The Administrative Data Research Centre Scotland: A scoping report on the legal & ethical issues arising from access & linkage of administrative data

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Edinburgh School of Law Research Paper Series
University of Edinburgh
Keywords: legal, administrative data, data protection, consent, anonymisation, governance, principles-based regulation

Abstract: This initial scoping report outlines the original research to be undertaken for the legal work package of the Economic and Social Research Council (ESRC) funded Administrative Data Research Centre-Scotland (ADRC-S), by Professor Graeme Laurie and Ms Leslie Stevens based at the University of Edinburgh, School of Law and J Kenyon Mason Institute for Medicine, Life Sciences and the Law.1

The report provides an overview of the regulatory context in which administrative data linkages currently operate in Scotland, highlighting the crucial legal and ethical issues which arise from the current mixed legal landscape under which administrative data linkages operate. Adopting an approach that takes into account both the risks and the benefits that can be achieved through administrative data linkage research in the public interest, Laurie and Stevens argue for a principles-based approach to the governance of administrative data used for research purposes. By looking to established best practice in the field of data linkages in the health sector, and most notably the Good Governance Framework developed for the Scottish Health Informatics Programme (SHIP), the paper argues for an approach that will determine which principles can operate in a framework of robust and proportionate governance of administrative data linkages in Scotland.

This is the first in a series of papers for the legal work package of the ESRC-funded ADRC-S. Subsequent papers will focus on particular research questions of the legal work package, notably the adoption of a principles-based approach to the governance of administrative data; use of historical administrative data and the risks and benefits of commercial involvement in research.

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# Table of Contents

1. **Introduction: the current status of administrative data linkages in the UK** ........................................... 2
   1.1 Into the thicket – the establishment of the Administrative Data Research Network .................................... 4
   1.2 Distinguishing administrative data ........................................................................................................... 5
   1.3 Understanding barriers to administrative data linkage ............................................................................... 9
      1.3.A Statutorily created bodies ................................................................................................................. 11
      1.3.B Government departments .................................................................................................................... 13
   1.4 Navigating the thicket of the administrative data legal landscape ........................................................ 19

2. **Research Questions** ................................................................................................................................. 21
   2.1 RQ 1: Adapting the principle-based approach to administrative data ...................................................... 21
      Risk analysis in administrative data research ............................................................................................. 23
      2.1.A RQ 1.1 Historical data ..................................................................................................................... 24
      2.1.B RQ 1.2 Commercial partnerships ................................................................................................... 25
   2.2 Facilitating the lawful and ethical use of administrative data ...................................................................... 26

3. **Review of established standards and frameworks of governance** ....................................................... 29
   3.1 A principles-based approach, rules and regulation .................................................................................... 29
   3.2 Good governance of health data under SHIP – lessons learned ............................................................... 31
      3.2.1 Principles of good governance ......................................................................................................... 32
      3.2.2 Promoting the public interest in research ......................................................................................... 34
      3.2.3 Public interest principles restated for administrative data ................................................................ 35
      3.2.4 Protection of privacy and other individual interests ....................................................................... 36
   3.3 The ESRC Framework for Research Ethics ............................................................................................... 40
      3.3.1 Principles operating as rules: the FRE principles ......................................................................... 41
   3.4 Complementing principles with best practices ........................................................................................ 44
   3.5 A starting point for deliberation and decision-making ............................................................................ 45

4. **Historical data** ......................................................................................................................................... 47
   4.1 Indications of future use and temporality ................................................................................................. 47
   4.2 Consented or non-consented collections .................................................................................................. 48
   4.3 Length of time since collection ................................................................................................................ 48
   4.4 Historical data considered for ADRC-Scotland ....................................................................................... 49

5. **Commercial partnerships** ..................................................................................................................... 51
   5.1 Increased public sensitivities to commercial access ................................................................................. 51

6. **Conclusions: need for joined up approach to administrative data** ..................................................... 55

Bibliography ......................................................................................................................................................... 57
1. Introduction: the current status of administrative data linkages in the UK

There is currently an unmet need with regard to the legal position on the ethical and lawful use and linkage of administrative data in Scotland. Where the legal strand of the ADRC-Scotland will add its original contribution and ultimate value is in identifying the key legal concerns and clarifying the current legal position on administrative data linkages in Scotland while offering a principles-based approach to ethical decision-making that bridges the gap between the law and ethics. Potentially unhelpful (and harmful) distinctions made between the public and private, perceived versus real barriers, will be confronted. Where the law remains clear, but caution or inertia perpetuated by legal myths or perceived controversy remains, a proportionate yet robust governance framework can bring confidence to the necessary ethical decision-making that data custodians must engage in.

This initial scoping report outlines the general approach to the legal work package of the Administrative Data Research Centre-Scotland in undertaking original research into the legal and ethical issues arising out of administrative data use and linkages in Scotland.
Context

This report will first provide an overview of the mixed legal landscape under which administrative data linkages operate in Scotland – a landscape characterised by a plethora of national legislation, case law, government and professional, sector-specific guidance with further input from European Union law and case law. By clarifying the legal landscape as it applies to administrative data we will identify challenges and opportunities to building upon current governance models, and, where appropriate, legislative change.

Novel and systematic approach

Second, the report will examine the nature of the research questions to be addressed by the legal work package over years one and two of the ADRC-Scotland project, including adapting a principle-based approach to governance of administrative data, and addressing second-order research questions regarding use of historical administrative data and the risks and benefits of commercial involvement in research. An evidence review will be undertaken to understand the nature of potential harms, adopting a perspective that explores the relative nature and degree of risks involved in the use and linkage of administrative data. The findings of this evidence review will inform the recommendations made for the governance of administrative data use and linkages in Scotland.

Impact

The outputs of the legal work package will provide:

✓ A robust evidence base of the relative risks relating to the nature and degree of harms, public and private interests, to inform approaches to the governance of administrative data linkages in Scotland.
✓ An assessment of the flexibilities and limits of the current legislative and wider legal landscape, and a commentary on the need for legislative intervention.
✓ A risk-based analysis of the private and public benefits and harms involved in the use and linkage of administrative data.
A proposal for a good governance framework suitable for the use and linkage of administrative data across a variety of health and non-health, public and private sectors in Scotland.

This research will provide key insights into the governance of administrative data by embarking upon the first dedicated, legal and ethical study into the use and linkage of administrative data in Scotland. The impact sought will be to inform and support a proportionate yet robust approach to the governance of administrative data in line with key recommendations of the UK Government's Administrative Data Taskforce and building upon current best practice in governance – notably the Scottish Health Informatics Programme, whereby our intended approach to achieving these aims will now be explored immediately below.

1.1 Into the thicket – the establishment of the Administrative Data Research Network

The Administrative Data Research Network (ADRN) and Administrative Data Service (ADS) was announced in October 2013 as part of the UK Government’s commitment to Big Data – the Economic and Social Research Council’s (ESRC) investment of £34 million would contribute to the establishment of the ADRN to ‘…enable research based on linked data between government departments and be overseen by a single governance structure that will allow for consistent and robust decision-making.’ The ADRN and ADS will streamline access to administrative data for publicly-beneficial research within frameworks of robust and proportionate governance and promote the establishment of trust between the range of stakeholders including the public, researchers and government data controllers. At the heart of the ADRN are four Administrative Data Research Centres (ADRC) in England, Northern Ireland, Scotland, and Wales.

Unlike the case of health data, administrative data, has until recently, received relatively little critical attention as to the legal and ethical issues that arise in relation

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3 The use and linkage of health data by the UK’s researchers, and in particular from Scotland, have benefitted from a vibrant field of research and policy-driven action regarding the ethical and legal issues
to the access, use or linkage of data collected primarily for administrative reasons, but to be used for other purposes such as research.\textsuperscript{4} As part of the ADRC-Scotland, based in the University of Edinburgh at the JK Mason Institute for Medicine, Life Sciences and the Law, Graeme Laurie and Leslie Stevens will draw upon expertise in confronting the governance challenges of cross-sectoral data linkages to produce original legal and ethical research that will identity challenges and opportunities in the field of administrative data linkages. Their work will address the unresolved issues that persist as barriers to the linkage of administrative data for research in the public interest. The research will contribute towards the achievement of a common legal and ethical approach to the governance of administrative data within the ADRC-Scotland, and – potentially – to the entire ADRN.

\textbf{1.2 Distinguishing administrative data}

Administrative data refers to information collected primarily for administrative purposes including for example, census taking or managing income tax payment schemes.\textsuperscript{5} Thus administrative data ranges from data on tax, income, labour status, government benefits, education, social care, vital events, and so forth. While the law does not recognise a specific category of “administrative data” as such, it does recognise different sensitivities for different kinds of data as they relate to, or impact upon, an individual. For example, data which speak to an individual’s physical or mental health or condition are provided enhanced legal protection under the UK’s Data Protection Act 1998 (DPA), more so than data regarding the individual’s financial standing.\textsuperscript{6} However, research indicates a difference between self-identified sensitive categories of data and those that are legally defined in these terms, revealing a potential mismatch between citizens’ perspectives on the relative sensitivity of their

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\textsuperscript{5} Administrative data can include, for example: educational attainment records, employment records; social security payment records; tax records; health records and court records. ‘Administrative data: What are they?’ (2014) <http://adrn.ac.uk/admin-data/what> accessed 25 July 2014.

\textsuperscript{6} Data Protection Act 1998, s2(e). (DPA)
data and the legal protections available. The consequence of this is that careful consideration must be undertaken into the particular sensitivities surrounding the broad range of administrative data which the ADRC-Scotland will link for publicly funded research, and especially if linked for other purposes (e.g. commercial access). Simply because the law does not categorise financial or educational data as 'sensitive' does not necessarily justify the deployment of lesser safeguards, nor legitimate such uses. Robust justification and protection measure are required.

Related to the law's recognition of different sensitivities of data, are the different risks inherent to different uses of data, and this in turn impacts upon issues of proportionality of applicable governance measures. Robust, yet proportionate governance requires taking into account the specific risks and public and private benefits associated with a particular use of data. In the case of administrative data, a further way such data can be distinguished from health data is through the different risks posed by such use, and thus requiring careful consideration of what proportionate governance of administrative data looks like. The research undertaken by the ADRC-Scotland legal research package will take a risk-based approach to identifying appropriate governance mechanisms for administrative data linkages – the governance tools suggested will be informed by a robust evidence base which reflects the risks entailed by the use and linkage of administrative data – translating into proportionate yet robust governance. This approach is in direct response to the Administrative Data Taskforce's (ADT) recommendations for the governance of administrative data in 2012.

