HDRUK
Health Data Research UK

Data A New Direction – HDR UK Response

Health Data Research UK (HDR UK) is the UK's national institute for health data science with a mission to unite the UK's health data to enable discoveries that improve people's lives[1]. Established by nine founding funders in 2018, HDR UK is a charity that provides independent and trustworthy capability and coordination across the UK's health data research community to accelerate the pace and scale of data-driven health and biomedical science for societal benefit.

The world is on the cusp of a data revolution in biomedical research and health and care design and delivery. We are already witnessing the value and transformative impact that data can have on our health and lives. Through its research strengths combined with the National Health Service (NHS), the UK provides a distinctive contribution.

We are seeing rapid growth in the use of vast amounts of data for health research, for example, an estimated 40 exabytes will be required to store the genome-sequence data generated worldwide by 2025. Linkage of data across health, care, environmental, social and molecular data is becoming critical for research with an increasing number of new data sources including wearable devices, sensors and imaging. Realising public and society benefits from linked, diverse, large-scale data requires citizen involvement and engagement to help demonstrate a trustworthy approach to patients, clinical practitioners and the public.

In addition to its work in the UK, HDR UK coordinates international health data science initiatives including the ICODA programme[2], funded by the COVID-19 Therapeutics Accelerator, that supports a principle-based governance approach to enable safe data access across 42 countries.

Our work was amplified by the outbreak of COVID-19, underscoring the importance of health data in powering the scientific, innovation and public health response to the pandemic[3]. It also exposed the need for robust, reliable and scalable technology, data and governance infrastructures vital for the rapid and trustworthy sharing and analysis of data across the UK and internationally. Throughout this work public and patients have been involved in developing health data science in a trustworthy way.

HDR UK welcomes legal reforms that facilitate the greatest possible scientific and societal benefit from health data research, whilst protecting individuals' privacy and we support the Government's ambition to improve researchers' access to data. However, we do not believe that there is a strong case for many of the legislative changes proposed, as regulator guidance would address many of the areas of concern or ambiguity. We are concerned that some of the proposed changes would put the UK's data adequacy status with the European Union, which is vital for health data research, at risk. We are also concerned that the proposals could damage public trust in the use of their data and believe that meaningful citizen involvement and engagement in the proposals is needed to demonstrate a trustworthy approach to patients, clinical practitioners and the public.

[1] https://www.hdruk.ac.uk

[2] https://icoda-research.org/

[3] https://www.hdruk.ac.uk/covid-19/covid-19-national-core-studies/

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Data a New Direction

Research Purposes

1. Q1.2.1. To what extent do you agree that consolidating and bringing together research-specific provisions will allow researchers to navigate the relevant law more easily?

○ Strongly agree
○ Somewhat agree
○ Neither agree nor disagree
○ Somewhat disagree
○ Strongly disagree

Please explain your answer and provide supporting evidence where possible.

We welcome the Government's intention to help researchers navigate the relevant law but we do not think that changes to the legislative text are necessary. This is because in our experience the issues around enabling research do not stem from difficulties navigating the relevant provisions in the legislation, but from the areas where the interpretation of the law is unclear. Collating the provisions into one place would only resolve this if accompanied by guidance from the ICO on specific areas where there is currently ambiguity or lack of understanding. Further regulator guidance would be our preference to resolving areas of ambiguity as it can be more reactive to subsequent developments in the research sector. Guidance should be user-friendly and accompanied by clear practical examples.

Please see our response to question 1.2.4 for details of areas where we think additional regulator guidance would be helpful for the health data research community.

2. Q1.2.2. To what extent do you agree that creating a statutory definition of 'scientific research' would result in greater certainty for researchers?

○ Strongly agree
○ Somewhat agree
○ Neither agree nor disagree
○ Somewhat disagree
○ Strongly disagree

Please explain your answer, and provide supporting evidence where possible.

