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Contractual Mechanisms for Securing the Public Interest in Data Sharing in Public-Private Health Research Partnerships

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Abstract

Public private partnerships (PPPs) are increasingly common in health research, with large European investment over the last 20 years and renewed focus in the wake of the global health crisis COVID-19. PPPs have been used for health research that seeks to collect, analyse and share personal data from research participants, often on the basis of informed or broad consent. PPPs are underpinned by contracts, both to govern the use of data and samples necessary for health research, and to govern the agreement between the public and private contracting parties of a project. This raises the question of how far contracts adequately protect public interests, for example in privacy and data protection when patient data are exposed to a broader range of potential uses from the private sector. A core principle of contract law is that you cannot contract for unlawful activity. As such, contracts could be void if their design or performance entails a breach of statute or common law, for example data protection and privacy laws or the common law duty of confidentiality. This paper analyses the

implications of this general principle of illegality for contracts underpinning PPPs in health research, particularly to understand the extent to which it could operate to protect the public interest as conceived by privacy and data protection law. The paper will show how this heavily policy-driven doctrine has scope to ensure that contracts and contract terms that are contrary to public policy are void or unenforceable which, in the context of PPPs using personal information for health innovation and research, is a welcome, though limited, accountability mechanism in private law that could operate to serve the public interest.

Keywords
Public private partnerships; health research; contract law

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1 Introduction

Public-Private Partnerships (PPPs) are long term collaborations between the government and private partners to deliver and fund public services and assets.[1] PPPs are increasingly used for health research consortia and to accelerate health innovation; providing much needed stimulus to the research and development of innovative medicines. PPPs can take various forms, including project- based collaborations, long-term alliances, and complex multi-consortia, and in health contexts, can include: "hospitals, primary care practices primary care practices, specialist health providers, pharmaceutical and medical device companies, IT companies, non-governmental organisations (NGOs), private health insurers and construction firms."[2] These multi-sector collaborations are needed to leverage the infrastructure, multi-disciplinary expertise and other resources required to enable larger volumes of data to be processed, often volumes beyond the capacity of any one group or institution.[3] Rising healthcare costs and declining returns from traditional pharmaceutical industry research and development are also driving support for academic–industry consortia.[4]

In Europe, this approach has been driven by the public-private partnership the Innovative Medicines Initiative (IMI),[5] supported jointly by the European Union and the European Federation of Pharmaceutical Industries and

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1 OECD, *Recommendation of the Council on Principles for Public Governance of Public Private Partnerships* (OECD Publishing 2012).

2 Angela Ballantyne and Cameron Stewart, 'Big Data and Public-Private Partnerships in Healthcare and Research' (2019) 11 ABR 315. Citing Yildirim Oktay, Matthias Gottwald, Peter Schüler, and Martin C. Michel, 'Opportunities and challenges for drug development: public–private partnerships, adaptive designs and big data' (2016) 7 Front. Pharmacol. 461.

3 Jill S Altshuler et. al, 'Opening up to Precompetitive Collaboration' (2010) 2(52) Science Translational Medicine 52cm26.

4 Michael Morrison, 'StemBANCC: Governing Access to Material and Data in a Large Stem Cell Research Consortium' (2015) 11(5) Stem Cell Rev 681.

5 IMI, 'About IMI' <https://www.imi.europa.eu/about-imi> accessed 13 July 2023.

Associations. IMI exemplifies the operation of the model and the opportunities created for multi-partner, large-scale research collaborations sharing biological samples and data on a large scale. For example, the DIRECT (Diabetes Research on Patient Stratification) project[6] aimed to improve diabetes patient stratification and accelerate health innovation. The DIRECT project aimed to process and share human tissue samples and data to deliver patient outcomes in the public interest.[7] In England, further examples include the controversial Google DeepMind, Royal Free London NHS Foundation Trust partnership; formed to develop an app, "Streams", to manage acute kidney injury care using patient data.[8]

Sharing data, especially sensitive individual level medical, personal, and biological data, requires robust governance. In addition to project policies[9], PPPs are governed by contracts that a) govern the relationship between the partners and, in the case of PPPs conducting health research that involves human tissue samples and personal data, b) govern the processing of personal data and the use of human tissue samples. The governance of such PPPs is likely to include a Material Transfer Agreement (where human tissue in involved), Data Access Agreement, and Project Agreement, all of which are legally binding contracts enforceable by the parties of the contract in court. The terms of these agreements will vary according to the nature of a research project, but, in those projects where personal data is processed, it will be inherent to the contract that the parties agree

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6 IMI, 'DIRECT: Diabetes Research on Patient Stratification' <https://www.imi.europa.eu/projects-results/project-factsheets/direct> accessed 9 December 2022.

7 Scottish Health Informatics Programme, 'SHIP Guiding Principles and Best Practices' <http://www.scot-ship.ac.uk/sites/default/files/Reports/Guiding_Principles_and_Best_Practices_221010.pdf> accessed 29 November 2022. Principle 1 on public interest provides that scientifically sound and ethically robust research is in the interest of protecting the health of the public.

