information and decide: "What would be the best study for me to participate in, between my condition and environment?" So we help them with that type of decision-making.

Dr. María L. De León: That's wonderful. Thank you so much. And Dr. Isaacson, I was going to ask a lot of people have concerns or have asked if they are enrolled in a study and then they later find that they were in placebo phase, but the study turned out to be positive and yield some results. Can they later go on and switch to an active drug.

Dr. Stuart Isaacson: So, really when we're trying to think about new medicines, nobody would ever want to have a medicine prescribed by their doctors and nurses that we don't know if it works, so we don't know if it's safe. So we definitely all want to be part of trying to figure that out before. And some people volunteer. We need about 300 people to volunteer, to test a new medicine, to see if it's safe and effective. If it turns out that while you were in the research program, you were getting placebo, well, now that it's available and approved, you can have it prescribed and you can take it. And in many of the programs, it's only during the first two months or four months or six months where you get placebo and someone else gets the real drug. And after that, everyone may be able to get the real drug during an open label type of research program where we try not to compare it, but to see what happens over time.

Dr. Stuart Isaacson: So most research programs will allow people, even if they're on placebo to then get it through the next phase of the research program, even before it's approved. Many of our patients for this reason have tried and been using and benefiting from some of the new medicines that have been approved over the past five years for about 10 years, because they're able to get it during that period and stay on it during that period.

Dr. María L. De León: Great. Thank you for that wonderful discussion because that's been a lot of questions around that issue. So we're going to move on. So we all want to be part of the solution. So it's important to get involved. And of course, with everything there's always benefits and risks, but how do you determine what is best for you as we talked about, whether you have other medical conditions or whether it's the distance. So how do you go about discussing criteria with patients, Karen?

Karen Williams: We... Once the study is activated, we have what we call Institutional Review Board approval, which a lot of you probably have heard, is called IRB. We provide in a form consent to them, outlining what we believe are the benefits and the risks. And they are very carefully looking at the information that we provide on consent forms. Once it's approved, we review this information with our participants and we also go over the benefits that you are participating in a study and providing health and empowerment and giving, if it doesn't... You're helping someone, not only you but someone else in the future. You get access to Parkinson's experts where you're able to come into an academic medical center and to seek some well-known movement disorder specialists and also have potential access to all types of treatment. Those are the benefits of participating in clinical research.

Karen Williams: And one other issue that I want to expect that it is at no cost to you to participate in clinical research. So that is a good benefit. It doesn't affect your Medicare. It doesn't affect your insurance. Most of the clinical research visits are primarily at no cost to you at all. And in addition that most medical centers also provide transportation or other things for you to participate, where there are no barriers for you to participate. Like if you discussed with your movement disorder specialist: "I would love to participate, however, I don't have the transportation. I can't be this." And a lot of centers can provide that info... that systems for you. So that's one of the good benefits of participating in clinical research. The risks are, as everyone knows, there are side effects and adverse events. And what we ask as a research coordinator, if you've been involved in a study, we also ask at every visit, how have you felt since you participated in the study?

Karen Williams: So we are very active monitoring you to just ensure, if you had a known condition, we ask: "Has it worsened since you started the study? Is there anything else that's not normal since you participated?" So you're very closely monitored by the clinical staff, the coordinator and especially the investigator. And then there, as we all know, there's potential for data breach, but there are a lot of data systems in place and medical centers, especially on pharmaceutical, regarding electronic data capture. So that is very well controlled. And a lot of centers have to provide a data security policy or program. That's how will you keep patient information secure and safe? So centers are really working to keep the information from being breached. When as we all know that things can happen, but we are very much putting things in place, have policies and procedures before that.

Karen Williams: And if there are any risks at any time, and the patient feels that: "I'm really having difficulty. I... This is something I could no longer do." You are and can say I want to be removed from the study and it will not affect your medical care. We still will see you. We'll still ask you for future studies if you are eligible. So those are the potential benefits and risks of participating in clinical research.

Dr. María L. De León: Great. Thank you very much, Karen. It's especially important because a lot of people feel that, perhaps, is going to affect their Medicare or their insurance. If they don't have insurance, they can't participate. It's important to know you do not have to have insurance to be part of a trial, or is going to affect your insurance benefits like Medicare. Dr. Isaacson, how do you go about recruiting diverse groups, and minorities, for these studies?

