

Information Commissioner's Office

Consultation: GDPR consent guidance

Start date: 2 March 2017

End date: 31 March 2017

CLOSER (Cohort & Longitudinal Studies Enhancement Resources) consultation response.

March 2017

The UK Economic and Social Research Council (ESRC) and Medical Research Council (MRC) funded CLOSER Partnership is a collaboration of eight UK longitudinal studies, the British Library and the UK Data Service. CLOSER's mission is to maximise the use, value and impact of the UK's longitudinal studies to help to build a better picture of people's lives across generations.

The UK's longitudinal studies are recognised as one of the most crucial sources of evidence for policy development in health, education, economics and society as they provide insights about change that cannot be obtained from any other data sources. It is estimated that over 3million UK individuals are members of a longitudinal study.

There are currently eight studies in the CLOSER Partnership, with participants born as early as the 1930s to the present day:

- Hertfordshire Cohort Study
- 1946 MRC National Survey of Health and Development
- 1958 National Child Development Study
- 1970 British Cohort Study
- Avon Longitudinal Study of Parents and Children (Children of the 90s)
- Southampton Women's Survey
- Millennium Cohort Study (Child of the New Century)
- Understanding Society: The UK Household Longitudinal Study

Section 1: Your views

Please provide us with your views by answering the following questions:

1. Is the draft guidance clear and easy to understand?

Yes

No
Please explain why not:

We consider the language used to be clear and understandable, and the guidance informative. The 'at a glance' summaries are useful and the concept of separate web pages, yet a single downloadable PDF document seems appropriate. We have the following specific points:

- i. The document seeks to provide guidance for consent within any setting, and is therefore inevitably broad and generalised. We consider it would be clearer to provide a far greater depth of illustrative case studies set across different contexts (see 3.3);
- ii. The distinction and interplay between the six lawful basis for processing and the nine conditions for processing special category data is not clear (e.g. to process special category data do you need one of the six and one of the nine? Or is one of the nine sufficient?);
- iii. Minor points include the need for page numbering and section numbering within the document and also that the document would benefit from opening hyperlinks into a new browser tab/window rather than replacing the guidance document as well as into the appropriate section.

2. Does the guidance contain the right level of detail?

Yes

No
Please explain why not:

For some topic areas there needs to be more detail and efforts to define, or at least provide guidance on, the terms used. Including:

- i. "Name any third parties who will rely on consent" – the term 'third parties' is not defined. Does this relate to independent organisations (e.g. a commercial company who sells their

customer database to a separate company) or does it also include contracted service providers (e.g. if the IT system the data is held on is outsourced to a contractor, is that contractor then a third party who needs to be named)?

We encourage the ICO to consider producing specific guidance on the implications for GDPR for scientific research purposes, including a code of practice relating to Article 89 (although we appreciate this is out of scope for this consultation). CLOSER would be happy to contribute to this process if that would be seen as appropriate and useful.

3. Do you have any examples of consent in practice, good or bad, that you think would be useful to include in the guidance?

Yes

No
Please outline your examples:

CLOSER studies have extensive experience of managing consent with diverse populations (e.g. across the full spectrum of society) and across different ages from birth to old age. In practice we have rigorously assessed case studies describing the involvement in children in assessments from an early age (e.g. collecting child assent alongside parent/guardian consent), managing the transition from child participation to adult participation and managing consent in ageing populations and populations with limited personal capacity. Some CLOSER studies have extensive participation and involvement strategies, incorporating participant input into consenting and conducting in depth qualitative investigations into participant's views and understandings of consent.¹CLOSER studies typically operate biobank models – where we are collecting biological samples and processing these into genetic and other personal sequence information; these activities are aligned with both data protection regulation and those relating to the use of human tissue. CLOSER studies also conduct methodological research, into public acceptability for consenting for data use², processes (such as statistical anonymisation techniques) and policy/procedure (e.g. defining the frameworks for Data Safe Havens³, establishing the UKs first independent study ethics and law oversight committee). CLOSER would be happy to provide more information about our experiences, and to help develop case study illustrations.

