**Module 3 – GDPR principles - being lawful, fair and transparent -Transcript**

[Spaces indicate when the slide changes, and some timings are included where these are captured by the software]

[00:00:06] In this module we're going to start looking at some principles of GDPR, in particular the first principle. What does being lawful, fair and transparent mean, in particular for researchers?

[00:00:18] The old Data Protection Act said that when we were processing personal data we had to be lawful and fair.

[00:00:24] GDPR has introduced the word transparent. Transparent does not mean simply shoving some privacy notice on a website somewhere, hidden from view. It means a whole culture of being open and honest about the sorts of data that organisations collect and hold, the types of uses that data is being put to, and the rights and expectations that people should have around the use of that data. Providing transparency information is about ensuring information is easily accessible, people can find it easily, and also they can understand it. It isn't just some ghastly technical, jargon-filled document. We're going to talk a bit more about transparency later. So that’s the first principle of GDPR. The other things that GDPR has introduced, or changed slightly, in terms of data protection law - Accountability has been increased significantly by GDPR. In the previous model we talked a bit about responsibilities that data controllers had, well the ante has been upped in terms of accountability in GDPR. And equally, we, as data subjects, have now two new rights introduced: the right to be forgotten and the right to demand that one data controller passes our personal data onto a new data controller when we want them to, in other words the right to have portability of data. I put asterisks next to these two rights because in a research context we may actually be able to offer very limited access to these rights. We have got exemptions available to us if we do research on the GDPR, and these two new rights are subject to exemptions in certain circumstances. We're going to talk about this much later, but I thought I'd better mention it rather than making you think those rights are absolute across the park just now.

[00:02:16] So as I say let's look at the principles. They’re here. I'm not going to spend the same amount of time talking about all of them. These modules are very much about what researchers need to know, and as a researcher who uses personal data to support your research, you do need to know certain things about GDPR. But there are other things that you perhaps need to know less about, because if you follow local policy and you know what your DPO, your data protection officer, wants you to do, then you will be compliant with the law. But there are some things that you will be expected, as an individual, to either know or know how to do.

[00:02:54] One thing that you will probably need to tell people, particularly when you apply, say to access information, or you apply to an ethics committee, say using the IRAS system, you are likely to be asked: What is your lawful basis for processing? So it's really important that you know what your lawful basis is and how that feeds into these other requirements, fair and transparent, so that you are lawful, fair and transparent. Now this is a difficult, or fairly tricky, concept to get your head around.

[00:03:27] So, the Regulatory Support Center at the MRC has produced this little animation. You can access this from the URL given at the top [www.mrc.ac.uk/regulatorysupportcentre]. You go to that URL and you navigate towards GDPR resources. You could open up this animation, and you can also find lots of other things, bits of guidance, frequently asked questions, a growing mass of supportive guidance, which we're producing more and more as GDPR beds in and we start to understand where some of the issues and difficulties may reside. But suffice to say, this animation, (I'm going to talk to a little bit, but I'm not going to talk to it all the way through) it lasts about five minutes. It explains how organisations must be lawful, fair and transparent in order to ensure the public can trust them, whilst also remaining in control of their individual data. Lawful simply means you have a lawful basis or lawful reason to hold a use personal data. This ensures that only organisations that should be holding personal data, to do legitimate things with it, are doing so. The lawful bases that are available to you are defined in GDPR. It is most likely that your organisation will be relying on either: ‘task carried out in the public interest’ as your lawful basis, that's if you’re public sector, university or NHS; and for all those of you who work outside the public sector, charity organisations or possibly the commercial world, your lawful basis is likely to be ‘legitimate interest’. So these are the most likely lawful bases, the reasons why your organisation should be able to hold personal data in general terms. It should provide assurances that it is necessary for your organisation to hold personal data, and that that personal data will only be used to support legitimate research, or activities that are considered in the public interest. Legitimate interest, public interest, these two different lawful bases are roughly equivalent, just depends what type of organisation you work for. And this makes sure that participants’ interests are safeguarded and they can trust your organisation. As we've said before in the previous module, there's a good chance that if you're doing health or social care research that you aren't just holding personal data but you're also holding special categories of personal data, and therefore you will need an additional condition to your lawful basis for processing special categories of personal data. Again GDPR provides us with an additional condition ‘research purposes’ is your most likely additional condition for holding and using special categories of personal data.

[00:06:28] So we now understand what lawful means, you have a lawful reason, a reason defined in law, defined in GDPR for your organisation to be holding personal data to support research. That does provide the public with some kind of organisational assurance, they’re dealing with an appropriate organisation doing legitimate things. But the other thing we want to ensure we deliver is personal control. So this doesn't mean that because I work for an organisation doing legitimate things I have a divine right to hold your personal data – no. I do have a lawful basis to hold it, but you remain, as an individual, in control of whether I do or don't hold your personal data, and I treat you fairly, and to do that we have to be transparent and fair.

