Department for Culture, Media and Sport, Call for Views: GDPR Derogations

Response by the CLOSER Longitudinal Studies Consortium[1]

10th May 2017

CLOSER

1. CLOSER, the UK longitudinal studies consortium, is a unique partnership that brings together biomedical and social cohort & longitudinal studies (C&LS) with participants born as early as the 1930s to the present day. There are currently eight studies in the CLOSER Partnership, comprising four national and three regional birth cohort studies and Understanding Society (the UK Household Longitudinal Study). Funded by the Economic and Social Research Council (ESRC) and Medical Research Council (MRC), CLOSER's mission is to maximise the use, value and impact of these studies in order to build a better picture of people's lives across generations.

2. CLOSER is a co-signatory of the Wellcome Trust response to the General Data Protection Regulation (GDPR) derogations consultation. This supplementary response builds on Wellcome's response and is designed to provide additional perspective relating to the Cohort and Longitudinal Studies (C&LS), which have a complex research methodology and are multi-disciplinary in nature. We would welcome further engagement on the issues we raise and would like to offer our expertise in supporting the development of derogations in relation to the GDPR.

3. C&LS follow the same individuals over time collecting data at different points to build up a detailed picture of their lives and how they are changing. The UK's longitudinal studies are world-class research resources and the UK is seen as the global leader in this field. The studies are recognised as a crucial source of evidence for policy development and analysis across a range of domains, including health, education and employment. They provide unique insights about the dynamics of individual behaviour and the influence of early life circumstances on later life outcomes. World changing science has emerged from longitudinal studies, for example: the discovery that smoking is associated with an increased risk of cancer and heart disease; uncovering contributing factors towards obesity and common diseases such as eczema, diabetes, cancer and multiple sclerosis; and, identifying lifestyle factors involved in the development of dementia.

General Points

4. It is challenging for C&LS to meet processing requirements (e.g. Article 5(1)(b)) and explicit consent requirements (Article 9). Challenges are introduced by the methodological design of C&LS, which:
   a. Operate as research 'databanks', where the explicit purpose of the collected data is not known at the point of seeking consent;
   b. Routinely collect personal sensitive information which cannot be fully anonymised due to the need for studies to maintain databases of participant personal identifiers in order to collect and link data over time;
   c. Operate over entire lifetimes, often with relatively large gaps of five to ten years between direct contact with participants. This can result in consent wording being perceived as 'outdated';

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[1] Correspondence to:

d. Suffer from attrition where they lose contact with participants. Where those who are lost to attrition are likely to have different characteristics to those who remain in touch with the study. These differences may introduce bias into studies research findings and can result in marginalised groups (e.g. those with mental health issues or children taken into care) being excluded from the potential benefits of the research process.

It is therefore essential, that in addition to consent, clear legal bases are established for C&LS to process both personal identifiers, personal information (Article 6) and sensitive personal information (Article 9).

5. C&LS invest considerable resources into developing participant understanding of the research process, involving participants in decision making and developing a trust relationship between the study and the participant.

6. In relation to safeguards (Article 89(2)), the CLOSER partnership is committed to preserving the confidentiality, integrity and availability of all the longitudinal studies' physical and electronic information assets. C&LS have existing robust procedures for data acquisition and use based around 'Data Safe Haven' approaches[2]. Studies share data directly and via research repositories. Data are shared under contract through the 'Safe'[3] of 'Bona-Fide'[4] principles. Furthermore, studies operate under a wider ethico-legal framework including Health Research Authority (HRA) project review, the adoption of independently audited security standards (ISO/IEC27001 or NHS Information Governance Standard) and the requirement to adhere to regulatory codes of practice (e.g. Information Commissioner's Office anonymization code of practice).

7. C&LS are multi-disciplinary by nature. The data they compile are added to research databanks which are sometimes managed by third party academic repositories (e.g. UK Data Service run by the University of Essex, or the UK Secure eResearch Platform run by the University of Swansea). Data are provided to international researchers for any appropriate research investigation. Often C&LS collaborate through 'cross cohort comparison studies' in order to use the combined statistical power of many studies to investigate rare events. Given that C&LS are relatively rare, these cross-cohort projects are frequently conducted at an EU or global level.

Theme 5 - Archiving and Research

8. Article 89(1) requires "appropriate safeguards" to be put in place for processing for scientific research to benefit from special provisions in Articles 5,9,14,17 and 21.

9. DCMS should work to develop existing safeguards and guidance such as those issued by the Research Councils (e.g. 'Bona-fide' or 'Safe' research frameworks), ethics regulators (e.g. Health Research Authority ethics boards), regulators (e.g. revised Information Commissioner's Office code of practice on anonymisation and consent) and academic

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[2] 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. Available from: https://academic.oup.com/bioinformatics/article/31/20/3241/195451/Data-Safe-Havens-in-health-research-and-healthcare

[3] http://blog.ukdataservice.ac.uk/access-to-sensitive-data-for-research-the-5-safes/

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

lead groups (e.g. UK anonymisation network) and industry best practice (e.g. ISO/IEC27001 Information Security accreditation).

10. CLOSER encourages DCMS and those developing safeguards and guidance to explicitly acknowledge that the unusual design of C&LS remain compatible with GDPR requirements where this is the case (e.g. the current ICO anonymization code of practice acknowledges the requirement for longitudinal research studies to link data on the same individual which has been collected at different time points[5]).

11. Safeguards and implementation guidance should be designed to enable multi-disciplinary research and the combination of information from diverse sources, to enable C&LS to combine their databanks with routine records from health and administrative sources. Failure to do so will encourage 'data silos' and hinder the advantages to the UK which could be realised through efficient data sharing. It should be noted that this point extends to many research designs, not just C&LS.

