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# Co-developing resources for better public understanding of longitudinal population study data and the law

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## Abstract

### Introduction
The legal basis for using participants' data in Longitudinal Population Studies (LPS) is complex. Laws of particular relevance are (1) UK data protection legislation, including Data Protection Act 2018 and UK General Data Protection Regulation (UK-GDPR); (2) common law duty of confidentiality; (3) Digital Economy Act (DEA) 2017; (4) Section 251 of the National Health Service Act 2006; and (5) Health Service (Control of Patient Information) Regulations 2002.

### Objective
To develop transparency materials for LPS participants to raise awareness and understanding of key laws, legal principles and their rights.

### Methods
Public contributors from UK Longitudinal Linkage Collaboration (UK LLC), Health Data Research UK (HDR UK) and DATAMIND provided input to benchmark current public understanding of laws and legal principles relevant to research. Based on this involvement, we worked with the UK LLC Public Advisory Group (PAG) and external organisations to produce a series of infographics. These were available in written English, audio, British Sign Language (BSL) and additional languages, to reach as wide an audience as possible.

### Results
Input from 56 public contributors informed the work by suggesting low levels of awareness of the laws and legal principles. The DEA was the least well-known, with 11% of people aware of this legislation and the most well-known was UK-GDPR, with 88% awareness. We developed key messages for LPS participants on what they should be aware of as individuals, including what they should expect from their LPS. The information is available to the public and LPS participants as a series of infographics (https://ukllc.ac.uk/lps-data-and-the-law).

### Conclusion
Our series of transparency materials support LPS participants to understand the legal basis for study data use, and their rights. General awareness of the laws and legal principles involved in the use of longitudinal data is low and we recommend data providers should raise awareness in clear and accessible ways.

### Keywords
UK Longitudinal Linkage Collaboration, UK LLC, public involvement, public engagement, PPIE, longitudinal population study, legal basis, common law duty of confidentiality, COPI, Section 251, Digital Economy Act, GDPR, legislation, transparency

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# Introduction

> *'Jarndyce v Jarndyce drones on. The scarecrow of a suit has in course of time become so complicated that no man alive knows what it means.'* Charles Dickens, Bleak House, 1852-53.

The law is notoriously complex, it changes over time and its exact meaning is subject to interpretation in court: few outside the legal profession would claim to fully understand it. Within this, the law and regulations governing the use of data for research are complex and public confusion regarding these laws may impact on whether research is deemed trustworthy. There is a potential disconnect between, on the one hand, an individual's rights provided through data protection legislation and legal duties of confidentiality and fundamental human rights and, on the other hand, legislation designed to benefit society through enabling research [1]. This is a particular issue for Longitudinal Population Studies (LPS) which sample and recruit members of the population and follow-up their health, socio-economic status and other factors over very long timeframes, sometimes whole lifetimes.

The UK has a rich and cherished tradition of running LPS, with an estimated 200 LPS whose participants likely comprise 5-10% of the national population. These LPS vary in design features, but all are 'consented studies' where participants are volunteers and where their willingness to participate is bound into a trust relationship between each participant and their LPS. Maintaining this trust relationship is critical as it supports ongoing participation and participants' willingness to donate data [2]. Consent has been used for both ethical reasons and to address the common law duty of confidentiality (hereafter, common law) – the principle that information provided in confidence for a specific purpose, should remain confidential unless the individual agrees for it to be shared or there is a reasonable expectation that it would be shared. While a new LPS would be expected to identify a lawful basis and meet contemporary best practice for consenting participants, the situation for existing LPS is more complex. For these, the appropriate lawful basis may have changed over time, and the LPS would likely have adapted to take advantage of new scientific opportunities, or ways of working to be incorporated into the legal basis. Where this is not possible, then at least these new approaches need to be communicated to participants in a fair and transparent way and an alternative legal basis sought. Where these new possibilities clash with existing consented ways of using data, then this conflict needs addressing. Over the past 10-20 years, LPS have faced this situation as they increasingly seek to (1) realise new scientific opportunities from linking participants' routine records into LPS databases; (2) maximise the public benefit value by sharing data with bona fide experts for appropriate purposes; and more recently (3) use Trusted Research Environments (TREs) to improve the safeguards controlling data use. In the UK, many of these LPS have collectively – with academic governance and TRE experts – come together to establish UK Longitudinal Linkage Collaboration (UK LLC, see methods) as the national TRE for both linking participants' LPS collected data to their routine records and for providing an open and FAIR (Findable, Accessible, Interoperable, Reusable) research resource to the research community [3]. As LPS join UK LLC, they need to undertake 'fair processing' [3] (materials explaining changes in data use with an option to opt-out/object) to be transparent and for this commitment to transparency to be a driver of trust [4].