¹ Audrey S, Brown L, Campbell R, Boyd A, Macleod J. Young people's views about consenting to data linkage: findings from the PEARL qualitative study. BMC medical research methodology. 2016 Mar 21;16(1):34

² Sala E, Burton J, Knies G. Correlates of obtaining informed consent to data linkage: Respondent, interview, and interviewer characteristics. Sociological Methods & Research. 2012 Aug;41(3):414-39.

³ Burton PR, Murtagh MJ, Boyd A, Williams JB, Dove ES, Wallace SE, Tassé AM, Little J, Chisholm RL, Gaye A, Hveem K. Data Safe Havens in health research and healthcare. Bioinformatics. 2015 Jun 25:btv279.

4. Does the guidance cover the right issues about consent under the GDPR?

Yes

No
If not what do you believe is missing?

In the round, we agree that the guidance has covered many of the key areas relating to consent. In some areas there is overlap between GDPR requirements for consent, and other new or modified requirements being introduced under the GDPR. For example, the GDPR has increased rights for withdrawal, but how do these interface with 'restricted processing' and other rights such as 'right to be forgotten'? Guidance should be provided, and interlinks such as these highlighted.

We support your stated aim to produce specific guidance relating to children's privacy. CLOSER studies are able to produce good examples of involving children in the research process and how good practice changes as children age and transition into adulthood (See our response to question 3).

As stated above, we also encourage you to develop specific guidance for scientific and research purposes.

5. Please provide any further comments or suggestions on our draft guidance.

5.1. This submission is in response to the ICOs GDPR consent guidance consultation, as this is related to our work and expertise. Our response highlights the importance of consent in longitudinal studies both in terms of establishing a legal basis for the processing and use of participant's information and also as a means of maintaining study-participant trust relationship.

5.2. Much of the guidance provided, and the expectations for consent within the GDPR aligns well with established good practice within the longitudinal research community. However, we highlight the challenges faced by cohort studies, who operate complex research designs typically over very long time frames (whole lifetimes). This raises challenges in ensuring that consents maintain their validity over time, as processes change and new scientific opportunities emerge.

5.3. It is our observation, based on experiences working with third party data owners (e.g. linking study participants to their health records), that data owners place great emphasis on the ICO codes of practices. We therefore note the importance of these documents during data sharing negotiations, and that therefore they should accommodate the use case of negotiations between data

controllers over access and use of individual's data as well as the use case of a data controller's direct relationship with individuals' (i.e. the differing nuances of an individual being both a patient or participant, depending on which data owner you are). These use cases should distinguish – as the regulations do on numerous occasions - between scientific research purposes (that aim to improve the public good) and commercial use of data.

5.4. CLOSER are pleased there is a new provision for scientific research purposes, but concerned about the potential inconsistency in how the sentiments expressed within Recital 33 are interpreted. Specifically we are concerned that the interpretation/assumed definition of *purpose*, within “It is often not possible to fully identify *the purpose* of personal data processing for scientific research purposes at the time of data collection”. Will *purpose* be taken to mean the *scientific hypothesis* under investigation as distinct from the wider *scientific process of investigating a given hypothesis*. This distinction is important, as the latter interpretation allows for unforeseen change in specific granular detail (such as the name of the data controller, the institution where the investigator works). CLOSER believe those drafting the Regulations fully considered and agreed that requiring scientific research to fully specify the granular detail of the purpose at the time of data collection would be practically impossible to implement and would stymie public good research. We therefore ask the ICO to consider making it clear that leeway around being specific extends not only to the hypothesis under investigation but also the metadata around that (who will undertake the research, where they are based etc). CLOSER also consider it is fully possible to achieve meaningful, informed, consent while accounting for change over time. We therefore encourage the guidance to offer specific and detailed information in this area. We explore this issue further – with specific examples – in 4.2 below.

