TRANSCRIPT
Module 3: Understanding informed consent

- [Fiona] Hello, and welcome to Module 3. I am Dr. Fiona McKay, a Research Coordinator at MS Australia. Today I will be leading our discussion on understanding informed consent in clinical trials. Our outline for Module 3 starts with an introduction to the informed consent process and to a very important document in clinical trials which is the participant information sheet and consent form or the PICF for short. We will talk about the various elements of a PICF before moving on to discuss withdrawing consent in clinical trials. And finally, we will explore the lived experience with a person living with MS who has previously participated in a clinical trial. In Module 2, we discussed the regulatory, ethical and governance processes we have in Australia to protect the entire research community when considering clinical trials. But we also have to be aware of the critical importance of individualised informed consent and what this means in the clinical trial process. Let's start with a key document, the PICF. The PICF is the written guide to the clinical trial and is usually presented to potential participants when they first consider a clinical trial, usually after an initial verbal discussion. It is essentially the nuts and bolts of the clinical trial process and one of the most important documents. As we heard in Module 2, our human research ethics committees put a great deal of effort into ensuring this document reflects good clinical practise. The goal of the PICF is to provide potential participants with a necessary understanding of the proposed clinical trial in order to make a decision on whether or not to participate based on sound informed consent. The participant information sheet contains this key information and is followed at the end of the document by a consent form. Together these documents make the PICF. Next, we will cover the elements of the PICF in more detail. The PICF outlines the nature and aims of the research in lay language without medical jargon. It names the investigators involved in the research. It explains what participation really means in practise and what you'll be asked to do. The when, where, who, and what. It outlines the inclusion criteria for the study, which is who can participate. It outlines any known risks, inconveniences or discomforts that could reasonably be expected. These risks are generally known from earlier trials, from other research, or reasonably expected from similar class medications. It is important for you to read carefully through the risk section of the PICF, for the research team to explain this section to you and for you to feel comfortable to ask the research team any questions you may have. Inconveniences may involve more visits than you would usually make to the hospital or tests you would not normally have, such as additional blood tests or eye tests. The PICF also describes any potential benefits for the participant. It explains that participation is voluntary and that participants can withdraw from the study at any time and for any reason. The PICF discusses how privacy and confidentiality will be managed for both your data and for any biological samples such as blood tests. You and your clinical trial doctor must sign the PICF before taking part in a clinical trial. By signing the PICF, you show that you have been told all the details, you understand the details, and you wish to be part of the study. However, the informed consent form is not a contract. You can leave the trial at any time and for any reason which we will touch on next. What if you sign the PICF and then change your mind at some stage in the trial and do not wish to continue? You may decide to stop taking part in a trial if your condition is getting worse, if you develop side effects, if you are finding it difficult to participate because of work or home commitments, if the trial is too time-consuming, or any reason that is important to you. You may choose to leave the trial at any time without giving

a reason. You just need to let your doctor or clinical trial team know that you wish to withdraw. If you do withdraw from a trial, the relationship between you and your doctor should not be affected. The national statement we spoke about in Module 2 has very clear guidelines about this pathway. After you leave the trial, your doctor will talk to you about the other treatment options for your disease or condition if it is recommended. The ability to withdraw your data or specimens from the trial will vary depending on the trial and what has already been assessed. For example, if one of your blood samples is allocated a number as part of a wider group of samples to compare, it may not be able to to be traced to you and thus returned. Others can be easily traced and destroyed if this is your wish. You just need to let your treating doctor know your wishes. We will now hear from Erin who has firsthand experience participating in a clinical trial and has advice on things to look out for when considering a clinical trial. These include taking time to understand the PICF, seeking trusted opinions, highlighting questions, and asking for clarity.

- Today, I'll be talking to a familiar face to some, and that's Erin Brady who's one of our national advocates for MS Australia. Now, Erin was diagnosed with MS some time ago and has taken part in several clinical trials and many research projects over the years. So today we are going to have a listen in as Erin shares some of her lived experience, particularly around informed consent and the nature of volunteering for a clinical trial. So welcome, Erin.

- Thank you for having me.