Dr. Stuart Isaacson: Well, I think the recruitment for research programs really comes down to awareness. It's awareness that they exist. That we're looking for better options for people who have Parkinson's. Whether it's an interventional study with the medication, or it's an observational study, we need to get awareness. I think that's where organizations, such as The Michael J. Fox Foundation, comes into such a role in trying to spread the word that these opportunities are out there. Since people who have Parkinson's, and people who are involved with people who have Parkinson's, whether they're caregivers, families, therapists, exercise people, doctors, and nurses all are in the same boat together trying to find better options. Really, the awareness is key. Then, on top of awareness, we want education of what it's about like we do today. What are the other alternatives? What are benefits? What are risks?

Dr. Stuart Isaacson: What is there to gain? What is there to lose by being part of, or not being part of it? That's very important as well. We try to integrate both the medications we prescribe, research opportunities, and patients that we see in our clinics as many centers do around the world. There are other options, not just what's been approved by the FDA. There's other options of things we're looking at that might be best for you at this point. Unfortunately, trying to reach out to communities that we don't see can be very difficult.

Dr. Stuart Isaacson: Trying to include a more diverse population in research programs is critical, so we can understand how new medications could affect all different types of people, of different backgrounds, races, ethnicities, genders, and such. It's very difficult, and it's a big challenge. Then, I think everyone needs to make everyone else aware of it in the different groups. That no matter who they're seeing, they can still participate in research. Even if you're not seeing that center, that doctor, or nurse, and you can still be part of research, and keep your own doctor and nurses in your own community, or your own lives.

Dr. María L. De León: Thank you very much for that. Yes, it's important to bring awareness to the different communities, because oftentimes, most of the research goes on in the large university, so the rural communities may not be aware. It's important to have that interaction with the physicians, the patients, and other parts of that. They know what is going on. Also, what I wanted to ask you, one of the things

that I hear about a lot, especially within the minority community, the Hispanic community, and some others, sometimes they're a little discouraged about participating, because they say they didn't meet criteria for a particular study. Then, they get discouraged, because they're not told, or they feel, that they're not told why they were not eligible to participate. What can we do, or what are we doing, to improve that, so patients are more likely to, even though they may not qualify for one study, go ahead and try again? Don't get discouraged for it. Try in different trials.

Dr. Stuart Isaacson: Yeah. I think it's an important point. I think, as you've heard Karen describe, that studies have inclusion, exclusion criteria. Really, trying to make that into a setting where not every medication is right for everybody. We have 25 or more medicines for Parkinson's, and yet most people only tried a few, because not every medicine is right for everyone. Same thing with the research medicine, it might not be right for you. We have to see and look at certain criteria. Is this is good medicine that can help you? This the medicine that's safe for you? This a medicine that could interact with other medicines you have, or potentially worse than other medical problems you have? It's not that you're being selected. It's whether we can find out if this is something that might benefit you, and also be safe in, terms of overall. Talking about a research program, as if we were talking about a medication that's already available at the pharmacy, is important in trying to integrate this.

Dr. Stuart Isaacson: Also, to understand that, in the research programs, there's no cost. Transportation can be provided. If you live far away, you can have this. You may have a hotel you can stay in closer. If you don't speak English as your first language, we don't want you to misunderstand anything. We can have this translated, and approved, by the IRB, so we can make sure we give you important information that's understandable to everyone, and taking the time. The time to understand what's going on, and the time to take it home and think about it, formulate questions, and then come back in, and spend that time to really know we're looking for the best thing for you, but we have lots of choices. Some approved, some being researched, some that are just on the shelves in the health food store. There's many different things you have to understand what's best for you.

Dr. María L. De León: Right. I think that's an important point. Knowing yourself, and your medical history, and also talking to your physician about what is the best thing for you. Thank you so much for that. John, you have participated in lots of studies. Have there been times, or is the reason that you've done a lot of observation, because you've not qualified for other studies, or is that something you just chose to do?