8 Julia Powles and Hal Hodson, 'Google DeepMind and healthcare in an age of algorithms' (2017) 7 Health Technol. 351.

9 Adherence to which may also be a term of governing contracts; reinforcing project policies.

to abide by data protection law. For example, in England and Wales, in the health research context, the relevant regulatory frameworks might include the UK GDPR, DPA 2018 and the Human Tissue Act 2004.

Generally, as a partnership between both public and private organisations, and underpinned by legally binding contracts, the PPP is a ''hybrid'' legal structure. Contract law is traditionally conceived as a ''private'' law discipline, but the involvement of public bodies has the potential to influence the terms of the partnership, in view of the State's obligations to protect, for example, privacy rights under Article 8 European Convention on Human Rights (ECHR), and ultimately, promote the accountability of the research project to the public good.[10]

Considerable literature has followed the increasing popularity of PPPs concerning their effectiveness for health research in terms of IP and innovation, efficiency, sustainability and acceleration of research led health outcomes.[11] However, there has been comparatively little literature that seeks to understand the extent to which this hybrid model, underpinned by contracts that are traditionally designed to protect private interests of contracting parties, serves to protect the private interests of data subjects and wider the public interest in health research and data protection and privacy protection. This is a significant

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[10] Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (ECHR) Art 8. Traditional conceptions of public and private law distinguish the body of positive law that governs relationships between private individuals (natural or otherwise) i.e. "private law", from "public" law, the latter of which governs the relationship between individuals and the state acting in its capacity as the mediator of the public good: Kit Barker, 'Private law: Key Encounters With Public Law' in Kit Barker and Darryn Jensen (eds), *Private Law: Key Encounters with Public Law* (Cambridge University Press 2013) 4.

[11] E.g. Magdalini Papadaki, 'Adaptation through Collaboration: Developing Novel Platforms to Advance the Delivery of Advanced Therapies to Patients' (2017) 4 Frontiers in Medicine <https://www.frontiersin.org/articles/10.3389/fmed.2017.00056/full> accessed 19 July 2019; Remco LA de Vrueh and Daan JA Crommelin, 'Reflections on the Future of Pharmaceutical Public-Private Partnerships: From Input to Impact'(2017) 34 Pharm Res 1985.

gap, and the analysis is especially important in the context of PPPs that process personal data, with responsibilities for protecting both the privacy interests of the individual data subjects and also the public interest in that protection. Indeed, while data protection legislation like the UK GDPR are sector agnostic, and therefore the rules relating to data processing apply equally to data controllers and processors in the public and private sector, more broadly, "drivers, standards and reputational concerns for private sector actors are likely to be different from those of many public institutions."[12] For example, "there are reasonable expectations that public agencies will protect the public interest, use data to promote public benefit and demonstrate transparency. Private companies may share these goals, but they will also be motivated by innovations that offer a competitive advantage, protecting commercial secrecy and returning profit for shareholders."[13] It has been argued that this potential divergence of interests will need to be "carefully navigated" in the health data context.[14] To meet their own obligations, public bodies may, for example, expect certain values of public life[15] to be upheld by private organisations, who may therefore find themselves tied to meet public interest parameters.

There are many conceptualisations of the public interest and a plurality of potential meanings have been debated in academic and policy spheres. In the context of data protection and specifically health research data governance, it is accepted that there is a clear public interest in the promotion of scientifically robust research for public good, but also, that there is a public interest in the

12 Ballantyne and Stewart (n 2) 316.
13 Ibid 318.
14 Ibid.
15 Richard Craven 'The Legal and Social Construction of Value in Government Procurement Markets' (2020) 47 J. Law Soc. 29, 30.

protection of privacy interests of individuals.[16] Prompted by the introduction of a requirement that research processing of health data is in the 'public interest' in the UK Data Protection Act 2018 (DPA), this paper draws on Taylor and Whitton's framework for navigating the potential 'trade-offs' between individual control and privacy protection on the one hand, and research access to health data on the other, with a view to understanding the extent to which contractual mechanisms for PPPs achieve these aims.

In accordance with Article 9(2)(j) and Article 89(1) UK GDPR, s. 19 DPA establishes safeguards for the processing of health data for scientific research.[17] Relevant to this analysis is the condition that research processing must be in the public interest.[18] However, as Taylor and Whitton note, there is no further information or guidance to explain what this means. The authors note that where patient data are to be used in circumstances where consent would not be practicable, there is necessarily a 'trade-off' between the public interest in the health research taking place, and ensuring privacy.[19] For the authors, this raises 'a risk that diluting individual control may allow uses of data that are unacceptable to individual data subjects. This could ferment discontent, undermine confidence in effective governance, and discredit health research more generally.' To address this, and to bring clarity for how to navigate this

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16 Mark J Taylor and Tess Whitton 'Public Interest, Health Research and Data Protection Law: Establishing a Legitimate Trade-Off between Individual Control and Research Access to Health Data' (2020) 9(1) Laws 6.

17 Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (United Kingdom General Data Protection Regulation) (Text with EEA relevance) (Retained EU Legislation).

18 Data Protection Act 2018, sch 1 para 4 - 'This condition is met if the processing— (a)is necessary for archiving purposes, scientific or historical research purposes or statistical purposes, (b) is carried out in accordance with Article 89(1) of the GDPR (as supplemented by section 19), and (c)is in the public interest.'.

