UK data protection changes: impact on research

Summary note of roundtable held on 6 October 2021, convened by the Open Data Institute and Wellcome

About the Open Data Institute (ODI)

The ODI is an independent, non-profit, non-partisan organisation that works with companies and governments to build an open, trustworthy data ecosystem, where people can make better decisions using data and manage any harmful impacts.
Website: theodi.org

About Wellcome

Wellcome supports science to Wellcome supports science to solve the urgent health challenges facing everyone. We support discovery research into life, health and wellbeing, and we're taking on three worldwide health challenges: mental health, infectious disease and climate.
Website: wellcome.org

Background

In September 2021, the UK Government began consulting on changes to data protection legislation. Its proposals have the potential to have substantial and wide-ranging impacts, especially on research organisations.

In response, the Open Data Institute (ODI) and the Wellcome Trust collaborated to convene a roundtable with the aim of gathering the views of stakeholders across the health research community, and identifying common themes, concerns, and aspirations to feedback to officials at the Department for Digital, Culture, Media and Sport (DCMS). Discussion was held under the Chatham House Rule – this document, produced by the Wellcome Trust, is a non-attributable note that draws out some of the key points from the discussion. It reflects the discussion and does not necessarily reflect the views of either the ODI or Wellcome.

The consultation is open until Friday 19 November 2021, and at the ODI we are preparing a response which we will also publish. You can read more about our engagement on our project webpage, or contact the team on policy@theodi.org; we'll also be sharing updates on Twitter: @ODIHQ.

Government proposals in brief

'Data: a new direction' consults on a suite of changes to data protection legislation that seek to "unleash data's power across the economy and society for the benefit of British citizens and British business". We focused discussion on measures proposed in Chapter 1. The proposals, broadly, seek to:

- Permit a data controller to request 'broad consent' from data subjects to reuse personal data for broader scientific research when it is not possible to fully identify the purpose of personal data processing at the time of data collection.
- Remove the need to identify a lawful ground for using personal data for research. This would be replaced with a specific lawful basis for research to be outlined in legislation.
- Amend some of the operative and explanatory text of General Data Protection Regulations (GDPR) that form part of the UK's Data Protection Act.
- Extend an existing exemption in GDPR for data controllers to re-use personal data for research when data subjects may not be able to consent due to loss of contact.

Session structure

The session was structured around four themes that aimed to answer the following questions.

1. How is 'broad consent' applied currently? Is there an 'over reliance' on consent?
2. To what extent do you agree that identifying a lawful ground for personal data processing creates barriers for researchers?
3. Would extending the Article 14 exemption within GDPR, which loosens requirements to inform data subjects when data about them is used for research purposes, be welcome?
4. Would placing some of the recitals from GDPR into operative text benefit research?

Key points from the discussion

"Any divergence from the EU is problematic." - attendee

- A majority of roundtable participants were sceptical about many of the proposals and expressed a preference for clearer, more joined up guidance rather than legislative change.
- A few were open minded about changes to the law, provided it would provide greater clarity and reduce administrative burden, especially for NHS organisations.
- When it came to discussing the proposals surrounding lawful grounds in research, and the need for a separate provision for research, the consensus was that currently, researchers use existing provisions effectively. However, when it came to international collaborations, some flexibility when identifying lawful grounds for data processes, was identified as potentially helpful.
- A clear majority of attendees recognised that most health and medical research does not at present rely on 'broad consent' for its lawful basis to conduct research. Participants did not anticipate that the proposed changes to consent would benefit health and science research significantly.
- Many urged the Government to recognise the wider context in which research - including re-using data - is conducted, including the role of research ethics. It was felt that current proposals need to better complement existing research processes, at least when it comes to health-related and medical research.
- Participants were clear that they did not want any of the changes to risk EU data adequacy, which was perceived to significantly benefit UK research.