John Humphreys: ... Stay away from, because it is scary to try medication, but the good thing is, like I said earlier, I had a one clinical trial that I was doing. It was going to be a long clinical trial, and I had an adverse reaction to it, and I pulled out of it. You got to put yourself number one, and think what's, like the doctor said, best for you. The main thing is, the thing I don't like here, people in the Parkinson's

community, say, "I've tried to do a clinical trial. I didn't qualify. There's none for me." There's plenty of them, for them, if they do their research, and talk to their doctor, and talk to the people. It's really, basically, something I chose to do. Then, what came up at the time it just so happens. I did the trial for the INBRIJA inhaler, and while I was doing that, I couldn't do other things. It will regulate your time, what you can do, and what you can't do, as far as clinical trial.

Dr. María L. De León: Thank you. I think one of the other things that is important to keep in mind, the distance. How often you have to meet with the physicians, what kind of studies. Also, even though there may be some intervention, perhaps a study requires lumbar punctures, you can, depending on the place, but I think most times you can participate on different studies, but not have all the lumbar punctures they need. Maybe one, or two, because of whatever reasons. You can talk to your physician, and talk to the coordinators, about what you can do.

Dr. María L. De León: It's not all black and white. Say, "Well, I can't do the lumbar punctures. I'm not going to do that study, unless I saw their study, and the lumbar puncture is CSF." If they're doing that as part of other studies, you can still, perhaps, most likely, participate in the trial, but knowing yourself is important. I, for instance, have a lot of other medical illnesses. It really cuts down my eligibility for participating in a lot of medical trials. However, I have participated, like John, on a lot of trials that include sleep, visual problems, and doing smell tests, and things like that, so that you can still participate, and contribute, without having to take medication if you're not able to do that.

John Humphreys: [crosstalk 00:22:57] in these studies, too, because I've done one that I had went to a facility here, in Atlanta state, for seven days and didn't go home.

Dr. María L. De León: Right. It's important to have the family involved. Karen, what do you have to say about the family involvement? It's important.

Karen Williams: Another point, regarding study participation, last thing, and you can ask your physician, the study coordinator. A lot of studies are able to do what we call virtual visits, that we can do it from your home. You've don't have to come into the clinic. There are some observational studies, where if you have the technology of a smartphone, computer, or a family member that can assist you with that, we're able to do some studies via the computer. Especially if they're patient outcome reported type of studies, like questionnaires and forms. Those are also some studies you may be eligible for, without really leaving your home.

Dr. María L. De León: That's important. Thank you. You brought us to the next point. Dr. Isaacson, in this time of a pandemic and social distancing, how have you found that recruitment has shifted, or changed, and what can patients do to still participate if they're not able to come in in person, because of the restrictions we still have?

Dr. Stuart Isaacson: Well, certainly the COVID pandemic has really began to put a real crimp in research programs. This is problematic, because we want to finish the research program sooner, and get an answer, and get new drugs. A new answer. Luckily, remarkably, globally, all the sponsors of the programs, whether they were pharmaceutical companies or organizations, were able to shift very quickly to virtual, or telemedicine type visits, to allow the research programs to keep going. We found that a lot of our patients who were stuck at home, because of the pandemic, had time they may not have had before. They weren't traveling to see grandchildren. They weren't going on trips. They had more time, and were able to isolate our office, and have offices that were available, and not have other people there. We could really have people feel comfortable coming in a back door, and going into a room, and being isolated, of course, with all the proper protection.

Dr. Stuart Isaacson: Now, with the vaccinations, all the research staff, all the staff is vaccinated. People can feel a little more assured, and feel safe to continue doing this, because COVID has no time to ignore Parkinson's. In fact, COVID was an opportunity to double down on Parkinson's, and try to really re do and recruit, and get everything in order, so we could start really working hard and having everyone ready to keep the research going, so we don't lose any time in finding out the answers we want to know. I think we've been able to emerge from this. I think around the country, many centers have been able to emerge, better able to help patients know about, be aware, join research, and continue these studies that are so important.

Dr. María L. De León: That's good. Thank you very much. Yes, it's important that the patients, and family members, know that just because we're still having some precautions, you can still participate, and you may have more opportunities in participating than you had before, prior to pandemic, because now we do have that telemedicine enabled you to do that. Thank you. I think, now, we're going to shift a little bit. We're going to take a little short break, to call out the foundation's landmark study, the PPMI, which is recruiting. This is a Parkinson's Progression Markers Initiative. I apologize. This could change everything for the way we diagnose, we treat, Parkinson's in the future.

