**RSModule7.mp4**

[00:00:02] GDPR and accessing of information without consent. This module is designed for researchers working in England and Wales. If you work in Scotland you have a special module. It's been designed specifically for you. This is not because GDPR is implemented or interpreted any differently in Scotland compared to the rest of the UK but rather that the common law is interpreted slightly differently north of the border.

[00:00:27] We've already ascertained in module one that the common law of confidentiality is about delivering what is in the public interest. It is usually in the public interest to keep confidential information exactly that confidential because it helps to build and maintain trust.

[00:00:43] But we've also ascertained that very occasionally public interests may be better served by disclosing confidential information rather than keeping it confidential. In England and Wales this public interest really has to be overwhelming. The prevention of a crime for example research is very unlikely to fall into overwhelmingly in the public interest. But fear not.

[00:01:06] There is an alternative legal avenue to disclose information confidential information when there is no duty of confidence in place and when you cannot obtain consent. And that is Section 2 5 1 approval if I want approval is given by the Health Research authority confidentiality Advisory Committee CAG for short and I will slip into CAG I know throughout the remainder of this module can set aside the duty of confidence if they deem it to be appropriate. And in this module we're going to explore what some of the thoughts and some of the issues that CAG will explore are in order to come to that decision.

[00:01:51] The kind of situation we're talking about here is where we have a research team who has no relationship with their participants toll and not part of our team. They acquire confidential information about their research participants. The participants don't expect it. They're surprised. So we know that is the mark of there being a breach in the common law. This is not an acceptable situation. We have to manage that kind of situation. Research has to happen in this sort of environment but it cannot happen in an unmanaged manner.

[00:02:21] One way of managing the disclosure is to get consent. Ask the participants. Is it okay if we access your confidential information. If it is fair enough. Go ahead. Access it if not. No.

[00:02:32] Sometimes however consent is simply not possible. And the kind of situation where thinking of various things like if someone who is not part of the care team the university wants to do a clinical trial and needs to identify people to invite to take part in the trial but needs to know quite a detailed amount about the clinical characteristics of a patient's disease in order to invite the right kind of participant and therefore this person not advocating needs to go through medical notes. They're not part of a cat and they have no due to confidence they can't get consent. They don't know who these potential participants are. That's just an example. That's one of the workshop examples that you've worked through previously looking at both common law and GDPR implications. Consent simply not possible.

[00:03:16] You could also manage the disclosure by anonymized information so that there is actually no disclosure of confidential information. Is it possible to do this research using only anonymized information.

[00:03:28] Again sometimes it is particularly if you apply a technical solution to some kind of snazzy data linkage. Maybe someone who does have a duty of confidence can do a bit of data linkage for the research team and the research team only access is none identifiable and therefore not confidential information. Is that possible. Sometimes it is. Sometimes it isn't. Sometimes research requires the use of identifiable confidential information and there's no getting around it.

[00:03:57] And if that is the case then you would apply for 251 approval. Now 251 approval can only apply to patient confidential information it is accessing information about information from the NHS where there is no duty of confidence and you cannot obtain consent can temporarily approve the setting aside of the duty of confidence. It is not a mandatory approval but it allows NHS organisations whether that be NHS digital or a specific NHS local organisation. It allows them to disclose confidential information. It doesn't mandate them to do so. The one thing also that CAG cannot approve is the setting aside of anything in GDP are the fact that confidential information may be allowed to be disclosed to you. And if that means you are now holding processing using personal data you must abide by GDP. And therefore you must process that personal data fairly lawfully and transparently.

[00:05:06] Let's explore this in a pseudo real life situation.

[00:05:10] This is a study I have made up and I want you to imagine that you are a member of CAG and we are being asked to make the decision whether or not to release confidential information patient information from the NHS to support this specific research study and the study wishes to investigate the effect of an acute exposure to Aluminum sulfate in the water supply in a discreet location. Something happened in 1988. The research question is has this acute exposure to Aluminum sulfate resulted in an increase in the number of dementias within the contaminated population by contaminated population. I mean those who lived in the location at the time as well as children who attended school in that location and people who worked in that location may have lived somewhere else where they came into work. Is it appropriate for CAG to set aside the common law of confidentiality and allow this research team access to identifiable patient information. And if we were to approve it what conditions are we going to ask the research team to meet. What would make it really robust and appropriate for this research team to be holding confidential information even though they have no duty of confidence towards their research participants.

[00:06:25] So the first thing I think I will always do and I know I keep banging on about it but it really does help is to draw an informational data flow diagram to get an idea of where data is coming from where it's going to when is it identifiable when is it not. Just so you get a real picture of exactly what is being asked for and how is data going to be handled within this study. They really are helpful and they can really help you unpick precisely what the issues are.

[00:06:55] Having done that I think as a member of CAG we're going to have to ask first of all. Are they proposing to have access to confidential patient information. Well yes they are. So yes they they probably are asking for our approval. And would it be reasonable for the population to expect them to have access to that information. Or would it come as some kind of surprise if they find out that the information being disclosed to this research team.