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7 Whereby, for example, citizens found financial data as especially sensitive although this is not recognised as sensitive or thus deserving of enhanced legal protection either on the European level under the DPD or in the UK under the DPA 1998. TNS Opinion & Social, ‘SPECIAL EUROBAROMETER 359 Attitudes on Data Protection and Electronic Identity in the European Union’ (Directorate-General Communication June 2011) 12-13 <ec.europa.eu/public_opinion/archives/ebs/ebs_359_en.pdf> accessed 7 March; Sara Davidson, Christopher McLean, Steven Treanor, Graeme Laurie, Mhairi Aitken, Sarah Cunningham-Burley, Claudia Pagliari, and Nayha Sethi, ‘Public Acceptability of Data Sharing Between the Public, Private and Third Sectors for Research Purposes’ (Scottish Government October 4, 2013) 69-73 <http://www.scotland.gov.uk/Publications/2013/10/1304/downloads#res435458> accessed 7 March 2014.

In 2012, ADT recommended that the ADRN be established to facilitate the linkage of administrative data within the UK for research purposes. The ADT’s commission and the recent establishment of the ADRN were two steps in a phased approach towards addressing the mired legal and ethical landscape that administrative data linkages for research and policy operate under in the UK.\(^9\) The ADT’s survey into this landscape found that whilst ‘…the potential value of using administrative data for analytical purposes inside and outside the government is well understood, the legal and ethical issues surrounding data access and linking are complex.’\(^10\) Although ‘…the problem of the regulatory thicket is well-recognised in the research community’,\(^11\) it is our contention that the thicket that dominates the regulatory landscape for administrative data linkages is significantly underexplored as it impacts across a range of stakeholders, and most especially data custodians and members of the public whose data might be held and used.

The legal research to be conducted under the auspices of the ADRC-Scotland aims to identify the most pressing of unresolved problems that present legal or ethical barriers to the linkage of administrative data in Scotland that can be demonstrated to be in the public interest. This initial scoping report is the first step in this endeavour. Despite the current availability of lawful means to link or share identifiable personal data or de-identified data for research in the public interest, ‘…in the vast majority of cases…the complexity of the law, amplified by a plethora of guidance, leaves those who may wish to share data in a fog of confusion.’\(^12\) The fog of confusion is arguably ‘thicker’ for administrative data, and persists despite policy recommendations to simplify the current governance of data in the UK for researchers.\(^13\) This persistence

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of legal uncertainty, surrounding the boundaries of the law, has resulted in cautious decision-making\textsuperscript{14} and at worse the cessation of potentially publicly beneficial research.\textsuperscript{15} The ADT found that ‘…on occasion, data have simply not been made available even though there may have been a lawful solution.’\textsuperscript{16} The identification and understanding of the implications of barriers to data linkages will inform later work that will consider and propose potential solutions to such challenges.

Thus in distinguishing administrative data, such data may be further distinguished (and its use potentially complicated) by the legal basis for use, sharing and linkage in the first place. Different sectors of public life are subject to different legal provisions, and some might have additional legal obligations or constraints imposed on them. Therefore complexities will arise in terms of (i) the privacy perspective from citizens considered and (ii) the organisational or institutional perspective from administrative data custodians. The risks at stake are both with respect to privacy, but also in terms of organisational/institutional reputations and standing, as it is impacted by potential uses of data.

In addressing the legal basis for use, sharing and linkage of administrative data in Scotland, we provide the following matrix as an analytical framing device to help understand the legal concerns at stake and assist administrative data stakeholders in identifying the types of challenges they are dealing with. This matrix will help frame the discussion below focused on unpacking the complex legal landscape governing administrative data linkages in Scotland.

\textbf{Administrative data decision-making matrix}

\begin{footnotesize}
\begin{enumerate}
\item[15] There is ample anecdotal evidence that current research governance frameworks in the UK do in fact delay or otherwise impede research activities. Social science research, which often relies upon administrative data, is particularly at risk due to the lack of harmonisation of procedures governing access to such data from the range of relevant data controllers including local authorities, individual government departments and other public authorities. For example see: Gayle Munro and Fleur Bragaglia, ‘Who determines what is “ethical”? Some challenges of research governance within the voluntary sector’ (2012) 3 Voluntary sector review 407–415; Emily R Munro, ‘Research Governance, Ethics and Access: A Case Study Illustrating the New Challenges Facing Social Researchers’ (2008) 11 International Journal of Social Research Methodology 429–439; Alysun M Jones and Bryony Bamford, ‘The other face of research governance’ (2004) 329 BMJ 280–281.
\end{enumerate}
\end{footnotesize}
As the decision-making matrix reveals, the legal basis for use, sharing and linkage of administrative data is far from straightforward. Administrative data custodians and other stakeholders are faced with at least five possible scenarios in deciding to use, share or link data, when there is an absence of an appropriate governance framework to guide such decision-making. Where the legal strand of the ADRC-Scotland will add its original contribution and ultimate value is in clarifying for administrative data stakeholders which concerns have legal basis and must be addressed while offering ethical decision-making tools to bridge the gap between the law and ethics. Where the law remains clear, but caution or inertia perpetuated by legal myths or perceived controversy remains, a proportionate yet robust governance framework can bring confidence to the necessary ethical decision-making that data custodians must engage in. A first step in this process is clarifying the legal status of administrative data in Scotland – what are the precise limits and flexibilities in the current law?

1.3 Understanding barriers to administrative data linkage

The information governance legal landscape as it relates to linkage of personal data, and subject to the common law of confidentiality and statute law such as the Data Protection Act 1998, has been extensively scoped in other contexts.\(^\text{18}\) As mentioned

\(^{17}\) However, a key question that arises is when or how would administrative data custodians know when a lawful use of data is unethical and should not be pursued?

\(^{18}\) The Information Governance Working Group of the Scottish Health Informatics Programme, ‘SHIP Guiding Principles and Best Practices’, 22 October 2010; Graeme Laurie and Nayha Sethi, ‘Information
above, a particular and additional feature that concerns the linkage of administrative data is that such linkages are additionally constrained by the legal basis for use, sharing and linkage in the first place. This is specifically in terms of the “express” or “implied” - statutory or common law - powers that define the purposes to which Government administrative data can be used or shared.\textsuperscript{19} Thus when considering whether administrative data can be used, shared or linked, it is important to first consider the class or kind of entity that holds the data in question as different types of public bodies are more or less constricted in terms of sharing their data.

1.3.A Statutorily created bodies

Statutorily created public bodies, such as Her Majesty’s Revenue and Customs (HMRC), do not enjoy broader common law powers to share data that exist in, say,
the health context. Rather, statutorily created bodies are limited to what is allowed by their governing statutes – meaning – whether or not that body can share and/or link data is entirely governed by what is indicated in the governing statute. However, statutorily created bodies, might be empowered to share and/or link administrative data by virtue of implied statutory powers ‘…given the difficulty of defining expressly all the activities that [such bodies] may carry out in connection with their day-to-day functions.’

The Ministry of Justice specifically contemplates this in terms of English and Welsh local authorities, that while entirely governed by statute, these bodies might have power to share data under the broad language of certain statutory provisions, such as Section 111(1) of the Local Government Act 1972, which provides that local authorities ‘shall have power to do anything...which is calculated to facilitate, or is conducive or incidental to, the discharge of any of their statutory functions.’ An equivalent provision is applicable to Scottish local authorities under Section 69 of the Local Government (Scotland) Act 1973. In reliance upon these statutory provisions, it is possible that data sharing could be conducive to or incidentally related to a local authority’s statutory functions and thus lawful. However, this diverges sharply with the UK Government’s guidance on use and sharing of social security data (an example of administrative data) with the Department of Work and Pensions (DWP) and local authorities whereby it is considered that local authorities ‘…must not act outside their statutory powers’ and ‘[a]ccount must be taken of any specific data sharing legislation that applies to the function being undertaken.’ Thus it is unclear whether data sharing and/or linkage would be permitted under an implied statutory power as opposed to an

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20 The ADT importantly points out that the ‘HMRC may agree to data linkage for studies that fall within its statutory remit, but proposals for linkage to HMRC data for studies which do not fall squarely in this remit will require a specific legal gateway or, where feasible, the informed consent of subjects of research.’ The UK Administrative Data Research Network: Improving Access for Research and Policy 14.


23 Local Government Act 1972, s 111(1).

24 Local Government (Scotland ) Act 1973, s 69.


explicit statutory gateway. The uncertainty over legal authority to share data absent an explicit statutory gateway is not supported in the literature by robust findings or legitimised legal concerns – however there is ample anecdotal evidence that shows that such uncertainty does exist and perpetuates cautious decision-making. The legal research strand will consider the distinction between real and imagined legal concerns that act as barriers to proposed uses of administrative data in the public interest.

1.3.B Government departments

In contrast to statutorily created bodies, government departments benefit from wider common law powers (via the Ram Doctrine)\(^\text{28}\) which broadly permit undertakings such as data sharing without the need to point to a specific statutory power. However, similar challenges arise as with statutorily created bodies and implied statutory powers. Government departments may be constrained when their express statutory powers touch upon areas of remit where data might be shared; meaning, if express statutory powers govern a particular departmental function, it is arguable that common law cannot override and fill a space that is already “taken” by express powers (see the distinction between express versus implied powers in Box 1 above).\(^\text{29}\)

The ADT considered the example of the Department for Education relying upon its common law powers to disclose aggregated data to researchers in some areas. Legal uncertainty arises because the Department also has express statutory power to share individual pupil data via the Education Act 1996. This dual-basis for sharing data raises the question of whether data sharing that is broader than the scope provided by the express statutory power is permitted by virtue of common law powers.

As a result of this complexity, it has been reported that many Government data controllers will instead rely only upon a specific legal (statutory) gateway to share data

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\(^{28}\) The Ram Doctrine provides that a Government Department may do anything an individual citizen might do, absent restrictions prescribed by law. Importantly, the Ram Doctrine provides that common law powers afford a Government Department or Minister of the Crown the ability to undertake an activity without pointing to a specific statutory gateway. First Parliamentary Counsel, Sir Granville Ram ‘ “The Ram Doctrine”: Ministers of the Crown (Transfer of Functions)’ (1945) <http://www.parliament.the-stationery-office.co.uk/pa/ld200203/ldlwa/30122wa1.pdf> accessed 31 July 2014.