Dr. María L. De León: This study is really wanting people, brothers, sisters, parents, everyone related to Parkinson's, so we can hopefully find the markers we need soon to be able to treat, and diagnose early, and start making progress, and perhaps prevention, and curing, the disease. I think we've been talking about this all along, choosing the right study for you. We talked about the eligibility criteria. The time from diagnosis, age. Assess your DBS. Can you tell us a little bit about your criteria for DBS participation? I'm not sure if they're still doing some DBS studies or not, but if you could let us know a little bit, Dr. Isaacson, about what patients should think about when considering DBS?

Dr. Stuart Isaacson: I think two different ideas with DBS, one is there's been a lot of new systems for DBS, and those who went through research programs, to make sure that they were safe in how they work, and now there's three different systems. Actually,

with the old one, there's three new ones. That's very important. Certainly, surgical studies are something that's going on a lot now, trying to find some way of doing gene therapy, or trying to find safer, better ways to do brain surgery, and those surgeries go on. Those were a little bit different, because some of them have different ideas on how we might have a control placebo group. Who do we compare people to? Also, in many other studies, if you've had deep brain stimulation, you may not be eligible to test a new medicine, because we don't know enough about how that new medicine would work in someone who has a deep brain stimulator in the brain.

Dr. Stuart Isaacson: Other studies, you can have a DBS and be in the studies. We have ongoing studies from everything from constipation to low blood pressure, to new medications to try to slow down the disease. Some of the studies do allow deep brain stimulation, some don't. It's like any other medical condition, any of the medication. They all have to be looked at as a whole. Holistically, we have to decide, do you need more physical therapy? Do you need more education? Do you need to have your medicines you take adjusted to different times? You need a new medicine from the pharmacy? What new medicine that's being looked at in a research program?

Dr. María L. De León: Great. You brought an important question topic about the fact that you may have DBS, or considering DBS. It's important to, I guess, talk to your physician about whether or not this is going to affect later on participation in other trials, and also taking other medications, because sometimes patients may not be aware of that. They may choose to do a procedure, and then be a little disappointed later on when they're not able to participate in other things, or take other medications, but in choosing whether or not to participate, perhaps in a trial for a surgical procedure, any recommendations that you give them may differ from participation in other clinical trials?

Dr. Stuart Isaacson: Well, certainly once you've had some type of brain surgery, that's a threshold, and then you can't really go back. You can't unoperate on the brain. So, it's not as simple as saying, "Well, I'm in this research program, I thought it was a good idea. I don't think it's such a good idea for me now. I want to stop." And then we say, "That's absolutely fine. We can stop it. We'll still take care of you. You can still be... And we'll still..." With brain surgery it's a little different, because the brain surgery may have already occurred. So that's a little bit different, so you have to think about that beforehand and then make sure that it's right for you, because it's not as simple as to stop it if it's already been implanted.

Dr. María L. De León: Right. Thank you.

Larry Gifford: A landmark study that could change the way Parkinson's disease is diagnosed, managed and treated is recruiting participants now. PPMI or the Parkinson's Progression Markers Initiative, needs people with and without Parkinson's, especially people aged 60 and up, who have close relatives living with the disease. Take a short survey today at michaeljfox.org/PPMI to see if you're eligible. That's michaeljfox.org/PPMI.

Dr. María L. De León: We have a question from the audience. Why do studies require not taking medications prior to being evaluated or doing the studies?

Dr. Stuart Isaacson: So, there are two issues. When someone is not yet taking medicine to treat Parkinson's disease, after diagnosis, this may go on for six months or a year or two, depending on the symptoms, and there are some new medications that are being tested to see if they can slow the progression of Parkinson's. That would be great if we could find something that could slow or stop the progression of Parkinson's. In order to test and see if that's possible, it only enrolls patients, these research programs, who are not yet being treated for symptoms, so that we could evaluate the symptoms over time and see if they get more worse or less worse, depending on whether this research medicine is being taken or a placebo medication is being taken.

Dr. Stuart Isaacson: If someone was already taking levodopa and other dopamine type medicine, it might interfere with knowing whether or not this is working. But in any research program, no matter what medicines you could be taking for Parkinson's disease treatment, we'd want to hold them stable and not have them changed. Usually for about 30 days before and throughout the research program, so we can compare just the new medicine being added on without confounders that might make it confusing to understand how the medicine works or what side effects it might have.