We do not believe that lack of statutory definition of "scientific research" is a significant barrier to research. Recital 159 to the UK GDPR states that scientific research should be "interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research" and should "include studies conducted in the public interest in the area of public health"; this already provides some guidance at a general level. In our experience health data researchers are aware that their research is considered scientific research.

Careful consideration would be required if creating a statutory definition to ensure that the definition is not too prescriptive and does not cut off or exclude certain areas of research. For example, it is important that hypothesis generating activities fall within any statutory definition of scientific research. The nature of cutting-edge scientific research in the UK is continuously evolving and any statutory definition must not exclude future developments in research.

Additionally, we think that it is important for the UK to stay aligned with the general terminology used in the GDPR so as not to depart too much from standard EU principles which would put the UK adequacy decision at risk.

3. Q1.2.3. Is the definition of scientific research currently provided by Recital 159 of the UK GDPR ('technological development and demonstration, fundamental research, applied research and privately funded research') a suitable basis for a statutory definition?

○ Yes
○ No
○ Do not know

Please explain your answer, providing supplementary or alternative definitions of 'scientific research' if applicable.

Please see response to question Q1.2.2.

4. Q1.2.4. To what extent do you agree that identifying a lawful ground for personal data processing for research processes creates barriers for researchers?

○ Strongly agree
○ Somewhat agree
○ Neither agree nor disagree
○ Somewhat disagree
○ Strongly disagree

Please explain your answer, and provide supporting evidence where possible, including by describing the nature and extent of the challenges.

In our experience identifying a lawful basis for research is not one of the major barriers to research. We note that public entities and universities largely rely on public interest (under Article 6(1)(e) of the UK GDPR), while other organisations rely on legitimate interest (under Article 6(1)(f)).

The main issue with identifying the appropriate lawful basis under Article 6 occurs for projects with more than one Controller (i.e. one university and one private entity), where it is not clear whether both parties can rely on public interest in respect of the same research project. We note that existing ICO guidance states the focus should be on the function of the processing rather than the function of the organisation and use of task in the public interest is not limited to public entities. However, in practice we see that private entities and non-university research institutions are hesitant to use the public interest basis and generally do not rely on it. Therefore, we would welcome a clear and unambiguous guidance stating that for collaborations between universities and private entities for research purposes, public interest is an appropriate lawful basis for both parties.

In our experience identifying the appropriate lawful basis under Article 9 can be more challenging. We have encountered confusion as to whether (j) Archiving, research, and statistics (with a basis in law) is applicable in scientific research situations and we have encountered organisations using (a) explicit consent where we think using condition (j) would be more appropriate. It would be useful to have clearer guidance on which of the bases would be most appropriate, as well as guidance on what the appropriate safeguards under Article 89(1) should be.

As noted above, we do not consider that identifying a lawful basis is a major barrier to research; instead, we consider that the main barriers for research in respect of personal data are the following:

Confusion between UK GDPR and duty of confidentiality under common law. One area where we see some confusion is a misconception that consent of a data subject is always required for research purposes pursuant to data protection law (i.e., as a lawful basis for processing). However, in a research context, consent of a patient is required pursuant to the common law duty of confidentiality to permit the disclosure of that patient's data. Guidance on the interplay between data protection law and the common law duty of confidentiality would therefore be welcome to help clarify the requirements, including when the consent requirement can be waived.

Concern about inadvertent breach. Researchers often face large delays (up to six months, sometimes longer[4]) in gaining access to health data sets. There can be a reluctance by data custodians, including public bodies, to share pseudonymised health data that is still considered personal data, even where the data is subject to appropriate lawful governance processes and used for legitimate research in the public benefit. In our experience much of the reluctance and delays to share data comes from concerns that institutions will unintentionally breach data protection legislation, face large fines from the regulator and suffer from reputational damage. Guidance from the ICO as to what is permissible would therefore be beneficial to promote confidence in trustworthy data sharing.