[00:07:21] I think we can clearly say here that the research team is proposing to access confidential patient information outside of reasonable expectations. These people would be surprised. They are asking us to set aside the common law. Importantly they're also going to be asking for other agencies to release confidential information CAG cannot approve the release of confidential information from other organizations. So say from the pensions people or from the educational departments agencies or from well from any orphan banks from anywhere else only confidential patient information that is what we as members of CAG are now considering. Should this research group obtain confidential patient information to support the research team.

[00:08:07] The first thing I would like to know. I think we probably all would as members of Congress is consent really not possible isn't in the way the study is being presented but actually is or even a different way of addressing the same question where you could get consent. Is it really necessary to do this study in this way and access data or information without consent. If it is possible to get consent or to do it in a different way then we need to explore that with the researchers and find out why are they asking us for CAP approval. Because frankly if consent is possible that is what they ought to be seeking.

[00:08:41] Equally, are there other ways of managing this proposed disclosure. Is it possible for the research to be conducted on purely anonymized and therefore non confidential information.

[00:08:51] Is there some technical solution that could allow linkage to happen away from the research team and the research team only acquire anonymous pre linked information. Again I don't know the answer to that but that is a question we need to ask as members of CAG.

[00:09:07] If we were to give permission to disclose confidential patient information to support this research. I think there is another consideration at CAG would make and that is how would the local population actually feel about this if they found out that their confidential information had been used to support this research study. Would they be distressed or upset by it. Now this is a question that in some ways is quite easy to answer nowadays because relatively recently the National Opt Out has been introduced across England.

[00:09:39] I'm now going to describe what the National Opt Out looks like in general terms and then we'll apply what that might mean for this specific research study afterwards.

[00:09:49] Information flows confidential information flows around the NHS and enters NHS digital which is a central NHS agency that handles vast amounts of confidential information in order to manage individuals care and individual services. But also they can provide information to support research and actually this particular study that we on CAG are looking at here may well be asking NHS digital to release this patient confidential information to help address their research question. However all of us as users of the NHS in England have an option to opt out of the flow of information out of NHS digital.

[00:10:31] That is not going towards supporting our individual care so confidential information will still be used to support our individual care with the NHS but we cannot opt out to any information ever leaving NHS digital to support other things like research. So if CAG is members of CAG were to approve this research study looking at the affects of aluminium sulphate contamination and the researchers then went to NHS digital showing NHS digital their approval from CAG and say please can I have the data that carcase approved I should have access to NHS digital will likely not to give them all the patient confidential information for every single individual requested. Because some of the members of that population may have opted out to their information being used to support things other than their individual care and that would therefore include research. So those who have opted out their data would be held back and would not be released to the research team. So as members of CAG we can be assured that those who feel strongly about their information being used or not being used to support research that that will be upheld by the process of supporting the national opt out.

[00:11:50] I should say that in other situations obviously not the study we're looking at at the moment but in other situations where you can get consent so for example recruiting people to drug trials part of the consent process maybe. Is it alright if we follow you up for the next 20 years to see what your long term outcomes will be. Patient says yes you can still access their confidential patient information even if they opted out. In general terms because consent will overrule that generic opt out but that does have to be because consent is in place.

[00:12:24] Okay so setting that aside there are also further questions that CAG may well ask things like Is it actually an important question. Could it be addressed in some other way. Do they really need confidential invasion which we've alluded to actually already. Is there another way a different methodology that could be used or applied to this question. We probably also want to be sure that the information they're asking for is what they actually need. They're not asking for more information than is required to address the question and certainly they're not asking for lots of sensitive information when actually that information is really not necessary. So we may agree disclosure but it will be limited to precisely the confidential information that is required to address the research question. The other questions we may have are about the research team and the organisation we're about to disclose or allow the disclosure of information to do these researchers know what they're doing. Do they work for an organisation that has appropriate governance processes in place. So once the data is disclosed to them we know it will be safe. It's not going to disclose further. It won't be shared with the rest of the world that they do have appropriate oversight and managerial risk management things in place. The data will be safe. We are not approving a general open door policy that confidential information once it's disclosed to one research team is out there in the public domain. And as I say we can be fairly assured about any distress or people who feel very strongly about their confidential information being used to support research. We can be assured that the opt out will be upheld. So we don't really need to worry as members of CAG too much about that as a researcher we may worry it will mean that the research team may it's incomplete data sets but actually more to the point. Don't even know if you have got a complete or incomplete data set. You get what you're given what is released. It does pose a problem for researchers.

[00:14:18] OK so there's the common law considerations. I think we'd make as members of CAG but we also have some GDPR out considerations because once we've handed over this confidential patient information to the research team presumably they're gonna end up holding personal data and using that to support research. And therefore we're going to have to abide by GDPR.