\(^{30}\) This was indicated in the ADT’s 2012 report, but also in terms of the health sector in the Academy of Medical Science’s 2011 report ‘A new pathway for the regulation and governance of health research’. There is ample anecdotal evidence in the literature of the cautious decision-making that surrounds decisions involving the sharing of personal data. The UK Administrative Data Research Network:
with other Government entities for specific purposes.\textsuperscript{31} This highlights a key distinction between what an entity is \textit{legally} required to share data and the cautious data sharing practices that result from legal complexity. In other words, there is an important – and potentially valuable – distinction to highlight between law operating to mandate sharing, and law leaving open an opportunity to facilitate sharing. Contrariwise, even explicit data sharing provisions between public bodies would not typically allow for access by \textit{external} researchers. Notwithstanding, the prospect that has been mooted of a general legal gateway to share data \textit{within} Government leaves room to streamline and facilitate access to administrative data for research by the wider research community within the UK.\textsuperscript{32}

The distinction between what is in fact legally required versus what is \textit{perceived} to be required due to legal complexity and associated uncertainty draws attention to the utilisation of unhelpful and out-dated approaches to the governance of data, most notably ‘the “consent or anonymise” paradigm that has been so heavily criticised by the research community.’\textsuperscript{33} The consent or anonymise paradigm refers to the prevalent norm in research practice, as it relates to the use and sharing of personal data, to accept ‘that consent might not always be required so long as data or samples

\begin{footnotesize}
\begin{itemize}
  \item For instance the HMRC, DWP and CSA may share data collected for any functions relating to tax credits, child benefit or guardian’s allowance on the basis of the Tax Credits Act 2002, Sch 5(1). The HMRC provides specific guidance on the exact (and extremely) limited circumstances in which it would share the data it holds: \url{http://www.hmrc.gov.uk/manuals/idgmanual/idg40450.htm} accessed 31 July 2014.
  \item This is explicitly recognised by the ADT in their 2012 report: ‘While new legislation can help unlock access to and linkage between data held by specific government departments, there is much to be achieved in advance of a new legislative environment which will improve and facilitate research access to administrative data whilst laying the foundation for a new legal gateway for data linkage. ‘The UK Administrative Data Research Network: Improving Access for Research and Policy’ 17.
\end{itemize}
\end{footnotesize}
are sufficiently anonymised with respect to participants. In other words, where obtaining informed consent is infeasible or impracticable, or inappropriate under the circumstances, the most common solution is to anonymise data to protect citizens’ privacy. This has been criticised because, first, the “either/or” paradigm ignores the fact that consent is neither legally required in all circumstances, nor the most robust way of protecting an individual’s interests in their data. Second, it suggests that this single alternative governance strategy is, itself, sufficient, but the paradigm presupposes the infallibility of anonymisation, which has been seriously challenged. Finally, the paradigm completely neglects the other lawful bases upon which data can be shared, such as a public interest mandate.

Ultimately, neither consent nor anonymisation is a panacea for the legal and ethical linkage to administrative data. Consent neglects the temporal continuum of the research process and thus the inevitable change in values and interests over time, in a particular data resource. In other words, consent tends to be taken – and fixed – at a moment in time, which makes it ill equipped to reflect or protect the changing dynamics of data usage that might impact on a subject’s rights and the multiplicity of stakeholder interests in the data. Anonymisation similarly does not take into account temporality, and contrary to common opinion, cannot offer the sort of abrogation of legal responsibility given that Government holders of administrative data must always have a lawful basis to share data – regardless of whether they anonymise the data in question. Whilst anonymisation remains a relevant legal and data protection consideration for data custodians, technical measures are not ethical measures and


35 The fallacy of ‘anonymisation’ and likelihood of re-identification has been most notably explored by Paul Ohm in ‘Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization’ (2009) 57 UCLA Law Review 1701–1777. He cites to numerous, well-publicised cases of re-identification of supposedly “anonymous” data sets. More recently, efforts were made to test the strength of anonymisation techniques of genetic data and demonstrate the need for a more holistic approach to data protection, which encompasses more than just reliance on anonymisation or consent. See: Latanya Sweeney, Akua Abu and Julia Winn, ‘Identifying Participants in the Personal Genome Project by Name’ (2013) Harvard University Data Privacy Lab White Paper 1021-1 1–4 <http://dataprivacylab.org/projects/pgp/1021-1.pdf> accessed 4 April 2014.

36 Laurie and Harmon, ‘Through the Thicket and Across the Divide’ 9.
must be complemented by ethical frameworks that promote confidence in the decision-making necessary to using, sharing, linking and reusing administrative data.

Although the DPA 1998 does not apply to anonymised data, it has been contended that public bodies are still unable to share even non-personal data and must look to a specific legal gateway that allows them to do so. In the UK’s Ministry of Justice guidance on public sector data sharing it is provided that: ‘[a] public body may only share data if it has power to do so.’ Interpreted within the context of the Ministry’s entire report, and their wide definition of personal data (i.e. that data will be considered personal if the data holder still retains the means to identify the individual), it is clear that anonymisation is an unlikely basis upon which administrative data can be shared or linked by public bodies. Even though anonymisation might make data sharing more acceptable to the organisation and the public, the guidance provides that consideration must still be given to data protection principles, which notably includes reliance upon a valid legal basis under Schedule 2 (or 3 if sensitive personal data) of

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37 The ADT defines anonymised data as data which: ‘…have all personal identifiers removed and cannot be connected to the original person record. Anonymised data are suitable when no contact is needed with the participant or where the data do not need to be linked to any other data sources.’ The UK Administrative Data Research Network: Improving Access for Research and Policy. However, anonymisation is likely to be judged in the UK by the standard set forth in the ICO Anonymisation Code of Practice, which defines anonymous data as ‘data that does not itself identify any individual and that is unlikely to allow any individual to be identified through its combination with other data.’ The Information Commissioner’s Office, ‘Anonymisation: managing data protection risk code of practice’, 20 November 2012. <http://ico.org.uk/for_organisations/data_protection/topic_guides/~media/documents/library/Data_Protection/Practical_application/anonymisation-codev2.pdf> accessed 4 April 2014.


40 The Ministry of Justice provides that personal data remains “personal” if the data controller retains the ability to identify the individual who the data relates to. They support this by reference to House of Lords judgment, Common Services Agency v Scottish Information Commissioner [2008] UKHL 47, at [27] and [75]. What is key is that anonymisation, whilst supportive of the compliance with data protection principles, is unlikely to provide a lawful basis upon which public bodies can share or link the administrative data held.
The generic legal gateway, as proposed by the ADT, would do much to clarify existing complexity over the proper statutory or common law basis upon which data sharing and/or linkage may be justified. Whilst it would provide a clear and legislatively unambiguous power to share data internally with other public bodies, it would not necessarily address the current fetishisation of consent and furthermore, the scheme proposed only contemplates linkage of de-identified or anonymous data. Specifically, the gateway would allow access to de-identified administrative data by the ADRN, which in turn would give access to ‘publically-funded researchers, including those funded by or working on behalf of charities and the third/voluntary sector’.  

Box 2: Key questions for administrative data holders

Key questions remain as to the precise flexibilities and limits to fundamental aspects of data protection law as it applies to administrative data.

- What are the precise limits and flexibilities involved in justifying the sharing or linking of data on certain Schedule 2 (or Schedule 3 if sensitive personal data) conditions under the DPA?
  (e.g. Justifying the processing of personal data on the basis of it being in the public interest is not legally settled or thus certain).

- What, if any, sanctions or remedies would be triggered if a public body did share data without the appropriate legal authority to do so?

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41 However, the several alternatives lawful bases upon which personal data can be processed within the UK is arguably already unambiguous. Furthermore, because the ADRN is currently set to only link de-identified or anonymous data, only one aspect of the consent-or-anonymise paradigm is arguably addressed.

To complement the establishment of a generic legal gateway is the employment of a ‘…set of ethical standards … drawing on well-established ethical guidelines and covering the research uses to which administrative data (and administrative data linked to other types of data, including surveys) may and may not be put’.43 Harmonised standards for access to and use of administrative data could offer further clarity and confidence to researchers and data holders alike. The development of harmonised ethical standards on compliant uses of administrative data could address the challenges arising from a culture where consent or anonymisation prevails. Such standards could confirm and clarify appropriate lawful bases that can justify the use of administrative data within a robust and proportionate governance framework. However, recent events with care.data demonstrate a very important salutary lesson – that law, on its own, is still not enough. The care.data initiative did have a definitive legislative basis, yet this was not enough to stop the major public backlash that ensued. This highlights the important of ethics but also robust public engagement, which should influence governance design and delivery.44

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44 In a forthcoming article we consider how the care.data scheme failed to adequately provide a social licence for the proposed use of individual health data, highlighting the importance accounting and providing for the expectations of society regarding certain activities that may go beyond those formally...
1.4 Navigating the thicket of the administrative data legal landscape

This first section has summarised the complexities and highlighted the uncertainty that arises in sharing and linkage of administrative data in the UK. The problems described largely stem from an overly complex legal landscape. Issues further arise from the perpetuation of legal myths about what the law does or does not require, and indeed whether legal barriers are real or perceived. However a key issue remains that there is no single source of law that governs the proposed sharing or linkage of administrative data. In the first instance, a public body would consider whether it has the requisite “power” to share the administrative data it holds. However, even where a statutory or common law power is found to support sharing, the complexities and uncertainties that arise outwith explicit mandates to share data, result in cautious decision-making.  

Cautious decision-making leads to an overall hesitance to share data without explicit statutory permission, for specific purposes, despite the availability and legitimacy of legally valid solutions to share and link data.

Whilst, the adoption of a generic legal gateway would do much to clarify the relevant and currently mired legal determinations necessary to share and link administrative data within government, it is unclear how this gateway would address the deeper issues posed by adherence to the consent or anonymisation paradigm. Thus, the ADT’s recommendation to develop an agreed upon set of ethical standards and guidance for the use of administrative data in research would be a first step in promoting confidence in public bodies’ and researchers’ use of administrative data that could begin to address the challenges inherent to this paradigm. In addressing this recommendation, and in recognition of the current barriers to linking administrative data reviewed above, the legal research strand of the ADRC-Scotland will take the first steps in developing a common framework for governing the use and linkage of administrative data in Scotland.