Further opportunities to support research

We asked participants whether there were any common data protection and management issues for researchers that were not responded to directly in the proposals. After some reflection, attendees made a number of suggestions. Some of these highlighted were:

- Updating guidance to clarify what constitutes anonymised data.
- Clarity on transparency requirements, especially when researchers no longer have contact with data subjects (when participants are deceased, move address, etc.).
- More ambition when it comes to data governance models. 'Data stewardship' for example, is a concept that is gaining salience in the research sector and provides more flexibility when compared to more traditional data management processes. Deploying novel types of data stewardship, such as 'data banking' or more deliberative methods of engagement with data subjects could prove a long-term, sustainable way of using data for research more innovatively.
- Further work to understand the reasonable expectations of data subjects when it comes to further processing for commercialisation purposes. This could include conducting public attitudes research with the public.

Feedback to Government officials

1. Coordinated cross-sector guidance on a number of critical issues for research, such as confidentiality, anonymity, data controllers in international research, and transparency requirements, should be prioritised over changes to legislation.
2. Given the importance of collaboration with European research partners, where legislative changes are deemed necessary, they must not undermine adequacy with the EU.
3. Any changes to consent, including greater use of 'broad consent' for research, should not dilute its meaning.
4. A new data regime must be reinforced by transparency and public involvement.
5. Routinely collected health data must continue to require additional protections when re-used.

Limitations

The roundtable was a robust and high quality discussion that got to the heart of key issues facing the research sector when it comes to data protection requirements. However, the conversation was by design and by its nature focused on the potential impacts of proposed legislation changes on medical and scientific research endeavours. There are other considerations for Government and stakeholders to make when considering the proposals' wider impact on research. We suggest DCMS undertake specific engagement within social sciences and population studies which more routinely use de-identified data at an aggregate level, and with researchers in the private sector or charities, who operate in a different context.

Topic 1: Consent

"We need to focus on the guidelines and how to make it work, without changes to legislation." - attendee

Government proposals in brief

The Government proposes clarifying in legislation that data subjects should be allowed to give their consent to broader areas of scientific research when it is not possible to fully identify the purpose of personal data processing at the time of collection. This refers to Recital 33 of GDPR.

"It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose."
~ Recital 33

Key points

- The majority of health and medical research does not at present rely on broad consent for its lawful basis to conduct research, nor is it likely to in the near future. • As such, the Government could better define the problem that greater use of 'broad consent' in research, will solve.
- How to apply the common law duty of confidentiality to research needs to be more clearly understood and was highlighted as a more pressing issue than consent. • If the Government is to proceed with its proposals, the Government should avoid inadvertently undermining the meaning of consent through any changes. • The Government consider how changes can complement established ethical approval practices, at least in medical research
- Any changes to consent protocols or legislation must seek to comply with EU GDPR and not threaten adequacy.

Discussion overview

Whilst it's not the predominant legal basis for conducting research, it was made clear from the discussion that consent underpins most health and scientific studies as part of good research practice. As such, many discussants questioned the necessity of pursuing changes to legislation on this issue, stressing that a clearer case need to be made and further evidence provided that other changes, such as renewed cross-sector guidance could better achieve some of Government aims. Participants also encouraged officials to align proposals to complement standard research approval processes, such as ethics committees, and consider

how suggested changes would affect current research governance. One discussant also highlighted that the common law duty of confidentiality is regularly misunderstood in research, which required further guidance.

Discussants sought to separate distinct types of data in order to pinpoint where relying on broad consent as a legal basis for research may cause problems. Using aggregate data to produce descriptive analysis, as regularly used in the social sciences, for example, was deemed less likely to create issues when it came to applying broad consent. However, where there is a combination of individual data with statistical models to make specific recommendations (e.g. credit scoring or recommending a medical treatment), it was unclear whether the proposals on consent would constitute a risk to public trust. Given this complexity, participants called for a greater understanding of how broad consent could be applied in highly specific uses, such as commercialisation, which poses some ethical challenges.

There was also broad agreement that the vast majority of health and medical research does not at present rely on broad consent for its lawful basis to conduct research. As such, a further articulation of the anticipated benefit culminating from the proposed changes may be required in order to increase support for the proposed changes.

There were several novel solutions suggested, such as data donation, that might provide a framework for an increased use of broader consent. However, some participants challenged that approaches like this could risk undermining the meaning of consent and may increase uncertainty in the research community.

“We never apply broad consent. GDPR is applied as a subset of the research ethics process, trying to use broad consent would get [research] proposals rejected.” - attendee.