Dr. María L. De León: That's important. Thank you. Thank you very much. I also wanted to add a question that perhaps... I'm not sure if this is the right time, but... Now, I lost my train of thought. I apologize. But one of the things that a lot of patients, when they're looking to see whether they're a candidate for DBS, a lot of times we want to evaluate them off of their medications, and this is one of the complaints I hear a lot and now being a patient myself is horrible being off medication. So I was wondering now that we are using more telemedicine and telehealth and virtual meetings, is this become a little bit easier to do? Are we seeing patients at home off their medicine, so they're not having to do the traveling and having to be off medications away from home? Is that anything that we're doing or considering doing?

Dr. Stuart Isaacson: It's such an important point. And it's why it's so important, that when we design research programs, they're not designed in a vacuum, but they include all stakeholders. People living with Parkinson's, their families and caregivers, because this is really a very important point. In our field we've defined something called an overnight defined off, where we say don't take any medicine since last night, and come in in the morning. How unfortunate to make people who are having problems, symptoms and mobility, have to travel in in the morning, if it's not necessary. Sometimes it's necessary because we have to understand how things can be and in those situations, we're hopefully able to arrange for a local hotel where you can stay overnight and transportation and such, but many other times it's not necessary or perhaps it can be done virtually.

Dr. Stuart Isaacson: We've taken the approach with some of the programs to see someone after the first dose has worn off. So someone can come in when the medicine's still working with the first dose and then wait a couple of hours until it's not working and do the evaluations there, especially with some medications that can be administered on demand. So I think it's really important that we really understand the experiences of the journey and the days of what it's like to wake up and not take medication before we casually say, "Come in so we can evaluate." And that's not really not the best time of day to necessarily do it. And as people with Parkinson's know, if you delay that first dose for a couple of hours, whether it's for a research evaluation or just for other reasons, that first dose probably doesn't work so well anyway, so we're not going to get a good evaluation.

Dr. María L. De León: That's true. Thank you very much. Karen, going back to you, and choosing the right study, again going back to minorities and the logistics of travel and informed consent. Can you tell us about how that may differ within the different populations or what you're doing at your Institute to improve that, to bring specially with the PPMI and then we're going to be talking more about that in a bit?

Karen Williams: Right. In regards to travel or transportation, we have ensured at Northwestern for that not to be a barrier for anyone that wants to participate in clinical trials. We always ask the patient if... Because we're just saying DBS, if you have to be off meds or on, we'll provide car service for you, where you are not driving or when Billy has to come with you. And I think a lot of institutions [inaudible 00:36:03] academic centers are able to provide that and do provide there for their patients, that there are no actual barriers of limitation for coming into the center. In addition to the informed consent, coordinators review the informed consent with all participants on their level. We ask them, we give them a little brief overview of the study, we talk about it with them. And then we also just ask, "Do you have any questions and any concerns?"

Karen Williams: And we all know that maybe some patients will tell the coordinator more than they'll tell an investigator. A coordinator really develops a good working relationship with the participants, and we're able to know what is it that you really need? What are the barriers for you? In addition to the underrepresented patient population in clinical research, we are saying that providing people with more education about the symptoms of PD where a lot of people think that tool out there, is it a blood test that tells me I have it, or is there some type of x-ray? And a lot of people don't know that it's just clinical diagnosis.

Karen Williams: So we're educating all areas in that arena as well. And we're learning now too, for clinical research that we really are reaching out to family members, the younger generation of the participants, such as maybe the kids, the grandchildren, or someone that's able to get actively involved with research and Parkinson's disease as well. So they're are lot of different entities that clinical research and the research staff at all academic centers are making to be successful in clinical trials activity across the board.

Dr. María L. De León: Good. Thank you. Do you see that having a good support system improves participation or helps being able to stay the whole course of the trial? Do you recommend for patients to have at least someone there or have somebody at home that will support them?

Karen Williams: Yes, we've found that a caregiver or a spouse or something like that, that is actively with the patient and involved in the patient, is actively interested involved, we get a lot of additional support. We get... We'll talk later about the PPMI study for participation as a healthy control that, "Hey, I want to help my grandma. I want to help my mom. I want to help my husband." And so we are seeing that, that information and that collaboration is really growing in the field.