19 Ibid.

trade off, Taylor and Whitton construct the argument that there may be social legitimacy to proceed with the research without consent where it can be justified in terms that are accessible and acceptable to members of society: 'it is only in the public interest to allow research processing without consent when individuals can be provided with reasons to accept this use without consent.'[20]

Taylor and Whitton's proposal that health research uses of data without consent may be legitimate without consent where it is acceptable to individuals and there are reasons that are accessible, prompts a second order question about the mechanisms through which information about acceptability and accessibility may be obtained. Starting from the position that the public interest in protecting the interests of private individuals in participation in research, but also promoting research in the public interest, should be protected/promoted in a project that uses personal information, this paper considers the mechanisms available in contract law to protect and promote the public interest in PPPs between, for example, parties funding and conducting research, and whether additional contractual clauses could be added to bolster efforts to ensure the acceptability of data use over time.

Contract law is traditionally conceived as a 'private' law discipline, but the involvement of public bodies has the potential to influence the terms of the partnership and the accountability of the research project ultimately to the public good.[21] An important point of distinction, though, is that these questions are distinguishable from the question of whether a contract is a valid legal basis for data processing pursuant to data protection law requirements.[22] Rather, the

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20 Taylor and Whitton (n 16).

21 Barker (n 10).

22 UK GDPR art 6(1)(b) provides for a lawful basis for processing where 'processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract'.

analysis relates to those circumstances in which contracts are used to govern a project that processes personal data, but another valid legal basis exists, for example consent,[23] or performance of a task in the public interest.[24]

The focus of this paper is therefore on the nature, scope and implications of PPP contracts and the public interest, specifically the aspect of public interest involved in privacy/data protection. While a comprehensive consideration would be beyond the scope of the paper, we suggest practical examples and draw conclusions that may be of relevance to wider elements of the public interest and PPPs.

The remainder of the paper is in two parts. Next, the paper turns to the contracts underpinning the rights and responsibilities of contracting parties and describes the rules of contract that govern the partnerships, focusing particularly on the doctrine of 'illegality' or 'contrary to public policy' in contract law in relation to data processing. In this section (Part 2), we focus particularly on the requirements in data protection law for contracts to be considered 'lawful'. In Part 3 of the paper, moving beyond this conception of the public interest, the paper considers additional accounts of 'public interest' which may not be captured by the data protection rules, and how this position could be improved through express contract terms, and examples are provided of how these might look in practice for health research consortia.

2 Public interest limits to contractual agreements

Contract law is founded on the basis of ''freedom of contract'' and ''privity of contract''. These rules are based on the principle that, as a traditionally ''private''

[23] UK GDPR art 6(1)(a).
[24] UK GDPR art 6(1)(e).

law discipline, contract law only governs the relationship between parties to a contract who are generally free to agree contract terms. According to the classic view, the purpose of contract law is to uphold the interests of the contracting parties, to give effect to the wills of the parties as expressed in the terms of the contract, and to involve the courts only to determine the meaning of the contract and provide remedies for breach.[25] In the case of breach of contract, remedies are generally designed to place the claimant in the position they ought to have been in if the contract had been properly performed: to ensure that a contracting party will either enjoy performance or – in the case of breach – a money equivalent (damages).[26]

However, there are limits to contractual freedom, for example where contracts are contrary to public policy or are illegal. The principle of ''illegality'' limits the terms that can be contracted for, and requires that contracting parties cannot contract, in object or method of performance, to anything illegal or contrary to public policy. A contract will not be valid where this is found to be the case.[27] For example, parties cannot contract to commit a crime, such as to commit murder or engage in restraint of trade.[28] The courts have frequently drawn a distinction between statutory and common law illegality. Somewhat confusingly, this does not refer to the source of law from which the illegality stems but instead refers to whether the effect of the performance of the contract

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25 Broader, relational theories of contract law on the other hand pay greater attention to party conduct and the overall context of the agreement. For example, see: Catherine Mitchell, 'Vanishing Contract Law: Common Law in the Age of Contracts' (Cambridge University Press 2022).

26 For example: A contracts with B to pay £1000 to C. C cannot enforce A's promise even though C is the intended beneficiary of the contract because C is not a party to the contract. So, a third party cannot enforce a contact. Classic authorities include: *Tweddle v Atkinson* [1861] 1 B & S 393, *Dunlop Pneumatic Tyre Co Ltd v Selfridge* [1925] AC 847, HL. In both cases the rule was expressed as 'consideration not moving from the claimant'.