International Transfers. To realise the benefits to the public from health data research, international data transfers and linkage of data sets from different countries are essential. Navigating the complexities of international transfers is a difficult burden for organisations to overcome. The Standard Contractual Clauses (SCCs)[5] are often not fit for purpose in a research context and the requirement to put these in place can cause delays to or prevent research projects. In particular, the requirement to accept the jurisdiction of a UK or EU court is sometimes unacceptable to public bodies in other countries such as the US. For example, several articles detail the difficulties US bodies have in signing up to the SCCs[6] and how research can be impacted because of US government agencies unwilling to sign them[7] for example due to requests that institutions agree to European data audits or submit to other jurisdictions. In addition, the requirement for the data controller to complete a transfer impact assessment, involving individual evaluation of international legal regimes, is burdensome, costly and complex.

It would also be extremely helpful to have detailed derogations that research organisations can rely on for international data transfers for health research (rather than SCCs). In our experience research organisations do not typically rely on task in the public interest under UK GDPR due to lack of clarity as to whether it applies in a health data research context. It would be beneficial to have guidance confirming that this ground is appropriate in a health data research context and setting out appropriate safeguards.

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4 https://pubmed.ncbi.nlm.nih.gov/34413101/

5 https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/standard-contractual-clauses-scc_en

6 https://academic.oup.com/jlb/article/7/1/lsaa055/5871850?login=true

7 https://www.sciencemag.org/news/2019/11/european-data-law-impeding-studies-diabetes-and-alzheimer-s-researchers-warn

5. Q1.2.5. To what extent do you agree that clarifying that university research projects can rely on tasks in the public interest (Article 6(1)(e) of the UK GDPR) as a lawful ground would support researchers to select the best lawful ground for processing personal data?

○ Strongly agree
○ Somewhat agree
○ Neither agree nor disagree
○ Somewhat disagree
○ Strongly disagree

Please explain your answer, and provide supporting evidence where possible.

As explain in our response to question 1.2.4, in our experience this is not generally an area of confusion for universities.

We would welcome clear and unambiguous guidance that affirms that in collaborations between public and private sector entities both entities can rely on public interest as a lawful basis.

6. Q1.2.6. To what extent do you agree that creating a new, separate lawful ground for research (subject to suitable safeguards) would support researchers to select the best lawful ground for processing personal data?

○ Strongly agree
○ Somewhat agree
○ Neither agree nor disagree
○ Somewhat disagree
○ Strongly disagree

Please explain your answer, and provide supporting evidence where possible.

In our experience, we do not think there is a need to create a new lawful basis for research as sufficient options are already available as explained in our response to question 1.2.4.

We would be concerned that creating a new lawful basis under Article 6 could interfere with the transparency principle and undermine public trust in research. In addition, we are concerned that divergence from the lawful bases in GDPR could both undermine our EU adequacy agreement, which is vital for the research community, and create confusion or misunderstanding as to the lawful basis for cross-border research collaborations with EU member states.

7. Q1.2.7. What safeguards should be built into a legal ground for research?

Research must be able to clearly demonstrate the public benefit, through involvement from members of the public, and completed by bona fide researchers and if necessary subject to Research Ethics Committee approval. It would be useful to be clear on some of the technical safeguards that would be required such as pseudonymisation. We note the HIPPA privacy guidance regarding limited data sets[8]; it may be useful to implement a similar strategy here.

There are well established data principles that cover various form of research, from developing and encouraging best practices to implementation to maximise the use of health data. For example, the 5 Safes

[8] https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

framework[9] sets out appropriate safeguards for privacy and effective use of sensitive data when it is embedded throughout each stage of a project e.g., project, researcher, output review processes:

- Safe projects: Is the use of data appropriate and in the public good?
- Safe data: Is the data treated to maintain confidentiality and integrity?
- Safe people: Can researchers be trusted to use the data in an appropriate manner?
- Safe Settings: Does the access environment prevent unauthorised use?
- Safe Outputs: Are the results screened to ensure they are non-disclosive?