45 The cautious decision-making that results from the complex legal landscape governing data in the UK is often cited to. However, there is an absence of a robust evidence base illustrating the scale and prevalence of this caution. Anecdotal evidence exists, and may indicate this on the basis of a specific study, but more research is required into the degree and nature of this caution to understand further the role played by perceived versus actual barriers (legal or otherwise) to sharing and linking data.
In scoping the legal landscape we would work towards securing the minimum necessary for good governance – a legal basis for using, sharing, linking or reusing administrative data. However, even with legal sanction, this does not address whether a proposed linkage of data “ought” to be done in a given context. Decision-makers require ethical tools to take these decisions and to ensure that the decisions are ethically sound, have integrity and attract trust. This demonstrates where ethics and principles are crucial to the good governance of administrative data. While the law provides a necessary basis and outer framework for decision-making, it is not sufficient in and of itself. Equally, ethics also requires that internal frameworks do not come to represent – themselves – further thickets that must be navigated to justify sharing. The legal strand of the ADRC-Scotland will offer both a clarification of the legal position of administrative data but will also work towards the development of a good governance framework that would allow administrative data stakeholders to operationalize decisions on a sound, ethical and principled basis. Our plans for this will be outlined below in terms of the research questions the legal strand will address.
2. Research Questions

2.1 RQ 1: Adapting the principle-based approach to administrative data

The next phase in the development of a common legal and ethical approach for the linkage of administrative data has in part been left to the legal research to be undertaken within ADRC-Scotland. While the landscape for administrative data is mired with specific legal rules that purport to give (and deny) authority to share or link data for non-primary purposes, the research to date indicates that more rules is not necessarily the solution. Nor, as indicated above, would a single legislative portal necessarily address all of the issues from a position of ethical robustness and public acceptability. Rather, the culture of caution highlighted in the previous section suggests a need for an approach that can promote confidence in lawful sharing and decision-making on a sound ethical basis. Our experiences elsewhere, and notably on the Scottish Health Informatics Programme (SHIP) initiative, strongly suggest that a principle-based approach can help to address this unmet need. Therefore the legal research strand will first focus its efforts on drawing upon well-established, principle-based frameworks, notably SHIP’s Good Governance Framework and the ESRC Framework for Research Ethics (FRE) in order to determine:

1. Which **principles are** relevant to the facilitation of robust, yet proportionate governance of administrative data linkages?

2. Which **principles do not** translate into the context of administrative data linkages?  

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46 'Scottish Informatics Programme (SHIP)' <http://www.scot-ship.ac.uk> accessed 4 April 2014.
48 The ESRC’s FRE is currently under review, with Graeme Laurie as a member on the Advisory Group. We will revisit this report and its findings in light of the new version as and when it is released. Economic and Social Research Council, ‘ESRC Framework for Research Ethics (FRE) 2010 Updated September 2012’ (September 2012) <http://www.esrc.ac.uk/_images/framework-for-research-ethics-09-12_tcm8-4586.pdf> accessed 4 April 2014.
49 In our exploration of the principles that are most appropriate to the context of administrative data we will seek out case studies of successful initiatives involving the use, sharing, linkage and/or reuse of administrative data for research in the public interest, whilst also considering cases where such use may have been thwarted by real or perceived legal (or otherwise) barriers.
3. Which **best practices** are most suitable and can be adapted to the wide range of contexts in which administrative data will be accessed – from geo-spatial research, to socio-economic studies into deprivation, historical investigations in longitudinal projects, social-psychology and so forth?

Only with a grounded understanding of the lessons learned from well-established ethical standards and existing governance frameworks can the proposed legal research achieve a meaningful contribution towards a more harmonised approach involving the governance of administrative data in Scotland. However the diversity in administrative data means that we cannot and should not attempt a one-size-fits-all model to governance. Context is key. Principles are useful in responding to differing contexts because their interpretation must, necessarily, take into account the specifics of any given situation while, at the same time, provide a higher-level benchmark or toolbox of ethical action. Thus, the proposed review of existing standards and frameworks will take into account the body of literature critical of transplanting the clinically-based, biomedically-oriented approaches to the governance of other sectors, such as the social sciences.50 This review will contribute to a balanced understanding of what meaningful distinctions there are, if any, between the governance of administrative data, as compared to other forms of data. We will consider the role that attributes of the data themselves play, and/or the different contexts in which the data are accessed and used (for example any consequential differences between genomic versus historical versus social care data). This exercise will form the first step in understanding the feasibility of developing a common, principles-based approach to the governance of administrative data – one that is capable of adapting to the extremely varied contexts that are inherent to access and linkage of administrative data.

Given that there is currently no single ‘gold standard’ for the governance of administrative data, the difficulty will be in identifying a relevant benchmark from which we can assess the suitability of existing governance frameworks. However, what is possible and beneficial is to conduct a review that assesses suitability on the basis of risk analysis. A risk-based approach will specifically take into account the nature and degree of harms that could arise from the linkage of administrative data, which are likely different to those posed by research involving patient data, human biological data samples, or genetic data whereby the latter risks are those contemplated when developing existing governance frameworks such as SHIP’s Good Governance Framework. A systematic review of relevant literature, including UK and European case law, enforcement measures undertaken by the UK ICO, grey literature including government and institutional reports on data breaches, and peer-reviewed journals, will seek evidence of the harms that might arise from use of administrative data when data breaches occur. This evidence review will allow us to determine whether the risks taken into consideration and that inform mechanisms of current governance frameworks are appropriate and proportionate for the governance of administrative data. Thus risk assessment provides the specific context in which governance mechanisms must be employed, whilst a principles-based approach provides the mechanism for ethical decision-making and action.

Risk analysis in administrative data research

The ESRC indicates that while risks in health research are often understood in terms of ‘potential physical or psychological harm, discomfort or stress’, social sciences research, which often relies upon administrative data, involves a wider range of social risks including ‘risk to a subject’s personal social standing, privacy, personal values and beliefs, their links to family and the wider community, and their position within occupational setting’.[51] We extend this consideration to the governance of administrative data, and the likely differences in the risks posed by use of administrative data compared to, say, health data. Thus the particular principles and related best practices provided for within existing governance frameworks will be assessed for their suitability according to the risks accounted for in those frameworks.

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in comparison to the evidence of risk posed by the use of administrative data in research.

Aside from assessing the suitability of governance frameworks on the basis of risk, there are further challenges that governance of administrative data might raise under a principles-based approach. Thus a focused analysis will be undertaken on two areas of particular ambiguity for the linkage of administrative data: use and linkage of historical data and the prospect of commercial partnerships. These areas form the basis of our second-order research questions (see Box 4). In considering historical data and the prospect of commercial partnerships separately (at least initially), highlights the issue of temporality, which is an underexplored area in the literature. While historical data are retrospective and pose questions about the relevance of past attitudes to what might be done today, questions regarding commercial partnerships pose issues for current or prospective access and attitudes today, which might be different tomorrow.

**Box 4: Administrative data and principles-based approaches to governance**

*Historical data:* Given the prevalence of historical data within larger administrative data sets, what are the particular legal and ethical challenges that arise from data obtained and under radically different legal or ethical norms and social expectations?

*Commercial partnerships:* Given the potential for commercial partnerships in the linkage and use of publicly held administrative data – and in light of considerable concerns from the health context – what can principle-based approaches say about commercial involvement?

2.1 A RQ 1.1 Historical data

The uncertainties arising from the use of historical, administrative data was recently considered in the Scottish context with respect to a report for Scottish Government on its Guthrie Card collection with recommendations as to its further, future retention and use.\(^{52}\) In Scotland, Guthrie cards (blood spot cards taken from infants) have been collected since 1965, resulting in more than 2.5 million cards being stored to-date. Many other countries have similar collections, named after the original scientist who

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\(^{52}\) Laurie, Hunter, and Cunningham-Burley, ‘Guthrie Cards in Scotland: Ethical, Legal and Social Issues’.
pioneered the technique, and initially designed to test newborn children for treatable conditions. Retention of the cards thereafter has, however, become a widespread practice, despite changing social mores in the intervening decades. Guthrie cards include both the personal data of the child in question and their blood/DNA samples. Given that there is no single legal framework which governs the collection, due to its mix of tissue and data, ‘the resolution of social and ethical issues arising from its continued retention and future use require careful attention.’

What is pertinent to this report and the proposed analysis of historical data is the approach taken in the Scottish report to complications arising from the long-term nature of the collection – ‘historically and into the future - whereby social attitudes and regulatory frameworks have changed over time and might change again in years to come’. Furthermore, while the Scottish Guthrie Card example might primarily be a health example, the value of the collections have also changed over time – and it is not just a health use through robust research that could be valuable. There could be, for example, valuable research done on social determinants, poverty, effects of environment on educational or work performance etc. Given that numerous administrative data sets intended for linkage by the ADRC-Scotland will feature data obtained decades ago, careful consideration must be undertaken as to how social expectations and value in the data sets might have changed over time. The Guthrie Card report and other complementary case studies of historical data in research will be considered in this regard.

2.1.B RQ 1.2 Commercial partnerships

Whilst the ADT's report specifically excluded consideration of commercial access to administrative data through the ADRN, it did recognise the ‘...potential benefits that derive from private sector data and related research interests.’ In this regard, the ADT indicated that its Governing Board would ‘at an early stage, investigate guidelines for access and linkage by private sector interests, as well as commissioning public

53 Laurie, Hunter, and Cunningham-Burley, ‘Guthrie Cards in Scotland: Ethical, Legal and Social Issues’ para 1.3.
54 Laurie, Hunter, and Cunningham-Burley, ‘Guthrie Cards in Scotland: Ethical, Legal and Social Issues’ para 1.3.
55 For instance the Lothian Birth Cohort studies which follow up from the 1932 and 1947 Scottish Mental Health Surveys (http://www.lothianbirthcohort.ed.ac.uk) and the Aberdeen Children of the Nineteen Fifties study (http://www.abdn.ac.uk/childrenofthe1950s/).
engagement work on this topic.\textsuperscript{57} Within the legal strand of ADRC-Scotland questions regarding commercial partnerships and potential acceptability of commercial access to administrative data will be considered in light of previous public engagement work in the area of health research,\textsuperscript{58} and current initiatives that propose commercial access to publicly held personal data.\textsuperscript{59} Furthermore, this aspect of the research will draw upon the issues raised and insights uncovered from the public engagement strand of ADRC-Scotland to better understand how public trust might be impacted by commercial access to administrative data.

This work will question whether the public/private divide is a helpful distinction for the purposes of robust yet proportionate governance of administrative data. The public/private divide arises in numerous contexts for administrative data – in terms of funding datasets, who holds data, whether the purposes for access and use are to public or private ends, whether public bodies might nonetheless operate in ways that could be seen as sub-optimal to the public interest despite their “public” status and finally that private bodies might be better able to further public interests depending on their objectives and associated good governance.

2.2 Facilitating the lawful and ethical use of administrative data

The research proposed works toward the facilitation of justified, lawful and ethical uses of administrative data. Facilitating justified uses of administrative data, under a system of proportionate governance, can serve and account for a broad spectrum of public interests, including the public interest in promoting the robust protection of individual privacy. Individual privacy need not be diminished if a robust and proportionate governance framework ensures administrative data are used only when justified according to a harmonised standard of legal and ethical norms. Lawful and ethical use of administrative data, under robust technical and organisational security arrangements, as proposed by ADRC-Scotland’s electronic Data Research and Innovation Service (eDRIS), can serve numerous public interests including the

\begin{itemize}
\item[58] Davidson et al, ‘Public Acceptability of Data Sharing Between the Public, Private and Third Sectors for Research Purposes’ 61-98.
\item[59] This references the Care.data scheme proposed by NHS England, which purported to allow commercial access to patient and social care records for a set fee. The lessons that can be learned from Care.data will be considered with specific focus on how commercial access was managed, especially from a public engagement perspective.
\end{itemize}
increase of efficiencies to public services and the provision of valuable data for publicly beneficial research. By tailoring a principles-based approach to the governance of administrative data, the public interests at stake can be better served by taking into account the specific risks and potential benefits arising from the use of such data.