## The complexities surrounding awareness of the legal bases to use data for research

The complexity of the legal framework for using data for research presents a challenge to this transparent and trustworthy relationship for two key reasons: (1) LPS make use of various legal bases, under both data protection laws and common law to access participants' routine records for inclusion in research analysis (Figure 1); and (2) there are potentially low levels of awareness of some or all aspects of these laws and how they interact. While at a population wide level, there are generally high levels of awareness of key data protection legislation, there are potentially lower levels of awareness of the rights these contain. A 'Eurobarometer' European Union-commissioned public opinion survey (including UK citizens) found that by 2019 the majority of respondents (67% across the EU, 70% in the UK) were aware of the General Data Protection Regulation (2018, GDPR) although only 36% reported "they knew what it was" (30% in the UK) [5, 6]. Yet, while most (73%) respondents were aware of at least one GDPR right and almost a third (31%, 40% in the UK) were aware of all their GDPR rights, just over a quarter (27%) were not aware of any of these rights. Given the long-standing nature of rights of confidentiality over patient records in the UK [7], we might assume a general awareness of the protection that common law may provide. Yet, many individuals are likely unaware that some legislation specifically exists to enable the use of personal data for public benefit research without the need for specific consent. Notwithstanding, while being 'lawful' is critical, it does not in itself provide the 'social licence' for publicly acceptable research [8] and consultation with LPS participants has identified that the value of consent extends beyond being a lawful basis and is linked to etiquette and trust [9, 10].

Our motivation for this work was that a lack of awareness or understanding of the legal bases for longitudinal research could result in "surprises" to participants in how LPS use their data or the approaches LPS take towards ensuring transparency and enabling individuals' control over data use (e.g. if an LPS chooses to adopt informed opt-in consent or uses a different legal basis and ensures proposed data use is transparent and provides a clear means to object). Interactions with the UK LLC's public and participant involvement group suggest low levels of awareness and understanding of the law amongst both LPS participants and the public and confusion regarding the interactions between legislation and wider individual rights. If this low level of awareness is generalisable to the wider population, it suggests that for participants' decision-making to be informed and therefore ethically valid, our community needs to address a potential information asymmetry where those enacting data processing decisions (i.e. the LPS, TREs) have a more well-informed understanding of the law than those impacted by these decisions (i.e. the participants whose data are being used) [11].

Figure 1: Summary of the legal basis for longitudinal research, the use of participant routine records and anticipated potential misunderstandings

Both UK LLC and collaborating LPS maintain a lawful basis under data protection laws for holding and processing data and for the use of special category information. Although it is provided as an option, 'consent' is not used as the data protection law requires consent to be highly specific, which is not possible where the future uses of the data are not known. Rather, the basis for an LPS based in academia or a public authority such as the NHS or Education, would be 'task in the public interest' and to conduct 'scientific research'.

Confidential data for record linkage also carries a duty of confidentiality under UK common law, which arises from the implied relationship of confidence between a participant and organisations they provide their data to – including the data they give to their LPS, and for example, their doctor, school, employer or tax authority. LPS must meet the common law duty before confidential participant information can be used for linkage and research. There are a number of ways of meeting the common law duty including gaining explicit participant consent or – for health research – through 'Section 251' granted under the Health Service (Control of Patient Information) Regulations 2002 within England and Wales (Regulation 5 with support from the Health Research Authority's Confidentiality Advisory Group), or through undergoing public interest test assessments in Scotland. For NHS England and Wales records, UK LLC fully respects any participant objections recorded in the respective NHS National Data Opt-Out schemes, unless over-ridden by explicit consent. The Digital Economy Act 2017 provides a means to meet common law where public authorities (including LPS) use non-NHS data for research purposes.