Dr. María L. De León: Okay.

Karen Williams: And like I said, a lot of patients are even becoming very good advocates to even share with other patients that are a little hesitant about participating in clinical research and sharing their experience.

Dr. María L. De León: All right. Thank you very much. We're going to move on. So where do we find a study? So one, we can visit the Fox Trial at foxtrialfinder.org, which is linked in your resource list. And if you can tell us Karen, about local resource. Are your clinic finding studies in your community and telling other patients about studies, how do you go about doing that? What do you recommend?

Karen Williams: As you can see on the slide, foxtrialfinder.org is an excellent way of finding clinical trials for Parkinson's disease. You are a physician when they see you, they are heavily invested in clinical research as well. They will present a study to you and then say, "Hey, we have someone that will talk to you further to give you more information such as a study coordinator." You can go on to foxinsight.org. That's another good way that if you put in your information and your location, that it goes straight to a designated person at a specific site or medical center and they contact you and get back to you and talk to you one-on-one about the inclusion, the exclusion, and your interest and conditions and all the questions that we've already talked about.

Karen Williams: In addition, any medical center that you are aware of, you can go onto the website and look for movement disorders or Parkinson's disease clinical research. A lot of academic medical centers have a designated website for clinical trials. So that would be an easy way to do it as well. Just say, if you're in Houston at Baylor, you can go on, Google that area. If you were in Chicagoland, you can do Northwestern Medical Center, Rush Medical Center, and you will be able to find the different clinical trials that are at each medical center. And you will see that most of the medical centers are doing some of the same studies.

Karen Williams: So there is a way that you will be able to determine what area I want to go into, where, and even if you're out of state or out of location, don't be afraid to contact the center that's out of your area. Like I say, there's a lot of studies

[inaudible 00:42:03] for PPMI will cover travel so that you can participate. So those are additional things that you can think of as well and use to your advantage to [inaudible 00:42:16] participation.

Dr. María L. De León: Great. Thank you very much. So John, being an expert on clinical trials, how do you go about finding studies?

John Humphreys: I find my networking is my best source. Talking to my movement disorder specialist, get to know the clinical trial coordinators at the facility I go to because you're making their job easier. So they want to know you, and if you show an interest. Also too, I think that there's so many clinical trials that are actually... Something I want to point out that are actually fun. Like in Atlanta here, Dr. Madeleine Hackney, does tango dancing clinical trials.

Dr. María L. De León: That's fun.

John Humphreys: If you want to learn... Get free tango lessons, you can do that. But I just really network and find out the clinical trials that are in the area that I might be interested in and talk to different people. I think with your clinical trials goes along with your advocacy, because this was mentioned. Parkinson's is a condition that a lot of times it doesn't affect people... Slaps him in the face for somebody in their family. But this way you get more people involved too, so my networking would be my key source to this.

Karen Williams: Just to add to what John said, and when you're looking at clinical trials like he said tango dancing, there also exercise clinical trials out there that you can do and have fun. Exercise or different type of activities, which helps slow down the progression of Parkinson's disease. So there are quite a few different... Like wearing a watch. Sometimes if you're monitoring your use of just any medication and things like that, you get a free watch. So there's a lot of good [inaudible 00:44:12] to also doing research.

John Humphreys: I would say, 'Just do something." People say, "What should I do?" And I say, "Do something. Don't sit on Facebook, do something."

Dr. María L. De León: Yes, that's one of the benefits. Getting active and getting your natural chemicals to get going. But I wish I would've known about the chocolate study. That would've been one of the first enrollees in that. So anyway, another way that you can get involved with the Fox Insight, you can do this online. It's easy, you just fill a questionnaire and it comes, I forget, every three months or every few months, and they'll message you and you can fill out and you can still participate and you can be part of the cure and finding answers about the disease. So you can do that from your own home.

Dr. María L. De León: So now we're going to go to our last line. The PPMI Needs You. And we're going to let Dr. Isaacson tell us about the need to enroll people for this study and why it's important.