Increasing efficiencies in accessing and linking administrative data will provide researchers and thus government policy-makers with a robust evidence base for responsive policy that can improve the health and wellbeing of the UK population – in terms of socioeconomics, physical and mental health and security, etc. A common approach to the governance of administrative data could also remove current delays to processes of innovation that drive publicly beneficial outcomes for the whole of the UK. Public engagement work to-date indicates initial findings that individuals can recognise the importance and role of the public interest when drawing upon the rich data resources the UK holds. In this regard, we draw upon the public engagement of the ADRC-Scotland to discern the most recent findings on whether the public’s conception of the public interest can in fact encompass the lawful and ethical use of administrative data for publicly beneficial research. Equally, it must be acknowledged that the term ‘public interest’ is vague and open to considerable interpretation. Little deep research has been done to date to explore its precise, justifiable meanings, and

60 The ADRC-Scotland will link administrative data within an adapted form of the technical and organisational infrastructure of the NHS’ electronic Data Research and Innovation Service (eDRIS), providing robust procedures and technical security ensuring the highest standards of security protection for the data linked. <http://www.isdscotland.org/Products-and-Services/EDRIS/> accessed 4 April 2014.


how these can be used in a defensible and socially productive manner. This work aims to address this.

The following three sections indicate the planned, future trajectory of the legal research undertaken over the course of the ADRC-Scotland project. Section 3 relates to our first research question and considers what parallel lessons may be taken from established principles-based frameworks and approaches to governance – namely SHIP and the ESRC’s Framework for Research Ethics. Section 4 refers to our second-order research question and considers the nature of ethical and legal issues arising from the use of historical administrative data for research, set against the lessons learned from current principles-based approaches to governance. Section 5 relates to our research question regarding commercial partnerships and examines the legal and ethical position on the potential for commercial access to administrative data. The conclusion focuses on the issues uncovered in the process of engagement with the cross-sectoral research teams comprising ADRC-Scotland. Overall, our approach supports the ADT’s call for both the establishment of a generic legal gateway for internal, Government data sharing but also a joined-up approach to safe research access of administrative data for reasons in the public interest.
3. Review of established standards and frameworks of governance

3.1 A principles-based approach, rules and regulation

In its 2012 report, the ADT recommended the establishment of ‘an agreed set of ethical standards … drawing on well-established ethical guidelines and covering the research uses to which administrative data (and administrative data linked to other types of data, including surveys) may and may not be put’.63 The ADT recommendation, and particularly the call for guidelines on the research uses to which administrative data may and may not be put, is not indicative of a principles-based approach to governance, which will be drawn upon in addressing the first research question. Without going into depth on the debate over principles-based regulation versus rules-based regulation and now principles-based approaches, it is enough to acknowledge that ADT’s recommendation is indicative of rules-based regulation that encompasses ‘pre- and proscriptive rules for framing approaches to governance and decision-making.”64 Despite use of terminology such as principles or even standards, principles can mask rules-based regulation.65 By recommending the development of a set of guidelines on the uses to which administrative data may and may not be put, suggests required compliance with such ‘guidelines’ or rules, regardless of the broader standards provided for. While this can be an important and valuable component of good governance, it can fail to capture many of the nuances of robust ethical reflection that will be required when data custodians consider whether data linkage on a given occasion should occur. A stop-go rule-like approach does not support sensitive decisions that might depend on a range of considerations, not least the careful assessment and balance of benefits and risks involved.

A principles-based approach (rather than principles-based regulation) is underpinned by principles which serve as ‘fundamental starting points to guide deliberation and

65 For instance, the DPA 1998 provides for eight data protection principles – however breach of one principle is automatically breach of the statute and thus operates as a rule rather a starting point for deliberation and action.
action’ without prescribing pre-determined outcomes. Thus, opting to diverge from the best practices associated with a particular principle would not necessarily result in sanction if this were justified according to the agreed upon ethical and legal framework. A principles-based approach, as adopted in the SHIP Good Governance Framework, features:

An explicit statement of the core values and standards which underpin data sharing practices and arrangements (and so improves transparency, legitimacy and, hopefully, trust in systems that apply these)…a common frame of reference, values and a language with which to make decisions (and so facilitates engagement and mutual recognition of governance arrangements which can reduce undue overlap)…[and]…engages with the full range of governance tools to ensure that appropriate governance pathways are applied to each data linkage.

Seen in this light, the principles-based approaches drawn upon here, for the purposes of addressing the first research question, does not begin with predetermined outcomes. Any approach derived by this research will suggest that the predetermination of permitted and non-permitted uses of administrative data cannot deliver a complete picture of good governance. This should be supplemented with a necessary step in assessing the real risks involved with any proposed use of administrative data, with the overall objective to deliver both proportionate and robust governance. Whilst there is benefit in specifying potential, justified uses of administrative data, so as to promote legal certainty and confidence in decision-making, prescribing permitted and non-permitted uses of administrative data can have the unlooked-for consequence of promoting a tick-the-box culture.

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66 On the basis of the distinction between regulation and governance, it is submitted that it is preferable to consider principles-based approaches as opposed to regulation, given the ‘state-driven, vertically-oriented, top-down, command-and-control deployment of formal (hard law) instruments’ often associated with the latter. Laurie and Sethi, ‘Towards Principles-Based Approaches to Governance of Health-related Research using Personal Data’ 4.

67 The Scottish Health Informatics Programme, ‘SHIP Guiding Principles and Best Practices’; Laurie and Sethi, ‘Towards Principles-Based Approaches to Governance of Health-related Research using Personal Data’ 4. (emphasis added)

68 The impact of rules-based-regulation or principles-based-regulation (which in reality operate as rules) on promoting a tick-the-box compliance governance culture has been scoped extensively in the area of corporate governance and especially in financial regulation. The literature highlights the importance of promoting an overall ethical approach to decision-making as opposed to mere compliance with rules.
culture focuses on satisfying fixed requirements without consideration of inevitable changes to stakeholder interests and external factors that affect data sharing arrangements over time. It can mandate behaviour towards compliance without promoting genuine ethical reflection on what is at stake. This can be problematic for researchers and regulators alike. The former can seek to just “follow the rules” without engaging on the ethical imperatives, while the latter can tend to enforce said rules, without seeing any space for ethical discussion and accommodation of the range of ethical imperatives. The research undertaken seeks to foster the alternative to a compliance culture: one that is dynamic and reflexive over the life of the research relationship between the data holder, researcher and individual data subject.

In light of this, the forthcoming analysis takes the initial step in addressing the ADT’s recommendation by conducting a high-level assessment of the suitability of 1) SHIP’s successful principled proportionate governance approach for the use of health data in research, and 2) the ESRC’s Framework for Research Ethics, to the governance of administrative data in Scotland and the wider ADRN.

3.2 Good governance of health data under SHIP – lessons learned

SHIP was a Scotland-wide research collaboration that was established in order to ‘enhance the safe and secure collation, management, dissemination and analysis of Electronic Patient Records for research.’\(^69\) The key outputs of SHIP include:

- A Good Governance Framework;
- A national infrastructure within NHS Scotland, which promotes record linkage research in Scotland and adopts SHIP best practice for record linkage;
- A data linkage “tool kit”, which incorporates standards and document templates of governance, technology, audit and administration that is

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expected to provide practical help to others in developing safe and secure systems for data linkage research in the context of local safe havens.\textsuperscript{70}

This initial assessment will focus on SHIP’s Good Governance Framework, which is based upon a series of guiding principles and best practices for the use of non-consented health data in research.\textsuperscript{71} The Good Governance Framework will be assessed with a view to:

- Determine which **principles are** relevant to the facilitation of robust and proportionate governance of administrative data linkages.
- Identify which **principles do not** translate into the context of administrative data linkages.
- Understand how instances of **best practice** are formulated for specific research communities, in order to contribute to the development of those most suitable to the wide range of contexts in which administrative data linkages occur.\textsuperscript{72}

### 3.2.1 Principles of good governance

The foundation of SHIP’s Good Governance Framework are its guiding principles, which provide a necessary starting point from which considered deliberation and best practice can follow for the governance of health data. As recommended in the ‘Guiding Principles and Best Practices’, any departure from SHIP principles or suggested best practices will be justified according to the specific context of the linkage proposed. The following chart below illustrates the key areas identified in SHIP that relate to the governance of data and required further expression and/or explanation, where the


\textsuperscript{72} To achieve this end we will continue to engage and interact in a dynamic dialogue with Scottish and UK-wide administrative data communities. Likely candidates include key public bodies that hold administrative data that is of interest to ADRC-Scotland projects, regulators and also research communities within Scotland who are impacted and have interests in the development of a robust yet proportionate governance framework for administrative data. We will seek actual examples in due course of the downstream conduct of our research.
Good Governance Framework provides a statement of the relevant principles under consideration.

<table>
<thead>
<tr>
<th>Public interest</th>
<th>Data controllers and data processors</th>
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<td>Privacy</td>
<td>Clinical trials</td>
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<tr>
<td>Consent</td>
<td>Cross-sectoral data sharing</td>
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<td>Anonymisation</td>
<td>Public and stakeholder agreement</td>
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<td>Authorising/advisory bodies</td>
<td>Sanctions</td>
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<td>Governance</td>
<td>Benefit Sharing</td>
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<td>Access</td>
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<td>Trusted third parties</td>
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Clearly, some areas of governance are specific to the health sphere and thus will not be considered in this context (i.e. clinical trials). Yet we acknowledge the importance of facilitating linkages that would serve the public interest in combining, for example, clinical trials data or any other health data with administrative data. A key consideration in combining disparate types of data is the principle of proportionality as it relates to approval and ethical review; cross-sectoral linkages should benefit from the same robust yet proportionate governance as single sector projects enjoy. As a starting point however, and for the purposes of this initial scoping report, two key principles enumerated in the SHIP framework will be examined for their suitability to the administrative data context: (1) the promotion of public interest and (2) protection of the privacy and other rights and interests of individual citizens.