Some LPS have made efforts to describe data protection legislation and rights to their participants (e.g. the Avon Longitudinal Study of Parents and Children, ALSPAC, included fair processing information about this in their participant newsletter [12]), to communicate their legal basis under UK-GDPR, and to at least promote the right to object, and – for some LPS – to explain the lawful basis for using participants' linked health, socio-economic and environmental records in research without their explicit consent, subject to transparency and right to objection (e.g. ALSPAC's record linkage fair processing materials [13]). More generally, Understanding Patient Data (UPD) [14] have now (after the work described in this paper) produced explanatory guidance on cross-sector and health data policies, including summaries of relevant legislation. Yet, prior to our work, there was no known accessible information attempting to summarise legislation relating to data use to a diverse public audience.

This paper will first provide a narrative description of feedback from a public involvement survey designed to test this issue and second, describe the methods by which we co-developed our lawful basis transparency materials. We then discuss the materials themselves and their contribution towards this challenging aspect of ensuring fair and transparent data use and maintaining the trustworthiness of public good research. This paper does not test or investigate a specific hypothesis. Our primary objective for doing this was to develop more effective means to communicate LPS participants' rights by co-developing specific transparency materials with public contributors. We also wished to align UK LLC transparency materials with the Health Data Research

Alliance ('Alliance') Transparency Standards [15] which are used by TRE controllers to help provide information on policies and practice to the public in a fair, consistent and transparent way.

# METHODS

## UK Longitudinal Linkage Collaboration (UK LLC)

UK LLC is the national Trusted Research Environment (TRE) for data linkage in longitudinal research [3]. UK LLC is a partnership between academic governance and infrastructure experts and UK LPS for research 'in the public good'. UK LLC enables researchers to interrogate pooled LPS participant data, which UK LLC has systematically linked to participants' health, socio-economic and interdisciplinary records. All applications to access the UK LLC TRE are listed on UK LLC's publicly accessible Data Use Register (https://ukllc.ac.uk/data-use-register/). All UK LPS are eligible for inclusion in UK LLC and, to date, 22 LPS have joined the partnership, with a further seven LPS onboarding during 2025. The UK LLC TRE currently holds data on approximately 320,000 LPS participants. Where permissions allow, participants' records are linked to their NHS England, NHS Wales, and place-based records, with work ongoing to link to NHS data from Scotland and Northern Ireland, and non-health administrative records, including Department for Work and Pensions and HM Revenue and Customs.

UK LLC has an extensive Public Involvement Programme embedded across its work, including the data access application review process, which seeks to provide assurance that UK LLC is acceptable to LPS participants and the wider public [3]. The Public Advisory Group (PAG) was established in January 2022 and was recruited through a variety of methods, including volunteering websites, UK LLC social channels and communications from UK LLC partner LPS to participants involved in their own public involvement activities. The PAG consists of five members and includes study participants, NHS service users, parents, carers, and people with experience of disability, neurodiversity, and long-term health conditions.

## Background to the Alliance Transparency Standards

The Pan-UK Data Governance Steering Group [16] and Health Data Research UK's Public Advisory Board [17] co-developed the UK Health Data Research Alliance ('Alliance') Transparency Standards [18], designed to guide best practice for transparency of data access processes. UK LLC was awarded £12,365 from the Alliance to improve transparency by co-developing resources for better public understanding of LPS data and the law. This work aligned to Alliance Transparency Standard No.4: "Consider Target Audience that request websites feature appropriate language for the audience and should include content specifically developed for members of the public in readily understandable terms" [18].

## Background to the UK LLC transparency standards infographic series

The need for a straightforward way to communicate LPS participants' rights was identified through public contributor consultations with members of the UK LLC Public Involvement Programme. The aim of the consultation was to inform development of a new framework for agreeing consistency in assessment of the legal basis for linking participants' self-reported data to their health records. The consultation highlighted that the legislation is complex, confusing and often inaccessible to the public, suggesting it may prove difficult for many LPS participants to fully understand who is allowed to access their data, for what purposes, under what circumstances and their rights.

## Working in partnership with the public

UK LLC has a diverse range of public contributors across its Public Involvement Programme. Its PAG was invited to join the development of the grant application and, in the event of a successful outcome, co-develop the project and work as part of the UK LLC project team.

