Good day. My name is Malebo Malope. I'm a Genetic Counsellor and Lecturer at Stellenbosch University in South Africa. Today, we will be quickly going through what is informed consent, and who actually owns this data. When I think of informed consent, I always think of the Tuskegee experiment, which completely did not uphold informed consent. I really recommend for you to go read up about the study and learn more about which bioethical principles were not upheld, but especially informed consent and participant autonomy.

What they did in the study, however, is that they recruited participants. And some had syphilis, and the others served as a control group. They were informed that they were being treated for what they called bad blood. And this was an umbrella term, or a local term used to describe many ailments in the 1930s, including anaemia, fatigue, and also syphilis.

And what is happening during that time is that they were not being offered alternative treatment when it became available. They were offered or they were being provided with free medical treatment, burial insurance, and free meals, but nothing else. The problem with this is that the participants thought they are receiving some form of treatment. However, they were part of an active study throughout those years. And because they were not being offered any treatment or alternative treatment that became available during that time, they suffered through the natural progression of the disease.

So when we come back to informed consent, we ask ourselves, what does informed consent really means? So I broke it down into what does it mean to be informed, and what is consent. Being informed means to have a lot of knowledge or information about something. And consent is to give permission for something to happen, or an agreement to do something.

And when you put it together, samedical.org describes informed consent as sufficient information that is provided to the patient so they can make an informed decision, and that the patient actually understands the information and the implications of acting on that information. And what is key here is that they actually understand the information, and also the implications of acting on it. And what is important is that you always maintain human dignity and autonomy.

However, it's important to remember that you can't self-govern or be autonomous, especially when it comes to research projects, if you do not understand what is happening and you're not fully informed. And therefore it's important to remember that autonomy relies on one being fully informed. And it's the responsibility of the researcher, regardless of what sample has been taken or what the project is on, to fully inform participants about the entire scope of the project and also allow them to ask questions throughout.

Now, coming to the consent process, what do you actually need to discuss with these participants? What are the basic stuff, or the aims and objectives and the methods of the study? What are you going to do, what sample do you need to do, and what's going to happen to that sample?

Talk about the data management-- who is going to access the stats, and how it will be stored and managed? What are the benefits and the harms and losses-- and there's always a chance of data breach, especially in the time that we're living in. So what are the chances of that happening, and what will the processes be to ensure that they are kept safe?

And if you are recruiting for a big umbrella study, it's very important to have continuous consent. So every time a new, smaller study comes up in that broad study, even though you have the sample, you always need to go back to the participant and say, we have your sample, and this is what we will be doing exactly with your sample again. Because it's very easy to muddy the waters and never go back to participants because they consented for future research. However, just saying that I consent for future research under this big project doesn't say anything. And actually, the participants are not informed about that future research.

Additionally, you need to discuss the ability to withdraw from the study. How can they withdraw from the study? Do they have contact details of the person they need to contact, and under what conditions?

And there's a few things you always need to consider. First is the use of language. What is the literacy of the people that you're seeing?

South Africa is a perfect example for us because we see people from different backgrounds, others who are highly educated, and others who are not. And therefore, your informed consent should be able to accommodate all these people, especially when you're giving them informed consent sheets and information sheets. And always remember that just because people are highly educated doesn't necessarily mean that they understand all the medical jargon. So yes, it's still important to use layman's terms in these information sheets.

Ensure that the participant always understands the language very clearly. And when they can't, ensure that there is somebody who can translate the consent forms, and that there's an interpreter available who they can use to ask questions to. And always, always allow your participants to ask any questions about the study.

But remember an important thing is, is your participant giving you voluntary consent, or are they consenting under duress, which essentially means that if you're a health care professional and you're the treating doctor, sometimes participants may feel obliged to participate in your study because you're giving them medical treatment. And this also comes from history of how medical professions are viewed by the general public. So it's very important to assure your participants that they may participate or they may choose not to participate, and this will in no way affect the health care that they are receiving.

And also think about the cultural and language barriers that might be available. People in certain cultures will do anything or most things that their doctors recommend. And if a doctor says to them, oh, there's this interesting study my colleague is doing, it would be nice if you participate in it, that could also result in them just agreeing to participate under duress.

So multiple things need to be put into consideration all the time. Some people from certain cultural groups may be sceptical about being a part of research, especially due to the history of certain experiments like the Tuskegee experiment, and what was done to African-Americans. And that leads to a lack of trust between African-Americans, some of them, and health care professionals.

And important to consider other things, such as your continuous consent, as we spoke about it up there, that you need to always get consent for the smaller studies. Go back to the participant, make sure that when you're getting the initial consent, you have multiple ways of contacting them. Because we know that people can lose their cell phones, change phone numbers. But at least if you have alternative numbers or email addresses, it's easier to get hold of them.

And when you have samples from minors, I think it is very important to go back and re-consent when they are autonomous adults. So when they reach 18, it's important to go back, if you're going to continue doing more studies on that sample, to say, we have your sample. You previously consented on this. Would you still like to continue for us to use it for other projects?