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73 Clinical trials are an interesting case in point, given that an entirely separate and additional legal regime applies (i.e. the Clinical Trials Directive 2001/20/EC and further by the Good Clinical Practice Directive 2005/28/EC). Clinical trials data may hold some similarities to administrative data in that both fall under forms of mandatory reporting schemes. Clinical trials data must be reported as it relates to adverse events or reaction reports arising from clinical trials on medicinal products for human use. Alternatively, administrative data relating to income received, for example, are similarly mandated by law and obligate employers to report such data as it relates to individual employee earnings.

3.2.2 Promoting the public interest in research

What can be adopted from the SHIP Good Governance Framework is the key principle that only research in the public interest should be facilitated through an applicable governance regime. A governance framework driven by and in promotion of the public interests at stake is in conformity with the ADT’s recommendations and reflective of ADRC-Scotland’s proposed research outputs.

SHIP’s focus on the publicly beneficial use of data resounds through each statement of principles relating to the public interest:

- Scientifically sound and ethically robust research is in the interest of protecting the health of the public.
- The objective of SHIP is to facilitate scientifically sound and ethically robust research through the appropriate use of health data.
- The rights of individuals should be respected with adequate privacy protection, while at the same time the benefits for all in the appropriate use of health data for research purposes should be recognised.
- Data sharing and use should be carried out under transparent controls and security processes, and the purposes and protection mechanisms should be communicated publicly and to oversight bodies/individuals with responsibility for data processing.
- The responsible use of health data should be a stated objective of all organisations adhering to this instrument.75

A restatement of the above public interest principles, suitably adapted for the context of administrative data, would provide a starting point for deliberations over proposed linkages and help clarify instances where the public interest might be promoted in the research proposed.76 Such statements would provide shape to what the ADRC-Scotland considers research in the public interest to look and act like. With the ultimate objective being that only the ethical and safe use of administrative data can serve the

75 The Scottish Health Informatics Programme, ‘SHIP Guiding Principles and Best Practices’ 3.
public interest permitted via the ADRN, the following restatement of the SHIP public interest principles would clarify how this could be achieved.

### 3.2.3 Public interest principles restated for administrative data

*Scientifically sound and ethically robust research based on use, linkage and reuse of administrative data is in the interest of promoting and improving economic growth, personal and social well-being, and maximising the interests of current and future generations of citizens in the UK.*

In light of the ultimate objective sought, ADRC-Scotland would only consider applications for linkages that would support (i) the public interest; (ii) are academically and scientifically rigorous research and (iii) that is developed with a clear ethics plan for identifying and addressing any potential ethical risks that might arise over the course of the project.

*The objective of the ADRC-Scotland is to facilitate publicly beneficial research through the safe and efficient use and reuse of administrative data.*

This acknowledges that the public interest cannot be served without any publicly beneficial use of administrative data also being safe, requiring robust security and organisational measures, where the risks are proportionate to the benefits to be realised.

*The rights of individuals’ privacy should be safeguarded by robust and proportionate safeguards, in recognition of the public interests served by protecting individual privacy and in the promotion of publicly beneficial research.*

This restatement indicates that the research undertaken under the auspices of the ADRC-Scotland can only serve public interest if the linkage of administrative data does not diminish the public interests in protecting and respecting the privacy of the individuals’ whose data are being linked, as well as other interests, such as non-discrimination and non-stigmatisation. This requires adherence to robust technical

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77 The Scottish Health Informatics Programme, 'A Blueprint for Health Records Research in Scotland’ 22.
security and organisational safeguards that are proportionate to the actual risks posed by proposed linkages.

*Administrative data linkages should be carried out under a common approach of transparent controls, regularly communicated with the public and agreed upon by relevant oversight bodies and individuals with responsibility over the data.*

The importance of public engagement over the acceptability of uses of administrative data is a core feature of the ADRC-Scotland and represents the work being undertaken by the Public Engagement work strand. An aspect of public engagement should include transparent communications reporting the types of linkages authorised, and engaging in dialogues over the appropriateness of chosen governance mechanisms, as well as the possibility to have views taken into account on uses and reuses of data.

*The ethical and safe use of administrative data should be a stated objective of all organisations and individuals accessing data via the ADRC-Scotland.*

This is the ultimate objective of all linkages conducted by the ADRC-Scotland, and can only be achieved through consideration and deliberation over the other public interest factors as well as other principles within the agreed upon framework. This relates to the second key principle of the SHIP Good Governance Framework and will be considered immediately below.

3.2.4 Protection of privacy and other individual interests

It is often overlooked that safeguarding privacy and other personal rights and interests of citizens in society is also in the public interest. Too often there is a tendency to polarise debate of private rights v public interests, when in fact they two are sides of the same public interest coin. The second key principle underlying the SHIP Good Governance Framework is that of safeguarding the privacy and other interests of the individuals’ whose data resources make possible the research undertaken. Safeguarding the privacy and other interests of such individuals is merely another aspect of the public interest that must be considered in developing a common governance approach to the linkage of administrative data. SHIP’s statement of principles for safeguarding the privacy and other individual interests are:
Data controllers should demonstrate their commitment to privacy protection through the development and implementation of appropriate and transparent policies.

Every effort should be made to consider and minimise risks of identification (or re-identification) to data subjects and their families arising from all aspects of data handling.\textsuperscript{78}

These high-level considerations are useful for guiding initial deliberations on the issue of privacy and individual rights and other individual interests. However, a more nuanced approach regarding concerns for privacy and other individual interests, as related to the wide array of administrative data sought by the ADRC-Scotland, is required. As stated in Section 1 above we contend that the risks that potentially arise from the use of health data will differ from those posed by administrative data. A more nuanced approach to understanding such risks resonates with the risk-based approach developed by SHIP, which tailors the level of review required to authorise a proposed linkage according to the level of risk posed to individual privacy and related interests.\textsuperscript{79} Hence, the risk-based approach to research question 1 will seek evidence of the types of harms that may arise in context of administrative data uses and linkages. In order to guide the appropriate deliberation and fix an objective starting point for decision-making, the guiding principles must be developed in light of the risks that are specific to administrative data linkages. To support confidence in ethical decision-making, data custodians can publicly express the circumstances in which they will grant access for use and reuse, to whom and subject to which governance mechanisms. It is for data custodians to express what would be considered acceptable uses of their data in the public interest.

Whilst the evidence sought will not likely reveal that the use of administrative data poses the same form of physical risks as a medical intervention in research, this is not necessarily indicative of a more lax risk-analysis or light-touch approach to governance. One need not possess a creative imagination to consider the real risks that could arise from the unauthorised disclosure and re-identification of data relating

\textsuperscript{78} The Scottish Health Informatics Programme, ‘SHIP Guiding Principles and Best Practices’ 44.
\textsuperscript{79} The Scottish Health Informatics Programme, ‘A Blueprint for Health Records Research in Scotland’ 23.
to individual births, marriages, employment status, benefits received, or housing situation. The varied nature and meanings that can be attributed to the wide array of administrative data collected within Scotland and the UK must be considered when restating principles of how best to respect and provide for the privacy of the individual data subjects. The risk analysis conducted will work towards understanding this meaning on the basis of reasoned evidence gathering.\textsuperscript{80}

Aside from more \textit{substantive} distinctions between the different types of administrative data which will be explored in our proposed evidence review, future research might also consider differing sensitivities, depending on the type of, and length of, participation required from the individual – active versus passive, one-time versus long-term – extracting a human tissue sample versus obtaining data from a collection of centrally held administrative records; one-time study versus a longitudinal study. Unlike the risk analysis proposed above, these issues relate to public attitudes and acceptability of particular research activities in so far as they impacts individual data subjects. Thus public engagement work will be drawn upon to understand the dynamics of public acceptance of research and data linkages in context of administrative data. Evidence to-date revealed that ‘participants drew a clear distinction between research requiring the proactive participation of subjects (for example, research involving genetic samples) and research that draws on routinely collected administrative or statistical data (such as health records or census data).’\textsuperscript{81}

An important finding was that ‘[i]n terms of research that draws solely on routinely collected data, the prevailing view was that individual data subjects should not necessarily benefit directly and, instead, society in general should be the main beneficiary.’\textsuperscript{82} Such considerations will complement the risk-based analysis to inform key aspects of the governance of administrative data, especially in terms of ensuring

\textsuperscript{80} Our recent work for the Nuffield Council on Bioethics provided evidence on the harms arising from the use of health and biomedical data. The evidence uncovered would similarly support an understanding of how best to respect and provide for the privacy of the individual data subjects in specific context of health and biomedical data. Graeme Laurie, Kerina Jones, Chris Dobbs and Leslie Stevens, ‘A Review of Evidence Relating to Harm Resulting from Uses of Health and Biomedical Data - Prepared for the Nuffield Council on Bioethics Working Party on Biological and Health Data and the Wellcome Trust's Expert Advisory Group on Data Access’ (2014) (forthcoming).

\textsuperscript{81} Davidson et al, ‘Public Acceptability of Data Sharing Between the Public, Private and Third Sectors for Research Purposes’ 74, 77.

\textsuperscript{82} Davidson et al, ‘Public Acceptability of Data Sharing Between the Public, Private and Third Sectors for Research Purposes’ 77.
data are afforded protection commensurate with the actual risks involved but whilst respecting the public’s perception of such risks and of particular uses of data. Thus robust and appropriate governance of administrative data would reflect the public’s perception of any harmful impact caused by a particular use of administrative data that might not necessarily be legally recognised or recompensable. 83

Finally, given the methodologically different nature of health and biomedical research versus the often fluid, and identifiable nature of social sciences and humanities research, the role of anonymisation must be repurposed for the wide array of research contexts where linkages of administrative data will occur and to account for the diverse range of sectors where administrative data will come from. The importance of adequate anonymisation to the public acceptability of data uses must play an important role in this consideration. However, the meaningful contextual differences in the linkage of administrative data are equally critical and important to consider. 84 Thus, this aspect of the research will take into account the critical discourse surrounding research governance outwith the health sphere. In particular, research that argues against the application of principle-based approaches to research governance of social sciences will be considered. 85 We will also account for previous work undertaken in this area, notably with SHIP’s analysis of information governance models and in particular how consent, anonymisation and authorisation of research can work together – this analysis will lend to important discussion over the appropriate role of consent vis-à-vis other governance tools. 86 In particular, in much the same way as the report posits that it is unhelpful to imagine that a one-size-fits-all governance model could be suitable across all kinds of administrative data or linkage contexts, so

83 In our recent work for the Nuffield Council on Bioethics, we explore the dichotomy between impact and harms arising from the use of health and biomedical data. Whilst the latter is supported by legal standards and provisions, the former relates to individuals’ subjective perception of harmful impacts caused to them and thus may not be provided for in law. See: Graeme Laurie, Kerina Jones, Chris Dobbs and Leslie Stevens, ‘A Review of Evidence Relating to Harm Resulting from Uses of Health and Biomedical Data - Prepared for the Nuffield Council on Bioethics Working Party on Biological and Health Data and the Wellcome Trust’s Expert Advisory Group on Data Access’ (2014) (forthcoming).