The PAG were presented with a series of projects from which they were to select one for the grant application. After some discussion, the majority opted to develop a series of infographics aimed to raise awareness and understanding among LPS participants on the various laws and legal principles that relate to who is allowed to use their data, for what purposes, under what circumstances and their rights. The decision to create infographics rather than alternative methods of communication, such as an animation, was a result of the short timescale to deliver the project.

The PAG was keen to build in costs to ensure the infographics were developed with a range of accessibility options to broaden the potential audience. It was agreed to produce audio descriptions, British Sign Language (BSL) videos and alternative language translations.

## Wider public involvement

We sought involvement from a wide group of public contributors to identify areas of low awareness and understanding. To support a wide breadth of views, we asked contributors in established panels to provide input using an anonymous series of questions using Microsoft Forms (the 'survey', see supplementary appendices). This was shared across the UK LLC Public Involvement Programme, HDR UK Voices network and the DATAMIND Super Research Advisory Group [19] (approximately 250 public contributors across all three networks) for completion within one week. The survey consisted of 35 questions featuring open and closed questions, multiple choice, and Likert scales. This survey was not designed or conducted as a research exercise, but as an efficient way for contributors to help us establish more information on what LPS participants and members of the public may be aware of in relation to why, how, and when their data may be used, that would assist the project team in the format and design of the resources. Further exploration of levels of understanding using, for example, qualitative methods such as focus groups or interviews were

not able to be conducted due to the tight timescales for the project. The project team co-developed the survey with the PAG to make sure the questions were clear. Following National Institute for Health Research PPIE guidance [20], contributors were compensated for their time with a £15 e-voucher.

## The project scope

Our scope was to produce materials covering the following laws and legal principles: UK Data Protection Laws (UK-GDPR, Data Protection Act 2018); Digital Economy Act 2017; common law duty of confidentiality; Section 251 of the National Health Service Act 2006 and its current Regulations, the Health Service (Control of Patient Information) Regulations 2002, with a final summary infographic to complete the series. Selection of these laws and legal principles were determined by two key factors, 1) the primary factor is that we focused on the most relevant laws and legal principles involved in the use of LPS data (based on our experience in the sector), with a focus on clarifying the complex inter-play between Data Protection rights and common law duty of confidentiality and 2) we also had some concern that extending beyond this (e.g. to Human Rights) would be confusing and dilute the primary message of the exercise. Survey questions asked about these laws and legal principles and additionally included the Human Rights Act, Mental Capacity Act and the Human Tissue Act, which are all also relevant to research.

The project team worked up draft content, using the survey results and domain knowledge to try to identify: (1) a set of possible misconceptions that participants may have around the legal bases of LPS research; and (2) a range of acceptable and digestible language to effectively communicate a series of complex messages, which often can be interpreted and actioned broadly the same but with nuanced differences. Throughout the drafting process, the project team consulted with a range of individuals from the Pan-UK Data Governance Steering Group [16], including HDR UK's Director of Legal, Trust & Ethics, the MRC Regulatory Support Centre [21] and drew from UK LLC legal counsel who advised us on our lawful basis. They provided guidance on the legal technicalities, using their experience as individuals with roles in communicating these laws and legal principles to public and researcher audiences, as well as referencing the legislation itself. The UK LLC partner LPS were also offered the opportunity to comment, because not all LPS operate in the same way. These consultations were important to ensure the resources captured the more generalisable key messages that reflected the ways in which LPS use participant data.

## Production of the materials

The project team enlisted the services of a creative agency to undertake the design, and bring the written content to life in an engaging way for LPS participants and the wider public. The infographic content was then reviewed through progressive draft stages by the PAG to an agreed last version.

# Results

## Survey

A total of 56 public contributors out of approximately 250 in total from across the three networks (UK LLC Public Involvement Programme, HDR UK Voices network, DATAMIND Super Research Advisory Group) participated in the survey, resulting in an approximate response rate of 20-25% (the exact denominator is not known). From the respondents, fewer than half were LPS participants, and of those who were participants, approximately half had been participants for up to two years, with the remaining half longer-term participants. The survey results provided us with an understanding that overall, awareness of the laws and legal principles asked about were low. As might be anticipated, the Human Rights Act (89%) and UK-GDPR (88%) were top of the list.