27 Jack Beatson et. al , *Anson's Law of Contract* (30th edn, Oxford University Press 2016) 409-410.

28 *Esso Petroleum Co Ltd v Harper's Garage (Stourport) Ltd* [1968] AC 269, HL.

can on standard principles of statutory construction be seen to directly contradict the statute.[29] Crucially, the principle of illegality limits the terms of contracts that underpin PPPs for health research consortia, creating important inherent protections for the public interest, for example data protection and privacy protection. As will be explored, where a contract or contract terms are formed or performed unlawfully, case law suggests that they will be rendered void/unenforceable.[30]

2.1 Illegality and the limits of contractual freedom

The principle of illegality is the subject of ongoing academic and judicial debate. It has been argued that there is a 'fundamental clash of values' between private law's conception of justice as between the parties to the contract (''interpersonal justice'') on the one hand, and the public policy concern with the state's protection of its citizens on the other, i.e. between public and private law:

> If one were concerned purely with justice as between the parties one would simply ignore illegality in the realm of contract, leaving contract law to operate in the same way as it would if there had been no illegality involved. But the judges and the Legislature have felt compelled not to ignore the public policy concerns. The law has thereby committed itself to provide an answer to the complex question of how the clashing private and public law values are to be reconciled.[31]

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29 Andrew Burrows, 'The Illegality Defence after Patel v Mirza' (The Professor Jill Poole Memorial Lecture, Aston University, 24 October 2022) <https://www.supremecourt.uk/docs/illegality-defence-after-patel-v-mirza-lord-burrows.pdf> accessed 13 July 2023.

30 *Patel v Mirza* [2016] UKSC 42.

31 Andrew Stephen Burrows, 'Illegality as a Defence in Contract' (2016) Oxford Legal Studies Research Paper No.15/2016, 1 <https://ssrn.com/abstract=2758797> accessed 6 August 2023.

Perhaps because of this clash in values, the doctrine of illegality is contentious, and its boundaries are notoriously uncertain and ''untidy''.[32] For example, there is debate about whether it operates as a doctrine or defence:

> The rule concerned does not always function as a defence if that word is taken to mean a principle that prevents liability from arising even if all the elements of the cause of action in which the claimant sues are satisfied. Not infrequently, the rule prevents the claimant from establishing the elements of his or her cause of action.[33]

There is also debate about the approach that is, or should be, taken by the courts in deciding ''illegality'' cases. Historically three approaches have been taken: the ''reliance test'';[34] a ''rule- based'' approach; and a ''range of factors'' approach, the latter of which was adopted as the correct approach by Lord Toulson delivering the lead judgment in *Patel v Mirza*.[35] In brief, the approach of the courts may depend on whether the illegality in question is directly contravening a statutory provision or whether effect of the illegality cannot be determined by ordinary statutory interpretation, i.e. where the statute has not dealt with the effects of the illegality, in which case common law illegality will be applied, as confirmed in *Patel*.

In *Patel*, and against a backdrop of uncertainty and inconsistent approaches, the Supreme Court aimed to define definitively the circumstances in which illegal or immoral conduct might bar an otherwise good claim in tort or contract. The judgment recounts that the claimant paid a large sum of money to

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32 *Les Laboratoires Servier v Apotex Inc* [2014] UKSC 55; [2015] AC 430 (Apotex) cited in James Goudkamp, 'The Doctrine of Illegality: A Private Law Hydra' in Daniel Clarry (ed), *The UK Supreme Court Yearbook, Volume 6: 2014-2015 Legal Year* (2nd edn, Appellate Press 2018), 274.

33 Goudkamp (n 32).

34 The approach taken in *Tinsley v Milligan* [1994] 1 AC 340.

35 *Patel v Mirza* (n 30).

the defendant pursuant to an illegal agreement that the defendant would use the money to bet on shares using insider information. The insider information never materialised such that the bets were not placed, and the claimant sued for return of the sum paid. The defendant argued that the claim was barred by illegality, because the claimant had to rely on his own illegal conduct to prove his claim (a line of argument akin to the ''reliance'' test). This defence was rejected by the Supreme Court, and the Court held that the judgment of ''whether allowing a claim which is in some way tainted by illegality would be contrary to the public interest, because it would be harmful to the integrity of the legal system'', cannot be made without consideration of the following:

> a) considering the *underlying purpose of the prohibition* which has been transgressed, b) considering conversely any *other relevant public policies* which may be rendered ineffective or less effective by the denial of the claim, and c) keeping in mind the possibility of overkill unless the law is applied with a due sense of *proportionality*… that trio of necessary considerations can be found in the case law.[36] [Emphasis added]

As Patel has been followed and further clarified in recent cases,[37] this paper will follow the approach taken by the Supreme Court in *Patel* when assessing the scope and impact of illegality, i.e., the ''range of factors'' approach.[38]

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[36] Ibid.

[37] *Stoffel & Co v Grondona* [2020] UKSC 42; *Henderson v Dorset Healthcare University NHS Foundation Trust* [2020] UKSC 43.