5.5. Longitudinal studies operate over many decades if not lifetimes. Direct contact between study and participant is expensive and difficult to conduct. Direct contact (with the opportunity to refresh consent) is therefore periodic with potentially long intervals (up to or exceeding 10 years), although substantial efforts are made to keep a continuing flow of information through newsletters, web and social media channels, the mainstream press and in some cases study events. This design makes the maintenance of consent challenging to implement – given that at the time of seeking consent the precise details of the circumstances of using the consent are not known. We illustrate this challenge with two aligned examples:

- i. CLOSER studies link to centrally held NHS records. Between 2013 and 2016 the organisation – a *third party* with whom CLOSER studies share information - that holds these records changed on two occasions (the “NHS Information Centre” became the “HSCIC” which became “NHS Digital”). We argue that these changes are not critical to public acceptability, i.e. throughout this process the data remained the same, did not alter in sensitivity and at all times remained under control of an operational unit of the NHS. CLOSER seek clearer guidance as to how *consent* can be managed (or considered still valid) in this context. To seek new consent in these circumstances would have a substantial financial cost, would be

inconvenient to participants and would weaken the scientific potential for the study (resulting from non-response to repeated requests for consent). CLOSER suggest that in these circumstances a *layered approach* to information provision (as previously recommended by the ICO) is appropriate. This approach would allow for the consent form/accompanying information leaflets to describe the data and broad information on data controller (i.e. that the data are controlled by a unit within the NHS), while aligned, clearly referenced and dynamic web pages can specifically name organisations, and that change can be managed through notices in study newsletters and correspondence. All such changes would need transparent change management and easily access to historical wording. It is our experience that if the acceptability of such approach is not made specifically clear then data owners will insist on re-consenting despite the potential costs and harms of that approach.

- ii. Aligned with the example above, we also have concerns regarding the manner in which we achieve the '*specific and granular*' requirements when specifying the data which we wish to share/use. In a similar manner to the example above, we are not arguing against the principle of transparent and informed consent, rather we argue it is not possible to specify certain details about the data of interest in advance. For example, a study following an ageing population seeks consent to link to a very broad set of health records, for the investigation of an unspecified set of hypotheses, yet within a defined operational framework designed to meet good practice security requirements and ethical regulation. This consent should specify the type of information covered under the proposal (e.g. health records collected about you while you received care or treatment in hospital, including diagnoses made, procedures or operations conducted, any drugs you were given etc) but is likely to become restrictive when it comes to the *name* the dataset is given or the form it takes. For example, records relating to cardiac surgery may be held in centralised hospital administrative records (such as the current NHS Digital Hospital Episode Statistics dataset), yet – by the time the investigation occurs – may be held by within a high quality specialist register maintained by a different agency (e.g. Public Health England). We again argue that the important elements of the consent (i.e. the data to be collected and used, and the recognised standards under which research processing occurs) can be granular and specific, yet spread across different layers, of which some can be dynamic. Our concern is that unless flexibility to obtain and maintain consent is specifically described in your guidance, Data Owners will take a risk adverse position and demand '*specific and granular*' wording within the consent statement. Previously, Data Owners have insisted that studies re-consent participants, at great expense, at inconvenience to the participant and resulting in scientific harm (through incomplete response introducing reduced statistical power and potential bias). We note that in other instances, CLOSER studies have been criticised by ethics regulators for using too many granular options in consent forms (albeit under DPA1998 regulations). Clarity in this guidance will help guide ethical review processes.
- iii. Within a research context, CLOSER studies are established as research databanks with established data sharing mechanisms. The expectation, from UK government and other funders, is that the best value of the data - accumulated using largely public money and the involvement of the public

– will be realised through appropriately managed onward sharing to an international community of bona-fide⁴ or Safe⁵ researchers. It is not possible for studies to know in advance *who* these external, third party, researchers are. The sheer volume of users also prohibits re-consent (a fact acknowledged as the regulations were being drafted) for each new user. Again, we propose managing this process through transparent registers of data users and data uses which will be accessible via study websites and referenced as part of our consent materials and ongoing consent discussions (e.g. in study newsletters).

In these examples, we illustrate concern that overly cautious interpretations of GDPR consent requirements will inadvertently damage UK research’s ability to deliver the “legitimate expectations of society for an increase of knowledge” (Recital 113). We therefore encourage the ICO to consider, and publish, guidance as to how issues such as change in specific details over time can be both transparent and dynamic – and therefore remain compatible with GDPR expectations for consent.