As the group invited to complete the survey were public contributors – individuals who have actively sought out opportunities to use their lived experience in support of work to improve patient outcomes – it could be assumed that this group might be expected to have a higher level of knowledge than other members of the public who may be less involved in research projects, because they are often working with individuals within clinical and academic environments. As such, they are likely to be exposed to more information and language related to clinical and academic research. While the survey identified that the Digital Economy Act had the lowest levels of awareness (11%) we suspect that awareness may be lower still in the wider population. We drew the conclusion that members of the wider public, who are less involved in research, would at least have similarly low levels of awareness to this group if not lower. This finding supported our intention to highlight both common law and Digital Economy Act as these legal gateways are increasingly used with low levels of awareness.

The project team noted it is likely that the COVID-19 pandemic may have increased public awareness of the use of confidential patient data without consent. When posed with a series of questions relating to whether or not they would be surprised to learn various circumstances of permitted data use, the majority of respondents were not surprised to learn there is legislation that allows confidential patient data to be used without consent in the event of a major emergency, such as the COVID-19 pandemic.

It was also not a surprise for respondents to learn that where data is anonymised, it may be used for research purposes, without people's knowledge or consent, or that there are committees appointed to make decisions about what research is in the public interest. The area where respondents were surprised was learning that health treatment groups, such as cancer registries, can be compelled to provide data into research resources.

When establishing awareness levels of the various opt-out mechanisms, either as a member of the public or as an LPS participant, it was similarly balanced across all questions. Members of the public may choose to action the National Data Opt-Out (England only) [22] and LPS participants may request a partial or full opt-out process. Around half of respondents were aware of the various opt-out mechanisms and of those

who were LPS participants, around half of them were aware of how to opt-out, either fully or partially, from their LPS.

Overall, the survey was a useful way to establish a more accurate baseline of knowledge and awareness of the laws and legal principles involved in data use within research.

### Potential participant misconceptions

We identified a small number of potentially significant misconceptions that participants may have relating to how the law applies to longitudinal research:

1. That 'consent' is the lawful basis for all LPS research and all laws – this could cause confusion or a loss of trust if participants with knowledge of UK-GDPR consent requirements felt that an LPS consent was not valid or well designed.

2. That all UK-GDPR rights apply to LPS research, whereas by design, UK-GDPR provides 'exemptions' to enable equitable and effective scientific research in the public good – this is likely to cause confusion or a loss of trust where participants seek to exercise a UK-GDPR right that is not enabled by an LPS.

3. That explicit consent is needed to access potentially sensitive data from other sources (e.g. health records), whereas to support unbiased public good research alternative legal bases can be used to lift the common law duty of confidentiality – this could cause confusion or a loss of trust where participants receive notifications from their LPS about using these provisions.

While other potential misconceptions may arise (above those relating to general lack of awareness and understanding), we sought to address these specific risks in the infographics.

### Laying a path that the public can follow

The UK LLC PAG was involved throughout the project and their task, following every edit to content, was to let us know if it still made sense to them and whether changes improved the content, or not.

Use of plain language was highlighted as critical and feedback most often focused on making the language simpler. Where specific terms needed to be used, we were asked to explain them clearly.

The PAG also looked carefully at the imagery and associations that could be drawn from them, both positive and negative. For example, they pointed out that a quote relating to a participant's lack of capacity was connected to a wheelchair user and commented that this could potentially reinforce stereotypes about disabled people. They welcomed the addition of imagery of a mother with a child with Down's Syndrome, as they had not recalled seeing that featured elsewhere in their public involvement work with other organisations and thus, is more inclusive. Their attention to detail throughout the project was exemplary, from reviewing the top-level messaging right down to imagery selection, text reduction and proofreading.

### The infographic series explained

The first in the infographic series covers both UK-GDPR and the Data Protection Act 2018 (Figure 2). This was the most challenging of the series to complete, as there was debate on whether to explain these laws as they stand for the public, or focus on the exemptions specifically, where data is used for research purposes. The agreed approach was to make this the only two page infographic to enable communication of the standard rights followed by an explanation of the exemptions to these rights where data is used for research and the reason exemptions are required.

The second infographic in the series (Figure 3) focuses on the use of administrative data, explaining what type of data this is and how it may be used by LPS.