84 Davidson et al, ‘Public Acceptability of Data Sharing Between the Public, Private and Third Sectors for Research Purposes’ 74.


86 That the deployment of anonymisation, authorisation and consent together and where appropriate (as proposed by SHIP’s Good Governance Framework) would not permit consent to be used as a trump card for facilitating or disallowing research to be undertaken.
too much each governance tool – whether anonymisation, authorisation or consent – be considered as fit for purpose depending on individual circumstances. What might work in one context, such as a consent approach, might not be suitable or desirable in another. Rather, what is required is a proper evaluation for each governance tool, its benefits and limits, and its powers – alone or in combination with other tools.

3.3 The ESRC Framework for Research Ethics

As an ESRC-funded research centre, the ADRC-Scotland must take into account the ESRC Framework for Research Ethics (FRE).\(^87\) The FRE was not developed to operate as a self-sustaining framework, and therefore in contrast to SHIP’s Good Governance Framework, the key principles defining the ESRC’s FRE are important to consider in light of their development with social science research specifically in mind, as well as ADRC-Scotland’s obligations to promote such principles in its undertakings. As such, this section will provide an initial analysis of the FRE’s six key principles as stated in the September 2012 version of the instrument. These represent what the ESRC considers as a set of standard procedures and minimum requirements to meet the ethical standards of the ESRC at the time of writing. It is important to note that the FRE is currently under-going revision, as well as the ESRC’s Research Data Policy - both instruments are intended to be read together, and thus are considered as such within this report.\(^88\) This report will be revised in due course to reflect the outcome of the revisions. Moreover, its central message can inform the revision process.

It will be remembered that for the SHIP Guiding Principles and Best Practices the principles serve as a starting point for deliberation and the best practices are aspirational ‘instances of optimal governance’.\(^89\) In contrast, and rather than an ideal to strive for, the FRE’s six principles provide a minimum threshold that must be met. Must is an important word to consider – the ESRC considers the six key principles as minimum requirements to meet their ethical standards for ESRC-funded research. As such, the principles operate as rules rather than principles. However, in line with the


\(^{89}\) The Scottish Health Informatics Programme, ‘SHIP Guiding Principles and Best Practices’ 1.
approach taken by Laurie and Sethi in their recent work on principles-based approaches, a principles-based approach can accommodate both rules and principles.\textsuperscript{90} Thus the FRE’s six key ‘principles’ will be considered in order to determine:

*How principles, which operate as rules, can fit within a common, principles-based approach to the governance of administrative data in the ESRC-funded ADRC-Scotland.*

In contrast the two core principles underlying the ESRC’s Research Data Policy are more reflective of the principles set forth by SHIP in that they serve as a starting point for deliberating on issues of data access and sharing. These will be briefly considered as a current and relevant example of a principle-based approach to data access and sharing arrangements outwith the health sector.

### 3.3.1 Principles operating as rules: the FRE principles

The following principles are the FRE’s six key principles that the ESRC expects to be addressed whenever applicable:

1. Research should be designed, reviewed and undertaken to ensure *integrity, quality and transparency*.
2. Research staff and participants must normally be *informed fully* about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved. *Some variation is allowed in very specific research contexts for which detailed guidance is provided in Section 2.*
3. The *confidentiality* of information supplied by research participants and the *anonymity* of respondents must be respected.
4. Research participants must take part *voluntarily*, free from any coercion.
5. *Harm* to research participants and researchers must be *avoided* in all instances.

\textsuperscript{90} Laurie and Sethi, ‘Towards Principles-Based Approaches to Governance of Health-related Research using Personal Data’ 13.
6. The independence of research must be clear, and any conflicts of interest or partiality must be explicit.

Given that the ADRC-Scotland and ADRN are funded by the ESRC, any governance approach adopted must take into account the FRE. Specifically in how the data linkages are governed, including the authorisation process, staff’s role in the process and in protecting individual privacy. The FRE not only applies to initial approval of ESRC funded projects, but also presents on-going obligations to maintain these standards or risk sanctions depending on the severity of any breach. The FRE’s Research Data Policy further imposes obligations on how data is access and shared but specifically in terms of “Open Access” obligations. However, and importantly, the two principles that underpin the Research Data Policy are dedicated to promoting the value of research data as a public good, in the public interest and in facilitating reuse of such data.

If we consider the FRE’s six principles in light of their status as ‘minimum requirements’ to meet ESRC’s ethical standards, their role as rules in a future governance approach will be assessed. Take for example the first FRE principle:

*Research should be designed, reviewed and undertaken to ensure integrity, quality and transparency.*

It is contended that this particular ‘principle’, which operates as a rule by virtue of its role as part of the ESRC’s minimum requirements, is not substantively problematic for ADRC-Scotland’s purposes. Even if strict adherence to this ‘principle’ were required, this is squarely in line with the restated public interest principle adapted from the SHIP context: *Scientifically sound and ethically robust research based on use, linkage and reuse of administrative data is in the interest of promoting and improving*
economic growth, personal and social well-being, and maximising the interests of current and future generations of citizens in the UK.

If this principle were understood as a commitment by the ADRC-Scotland in the undertaking of data linkages in the public interest, this is still representative of a principles-based approach. SHIP’s Good Governance Framework is underpinned by a commitment to promote scientifically sound and ethically robust research in the public interest, whilst maintaining a high-level of protection for individual data subjects.\textsuperscript{94} What is key is framing the FRE principles as a commitment, rather than as a prescribed all-or-nothing rule, which merely seeks compliance rather than the holistic reflection and deliberation promoted within a principles-based approach to the governance of data. In fact, a principles-based approach relies heavily upon commitment to core values that form the basis of proportionate decision-making. Thus, despite the rules-like nature of the FRE’s six principles, restated as commitments, they can hold an important place within ADRC-Scotland’s future governance framework.

As a final thought, we briefly consider how the FRE’s six principles may be contrasted to the two principles the ESRC bases its Research Data Policy upon (as adapted from the Organisation for Economic Co-operation and Development (OECD)):

- Publicly-funded research data are a public good, produced in the public interest.
- Publicly-funded research data should be openly available to the maximum extent possible.\textsuperscript{95}

We contend that the approach taken by the ESRC in terms of its Research Data Policy operates less like rules and more like the principles advocated for in this report. The principles are followed by more specific requirements for ESRC grant holders and those do operate more as rules, which trigger sanctions if not complied with. However and importantly, the principles above highlight the balance needed between the public interests in protecting individual privacy and in promoting justified, lawful and ethical uses of data in the public interest. While the Policy maintains its adherence to all

\textsuperscript{94} The Scottish Health Informatics Programme, ‘SHIP Guiding Principles and Best Practices’
\textsuperscript{95} ESRC, ‘Research Data Policy September 2010’ 2.
relevant legal requirements, it balances this by recognising other public interests at stake – including undertaking research in the public interest and reusing the data produced from such research in the public interest.

### 3.4 Complementing principles with best practices

The FRE ‘principles’ that could inform the key commitments and core objectives of the ADRC-Scotland, would need to be complemented by more specific and delineated best practices that would stand as a ‘gold standard’ for the optimal governance of administrative data. Best practices, which are considered examples of best practice in action, and can promote confidence in decision-making by specifying ways in which good governance can be achieved whilst not prescribing a particular route to compliance. Best practices are aspirational, and thus represent standards that may be over and above what is legally required; that is why a principles-based approach allows for divergence from best practice where justified accordingly.

Work is needed to develop best practices suitable across the wide range of research contexts where administrative data will be linked by the ADRC-Scotland, and that which are in compliance with the FRE principles. Further to this, our research will specifically consider:

**What does optimal governance of administrative data look like, and how does this contrast to what is legally required to use and link to this data?**

Understanding the distinction between legal requirements and instances of best practice that are aspirational in nature is key to eradicating the adherence to unhelpful approaches to governance – namely the consent-or-anonymise paradigm discussed in Section 1 above, as well as the potentially overly rigid compliance culture. Thus a key element of the legal research strand will be to understand what is legally required to undertake administrative data linkages whilst underscoring how linkages can best serve the public interests at stake by striving for optimal governance in reference to appropriate instances of best practice. We reference here our administrative data

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96 Laurie and Sethi, ‘Towards Principles-Based Approaches to Governance of Health-related Research using Personal Data’ 11.
decision-making matrix on page 10 that reflects the legal considerations that will arise when a use for administrative data is proposed. The matrix is our initial analytical tool for distilling what is in fact legally required.

As stated throughout this report, the law must necessarily be complemented by ethics to achieve a principled proportionate approach to the governance of administrative data. Our research will consider suitable best practices in context of administrative data. This will require dynamic engagement with administrative data communities – we will seek out case studies of linkage projects in Scotland and the UK, which can illustrate the appropriateness of different ethical tools employed in the extremely diverse contexts inherent to administrative data. This work will be further informed by the evidence gathered on harms arising from administrative data, public engagement work to-date, and findings from the Public Engagement strand of the ADRC-Scotland. Each instance of best practice developed will be informed by the contextual factors specific to administrative data linkages.

3.5 A starting point for deliberation and decision-making

Much can be learned from the lessons of SHIP and from the role to be played by ESRC’s FRE principles within ADRC-Scotland’s future governance framework. Guiding principles can promote confidence in justified uses of administrative data and shape what optimal governance looks like in this context. However, calls for a common approach to the governance of administrative data must be tempered by the recognition of the inevitable divergence in implementation, given the broad nature of a principles-based approach to governance. For instance, implementation of the ESRC FRE into any common approach developed for the ADRC-Scotland and/or ADRN will inevitably vary at the level of implementation because the ADRN does not have an internal authorising body to approve administrative data based research; nor would such an authorising body automatically hold reciprocity with each individual public body data controller. If we consider the current FRE, each project need only
seek ethics approval from one body. This is a helpful example of proportionality in action and something to strive for in the administrative data context.

However the common approach called for by the ADT does not mean uniformity or complete harmonisation. The work undertaken by the legal research strand will reach for approximation of approach within certain agreed parameters – according to the principles and core objectives agreed upon by the ADRC-Scotland and other centres. By working from a common basis of core objectives and values, seeking mutual recognition and interoperability of decision-making mechanisms and outcomes will be more achievable than what is currently the case under the disjointed legal landscape of administrative data linkages.

Analysis will now turn to our second-order research questions, which address contextually specific issues that would arise in the development of principles and best practice for the linkage of administrative data.