[38] This proportionality/range of factors approach was taken in the context of contract in *Parking Eye Ltd v Somerfield Stores Ltd* [2010] EWCA Civ 1338, [2013] QB 840, where courts have favoured greater flexibility culminating in a 'range of factors' approach aimed at achieving a proportionate response to contractual illegality in preference to the traditional rule-based approach. This approach also drew on the work of the Law Commission, which initially favoured introducing a structured discretion by statute (on the grounds that this approach could not be reached by standard judicial decision-making) but ultimately concluded that a

This brings us to the question, what are the implications of the principle of 'illegality or contrary to public policy' for contracts underpinning PPPs for health research consortia? First, it is clear that the principle of illegality covers both criminal and civil wrongs. Therefore, contracts will not be enforceable if they breach statutory or common law. In relation to data processing and data sharing in PPPs, it seems that illegality raises the following questions in the context of PPPs and contracts for data sharing: what is necessary to be data protection compliant, such that a contract is valid and not 'illegal or contrary to public policy'? To what extent is that an adequate protection of public interest? This is an important question for projects contracting to transfer tissue samples and personal data. If a contract on its terms requires a breach of data protection law, as well as this breach potentially resulting in fines, the contract may also be unenforceable. For projects partnering with industry who pay large sums to access to such information, the fact that the contract is void may well be a bigger loss than fines under the GDPR, which might be perceived as 'worth the hit' for the collection of valuable data.

2.2 To what extent does 'illegality' provide public interest protection: key legal frameworks governing PPPs and health research

The relationship between public and private law values at the heart of the principle of illegality is particularly interesting in the context of public-private partnerships for health research, where there are a number of conceptions of the public interest at play. It is commonly accepted that there is a public interest in

similar approach was largely attainable by the courts so that legislation was largely unnecessary.': Law Commission, 'Illegality: Current Project Status' <https://www.lawcom.gov.uk/project/illegality/> accessed 29 November 2022.

scientifically sound research taking place.[39] There is also a growing acceptance that there is both a private interest in respecting privacy in the process of sound scientific research, as well as a public interest in respecting the private privacy interests of individuals in this context to realise the ultimately public interest in scientific research taking place.[40] As such, it can be argued that one conception of the public interest that may be bolstered by the doctrine of illegality is that conceived of by data protection and privacy law.

To understand the extent to which this contractual mechanism may operate to protect this conception of the public interest, and the circumstances in which a contract will be, in object or performance, 'illegal or contrary to public policy', analysis of the provisions the relevant legal framework is required.

In England and Wales, legal frameworks which apply to data processing for research in the context of PPPs, where aspects of the performance of the contract could feasibly involve illegality could therefore include, to name just a few examples in the interests of space, a) breach UK GDPR rules or the DPA 2018; b) breach the Human Tissue Act 2004; and c) breach the common law duty of confidentiality. These will now be discussed in turn.

2.2.1 Data protection law

It is not possible in this paper to set out all the rights and obligations that the data protection legal framework secures; rather we aim to provide a general overview

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39 Scottish Health Informatics Programme (n 7)

40 Nuffield Council on Bioethics, *The Collection, Linking and Use of Data in Biomedical Research and Health Care: Ethical Issues* (Nuffield Council 2015) <http://nuffieldbioethics.org/project/biological-health-data/> accessed 29 November 2022; Graeme Laurie et. al, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315; Mark J Taylor and David Townend, 'Issues in Protecting Privacy in Medical Research Using Genetic Information and Biobanking: The Privileged Project' (2010) 10 Med Law Int 253.

and highlight some key aspects that may influence whether PPP agreements and contracts relating to the processing of personal data are lawful.

The data protection legislative framework governs the use of 'personal data' only.[41] The GDPR sets out seven key principles for processing personal information that must be upheld in a contract for data sharing. The first principle for data protection requires all processing of personal data to have a fair and lawful basis.[42] 'Processing' includes all activities that relate to the collection, storage and use of data, including processing to alter data from an identifiable to non-identifiable form. Importantly, the GDPR contains provisions relating to 'scientific research', such as exemptions from both the 'purpose limitation' principle in art 5(1)(b), the 'storage limitation' principle in art 5(1)(e) and a derogation from the prohibition against processing of special category data (such as health data) under art 9(2)(j). To be lawful, these exemptions and derogations must be subject to 'appropriate safeguards' in accordance with art 89(1): they must be 'appropriate' to provide protection for 'the rights and freedoms of the data subject'.

The requirement for 'appropriate safeguards' when processing personal data as part of scientific research provides an example of how assessing the 'legality' of contractual agreements for the sharing and use of data may not be straightforward. For example, art 89(1) suggests that a technical safeguard such as 'pseudonymisation' should be used where that is compatible with the purposes of the processing. What would be the status of contract provisions for the sharing of personal data in an identifiable non-pseudonymised form if it could be argued that this was not necessary to achieve the research purposes?

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41 '[A]ny information relating to identified or identifiable natural persons', as defined in the General Data Protection Regulation 2016/679 of the European Parliament and of the Council, or any subsequent legislation with effect across the European Union.

42 GDPR, art 5(1)(a).

Likewise, what would be the implications of a contract to share data in a project with insufficient safeguards ensuring that only *bona fide* researchers could obtain the data? More generally, what would happen if a contract to share data is premised on a GDPR legal basis which, in fact, has not been complied with; for example, if there has been inadequate consent to sharing data? Or, more fundamentally, a contract to share assumed anonymous data that in reality involves processing of personal data, which therefore cannot be achieved lawfully? For instance, a contract to provide human genome sequence data which has in the past been considered by some as anonymous but is now increasingly likely to be considered identifiable, where it is not feasible to obtain new consent, and unfair in data protection law terms to swap legal bases, or it is not feasible to adopt an alternative legal basis?[43]

These hypothetical examples could all be contraventions of data protection law. Would this, in turn, be sufficient to render a contract, or specific provisions thereof, to share data in these circumstances void due to illegality?