The third of the infographic series (Figure 4) covers another area where consent is required for data to be used but again, there are exemptions that are important for participants to be aware of. It was important to highlight the right to object and how this legal principle interacts with the National Data Opt-Out (England only).

The fourth infographic of the series (Figure 5) is where it was necessary to highlight that LPS are required to provide transparent information to their participants if they move to use Section 251 as their legal basis. The involvement of our external experts was critical here, as they instructed that it was important for participants to know that Control of Patient Information and Section 251 allowed for the temporary lifting of the common law duty of confidentiality. The PAG wanted to include reassurance for the public that an NHS Research Ethics Committee is required to approve uses of Section 251, known technically as a 'favourable opinion', and therefore is not an automatically approved process without oversight.

The final infographic of the series (Figure 6) provides a quick-view summary of each of the laws and legal principles featured in the series with a snippet of information on the main topic for each infographic. This provides the recommended layering approach when it comes to relaying complex information for the public, starting with brief messaging and moving to deeper layers for those who wish to explore more detail.

## Discussion

We have created a series of five infographics which explain some of the laws and legal principles most relevant to research to an LPS participant audience. These are intended to clarify the range of legal bases used by LPS and to highlight participants' rights and our findings and approach may have generalisable benefits as an exemplar for public engagement and transparency in health data research. The infographics are intended to be accessible to a lay reader and to simplify the complexity of the laws and legal principles. This work addressed a need identified by the UK LLC PAG who identified a gap in participant and public understanding. The infographics form a set of publicly available resources, created and checked by experts across the LPS, regulatory and legal fields and public contributors.

The input from our public involvement supported the existing EU Eurobarometer survey to suggest that there is

Figure 2: Infographic on UK Data Protection Laws


widespread awareness of UK-GDPR and the Human Rights Act and much lower awareness of specific legislation to enable research (e.g. Digital Economy Act) and the exemptions of UK-GDPR rights that support research. The development of these materials builds on work a few LPS have conducted to explain UK-GDPR to their participants and expands to cover and connect a wider set of legislation and regulations. This was not a straightforward process due to the exemptions and conditions under each law/legal principle where data is used for public good research. This led to focus on highlighting the

Figure 2: Continued


practical implications for participants rather than explaining the laws/legal principles. Across the series, participants are directed to official organisations where they can explore more comprehensive information.

Figure 3: Infographic on Digital Economy Act


## Strengths and weaknesses

A strength of our approach is that public/professional co-development enabled us to simplify a complex topic, and through an iterative review loop reach a point where all stakeholders could agree that the content was appropriate and accessible. Had this project been undertaken without members of the public being involved, it would likely have failed in its objective as we would not likely have produced as accessible outputs.

This work could act as a springboard for more resources that go into detail about some of the topics referenced in the infographic series. Articles and blogs could be produced on topics, for example, explaining the opt-out process, what is