Topic 2: Legal grounds

“Public trust is easily damaged as shown by recent events such as the backlash to the GP data [GPDPR] roll-out. The current lawful grounds are sufficient and as others have mentioned, lawful grounds are already interpreted differently across Europe and internationally causing barriers to cross-border data sharing.” - attendee

Government proposals in brief

The government proposals seek to understand the extent of the challenge faced by researchers in determining what lawful ground should be used for processing personal data. Page 11 in Data: a new direction states: “the government has […] heard evidence that uncertainty about when different lawful grounds for processing personal data should be used has led to an over- reliance on seeking consent from individuals.”
It then asks stakeholders to respond to the following question, which we posed to participants: "To what extent do you agree that identifying a lawful ground for personal data processing for research processes creates barriers for researchers?".

Key points

- The current approach of identifying lawful basis under GDPR seems proportionate at the moment.
- However, having one lawful basis, or data controller, per research project could be beneficial for complex research that is conducted internationally, as national variations were highlighted as a barrier.
- In any case, there must continue to be a lawful ground for processing health data collected for the purposes of direct care when it is used for research.
- Transparency requirements were identified as a more important barrier than specifying lawful grounds.

Discussion overview

“In terms of identifying lawful grounds, it’s clear for universities that [under GPDR] it’s ‘public interest’. [For commercial companies] it’s clear that it’s ‘legitimate interest’. I think it’s very helpful to have legal grounds. The proposal is to have something specific for research, and I don’t think we need a research one.” - attendee

Lawful basis provides the social and legal license to conduct research. In general, it was felt that identifying a lawful basis for research provides a framework for sound decision-making and can offer some important legal protections for researchers. There were also some ‘special cases’ where it was felt that further processing of data without a defined legal basis would be especially sensitive, including using routinely collected health data and genomic data.

As such, there was consensus at the roundtable that there was no obvious need to introduce or amend legislation to clarify lawful basis for research. Some participants felt strongly that introducing changes had the potential to cause confusion.

Many felt that the current proposals did not respond to some of the more critical concerns within the scientific and wider health research community. As a result, discussion centred on identifying some other barriers to research that Government action could help to ameliorate and reduce. Two areas identified were:

1. International collaborations
2. Transparency requirements

A few participants referenced the complexity of managing international agreements when personal data is accessed across different jurisdictions. One consequence of GDPR, it was said, was that some individual researchers involved in international research collaborations became data controllers without adequate legal or administrative support to comply with its obligations. This was highlighted as a barrier to conducting vital research with non-elite institutions, as the changes skewed towards well-connected and well-funded academic institutions at the detriment of those that might be based in under-served communities.

Provisions to enable one or a limited number of organisations to 'take on' data controllership on behalf of other, potentially less-resourced organisations, was identified as something that would be highly valuable for complex, multi-institutional and international research initiatives. Some participants also highlighted the current difficulty in understanding the level of detail that is currently required for privacy notices for research participants. During the discussion, it became clear that one barrier to re-using data is a lack of clarity on whether transparency or privacy notices need to change in situations where personal data collected for a particular research purpose could be used many years in the future. This is especially difficult if contact details in the intervening years have been lost or if research participants are deceased.

"One of the big challenges for collaboration and identifying the lawful basis - some of them aren't in countries with GDPR. How do you manage the risk?" - attendee

Topic 3: Further processing

“GDPR is only a small part of research. We need to work together to make sure these proposals work for research.” - attendee

Government proposals in brief

The Government is considering changes to the law surrounding further processing – or re use – of data. It is considering, among other things, replicating the GDPR Article 14(5)(b) exemption for research purposes. The current exemption essentially means that data subjects do not have to be informed when data about them is used if it would involve a “disproportionate effort”, especially in the case for archival, historical, or scientific research purposes.

The UK Government is considering extending the exemption to controllers processing personal data.