2.2.2 Common law duty of confidentiality

The duty of confidence is crucial to uphold trust and confidence in the doctor patient relationship, and there is a public interest in protecting this confidence.[44] Under common law, the general position is that information given in circumstances where it is expected that a duty of confidence applies, that information cannot normally be disclosed without the information provider's consent or another lawful basis. In practice, this means that all patient/client information, however collected or stored, must not be disclosed without the

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[43] European Data Protection Board, 'Guidelines 05/2020 on Consent under Regulation 2016/679' (adopted on 4 May 2020), 25.

[44] Mark Taylor, 'Information Governance as a Force for Good? Lessons to be Learnt from Care.data' (2014) 11(1) SCRIPTed 1.

consent of the patient.[45] However, there may be instances where the duty of confidence may be overruled, for example, via a statutory gateway permitting lawful disclosure of confidential patient information in the absence of patient consent, subject to favourable review and opinion by the NHS Health Research Authority's Confidential Advisory Group (CAG).[46] If requests to use data are classified as sensitive and identifiable, researchers are subject to additional requirements, including that of undergoing scrutiny from CAG.

As such, any contract that includes terms to unlawfully disclose confidential information would potentially come within the scope of the common law illegality doctrine. and, in the event that the contract was under enforcement action, would be void.

2.2.3 Human Tissue Act 2004

The Human Tissue Act 2004, applicable to England, Wales and Northern Ireland, explicitly prohibits commercial dealings in human parts or material for transplantation other than by someone who has been authorised by the Human Tissue Authority.[47] In relation to PPPs contracting to transfer data and samples, the effect of this provision is that, if human tissue samples are contracted to be transferred to a party that has no licence, as well as constituting a criminal offence, this will likely render the contract void/unenforceable by virtue of 'statutory illegality'. By implication, a contract entered into on these terms could not be enforced by either party.

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45 It has been established that the duty only extends to identifiable data: *R v Dept of Health, ex p Source Informatics* [2000] 1 All ER 786.

46 Pursuant to s 251 NHS Act 2006.

47 s 32 Human Tissue Act 2004.

2.3 Summary

There are a number of hypothetical scenarios in which a contract to process personal data or transfer human tissue samples could be unlawful. An interesting question is whether the illegality doctrine requires express provision in the relevant contract for something illegal, or, whether a contract that was merely performed illegally would also be void for illegality. While there have historically been attempts to delineate different types of illegality, the majority in *Patel* cautioned against drawing bright lines in this regard.

On the basis of case law, it seems that both would be capable of rendering a contract illegal/contrary to public policy if it can be proven that there was known intention to perform the contract illegally.[48] If this cannot be established, there may still be circumstances in which illegality, including in performance, would render the contract or specific provisions void. There are several instances where this may occur, as have been outlined herein. Conclusions may turn on whether the illegality is considered to flow from contravention of a statute e.g. UK GDPR, DPA 2018, or HTA 2004. In these circumstances, case law suggests that the illegality will need to be tied to a central aim of the statute, i.e. ensuring the protection and lawful processing of personal data in the UK GDPR/ DPA 2018. On the other hand, the knowledge and intention of the parties may be more likely to influence matters where illegality involves contravention of a principle of common law, for example breach of the common law duty of confidentiality.

Either party to a data processing contract could rely on illegality, either as a defence to a breach, or in an action to set aside the contract. The effect of a being 'illegal or contrary to public policy' would be that the contract, or a specific provision, is declared void and unenforceable, which in the context of PPPs is

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[48] *Ashmore, Benson, Pease & Co. Ltd v. A.V. Dawson Ltd* [1973] 1 WLR 828 (CA).

reassuring given the potentially competing interests that could motivate contractual arrangements, and the potential imbalance of power between parties giving and receiving personal data. Where a private party seeks to enforce the terms of a contract against a public party who is in breach by withholding data, there is precedent in other contexts for the court deciding that this will be an illegality and the contract will be void. In addition, where a contract between PPPs is illegal in its performance because a private party acts contrary to data protection law and it can be proven that that was the intention all along, then this contract may also be void with the effect of stopping further contractual obligations.

3 Adequate protection for public interest in PPP contracts for health research?

Contractual protections provided by the doctrine (or defence) of illegality seem to provide inherent protection for public interest as conceived by the data protection and privacy law framework, i.e., to the extent that there is a public interest in protecting the privacy and data protection rights of the data subjects whose data is being processed and as dictated by contractual terms. But what about protections beyond this conception of the public interest? Arguably there are dimensions of the public interest that are not specifically captured by data protection law. Beyond this narrow conception of public interest, there are important reasons to consider broader notions of public interest in the context of PPPs, which have been described as raising particular issues that will now be explored.