Figure 4: Infographic on Common Law Duty of Confidentiality

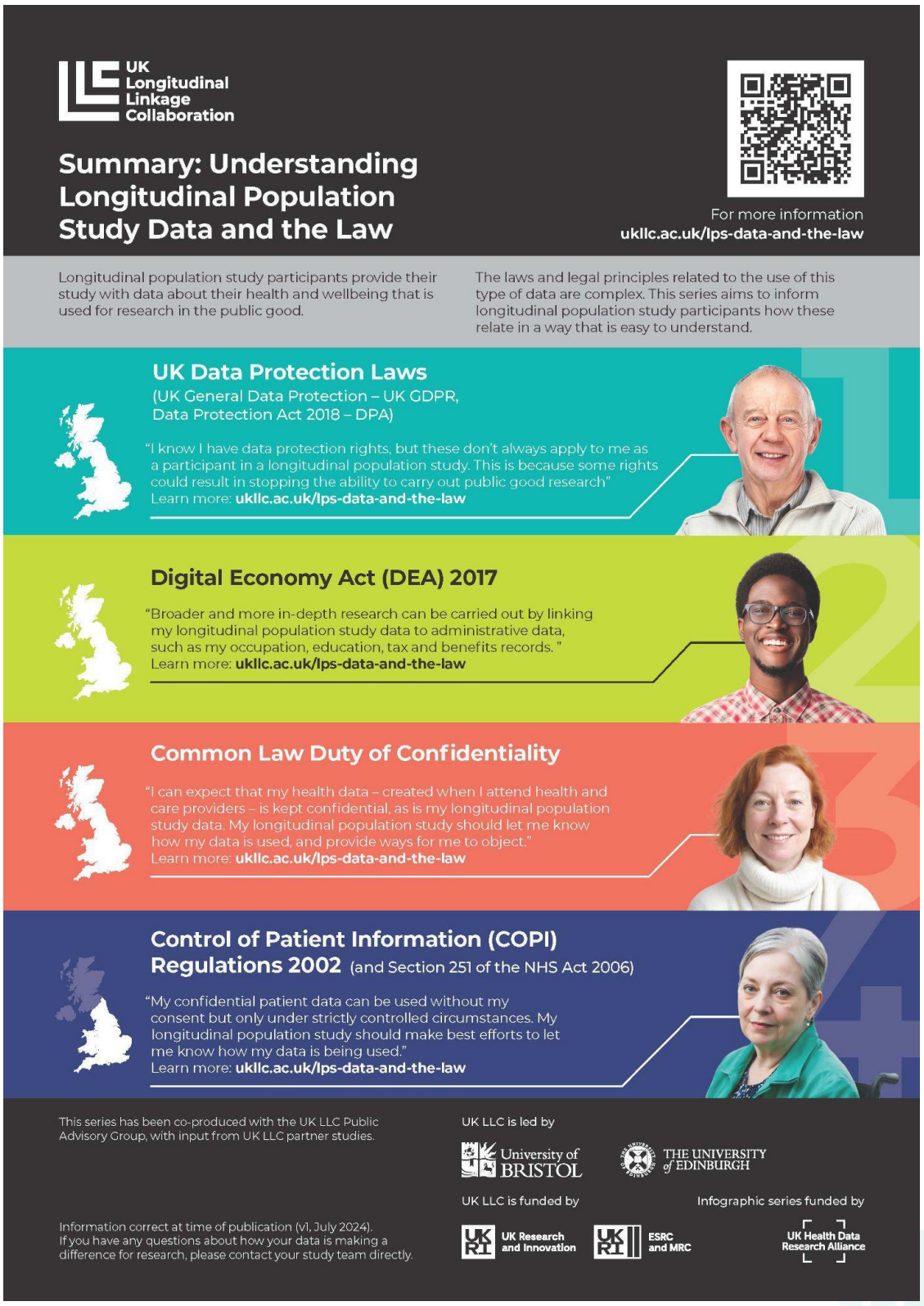

'fair processing,' or participants' rights after death. The PAG expressed a desire to produce an 'easy read' version for people with learning disabilities. This may be considered where future funding becomes available.

A weakness of this approach is that by reducing the complexity of law to a universally accessible infographic, it is highly reductive in terms of content and particularly the justification for why LPS make the decisions they do. However, since we undertook this work, UPD have now produced more detailed legal transparency materials and together these are complementary and establish a 'layered approach' to providing complex information in tiers of detail – as recommended by the data protection regulator in the UK. Sector specific adaptations could be needed to fit the UPD materials to the context of longitudinal research. A further weakness was that as the public contributor survey was undertaken as a method

Figure 5: Infographic on Control of Patient Information Regulations (2002) and Section 251 of the NHS Act 2006


of gauging levels of understanding to inform the production of materials, ethical approval was not sought, meaning the full survey results cannot be published. This was unavoidable due to the short timescales involved in this project which had an absolute deadline by which all funds needed to have been spent, and which could not accommodate the minimum 6-8 weeks needed for ethical review. This is something for consideration by the funders should future funding calls of a similar nature be available. Longer project delivery timescales, permitting time for ethical approvals would allow research data to form part of the outputs and to be extrapolated or applied to a larger population. It is also acknowledged that the work to understand awareness and the materials produced was done in consultation with public contributors who are potentially already engaged with research. This may mean our survey findings were unrepresentative of the wider population (i.e., they likely overestimate levels of awareness of the different laws). Furthermore, we acknowledge the potential for the

Figure 6: Infographic Summary




authors and contributors support for research to introduce unconscious bias impacting on the neutrality of the infographic content. Finally, a testing phase with people outside of the PAG was not part of the project aims meaning that the materials did not go through a preliminary testing phase before release to the public.