The five safes framework is widely respected and adopted in the health data research community. In addition, there are also exemplar data principles: FAIR Framework, CARE Framework, WHO Data Principles and Roche's Policy on Sharing Clinical Study Information. These principles help set out the rules, standards, tools, processes, roles and responsibilities to help access, use and share data at all levels – organisational, project, regional, national and international.

Q1.2.8. To what extent do you agree that it would benefit researchers to clarify 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 data collection?

○ Strongly agree
○ Somewhat agree
○ Neither agree nor disagree
○ Somewhat disagree
○ Strongly disagree

Please explain your answer, and provide supporting evidence where possible.

It is important to distinguish between consent under medical confidentiality and consent under UK GDPR as a lawful basis for processing.

We have not encountered consent being used as a lawful basis for processing under UK GDPR for health data research projects. This is because of the strict requirements of consent under GDPR, including the requirement for data subjects to have actively given informed consent, and the obligations on the controller to demonstrate and prove that such active and informed consent was given. For data collected for research purposes it is frequently not known which further projects will require the data and therefore it is difficult to reach the threshold of consent under GDPR. Additionally, we note that it can be difficult for data subjects to exercise their rights once data is being used in a research context and withdrawal of consent could undermine types of scientific research that require data that can be linked to individuals. Given that health data research does not rely on consent, changing the legislation in this regard is not likely to affect what research can take place.

In our view the public should be consulted on any such proposals to ensure that changes to the consent requirement are not perceived as reducing the rights of data subjects. If broad consent is adopted, it must be subject to robust, ongoing governance and ethics oversight to maintain public trust, ensure the rights of individuals are preserved and ensure inclusivity of participation in clinical trials. As noted above, in our experience sufficient lawful bases already exist for research.

9 https://blog.ons.gov.uk/2017/01/27/the-five-safes-data-privacy-at-ons/

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8. Q1.2.9. To what extent do you agree that researchers would benefit from clarity that further processing for research purposes is both (i) compatible with the original purpose and (ii) lawful under Article 6(1) of the UK GDPR?

○ Strongly agree
○ Somewhat agree
○ Neither agree nor disagree
○ Somewhat disagree
○ Strongly disagree

Please explain your answer, and provide supporting evidence where possible.

We encounter significant difficulties with public bodies being reticent to re-share clinical data for fear of breaching UK GDPR and data protection requirements. This reticence can delay or prevent researchers being able to access data for research which is in the public interest and has the potential to deliver life-saving insights as we have seen during the pandemic.

We believe that the existing law does facilitate re-use of data for research purposes however we have seen confusion about and misinterpretation of the law. We would therefore welcome clear and specific guidance stressing that the re-use of data sets for research purposes, especially with respect to public bodies, is lawful and the relevant considerations and safeguards. Clarification on when further processing can be undertaken by a controller that is different from the original controller should be included in any guidance.

In our experience much of the reluctance and delays to sharing data comes from concerns that the data custodian will unintentionally breach data protection legislation and face large fines from the regulator. This is a particular concern for smaller organisations or those that do not have significant information governance and legal resource. Guidance from a regulator as to what is permissible would be helpful in this regard.

COVID-19 has highlighted the importance and potential benefits of quick access to clinical data for research purposes. However, we are still encountering significant issues with accessing relevant data from public institutions and data linkage for the purposes of research into COVID-19; it can take up to six months to gain access to research data relating to COVID-19 which is hindering research progress even in a health emergency. One proposal to resolve this could be for the government to underwrite the liability of public bodies in respect of the sharing of data specifically in the context of pandemic health research, subject to appropriate controls and safeguards.

9. Q1.2.10. To what extent do you agree with the proposals to disapply the current requirement for controllers who collected personal data directly from the data subject to provide further information to the data subject prior to any further processing, but only where that further processing is for a research purpose and it where it would require a disproportionate effort to do so?

○ Strongly agree
○ Somewhat agree
○ Neither agree nor disagree
○ Somewhat disagree
○ Strongly disagree

Please explain your answer, and provide supporting evidence where possible.