Dr. Stuart Isaacson: Only one of the most common and probably the most frustrating questions for someone with Parkinson's and for someone like me trying to answer it is, why did I get Parkinson's? We're trying to understand, well, why did you get Parkinson's and not your brother or sister or cousin, or how come you have Parkinson's and your parent does, but not your sibling. We're trying to understand this. And we also know that Parkinson's disease may begin 5, or 10, or maybe 20 years before we diagnose it with things we never really think about, like constipation, or acting out of the dreams of sleep disorder, or loss of smell.

Dr. Stuart Isaacson: So we have some ideas that maybe if we could figure out who has a certain gene that raises the risk of developing Parkinson's, but they don't have Parkinson's now, or they have a sleep disorder and they act out their dreams, or maybe they don't have risk for Parkinson's, but they want to help find a cure for it.

Dr. Stuart Isaacson: We're trying to find people who are at risk of developing Parkinson's so we can follow them and then see if Parkinson's occurs and compare them to people who are at risk and Parkinson's doesn't occur, so we can find a difference. Maybe that would be a clue that we could find something to stop Parkinson's from occurring in people who are at risk for it. And that's what the Parkinson's Progression Markers Initiative, or PPMI, is. This important landmark study that's been gone on for over 10 years, and now it's been rebooted to really focus on trying to figure out what causes Parkinson's and how can we find something that we can intervene with. So anyone who thinks they know people, or maybe at increased risk. You might have a gene, or you have acting out of the dreams or... Now, in most people with the gene who act out the dreams don't get Parkinson's. But some do. And that's what we're trying to figure out, who does and who doesn't and why.

Dr. María L. De León: Thank you. Yes. And something I want to know, how can the relatives of people with Parkinson's participate in this research? And I think you mentioned that before, but if you can just remind us what they can do.

Dr. Stuart Isaacson: So I think anyone who has any interest in finding out more about it, either because they want to be part of it, or they have someone they know who may want to be part of it, or they just want to know about it because they want to spread the word to other people at groups and meetings and such, can log-on to a website, the michaeljfox.org website. And if you do backslash and PPMI, you can get a lot of information on the resources there, on how you can be part of trying to either be part of it or seeing if it's right for you or someone you know, or if you just want to get information to hand out to people and try to spread the word that way.

Dr. María L. De León: Yes. Thank you. And just to remind everybody, the michaeljfox.org/ppmi, you can get more information. And they're recruiting people, Parkinson's diagnosed, within the last two years and not yet taking PD medications. Karen, just if you can briefly tell us before, we're running close to time, tell us about your

experience being a coordinator for PPMI, and your book club and sense of community you have with this.

Karen Williams: I have been part on the PPMI study for over 10 years, and it has been such a rewarding and excellent experience. I think, not only for me and the other coordinators that work on this study, but also for our patients. We have developed a real cohesive community family because we do have a lot of participants that are enrolled in the PPMI study. And before the pandemic happened, each medical center would have an annual event bringing the participants together to talk about the results, to talk about what has been shown with the data thus far.

Karen Williams: And since the pandemic has happened, we have done virtual visits. So we're just still trying to keep our community together, talking to patients, getting them involved. And because we want to keep them engaged, me as a coordinator, I am so heavily invested with my participants in all of our research, I've started a book club for us to read the Michael J. Fox new book for us to talk about it, to see if there's any similarity or things that we can discuss. So that is currently in process.

Karen Williams: We are also thinking about just doing a community get-together for maybe having a toast or a drink to all of the participants in the PPMI study. So once you purchase a [inaudible 00:49:56] in the study, your center... Because all of the research coordinators that work with the PPMI study meet to talk about our different experiences, share things, help one another for engaging and retention. So not only are you getting a person like me [inaudible 00:50:17] you're giving it throughout all of the centers that participate in PPMI because we're all on the same page, we're trying to keep community, and to keep our participant first. So we're not looking at people that enrolled in the [PPM 00:50:31] as research, they are our participants that we have become like family because PPMI is a long-term study, as Dr. Isaac has already said, was a 10 year study and is rebooted for another study. And patients seem to be willing to stay in it. And I think that's really great and we love it.

Dr. María L. De León: That's great. Thank you very much. I guess this question is for everybody, do you guys know if patients from other countries can participate in any of this? The PPMI, or the Fox Insight, or any of the other?

Karen Williams: The PPMI study has brought on new sites across international globe, right Dr. Isaacson? There's quite a few.