For example, Ballantyne and Stewart draw on empirical research that consistently shows public discomfort with the use of health data for commercial gain, and commercial (for-profit) companies accessing their health data. The

authors argue that the acceptability of public sector data use may not extend to the private sector, and to ensure social licence, initiatives will need to take steps to make sure that their activities are aligned with the reasonable expectations of the public.[49] Indeed, maintaining trust and confidence in uses of personal data over the lifespan of a PPP and beyond will be key to ensuring and demonstrating trustworthiness[50] and ensuring continued support and trust and confidence in use of data. Without this, it may be that the concerns that public(s) have expressed over private parties accessing health data will encourage them to 'vote with their feet' and withdraw their data or refuse consent to the continued use of their data, in turn threatening the quality of a dataset or the reputation of a project.

Indeed, research suggests that views of participants in health research can change according to contextual factors which may change over time. So, while research participants may be happy with their data being used by public organisations, there is empirical research that suggests they are less comfortable with their data being used by commercial organisations.[51] And, while an individual may provide consent at the beginning of a research project, by the time the research project reaches completion or even legacy stages, their consent preference may have changed.

These nuances have led to proposals for new models for consent for participation in health research such as 'Dynamic Consent'.[52] The premise for

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49 Ballantyne and Stewart (n 2).

50 Onora O'Neill, 'Linking Trust to Trustworthiness' (2018) 26(2) International Journal of Philosophical Studies 293.

51 Ipsos MORI Social Research Institute, 'The One Way Mirror: Public Attitudes to Commercial Access to Health Data' (2016) <https://www.ipsos.com/sites/default/files/publication/5200-03/sri-wellcome-trust-commercial-access-to-health-data.pdf> accessed 13 July 2023.

52 Jane Kaye et. al, 'Dynamic Consent: a Patient Interface for Twenty-First Century Research Networks' (2015) 23 Eur J Hum Genet 141.

more dynamic approaches to consent is that more engaged governance approaches to participation in health research that respect more granular participant choices can improve public confidence and trust in research, and ultimately ensure sustainable and legitimate research in the public interest. Dynamic approaches can ensure sustainable and legitimate research practices over the duration and potentially after a project by keeping the channel of communication and consent open and responsive, thereby helping to ensure public interest research can continue over the longer term. In Part 3 of this paper, we suggest ways that this may be incorporated in contract terms.

Other best practice approaches to inspire and maintain trust and 'social licence'[53] for health research consortia have been to develop internal governance mechanisms that project partners agree to abide by, although often this agreement is not legally binding. For example, mechanisms have been adopted that are designed to improve the transparency and public understanding of research activity;[54] policies have been adopted to ensure rigorous scientific merit for access to data and tissue samples;[55] and committees have been established to consider the ethical concerns associated with a project and to represent the public interest in decision-making regarding data access.[56]

While data protection law principles such as purpose limitation and data minimisation, and data subjects' rights under the UK GDPR, go some way to

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53 Pam Carter et. al, 'The Social Licence For Research: Why care.data Ran Into Trouble' (2015) 41(5) Journal of Medical Ethics 404.

54 Victoria Coathup et. al, 'Making The Most of The Waiting Room: Electronic Patient Engagement, a Mixed Methods Study' (2018) 4 Digital Health.

55 Harriet Teare et. al, 'The Governance Structure for Data Access in the DIRECT Consortium: An Innovative Medicines Initiative (IMI) Project' (2018) 14 Life Sciences, Society and Policy 20.

56 UK Biobank Ltd, 'UK Biobank Ethics and Governance Framework' (Version 3.0, 2007) <https://www.ukbiobank.ac.uk/media/0xsbmfmw/egf.pdf> accessed 20 December 2022.

achieving this balance,[57] the research exemptions in DPA 2018[58] can mean that some of these rights and responsibilities are not a requirement of health research projects and therefore are not included as contract terms. As such, there is an argument to be made that contracts for health research projects could be strengthened by the inclusion of express contract terms that, although not a requirement of data protection law, are specifically incorporated to engage participants in the governance of health research projects (an example of which is set out in Part 3 of this paper) with a view to ultimately inspiring ongoing public trust and confidence in the use of their data and samples for research in the public interest.

For example, a particular problem noted in the literature[59] is the matter of what happens when a project reaches the end of its funding and, although there is the potential for sound scientific research to continue in the public interest, there is no mechanism in place to evaluate research practices in line with the original terms of consent and as such, the decision is made that a project must come to an end, potentially leading to thousands of tissue samples and rich data sets being destroyed.

Further, as Taylor and Whitton suggest, health research that takes place for public interest and potentially without consent will only be socially legitimate where terms are provided that are acceptable and accessible to those whose data are processed. This arguably prompts a requirement for mechanisms that can

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57 Jessica Bell et. al, 'Balancing Data Subjects' Rights and Public Interest Research' (2019) 5(1) European Data Protection Law Review 43.

58 DPA 2018, Sch 2, para 27.

59 Ma'n Zawati et. al, 'Closure of Population Biobanks and Direct-To-Consumer Genetic Testing Companies' (2011) 130(3) Human Genetics 425. See also Michael Morrison et. al, 'Governance of research consortia: challenges of implementing Responsible Research and Innovation within Europe' (2020) 16(13) Life Sciences, Society and Policy, <https://doi.org/10.1186/s40504-020-00109-z> accessed 25 July 2023.

assess such acceptability over time. Can contract law provide mechanisms to further bolster public interest protection and promotion in health research consortia? Arguably, embedding safeguards into the contractual arrangements could go some way to assuaging concerns and demonstrating trustworthiness and the public interest intentions of the contacting parties.