We note that in practice the transparency requirement is typically fulfilled by the data controller publishing a privacy statement or notice, rather than by individually contacting data subjects. This is not typically an onerous exercise.

Our concern with this proposal is that it could undermine public trust in research and specifically the use of health data in research. We note that the public has previously raised concerns regarding the use of their health data for other purposes than their direct care.

If this proposal were to be implemented, in our view the disapplication would need to be clearly defined with transparent principles and detailed examples of when this would be acceptable to use, including the safeguards to prevent misuse, would need to be developed with the meaningful involvement of public and patients.

10. Q1.2.11. What, if any, additional safeguards should be considered as part of this exemption?

There should be clearly detailed proposals as to when use of the exemption would be acceptable. We would suggest that there should be clear guidelines on appropriate pseudonymisation of any such data so that, as a minimum, data subjects cannot be easily or generally re-identified.

Please see our response to question 1.2.7 regarding the use of the 5 safes as an additional safeguard.

Data Minimisation and Anonymisation

11. Q1.6.1. To what extent do you agree with the proposal to clarify the test for when data is anonymous by giving effect to the test in legislation?

○ Strongly agree
○ Somewhat agree
○ Neither agree nor disagree
○ Somewhat disagree
○ Strongly disagree

Please explain your answer, and provide supporting evidence where possible.

Given that this is an evolving area, and privacy-enhancing technologies are rapidly evolving, we believe that guidance rather than legislative change is the best way to provide clarification. Guidance that includes specific case studies would be particularly helpful. We believe that the forthcoming guidance from the ICO on anonymisation, pseudonymisation and privacy enhancing technologies will be helpful for the research community.

Further we are aware that any such changes to legislation could impact our EU adequacy status and therefore would prefer guidance over legislative changes.

Please also see our response to question 1.2.4.

12. Q1.6.2. What should be the basis of formulating the text in legislation?

○ Recital 26 of the UK GDPR
○ Explanatory Report to the Modernised Convention 108+
○ N/A - legislation should not be amended

○ Other

Please explain your answer, and provide supporting evidence where possible.

13. Q1.6.3 To what extent do you agree with the proposal to confirm that the re-identification test under the general anonymisation test is a relative one (as described in the proposal)?

○ Strongly agree
○ Somewhat agree
○ Neither agree nor disagree
○ Somewhat disagree
○ Strongly disagree

Please explain your answer, and provide supporting evidence where possible.

We agree with that the re-identification test is a relative one, but would prefer that any test to help clarify this point is articulated in guidance rather than legislative change.

14. Q1.6.4. Please share your views on whether the government should be promoting privacy-enhancing technology, and if so, whether there is more it could do to promote its responsible use.

We believe that privacy enhancing technologies play an important role in enabling responsible research and maintaining public trust. The health data research community is increasingly using Trusted Research Environments (TREs) to ensure the security of data. We believe that a formal accreditation scheme for TREs would promote their responsible use.

We would also welcome specific guidance on the use of pseudonymised data in Trusted Research Environments (TREs).[10] [11] TREs provide a secure environment where researchers can access and analyse data in this environment only and are unable to download the data, with all research outputs being subject to an approval process to ensure that they do not contain personal data. TREs therefore aim to maximise data security and protect individuals' privacy and are an important tool to demonstrate trustworthy use of data. TREs can also create efficiencies by streamlining processes and use economies of scale to collect, use and share data, enable research and innovation and build trust between data custodians, researchers and public. Another key benefit of TREs is that they enable remote research with researchers working across institutional and geographical boundaries.

We would particularly welcome guidance that recognises that TREs and other secure data environments can play a significant role in facilitating compliance with data protection obligations and can provide important safeguards against re-identification of data subjects as well as promoting public confidence that data is used in a secure and safe manner. Such guidance should set out good information governance practices for TREs for example incorporating the 5 safes.

[10] https://www.hdruk.ac.uk/access-to-health-data/trusted-research-environments/

[11] https://understandingpatientdata.org.uk/news/what-why-trusted-research-environment