12. Article 89(2) allows the UK to provide derogations from the rights in Articles 15, 16, 18 and 21. CLOSER supports the view of the Wellcome Trust response that derogations are required for Article 15, for commensurate derogations from Article 16 and that derogations are not sought (from this community) for Articles 18 and 21.

Theme 6 – Third Country Transfers

13. CLOSER support the statement set out in the Wellcome Trust response regarding the value of Third Country Transfers. In our setting this includes utilising the expertise held in international academic groups but also in the processing of biological and genetic sample information. CLOSER are concerned that the move to define genetic sequence information as a direct personal identifier (and thus nullify the possibility of anonymising genomic information) may have on these activities.

14. C&LS frequently supply data for cutting edge research investigations involving specialist expertise. For example, genetic epidemiology may require the specialist processing of biological and genetic samples which may only be available in Third Countries (e.g. the USA). Derogations available in Article 49 should be considered that enable the transfer of genetic samples which are otherwise effectively anonymised through either historical consents (which don't explicitly refer to genetic sequence data as a direct identifier) or provide an alternate legal basis for such transfers where the purposes is for the processing of genetic sequence information for scientific or historical research purposes.

Theme 7 – Sensitive Personal Data and Exceptions

15. In some situations it is not practical or possible to obtain consent for the use of personal data in research. While this is currently recognised by exemptions in the Data Protection Act (1998) and in exemptions from the common law of confidentiality for the use of health information (as issued by the Secretary of State for Health) it is not possible to use these exemptions consistently across all data. As illustrations, CLOSER studies have found the following challenging:
    a. Establishing exemptions for non-health sensitive personal information (e.g. records on criminal convictions and cautions), which limits the possibilities of public good research;
    b. Establishing exemptions for health information held outside of the NHS system (e.g. within the care records for looked after children);

[5] https://ico.org.uk/media/1061/anonymisation-code.pdf

c. Using administrative records as a sampling frame from which to invite individuals to take part in research. Initiatives to do this have been blocked through data owners insisting on needing consent in order to use records to seek consent (known as the 'consent for consent' phenomenon).

16. As argued within the Wellcome Trust led response, DCMS must ensure there is a clear alternative to consent as the legal basis for processing of sensitive personal data for health research (Article 9(2)(j).

17. However, if consent were to be selected as the appropriate legal basis, then DCMS must implement sufficient derogations to enable 'broad' consent that describes the framework in which data are to be used, and that studies can supplement this information with explicit and precise use case information via electronic means (e.g. website or phone apps) as this becomes known over time. CLOSER supports the rights of individuals to object and withdraw from studies use of their data. To take an extreme example; it would not have been possible for participants in the National Survey of Health and Development to have explicitly consented for the study's genomic research conducted in 2017 at the time of enrolment in 1946 – particularly given that the structure of DNA was not identified until 1953. More routinely; databanks are called on by members of the bona-fide research community to investigate a diverse range of hypotheses. It is not possible to predict who will make a request, where they are based or what they will investigate. Rather, the key criteria relate to the bounds of acceptable data use, researcher expertise, the importance of any hypothesis, the intention to further the public good and that the investigation occurs within appropriate safeguards (e.g. they are under contract to a respected institution, face penalties for misconduct and have robust information security in place).

18. DCMS should consider the impact of changing expectations of consent wording. Consent, like many aspects of research governance, is perceived through an evolving lens which changes in reaction to events (e.g. data breaches) and changes in technology (e.g. the emergence of personal DNA sequencing). Given that C&LS may not contact participants for extended periods of time, it is challenging to create 'future-proofed' consent wording. CLOSER recommend that efforts are made to permit the use of 'outdated' consent in these circumstances, or to permit the mixed use of consent and consent exemptions as a legal basis (in both cases, CLOSER supports the rights of individual's to explicitly object (or withdraw) to the use of their information in the research process).

19. CLOSER recommend that DCMS must work with a wider range of stakeholders (i.e. including the HRA and Department of Health, but extending to include the Department for Education, HM Revenue and Customs, Ministry of Justice, Department for Work and Pensions and others) to ensure wide acceptability and applicability of a harmonious solution for derogations that permit the processing (including combination) of special categories of health and non-health data without consent.

20. CLOSER strongly recommends that no additional controls are implemented for the processing of genetic data, biometric data or data concerning health where these data are used for scientific or historical research purposes.

Theme 12 – Processing of Data

21. The Regulation makes use of the term 'purpose' in several instances (e.g. Article 5(b), Article 89), yet does not define this term. It is CLOSERs experience that risk averse

interpretations of legislative terms and conditions can lead to barriers for the safe and effective sharing and use of personal (sensitive) information. We therefore recommend that DCMS should define 'purpose' within the derogations in order to support the sentiment within Article 89. Specifically, we are concerned that the interpretation of *purpose* within Article 89(1) and Recital 33 will be taken to mean the scientific hypothesis under investigation as distinct from the wider scientific process of investigating a given hypothesis. Any such definition must allow for unknown and unforeseen changes in specific granular details (e.g. the who, where, why, when, what and how of any given investigation), otherwise it will severely restrict the research process (as illustrated in point 17). It was clear that legislators accepted representations by the research community in this regard during the development of the regulations[6].

[6] Impact of the draft European Data Protection Regulation and proposed amendments from the rapporteur of the LIBE committee on scientific research – https://welcome.ac.uk/sites/default/files/wtvm054713.pdf