Dr. María L. De León: Okay.

Karen Williams: So if you log-in to the PPMI at michaeljfox.org/ppmi. It will tell you all the sites that are actively involved in the PPMI study. And you'll see there are a lot of new international sites that have joined us in the study as well.

Dr. María L. De León: Wonderful. Thank you. And another person asks, is there a spinal tap included in this PPMI? Anyone?

Karen Williams: Yes, it is. And I can only speak for Northwestern. Yes, it is a spinal tap, however, it depends on your site in the center. The investigators that perform the spinal tap... I know we get a lot of people that have historical experience, but they are very well versed in conducting the spinal tap at Northwest, and we have an expert, the pain specialist, that does ours, and that's done within five minutes and it's over. But as this study has been going on for some time, all of the investigators are very experienced in doing the spinal tap and there is very minimal headache because there's a special needle that they're using. So it is very... It's not as bad as people think it is, or used to be.

Dr. María L. De León: Wonderful. Thank you so much. And just a reminder, you can go to the link we mentioned before michaeljfox.org/ppmi, and you can learn about more information, also the sites, they're recruiting. But I think I want to thank everybody right now for being part of this wonderful webinar and for joining us today, for all of your expertise and knowledge and for giving of your time. And we'll be sending a link to everyone on demand to listen again and share if you like. Hope you found this webinar very helpful, and mark your calendars for the next webinar on May 20.

Dr. María L. De León: We have a few minutes. If you have a last minute question that you'd like to send us, we will be glad to respond. Okay. The last question, do we need a Neurologist's approval to participate in a trial? Anyone?

Speaker 3: Well, it's not that you need any neurologist's approval, but you should discuss it with whoever's taking care of and helping you with your Parkinson's, your doctors and nurses, as well as at the research site, if it's different, the doctor and nurses that are involved. Everybody should be in agreement, so everyone's of like-mind.

Dr. María L. De León: Great. Thank you. One last question I wanted to ask John. Some people they live alone and so they may feel they may not be able to participate in studies, but John, tell us about your experience since you've done a lot of this. Has traveling, or going to a study been an issue since you live by yourself?

John Humphreys: It can be. You talk about the going off the medication, but sometimes that's really a good thing. I mean [inaudible 00:54:28] to go see your doctor, because sometimes the doctor doesn't... you can only tell him how you feel. And if he can see it, when you go in there... There have been times when I actually was having a problem and I've actually had somebody take me and I went off on medication on purpose to go to my exam. And if not, you can take a video of it with your phone because he might not... he or she might not understand. But no, other than the... If you do have to go off, there are some issues there for me, but other than that, there's so many clinical trials out there that it shouldn't be an issue. And especially today with being so many things virtual.

Dr. María L. De León: And I guess... A couple of questions. Someone wants to know, have there been any issues when you've done experimental drugs, participated in trials, like Inbrija? Any issues that you experience with the trials, or anything you'd like to share with us?

John Humphreys: Well, there's been one that I did bail out on because I was having problems with hallucinations for a trial. But then there were some that we would just work our way through because we could see the advantages of it. I just think that everybody needs to get involved. Because it's different for everybody, how they're going to have to respond in doing a clinical trial. It's something they have to feel comfortable with.

Dr. María L. De León: Good. The last question, any issues with reading through the consent forms, anything that... Were you able to, for the most part, all the trials that you've done, able to have a good working knowledge of what you were signing up for? Were there people there to help you navigate that? That's something that sometimes is a concern for some patients or families.

John Humphreys: They will go over that entire thing with you, but it's like buying your own... reading your mortgage if you buy a house. If you read all that [inaudible 00:56:28] to the trial. But another thing that was not mentioned here was, a lot of these clinical trials you get compensated for. And I've actually used the money to donate to people doing fundraising efforts. We have a mutual friend down in Arizona that does different things and I will donate money from my... part of that money I've gotten from doing clinical trials.

Dr. María L. De León: Well, thank you very much. We've come to the end of our journey and I thank you. But I wanted to just remind everybody to get involved in research and don't forget to click on the, Get Started link in the Take Action box. And I hope everybody has a wonderful rest of the day and weekend. And if you have any questions, shoot us some emails and thank you again for all the participants and the expert panelists. Have a wonderful day.

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