"*The provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, subject to the conditions and safeguards referred to in Article 89 (1) or in so far as the obligation referred to in paragraph 1 of this Article is likely to render impossible or seriously impair the achievement of the objectives of that processing. In such cases the controller shall take appropriate measures to protect the data subject’s rights and freedoms and legitimate interests, including making the information publicly available.*"
~Article 14 exemption

Key points

- Social sciences – as opposed to medical sciences – appeared to be particularly impacted by the proposals, which require further discussion and engagement with the sector.
- We evidenced uncertainty about whether data reuse can occur if they were originally processed under the consent legal basis.
- There was little consensus on whether researchers typically rely on the ‘research resumption’ in recital 50 rather than Article 6 of GDPR.
- The Government should prioritise working with the Information Commissioners Office (ICO) to help improve researchers’ ability and confidence in use pseudonymised and anonymised data.

Discussion overview

“It can be quite difficult to re-use the data if you haven’t got approval for the research question in advance. To allow for valid research, perhaps the type of consent we get needs to be changed.” - attendee

There was a general agreement with the Government, as outlined in the consultation document that “there is uncertainty about the concept of broad consent and how to reconcile it with the standards for valid consent as a lawful ground for data processing”. However, there were divergent opinions about how to reconcile this.

In general, participants wanted to see greater clarity on concepts such as anonymity as well as outlining what transparency requirements are necessary, which many felt would be a more fruitful avenue for greater levels of innovation.

There was some uncertainty from the group about exactly what constituted further processing and whether the proposals would include, for example, personal data that was collected for the purposes of direct care. Some participants also questioned whether anonymisation processes were more important to get clarity over and provide an easier legal avenue for increasing the re-use of data for research purposes.

Topic 4: Consolidating research-specific proposals

“Anything that makes it easier to understand would be a good thing. I’m not sure whether this needs to be done in legislation or the more important part is the guidance.” - attendee

Government proposals in brief

The Government hopes to ‘consolidate’ and bring together research-specific provisions. It hopes to clarify the definition of scientific research by moving Recital 159 and Recital 50 into legal text.

"*The processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research. Scientific research purposes should also include studies conducted in the public interest in the area of public health.*"
~Recital 159

“Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be considered to be compatible lawful processing operations.”
~ Recital 50

Key points

- There was general agreement that consolidating research provisions as proposed wouldn’t change how researchers work. Twinned with that was a widely-held concern that in practice, the changes could create more areas of uncertainty.
- There was concern that plans to amend specific Recitals in GDPR would deprecate other Recitals that are not in the operative text.
- Changes might provide greater clarity and therefore less interpretation from ICO. Relying on bespoke guidance and advice from the ICO, it was argued, can slow down innovation, particularly for international transfers
- There was concern that researchers are unlikely to read and interpret legal text directly or correctly.
- However, attempts to clarify the wording of the legal text and provide clearer guidance were welcomed.

Discussion overview

“I would be very aware of unintended consequences. We don’t want researchers reading and interpreting legislation.” - attendee

There were numerous and nuanced opinions about the proposals to consolidate some research provisions. They fell into two categories: 1) people perceived them to be a risk that could add greater uncertainty 2) the changes could provide greater steer for regulators to make clear and unambiguous decisions and were therefore welcomed.

The intention to amend or clarify recitals in GDPR also came alongside questions about longer-term intentions. For example, a number of participants commented that there is a longer list of Recitals in GDPR that cause problems for research, so the decision to 'cherry pick' a small number prompted debate about the rationale behind why specific Recitals were chosen for review. For example, it was highlighted that some provisions in GDPR that deal with international transfers as currently written can make research collaborations difficult.

On the other hand, making the operative text of GDPR clear, even in a small number of places, was perceived to come with advantages. There was a perception that some regulators when making judgements can pursue their own policy objectives so making legislation clearer would reduce the need for back-and-forth with various regulators. That said, producing clearer guidance and extending more hand-on support to researchers was still perceived as a priority for the research community.

When it came to broader proposals around converting Data Protection Impact Assessments into 'Privacy Management Plans', some suggested that whilst changing the name might be unnecessary, providing a single basis of information for grant proposals, ethics committees, and public consumption would be beneficial and reduce bureaucracy.