[00:07:17] Now throughout that animation we didn't see any mention of consent. There has been a strange rumour going around that the lawful basis for research is likely to be consent. No it is not. It is likely to be either: to support a task in the public interest or to support legitimate interests. Because this is what provides the general public with the assurance that your organisation is doing what it should be doing. Relying on consent as your lawful basis is in effect saying: hey I've got no reason to be doing this, my organisation really doesn't need to do this, so do you want to risk it with me? Do you want me to look after your personal data or not? I'll leave it entirely up to you. That isn't what we want. But, I'm not saying consent isn't important, I'm just saying it's not likely to be your lawful basis.

[00:08:09] Consent is a cornerstone of ethical research. It helps protect autonomy of individuals. It enables people to make decisions that are right for them. It is usually the right thing to do in a research context. Sometimes it’s not practical, but if it is possible and it is practical, it is usually the right thing to do, to get consent. It does help support transparency and fairness. Part of the consent process is disclosing exactly what data you would like to collect for your research; exactly what it is you're going to do with that data; to what ends it's going to be put to; and how are you going to try and keep it safe. And if people say ‘no’ in the consent process, you would treat them fairly, you don't recruit them any way and collect their data anyway. So it does help support transparency and fairness. It's not all that's required for transparency, but it is part, a good part of it. You may be required to get consent because the common law of confidentiality requires you to. In previous modules we've talked about sharing data in line with reasonable expectations. And one way of managing people's expectations is to get consent. It's a very explicit way of managing expectations, but it's definitely a way of doing it and it's a very common way of doing it. If you want to share data with others you would normally get consent to do that, if it's confidential. And of course there's other reasons, like Clinical Trials Regulations require consent to be in place, the Human Tissue Act requires consent to be in place in certain times, etc, etc. So not for a moment are we saying consent is not important, it simply is not your lawful basis, and it may have a role within GDPR, playing in to transparency and fairness.

[00:09:57] Now I’ve said transparency is not consent on its own, there is a distinct difference. Transparency is a complete culture about being open and honest at all levels about how organisations handle data; the sorts of data they use; and what they are using it for; and what people should expect from the organisation, with respect to that data and the use of that data. So project-specific information and participant information sheets is obviously part of the transparency ethos, but it goes way beyond that. All research active organisations should be producing high-level corporate information which clearly states that research is part of what they do. It won't be the only thing they do. Universities will teach students, they will recruit staff, they will do with all the things that employing organisations deal with. They also will do research, and universities will use personal data to support research and they will try and keep it safe, and again, a corporate essence of how that university, or other organisation, goes about keeping personal data safe and what they do with it, is really important from a high level. Research groups, departments - they might also produce information about specifically how data is used here, in this context, within this setting. Again this transparency information doesn't have to be a notice on a website, it can be a poster in a clinic waiting room; it can be a leaflet handed out to people; it could be something on a departmental website; whatever. But it's all of this information together is what contributes towards this whole ethos and culture of being transparent, it isn't any one thing in isolation.

[00:11:40] So getting consent, as I say, it is different from being transparent and fair. Consent for the common law: you have to inform people and you actually get them to...

[00:11:50] ...either say ‘yes’ or ‘no’ or at least get them to indicate in some way, it might be an implied ‘yes’ or ‘no’, but you do get a ‘yes’ or ‘no’, I'm in or I'm not. And then we can share and move data around ensuring there are no surprises, sorry information I should say as it’s about the common law. GDPR: you provide information....

[00:12:10] …in an accessible place, in an accessible form. People have a limited right to object to it and you treat them fairly in response to that. But as an organisation, it’s to say, transparency is something you should embrace throughout the organisation. It isn't just about shoving a consent form under somebody’s nose.

[00:12:33] Talking about data, and I've said repeatedly that transparency is about not using jargon but about providing accessible information about what data you use and what you're doing with it. Talking about data is difficult, there is a lot of jargon. I've struggled producing these modules not to slip into just ghastly jargon. It's very difficult to write stuff that the general population will understand. There is help for you out there: Understanding Patient Data is a group set up to explore with the public what terminology is understood, what concepts need further clarification, how can we best communicate some of these very difficult concepts to the general public - a very useful website. They're developing lots of resources all the time. And another place I would encourage you to have a look is the Plain English Campaign, who have for years been defining how best to produce written documentation that anyone can understand, or that I should say, that the audience that it's intended for can understand. So I would encourage you also to engage with some of the plain English guidance and documentation. And of course in terms of writing a PIS, the participant information (only part of your transparency information, but a part nonetheless) obviously the Health Research Authority, the HRA, have guidance on what should appear in a participant information sheet.

[00:14:01] To help you really start to think about transparency and what it might actually mean for you in real life, we've produced some examples. Again you can have a look at them, see what you think. How transparent do you think these examples really are? And how do you think you'd go about improving them? And again I'd encourage you to think about this in terms of what you're really trying to achieve, truly open and honest, understandable informing.