One way of achieving this could be to include a specific contractual term or clause, the 'evaluation clause', that could require parties to engage with participants as the project end date approaches, evaluate the practices that are in line with the original consent, consult with participants about the findings so far, and, subject to upholding their right to withdraw, continue the research after the funding for the project comes to an end to the extent that the research is consistent with the original terms and trust and confidence is maintained. Embedding terms such as this in contracts could arguably add significant legal weight to secure acceptability of data use in the public interest.

3.1 Further contract terms that could protect the public interest

What might these express contract terms might look like in practice? Standard contract terms could be as follows:

> *Evaluation*: the project partners agree that one year prior to the funding end date, a meeting will be held to plan an evaluation exercise, both in terms of the scientific merit of the research continuing beyond the funding agreement, and the appetite amongst participants for the research to continue moving forward. Following consultation with project partners and participants, a decision will be made as to whether the project will continue beyond the funding end date and on what terms. This will be decided no later than 6 months prior to the project funding end date.

Embedding terms such as this, not only in a project's internal governance

arrangements, but as express contractual clauses in project agreements, has the benefit of legal mechanisms such as breach of contract and ultimately, damages for parties seeking to remedy the breach. But why should project partners agree to sign up to these terms if they go beyond data protection compliance? It is argued that express contractual terms such as these will enable the continuation of research that is in the public interest but also in the interests of those researchers that have invested considerable time and energy curating datasets and have an interest in not losing such valuable resources.

3.2 Limitations

A relevant question is, of course, how likely it is that those contracting to conduct health research will be inclined to adopt them, and who could enforce them. As has been outlined in this paper, as a fundamental principle of contract law, only those privy to a contract can bring an action to challenge or enforce that contract in court. This excludes data subjects and health research participants entirely from the contractual relationship. But, in the context of a PPP, where there are public parties responsible for acting for the public good, perhaps it is a more likely scenario that a questionable contract would be challenged by a public body or, where an action was brought against the public body by the private party, the courts would uphold the public interest over conflicting private interests. Moreover, whereas data sharing agreements are between public bodies and there are questions of illegality at stake, how likely it is that these contracts would be challenged in court, given the use of public resources and competing policy considerations? These are all concerns that indicate the limits of how far a contract can protect the public interest in health research consortia.

4 Conclusion

This paper has shown some of the legal mechanisms associated with contract law that can protect the public interest in health research in PPPs. While freedom of contract is a fundamental principle of contract law, there are exceptions and most relevantly, the doctrine and defence of illegality has the potential to operate to ensure that contracts which are in contravention of the data protection law framework are not only punishable under the data protection regime but are also unenforceable at common law. There are conceivable reasons why public policy should impose certain limitations of the contracts that underpin PPPs for health research, not least because of the numerous and varied interests that are at stake in the contracts, and the balance of power that can be potentially skewed by the involvement of powerful private corporations.

Although entrenched in jurisprudential uncertainty as to the nature and scope of the doctrine, recent case law suggests that either party to a data processing or material transfer agreement could rely on the illegality, either as a defence to breach, or in an action to void the contract. Whether or not the nature of the illegality is sufficient would likely be determined by a calculation of a 'range of factors' and what is proportionate in the circumstances, with the effect that there might be different approaches to minor breaches versus major security issues.

However, in the face of such uncertainty, and given the limits of this particular conception of the public interest, this paper has also explored some of the express contractual terms that could be incorporated as standard contract terms in research consortia, in a bid to promote best practice data and sample sharing and overcome issues prevalent in the research community. These issues include legacy questions such as what happens to research resources when funding comes to an end but researchers wish to continue their research.

Overall, the contractual model that underpins PPPs gives rise to protections that have the potential to protect public interest. Common law rules of illegality can act as a shield protecting the data protection adherence in a data sharing arrangement between public and private partners, embedding data protection law in a way that 'trumps' fundamental principles such as freedom of contract. However, arguably this does not go far enough to link the contractual arrangements with participants and, ultimately, society, and in the context of health research that relies on participation and public trust and confidence, there are clear advantages to new express contractual clauses designed specifically to foresee activities and contextual changes that participants may wish to be engaged about. Although not necessarily a data protection law requirement, recent events in the health sphere indicate that it is equally necessary to protect and promote a conception of public interest in health research that centres on engagement and communication. While the law may be necessary in this regard, as upheld by the principle of illegality, it may not be sufficient.[60] The express contractual clauses recommended in this paper are intended to prompt debate as to how contracts can move beyond mere compliance, and towards genuine participatory and acceptable health research in the future.[61]

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60 Colin Mitchell et. al, 'Health Database: Restore Public Trust in Care.data Project' (2014) 508 (7497) Nature 458; Carter et. al (n 53).

61 Effy Vayena et. al, 'Research Led by Participants: A New Social Contract for a New Kind of Research' (2015) 42 (4) BMJ Journal of Medical Ethics 216.