"We have excellent guidance from the Health Research Authority (HRA), research funders, and ICO. A consolidated guidance that is co-produced would be very welcome." - attendee

Appendix: thematic analysis

Theme	*Key comments*
Topic 1: Consent	
Broad consent/ commercialisation	We've changed our consent forms to be broader, but none have been used to look at commercialisation. They are looking at whether they can take a risk.
Broad consent	Need to distinguish two uses of data: (1) aggregation, combination and analysis of bulk data to produce descriptive summaries vs. (2) the combination of individual data with statistical models to make specific recommendations (e.g. credit scoring, recommending a medical treatment, etc). GDPR missed that distinction. Broad consent seems legitimate for use (1), but it's in (2) where issues arise.
Broad consent/ negative	We don't ever use broad consent, as ethics process will overrule.
Broad consent/legislation	I worry that moving broad consent into legislation would produce more uncertainty. Would it clash with Recital 43? The notion of broad consent might cause a further imbalance as you are going further and further away from being able to explain what people are actually consenting to.
Broad consent/negative	Changes to broad consent won't change much, as researchers use a different legal basis for conducting research anyway.
Broad consent/non medical	I think there is a lot of clear guidance about data protection and medical research but not necessarily on other disciplines.
Broad consent/positive	Clarification might be helpful, although it might not be impactful for research.
Broad consent/positive	There are sectors of the research community very used to broad consent. There's a lot to learn from the sector on how broad consent can be of good use.
Confidentiality	Confidentiality is often misunderstood. Consent is often legally required for sharing of research data to meet common law of confidentiality.

Confidentiality	People aren't aware of the requirements out there [for confidentiality]. Consent requirements often aren't the problem. If the objective is to facilitate more research, it is important to address confidentiality at the same time.
Consent/ confusion	Consent is such a high bar in GDPR, changing one aspect of it, inconsistency will be introduced. We may have a difficult legal framework for those that do reply on consent, which is by far the minority. Two part consent is used in Biobank and clinical trials regularly and broad consent is actually a good thing, but that is a different discussion and shouldn't be confused with the conversation about GDPR.
Cross-sector guidance	We are looking more at co-morbidity research, cross-sector research, social care research, integrated and commercialisation. I think we need to focus on the guidelines that we've got rather than on legislation.
Data categorisation	I agree with the point around ambiguity being a key impediment to effective statistical/technological solutions to the identification/privacy spectrum. The most useful thing I've come across in reframing the discussion (in a productive way) is to introduce the idea of individuation versus identification. Legislation straddles both, without appreciating that the people we are trying to serve (i.e., the general public) care more about the latter than the former, which in turn has significant implications for how one might handle that data.
Data donation	This could be a way to seek broad consent, but cannot be relied on

EU adequacy	Divergence / rewriting of the legislation could lead to a 2 tiered framework (UK / EU activities) and increased bureaucracy and paperwork.
EU adequacy	How will this affect adequacy?
Further processing	We already have strong data governance around participation in research. The interesting thing is when you want to re-use that data. I don't think amendment to GDPR are going to be helpful here. That re-use of data has to be aligned with a lawful purpose.
Guidance	How well are the existing guidelines reaching people? Materials from the MRC are excellent, but how far is that being used?

Guidance	HRA has GDPR guidance which serves NHS research, other non NHS health research isn't well serviced by HRA
Informed consent	One of the ironies of GDPR is that if you are unable to use consent as a basis for research, there are other lawful bases to use. I think informed consent is better than broad consent.
International collaborations/ EU adequacy	To add a general additional point on the international dimension (not specific to consent): science research is a global endeavour - any legislative divergence from, in particular, EU GDPR and the equivalent US regime simply adds to the complexity the research community needs to navigate. For some areas of research, in particular rare disease where data is very sparse, and requires aggregation across national boundaries to be meaningful, divergence will have a disproportionately negative impact.
NHS	If you are using the NHS, it is an ethical imperative we should be using the data we collect in the NHS to improve services. There should be an expectation that we use the data in that way. In other instances, we may require a privacy notice.
NHS / changes to consent/ positive	I think the consent process is overly bureaucratic at present. I'm not sure how well grounded this is in legislation, but the requirement to add at least three paragraphs on GDPR to every patient information sheet does not facilitate research. Again, a proportionate approach would be better. I think adding so much text about IG [Information Governance] makes patients worry more - and I'm not personally aware of any instances where this has influenced their decision to consent in a clinical study.
Personal data/ controversy	Two different types of data: data used for aggregate and descriptive summary and data that can identify individuals. Broad consent for 1 (largely medical research, pharmaceuticals etc.) but 2 is where issues arise.
Topic 2: Lawful grounds	
Anonymisation	If you want to speed up innovation, do not produce new law. What happens more guidance is that you produce a council of perfection. Guidance on anonymisation would be much more helpful.
Collaborations	The difficulty comes when you have a collaboration between a commercial entity and a public body, which lawful basis do you choose? But that's good data protection management.
EU adequacy	Do we want to change the law and potentially jeopardise EU adequacy?
EU adequacy	Any divergence from the EU is going to increase bureaucracy.