And it's important to update participants when there are new project managers or contact persons. Because remember, if you've given me a consent form and information sheet that I'm holding onto from 2020, and then there's a new project manager, the phone numbers have already changed. So those updates and phone numbers of a person I can contact should I want to withdraw from the study should be made available.

Coming to the topic on data ownership, everyone asks themselves who actually owns this data. And a good example is Henrietta Lacks. Mrs. Lacks was seen for cervical cancer, and some of her cells were used in the lab. And over the years, because her cells were the ones that were not dying, were then used for other experiments in future. And they created stem cells, right?

And here, what happened is that they didn't get informed consent from Henrietta Lacks. But now that she has passed away, her family was really concerned that you guys have this genetic information about us. You've published this genetic information about us, which reveals a lot about our family.

So therefore, this just shows you that this genetic information belongs to Mrs. Lacks and her family, regardless of what it's doing and what progress it's having in society in terms of health. So there always needs to be proper informed consent between participants, and remembering that just because you have the information or the data on your patient, it does not mean that you own it. And even if there can be great progress in research, it's not yours. It still belongs to the patient.

And for example, I would use maybe a safety deposit box at a bank. You go to the bank, and you ask for a safety deposit box to put in all your valuable information, right? You, as the researcher, are the safety deposit box. And the institution that you're at is the bank.

So now, when we're looking at samples for example, be it DNA or blood, whatever it is that you're using for your research, that belongs to the participant. And your role and your responsibility is to use it in a way that always upholds your ethical principles. For example, if this patient or this person has put all their valuable possessions in the safety deposit box, the bank will be very responsible, will protect it by all means, and will not just let anyone have access to your safety deposit box. So that's an important thing to remember, is that people shouldn't just have access to especially the raw data, which has the person's information within.

And when it comes to managing the data, you should only use the data for its intended use. You can't recycle it for a different project, especially one that was not consented for by the participant. You need transparency on how you manage the data, where will this data be stored, who has access to this data, and under what conditions it's being shared.

And this is very, very important because we know there are many shared databases nowadays because of technology and how it's improving. And many people use collaborators from different countries so that we have bigger samples, right? But how are we managing this data? Who has access to it? And how is it being moved from one place or shared in a way that is safe and reduces the risk of having breach, or other people accessing this data when they should not?

And a very important thing, then, is withdrawal from the study. Explain to the participants under what conditions can they withdraw from the study. It's ethical to allow people to be able to withdraw at any time during the study, but explain certain things where we wouldn't be able to just remove the information.

For example, if an article has already been published with that person's details and information, obviously, that can't be retracted. But going forward, any other thing that requires that person's data, you may not use that data. And that needs to be explained clearly to the participants so they know exactly what is happening with their information.

When I think of data ownership in South Africa, we have our POPI Act, which is the Protection of Personal Information Act. And they reinforced it in the past two years. And it'll be attached here as a link.

And it's very good to look at because it explains conditions and how to use personal information in a way that upholds our bioethical principles and allows for human dignity. A few examples that they would have is that the data should only be used for the purpose which is processed. And it should be adequate, relevant, and not excessively be used.

For example, if you collect a sample today, even if it's under a big study, and there's going to be many small studies underneath, my data should not be used excessively because it still belongs to me. And personal information should be collected for a specific and explicitly defined and lawful process. So we should not be using this data for anything else than what was specified in our informed consent with the participants.

And you must always ensure that the subject or the participant is aware of the purpose or the connection of that information. Remember the Tuskegee experiment, and also with regards to Mrs. Henrietta Lacks, there was no clear indication of what they were actually doing with the samples or why are they looking at them. And for the Tuskegee experiment, to see the natural progression of syphilis, there were not aware of the purpose of that study and what information the health professionals were collecting, making it very unethical.

With this Mrs. Lacks, there has been great progress with that because the family members, they had argued that the genome that was passed down has the potential to reveal their genetic traits. And therefore, they came to a good compromise with that family. And they had a HeLa genome data use agreement. And such things are very important, but we shouldn't wait to do them after there has been trouble, after people have complained. We should put in the steps to ensure that everyone is aware.

And if we are using any genetic information or genomic information, we must remember that it belongs to the participant, but it also belongs to the participant's family. And certain traits or certain information about the family can be revealed. And therefore, we have to be careful with what we are doing.

We have provided you with a checklist of things to think about when you are doing informed consent and thinking about the data, who owns it, and the data management. So firstly, ask yourself, was the study information provided in a language the participant understands? Were all the aims, objectives, methods, data storage, and data dissemination explained to the participant, and did you ensure that they understand?

Were contact details provided to the participant? If verbal consent was obtained, did you provide them with a copy of the information sheet also? So just because you're getting verbal consent doesn't mean that you mustn't give them the information sheet to take home with them to read at their own leisure.

Did you explain the circumstances in which they may withdraw from the study and who they can contact? Did you discuss privacy and confidentiality and how this data will be protected? Did you explain how the data will be de-identified and stored?

And for umbrella or large studies, did you explain how long the data or sample will be stored-- so is it for the next 10 years? Is it for the next 20 years?-- and if any further consent will be done for future studies? Thank you.