5.6. It is clear from the Article 89 that there is scope for national legislation to establish a legal basis for using personal data for purposes other than those for which the personal data were initially collected; with “*public interest, scientific or historical research purposes or statistical purposes*” being specifically highlighted. CLOSER encourage the ICO to both 1) clarify within the guidance the relationship between these (currently potential) powers and consent and 2) to do whatever lies within their power to encourage UK Government to provide specific legislation in a timely fashion (we appreciate that this later point lies outside the scope of this consultation).

5.7. Further to this, clarity is needed as to the relationship between adopting alternative legal basis to consent, and then subsequently seeking consent at a later time point (or vice versa). Current mechanisms – such as ‘Section 251’ provisions considered by the Health Research Authorities Confidentiality Advisory Group – stress the incompatibility of consent and alternative legal basis, while also stressing the importance of an exit route away from requiring alternative legal bases (e.g. moving to consent or effective anonymity). The current guidance states, within a different context, that “*If you would still process the personal data on a different lawful basis even if consent were refused or withdrawn, then seeking consent from the individual is misleading and inherently unfair*”. It would be helpful for the guidance to discuss the interplay between alternative legal bases and consent in circumstances where the data controller (e.g. a CLOSER study) *would* respect refusals or withdrawals of consent. Example scenarios would include:

- i. A study who initially relied on an alternative legal basis for data collection, who then subsequently sought consent as and when they made direct contact with their participants (ensuring they respected dissent and provided simple and transparent means to withdraw consent). In this

⁴ <https://www.mrc.ac.uk/publications/browse/mrc-policy-and-guidance-on-sharing-of-research-data-from-population-and-patient-studies/>

⁵ <http://blog.ukdataservice.ac.uk/access-to-sensitive-data-for-research-the-5-safes/>

example is the interplay between legal basis appropriate? Can the two states coexist alongside each other (e.g. some participants have consent, others use an alternate legal basis, or a mixture of the two)?

- ii. A study who initially collected specific and informed consent from participants to collect, process and use biological samples for genetic sequencing (the consent included information that the sample would be shared with a specialist laboratory who would conduct the sample genotyping under contract to the study). If, several years later – at the point of commissioning the sequencing - an alternative laboratory could offer a better service then would it be possible to use an alternate legal basis to use this service provider without seeking renewed consent?

Further clarity on these issues and similar scenarios would be welcomed.

- 5.8. CLOSER encourages the ICO to, if they do not already, work with the Wellcome Trust *patient data taskforce*⁶, which seeks to advance the transparent use of patient data in medical research and to start a discussion with the public and professionals on how this is best achieved (including issues such as clarity of terms used in consenting).
- 5.9. CLOSER encourages the ICO to, if they do not already, work with the Human Tissue Authority⁷, who license and inspect research studies use of biological samples; with emphasis on the collection and management of consent.

31 March 2017.

⁶ <https://wellcome.ac.uk/news/independent-patient-data-taskforce-announced>

⁷ <https://www.hta.gov.uk/regulated-sectors>

Section 2: About you

Are you:

<p>A member of the public who has used our service?</p>	<input type="checkbox"/>
<p>A member of the public who has not used our service?</p>	<input type="checkbox"/>
<p>A representative of a public sector organisation? Please specify:</p> <p>Andy Boyd ALSPAC Data Linkage & Information Security Manager^a, Member of CLOSER Leadership Group and lead for record linkage in CLOSER^b</p> <p>^aAvon Longitudinal Study of Parents and Children, University of Bristol. ^bCLOSER (Cohort & Longitudinal Studies Enhancement Resources)</p> <p>a.w.boyd@bristol.ac.uk 0117 3310033</p>	<input checked="" type="checkbox"/>
<p>A representative of a private sector organisation? Please specify:</p>	<input type="checkbox"/>
<p>A representative of a community, voluntary or charitable organisation, or of a trade body? Please specify:</p>	<input type="checkbox"/>
<p>An ICO employee?</p>	<input type="checkbox"/>

Other? Please specify:	<input type="checkbox"/>
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**Thank you for completing this consultation.
We value your input.**