GDPR	We've worked with GDPR for 3 years now and we have a system that works for a greater or lesser extent.
Health data	Data collected for individual care first and then used for other use. There absolutely must be a lawful basis because it may be beyond the patient's realistic expectations.

Identifiable data/ anonymisation	The real focus should be what do, what does and what does not count and de-identified data?
International collaborations	One of the big challenges for collaboration and identifying the lawful basis – some of them aren't in countries with GDPR. How do you manage the risk?
International collaborations	Researchers will often join collaboration in a semi-autonomous way. When GDPR came in, it meant that some collaboration meant that individual researchers and their organisation became data controllers without a lot of understanding of what that meant.
Negative	We don't know what the implications would be for re-use of data further down the line. So, a specific lawful basis for research won't be helpful.
NHS	NHS should provide good transparency information. All NHS organisation need to get on board the idea that use of data is part of their business
NHS	We need to move to a culture that when using NHS services, we will use the data to improve services and understand how to do things differently.
Policy suggestion	It would be really helpful if we can find a way to lower the risk for some organisations involved in conducting international collaborations. Could there be one lawful basis for international projects, or could the risk be shared, and consolidated/ could they alone fulfil the requirements of GDPR?
Public interest task vs consent	We rely on the public interest task basis, though other organisations often rely on consent, which already causes issues with international collaborations. The proposals are unlikely to change this.
Public trust	Public trust is easily damaged as shown by recent events such as the backlash to the GP data roll out. The current lawful grounds are sufficient and as others have mentioned, lawful grounds are already interpreted differently across Europe and internationally causing barriers to cross border data sharing.

Public trust	Public trust is so important to this.
Status quo	The question is a bit of a moot point. We've taken steps to remove barriers to researchers. The only difficulty we do get is when people go outside those bases.
Status quo	In terms of identifying lawful grounds, it's clear for universities that test in the public interest, it's clear for commercial companies that it's legitimate interest. I think it's very helpful to have legal grounds. The proposal is to have something specific for research, and I don't think we need a research one.
Status quo	It seems proportionate at the moment.
Transparency, contact with participants	We have a real difficulty meeting transparency requirements when we no longer have contacts with participants.
Transparency, contact with participants	That's a very good point as it's a real problem with some of the old trials (tomoxifen ones for example) where it's just not possible to contact the original participants (deceased, no contact details etc.)
Topic 3: Further processing	
Broad	There are examples of researchers that wanted to use research that was consent/barriers collected using consent that has not been able to re-use it.
Consent	The bar for consent is so high that consent is rarely used.
Consent/lawful basis	For health research, care doesn't use consent at its lawful basis.

Data re use/positive	These proposals could have implications for clinical research in the case that secondary research is necessary. It can be quite difficult to re-use the data if you haven't got approval for the research question in advance. To allow for valid research, perhaps the type of consent we get needs to be changed.
EU	Worth bearing in mind that the EU is pulling in a different direction on anonymisation. The recent Irish DPC WhatsApp decision is very restrictive (noting that motivation and policy are irrelevant in looking at anonymisation). Important for everyone to encourage ICO to continue to take a different line on this and avoid looking over its shoulder at what European Data Protection Board (EDPB) is doing.
GDPR/public task	Not relying on the purpose limitation is problematic. Before GDPR, it was more common to rely on consent. After GDPR it would be