- So sometimes the participant information sheet outlining all about the clinical trial can seem very overwhelming. They can be very long and complex, and sometimes it can seem like there's a lot of legal jargon in there, and it resembles something like a legal contract, particularly if it's an early phase study or a very complex study. So how have did you approach looking at that participant information sheet and really feeling like you understood it?

- What you are given can sometimes considering your circumstances at the time and when you receive the information, it can feel incredibly overwhelming. You may have a lack of understanding of what it means and what your rights and responsibilities are. So one of the best things I do and that I would highly recommend is taking your time. Take your time to read it. Take your time to talk to your doctors, talk to your family, talk to your friends, your partner, and try and get a greater understanding of what is being asked of you. The most important thing is is don't feel pressured into having to do something right then and there when you're asked. Take it away with you, sit on it for a little bit, have a read over it, and if you don't understand something, ask questions. And the researchers are always happy to answer them. So don't feel like any question is stupid. Just take your time and so you can then fully understand where you're at and what is actually being asked of you in it.

- Oh, that's great advice, Erin. You've just touched on so many different points there that can be really helpful. So when you've seriously considered a clinical trial, what have the research staff done in particular to ensure that you do feel that you're fully informed? What sorts of things have they done to make it easy? Well, they make the time to answer the questions that I have. They communicate. Some of these things, wording around these things can be very confusing, so ask the questions that you may not understand what a particular word

means or or what the trial might be about or what you're being asked to do. So the staff are fantastic in checking in with you. Making sure you're okay is their primary goal here. They don't want to pressure you. They don't want to make you feel like you have to do something. They don't want you to feel overwhelmed in doing something either. So they check in regularly, they answer your questions and they just make sure you're okay. So it's ask questions. And trust me, the researchers, they are fantastic and they don't pressure you, and you can withdraw from a trial at any time you like. If it's not for you, you don't have to continue on. And if you do participate, don't feel like you have to continue to participate. So it's okay to not... If you get to a point in the trial and you're like, "Hmm, this isn't for me," well, then it's okay to withdraw as well and you will be supported in doing that.

- So what sorts of things did you take upon yourself so that you were fully informed? So you've told me what the research staff did, but what are the things that you did as an individual to make sure that you were getting the most out of this?

- One of my favourite things is to ask why, why, why, why? And if I don't understand it I'm going to continue to ask until I do understand it. And then if I still don't, I'm still not happy or I still don't understand it, I'll do a lot of research behind, my own personal research, about what is going on in this space and what this trial is about. I will talk with my partner and I will talk with my friends and I will do those things to satisfy myself for whether I am making the best decision for me to participate. Is it okay for me? Will it be okay for me? What are the consequences for me if I take upon this trial, if I do this, what will happen to me? What could happen to me? And you need to be okay with whatever those answers may be.

- And so part of informed consent's also understanding that you can withdraw from the study at any time. And you mentioned that, and it's at any time and for any reason, and that should not impact upon your MS care at all in the long run. So did you ever feel like that was a real option for you, that you could say to the investigators or researchers at any point, "Hey, look this isn't working out how I sort of thought it would"?

- Yeah, absolutely, absolutely, I felt I could do that. And no point in any study that I've ever done did I ever feel pressured into continue on in the space. In fact, it's the complete opposite of that.

- That's so good to hear. So just to finish off, Erin, just to get the benefit of your lived experience for people that might be considering taking part in a trial either now or in the future, do you have any tips for ensuring that the clinical trial is a good option for you and the right option?

- Find something that you're interested in, find something that you might enjoy, that might be exciting. I mean, there are a myriad of trials out there that cover everything from exercise and health to meditation, to brain scans and functional MRIs.

- Thank you, Erin. I love that bit of advice, especially around finding something that interests you. Because if you are interested in it you're going to be more likely to engage with it as well. Thank you for joining us to talk about informed consent, Erin.

- No worries at all.

- [Fiona] Thank you for joining us in Module 3. Don't forget to try the quiz to ensure that you have taken home the key points about informed consent. We will have a full list of resources and references available from this module to explore things in more detail. In Module 4, we will be exploring a good fit in clinical trials, weighing up benefit and risk and making decisions to go ahead in a clinical trial. We will see you then.