[00:14:41] Just to remind you confidential information is not the same thing as personal data. So will this confidential information that's been handed over to the research team also be personal data. Well is it structured properly as it's going to be on an Excel spreadsheet or something on a computer somewhere. Does it relate to or is it about a living person. Most of the population will still be alive if they were alive in 1988. Some will have died but most will still be alive. And finally is it identifiable either on its own or in combination with other information the research team are likely to have access to. And again if they are wanting confidential information we know that it must be identifiable by definition. So in other words I think we are fairly sure that what we're being asked to release will indeed be personal data. Once the research team have it and therefore the research team must ensure that they are compliant with GDPR.

[00:15:37] And they have to ensure that all processing they do is lawful transparent and fair.

[00:15:42] So let's explore how on earth they're going to do that lawful First of all lawful means that their organization has a lawful basis to hold and process personal data. As we've already found out we have an animation you can watch again if you've forgotten it is very likely that if you work for a reputable research organization and you are doing standard type research that organization would expect you to do that you will have a lawful reason for organization to hold personal data for research purposes and that lawful reason or lawful basis is likely to be to support a legitimate interest. If you do not work for a public body or if you work for a public body to support a task in the public interest. So you are likely to have a lawful basis. Be aware as well you do need a condition. If you are holding anything that is a little bit more sensitive these special categories of personal data which I think this is likely to be because it is information about the development of dementia health information it will be special categories of data if it's personal data you will need it. What are the conditions and the condition that you are most likely to be reliant upon.

[00:16:52] Is you're doing research for research purposes so your lawful basis is actually quite easy to ensure you have in place but you must be aware what it is because members of CAG they're going to ask you they're going to want to know what you're how. How are you ensuring that your processing is lawful. But we don't just need to be lawful. We also have to be fair and transparent.

[00:17:13] So in terms of being fair and transparent we do need to know what does this local population think their data could possibly be used for. What kind of information is made available to them about how their patient data could be used. Are they told it could be used to support research or not.

[00:17:30] On that same sort of topic I guess we we already know from previous module that if we're doing research provided that research has adequate safeguards in place research is not considered an incompatible purpose with what it was originally collected. So the reasons that people understood and all the rest of it really attracted far if not incompatible. However it may be a new purpose. And again this gets back to what information is being made available to this population about how their personal data is likely to be used in this day and age. If the NHS organisations that they attended simply had wording that said we use your data to support research full stop. That probably isn't transparent enough. Now in terms of GDP. And we need to be significantly more transparent with these people who have potentially been contaminated by Aluminium sulphate. We need to be much more transparent and describe actually data collected by the NHS it can be used to conduct population wide or population based studies where we look at the impact of environmental factors on health for example. So I think just a very simple statement that they have maybe come across at some point in the past which really doesn't say terribly much about this kind of use of data probably won't cover what is being planned now and we could safely say that actually it is a new use and the research team do need to be transparent about what they are doing. People in the general public do needs to be able to find out how their data is now being used.

[00:19:11] So it's a very long story short in terms of GDPR. The research team do need to first of all know they have a lawful basis which as I say they are likely to have and they also need to know what their condition is likely to be research without additional condition and they need to ensure that they can be as transparent as possible with the local population and treat them fairly. And this does mean really that you use best endeavours to let the population know that first of all a new data controller a data controller this population were not aware of is now processing data about the population and the sorts of things the sorts of purposes that data is being put to. You cannot contact each individual who once lived in this location and who may be involved and whose data may be involved. You don't know who they all are. So that is not best endeavours is not writing out a letter to each individual that is simply not possible but best endeavours to to let people know could involve putting something in the local newspaper doing something on the local radio. Putting something up on on various websites that are appropriate the people are likely to find that people may access and discover more about how their data is being used. And again if we sit on CAG we are going to I think ask the research team how are you going to do that. How are you going to make sure that people do have some idea about the fact that you are now processing their personal data. Please can you do something about transparency. I haven't given you all of that.

[00:20:45] I'm going to let you decide whether or not you would allow this research team to have access to patient confidential information. I guess part of the decision also has to be it's not just patient information they are wanting. They do need information from other agencies. Does the research fall apart if they don't get that. How are they going to get that. Would it be worth supporting the disclosure of patient information if the other bits of information cannot be got hold of. So it's a it's a complex question. I'm not going to tell you what the answer is because actually we don't know enough. We don't know enough details about what is being proposed by the research team. The reason I set that scenario to think through and trying to get you to think about what questions you'd ask the research team I haven't delivered it all to you on a plate with all the information available is to really get you to think about what is involved when you apply to CAG to really understand what's involved.

[00:21:41] To understand the questions you're likely to be asked in terms of the common law to understand the questions you are likely to be asked in terms of GDPR. And to really get a feel for what it is you're asking and the context in which you're asking it.

[00:21:58] Ok, in that scenario I think we put together the common law with GDPR are the final module we're going to do that again while exploring some common myths that have grown out of the introduction of GDPR.