	public task for university, legitimate interest for charities and commercial companies.
NHS	There are legal abilities to use clinically care collected data for research and an expectation for all NHS organisations. The focus should be on ensuring patients are aware of that. then allowing them to use the opt out system if they so wish. I don't think we need to be worried about secondary use of clinically collected data
Policy alignment	DCMS wants to clarify when further processing is happening. ICO has said that under the current legislation, new controller = new processing = new lawful basis. Does this match up?
Policy suggestion	would be useful to clarify that one joint controller can take on responsibility for all joint controllers and that one joint controller could (potentially) provide a lawful basis for other participants.
Research	GDPR is only a smaller part of research. We need to work together to make sure these proposals work for research.
Research	Research often requires the collation of data that is specific to that research question. Perhaps you'll get follow up research in the same lab/research team. There is limited use for this.
Social sciences	For social sciences, re-using data is very important.
Transparency	More of the difficult work around re-use of data is the transparency requirements. Perhaps think more about the requirements.
Topic 4: Research-specific provision consolidation	
Easy to read	Anything that makes it easier to understand would be a good thing. I'm not sure whether this needs to be done in legislation or the more important part is the guidance.
GDPR	There are a number of recitals that are really helpful, some that are deeply problematic. The provisions in GDPR that deal with transfers make it difficult to deal with. Is this part of a plan to deprecate over recitals if they are not included in the text?
Guidance	We have excellent guidance from HRA, research funders and the ICO. A consolidated guidance that is co-produced would be very welcome.
Legislation changes/negative	I would be very wary of unintended consequences. We don't want researchers reading and interpreting legislation.
Legislative changes/negative	I don't want researchers to draw a line through legal text, they do it badly. That's why we have a framework. Tidying up the text would be nice, but it actually wouldn't change anything.

Legislative changes/positive	ICO is not always neutral in its views. It has its own policy objectives. So clear guidance is good, but changes to legislation could bring benefit by removing any doubt.
Technical solutions	On the proposals around converting DPIA into privacy management plans: proposals are a good description of what a DPIA should be, but I wouldn't change the name. When you are conducting a DPIA you are re-using a lot of meta-data. A single basis of information to conduct those processes would be beneficial and reduce repetition.
What's missing?	
Anonymisation	Very much agree with the point on clarifying the boundaries of anonymisation. The subjectivity that exists in this area is a cause of significant anxiety within the NHS and often leads to an overly restricted use of secondary data.
Anonymisation	If you break the link between the participant and pseudonymised data, it means it is not of much use
Anonymisation/ pseudo anonymisation	Pseudo-anonymised can be rendered anonymised in the eyes of the law, not because of breaking the link between the personal data but because of 'wrappers' around it i.e. employment sanctions, confidentiality agreements. To have more detail to do that in practice is really important.
Confidentiality	The ideal would be to tackle GDPR + confidentiality together. This would deliver greater clarity and benefits all round. Just tackling DP delivers much less.
Cross-sector guidance	What would be appreciated would be for the ICO and the research sector (not just the ICO as they are not experts in research) to work closer, create guidance/processes for all to follow which bridge the gaps that remain confused (& appear to be the basis for some proposals) and work within the frameworks which are already in place.
Governance	The interplay between the Duty of Confidence, research governance and data protection needs a separate discussion. I look at GDPR as a lynchpin for sense-checking processes after fully understanding the other regulatory and ethical matters (that straddle a care relationship with innovation and improvement)
Guidance	Is there more guidance needed on roles of controllers and processors, and how to identify controllers in collaborative research?
Guidance	Further guidance on genetic data would be great for the ICO to consider.

Transparency	Can we think about the transparency requirements for direct vs. indirect data collection, particularly when you've no longer got contact with participants
Closing remarks	
Feedback for DCMS ● Specify advice on genomic data ● Provide clarity over anonymisation ● Specificity around transparency requirements, especially when researchers don't have contacts and access to participants ● Help reduce the risk of international collaborations but allowing flexibility of who can be data controller. ● Adequacy must not be compromised. ● Co-produced guidance for research more beneficial than legislation ● Some practical support would be really beneficial to researchers	