## Collaborative working: bringing together a jigsaw puzzle of experts

Although there were decades of experience across the project team it became clear that the interpretation of the laws and legal principles and how these should be implemented differed

depending on the experiences of individuals. This made it particularly challenging to deliver a defined understanding, and even more challenging to reach a lay version that would be suitable for a public audience. It was essential to bring in experts to help the project team accurately simplify the complexities and iron out the range of interpretations that those decades of experience had formed. A principal challenge was to find a generalised overview that could be agreed upon. We had people who were expert in the knowledge of their own jigsaw piece, but less knowledgeable about others' jigsaw pieces. The question we faced was how to complete the puzzle correctly and ensure it formed a picture that was instantly recognisable and clear to the onlooker?

From the survey results the laws and legal principles involved in the use of data for research are not commonly known about or, if known, not well-understood by participants and members of the public.

Public involvement is non-negotiable when it comes to delivering important messages for the public as the pull to include legalese, technical jargon and verbose language is strong, resulting in a hit and a miss for public understanding. An example from our own experience is the co-development of UK LLC animations with UK LLC public contributors [23, 24], where their input significantly improved the language and imagery used.

## Conclusion

The legislation around the use of data within research is complex and confusing, and can be inaccessible to the public. These resources provide clear information using visual, written and audio communication methods for LPS participants to understand the legal basis for their research study and their rights. The materials align with key points of Alliance Transparency Standard No.4, which recommends 'the use of appropriate language for the audience', 'include content specifically produced for a public audience' and to involve a range of professional and public individuals in the 'writing and checking of all materials intended for the public'. Public co-development and involvement was essential to ensure the materials are suitable. The approach and content are generalisable both to other research sectors and internationally (with local adaptations). As awareness of the laws and legal principles is low, we recommend that data providers increase endeavours to raise awareness among those whose data is being used for research in the public good as a means to drive the trustworthiness of the research process.

## Authors' contributions

KC led the grant application and project team, the paper writing and review process.

ABoyd, KE, ET, JO, SM, SC, RH, MG, MD co-developed the resources as members of the project team and reviewed the paper.

RF, RW, LG, ABailey and CS contributed to the content and review of the resources and reviewed the paper.

## Statement on conflicts of interest

We note ABoyd's potentially conflicting role in both HDR UK, as the awarding body for the transparency standards work, and as Director of UK LLC. This was managed by HDR UK, with ABoyd declaring this conflict prior to the application review process and HDR UK ensuring he had no role in or visibility of the decision-making regarding the transparency standards funding.

No other conflicts of interest were declared.

## Ethics statement

Following the relevant UK regulatory guidance (https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-do-i-need-do/) this project was determined to have two parts: (1) public involvement to design information materials which does not constitute research; and (2) the production of generalisable materials which may constitute research. For the first aspect, this project involved public contributors from three established panels (UK LLC, DATAMIND, HDR UK) which have each been convened to inform decision-making in research. Ethical approval for this specific involvement was not sought in line with the guidance. For the second aspect, the involvement of the UK LLC PAG in the co-production of the materials sits within UK LLC's ethical approval from the Health Research Authority Research Ethics Committee (Haydock Committee; ref: 20/NW/0446).

## Data availability statement

Data are available in the submitted article and supplementary appendix. Neither the PPIE findings nor public survey data are available due to ethical restrictions.

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## Abbreviations

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| ALSPAC: | Avon Longitudinal Study of Parents and Children |
| BSL: | British Sign Language |
| DEA: | Digital Economy Act |
| FAIR: | Findable, Accessible, Interoperable, Reusable |
| HDR UK: | Health Data Research UK |
| HM: | His Majesty's |
| LPS: | Longitudinal Population Study |
| MRC: | Medical Research Council |
| NHS: | National Health Service |
| PAG: | Public Advisory Group |
| PPIE: | Patient and Public Involvement and Engagement |
| TRE: | Trusted Research Environment |
| UK: | United Kingdom |
| UK-GDPR: | UK General Data Protection Regulation |
| UK LLC: | UK Longitudinal Linkage Collaboration |
| UPD: | Understanding Patient Data |