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4. Historical data

Within administrative data sets, historical data are prevalent. For the purposes of this scoping report, we define historical data as:

*Administrative data, collected primarily for administrative purposes at a point in time when research may, or may not have been indicated as a potential future use of the data; when consent may or may not have been sought and a period of time has lapsed since the collection, giving rise to the opportunity for changes to interests and values attributed to the data by the individual in question or data controller.*

4.1 Indications of future use and temporality

Dealing with the first feature of historical data, in this context, the individual in question may not have been informed of the potential, future use for research. In many cases, they will have been completely unaware of it. The legal and ethical issues relating to non-primary uses of personal data have been sufficiently examined in the context of sensitive personal health data, and especially within context of the SHIP initiative. However, more work is needed to investigate the impact of temporality, i.e. the ‘historical’ aspect of the data, on legal and ethical obligations and specifically whether it impacts on any putative duty to individually trace and consult on new uses of such data.

The authors have considered the issue of temporality in context with biobanking whereby the temporal challenge presented is that of ‘…establishing resources the benefits of which might not be realised for a considerable time, and which most probably will only be enjoyed by generations to come.’

The factors contributing to the temporal challenges for biobanking are also likely to arise in context of administrative data linkages, where scientific or natural restraints prolong research endeavours’ translation into publicly beneficial outcomes.

The longitudinal social sciences research that ADRC-Scotland would facilitate through linkages consults and relies upon historical data sets to inform research findings that

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99 We also consider this above in context of the Scottish Guthrie Card Collection. See pages 26-27.
speak to important socio-economic, health and environmental trends that affect the well-being of individuals and society. Such studies require research participation over time, which will inevitably raise issues of changing value or interests in the data in question for both private and public interests. Thus the legal research strand must consider the challenges for ensuring that ‘governance policies and mechanisms remain fit for purpose over time with respect to both the private and public interests that are – or might be – at stake’. These challenges must be evaluated in context of the potential harm and benefits to public and private interests arising out of administrative data sets held for long-term studies. This issue was specifically flagged in the ADRC-Scotland’s project bid, underscoring the need to provide for long-term data storage (and specifically of historical data). Long-term data storage is a necessary area of development from the short-term use and destroy scheme developed for the SHIP initiative. Furthermore, historical research in the DPA is a feature exemption, but currently under-explored (and arguably under-utilised). This exemption might reveal future flexibilities for this kind of research.

4.2 Consented or non-consented collections

Very much related to how informed the individual in question was at the time of collection, is the second feature of historical data: whether the collection of historical data was consented to. However, regardless of whether data reuse was consented to at the time of collection, prior consent says nothing necessarily about that individual’s current or future interests. Thus, legal and ethical obligations will need to be re-assessed upon proposed long-term use of data and specifically whether any putative duty to individually trace and consult on new uses of such data arise at the point of linkage if historical data, or at a designated point in the future for data held in the long-term.

4.3 Length of time since collection

The third and final feature of historical data, which is essentially intertwined with the two former features, is the ‘historical’ nature of the data or the length of time that has passed since collection. For this aspect of the research, the insights from, and

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100 Laurie, ‘Reflexive governance in biobanking: On the value of policy led approaches and the need to recognise the limits of law’ 349.
101 Laurie and Harmon, ‘Through the Thicket and Across the Divide’ 9.
recommendations made, within the 2013 report, ‘Guthrie Cards in Scotland: Ethical Legal and Social Issues’ will be drawn upon given that Scotland’s Guthrie Card collection poses similar issues to those likely to arise out of long-term storage of historical data:

The long-term nature of the collection poses considerable dilemmas about whether and how it is appropriate or possible to impose contemporary governance requirements – such as consent – on collections that were established at a very different time.¹⁰²

The report’s recommendations for developing ‘robust and flexible governance mechanisms’, in consideration of the on-going reassessment needed for long-term collections such as Guthrie cards, will inform similar considerations as to the potential long-term storage of historical data.¹⁰³ In particular, the viability of ‘a clear, well-publicised, accessible and efficient opt-out system’ as governance tool to manage long-term collections will be assessed.¹⁰⁴ Finally the recommendations made for managing access to long-term collections like Guthrie cards will be contemplated in terms of optimal governance arrangements for linkage to data via the ADRC-Scotland.¹⁰⁵

4.4 Historical data considered for ADRC-Scotland

The legal and ethical complexities that arise out of historical data collections will be examined in light of specific administrative data sets and thus contextual features of the data to be linked for research by the ADRC-Scotland including the:

- 1932 and 1947 Scottish mental surveys;
- Civil registration data from 1855-present;
- Aberdeen Children of the Nineteen Fifties data.

¹⁰² Laurie, Hunter, and Cunningham-Burley, ‘Guthrie Cards in Scotland: Ethical, Legal and Social Issues’ 11.
In recognition of the ADRC-Scotland’s aim to link to the widest possible range of administrative and health data in Scotland, the implications of such linkages for public and private interests will be considered including:

- The practical impacts of creating such large and interconnected databases, thereby increasing challenges to protecting individuals’ privacy;
- How the implicit public and private (commercial) value in the creation of large historical data sets will be managed in light of its potential utility for e.g. insurance policies, personalised medicine according to genealogical factors, etc.;
- The way historical data, when linked to other administrative and health data, can affect notions of family history and individual identity;
- The role for appropriate governance tools in managing public and private interests in the arguably new and vast data sets created when historical data are linked in this large-scale;
- The impact on optimal governance if historical data are already publicly available and whether this changes any obligations or duties to the individuals whose data will be used.

The construction of novel databases, connecting historical data to wide arrays of administrative and health data can inform research that produces publicly beneficial outcomes that inform society about key determinants to socioeconomic status and overall health and well-being. However, both the unique benefits and challenges that historical data presents must be taken into account in the development of proportionate governance arrangements over administrative linkages.
5. Commercial partnerships
In this final section, the commercial value and potential access to administrative data linked by the ADRC-Scotland will be considered as a direct response to ADT’s commitment to considering this issue in the early phases of the ADRN. We consider this issue from a perspective that considers the possible fallacy of the public/private distinction – whereby attention, might instead, be better placed on an organisation’s ability to meet certain accreditation standards before access is granted (regardless of the character of that organisation) whilst ensuring robust public engagement into acceptable uses of administrative data, including by commercial partners, is explored and used to inform design and delivery of governance.

5.1 Increased public sensitivities to commercial access
There are increased sensitivities regarding the access, and use of, publically held data by commercial entities.106 Public scandals involving commercial access to publicly held data, such as NHS England’s access policy for the forthcoming care.data scheme, highlight the importance of exploring the implications of potential commercial access during the initial phase of a research project involving linkages of personal and sensitive personal data such as the ADRC-Scotland. The implications of public scandals are necessarily reflective of social concerns regarding data access arrangements but offer important lessons for the management of access to administrative data and thus optimal governance of such data.107

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107 In a forthcoming article ‘The social licence for research: why care.data ran into trouble’, Pam Carter, Professor Laurie and Mary Dixon-Woods consider the idea of social licence and how the expectations of society regarding certain activities may go beyond those formally required by law. Whilst technically lawful, the Care.data scheme lacked focus on engendering a social licence for the proposed use of sensitive persona health data, which neglected the fact that legal authority does not necessarily command social legitimacy. Pam Carter, Graeme Laurie and Mary Dixon-Woods, ‘The social licence for research: why care.data ran into trouble’ (2014) (forthcoming).
The ADT did not offer definitive guidance on the issue of commercial access to publicly held administrative data, but it did recognise that increased data sharing in the public sector would increase interest from commercial quarters.\textsuperscript{108} The same efficiencies that could be achieved within the public sector would similarly benefit commercial organisations. However, a key consideration raised by the ADT is that commercial involvement does in fact hold ‘…the potential to inform research with strong public benefits.’\textsuperscript{109} The ADT indicated that future, common approaches for the governance of administrative data would consider \textit{restricted} access to data by private industry only when such access would result in strong public interest outcomes.

The legal strand of ADRC-Scotland will consider the potential for commercial partnerships in administrative data not so much in terms of the nature or provenance of the entity seeking access but in terms of their commitments about what they will do with data and their research findings. These commitments and the research findings are what must serve the public interest, not that the entity seeking access must come only from a public entity or sector. Commitments to the public interest in terms of data handling and research findings should be built all the more clearly into governance mechanisms if and when commercial partnerships are considered.

From the European legal perspective, those who would access administrative data, whether a researcher from a University or from a commercial organisation, are bound by the same data protection principles \textit{if} personal data are used. While there are specific exemptions in data protection legislation tailored to the public sector, largely, obligations to safeguard the relevant interests in personal data remain the same across sectors. However, the ethics and social implications of such use \textit{do} vary according to sector. Therefore this aspect of the research must take into account findings from public engagement activities with bearing on the acceptability of commercial access to publicly held data resources.

The importance of robust, public engagement work cannot be understated if and when the ADRC-Scotland or wider ADRN contemplates commercial access, as the ‘public perception of requests for access and linkage to public sector administrative data by
private sector organisations’ could lead to ‘reputational damage, with negative repercussions for public sector agencies.’ In line with the ADT’s recommendation, the public engagement activities of the ADRC-Scotland will conduct a review of the ‘range of interests in access to administrative data expressed by public and private bodies and establish guidelines for access according to the nature of the research.’

It is clear that any commercial access would need to be predicated on the public interest being served by the proposed research undertaken by a private sector organisation. Evidence to-date indicates that public acceptability of commercial access can relate to the level of profit attributed to such access, where excessive profit has been flagged as indicative of public concern. In this regard, the prospect of benefit-sharing schemes should be considered, particular to the type of research project undertaken. Also in furtherance of the public interest being served by any proposed commercial access, would be the adherence to robust technical security mechanisms, given that public attitudes towards commercial involvements may be tied to the identifiability of data accessed. However, rather than restricting governance tools to any particular mechanism such as anonymisation or explicit consent, the appropriateness of a wide array of governance tools will be considered in light of the holistic functioning of a principles-based approach to the governance of administrative data.

Thus the legal strand will consider:

- What are the nature, scale, benefits and pitfalls of current and future commercial partnerships in context of administrative data linkages?
- What lessons can be learned for the governance of administrative data from public engagement exercises?

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112 Davidson et al, ‘Public Acceptability of Data Sharing Between the Public, Private and Third Sectors for Research Purposes’ 65.
What is the likely impact on public trust and how can this be accounted for in robust yet proportionate governance of administrative data?
6. Conclusions: the need for a joined up approach to administrative data

The mixed legal and cultural contours of the administrative data landscape create the need for focused investigation into how the governance of administrative data can be practically achieved in light of potential risks and benefits. This endeavour will necessarily be informed by the lessons learned from other contexts, resulting in an exploration of the suitability of a principles-based approach for the governance of administrative data. Suitability will be measured against a benchmark of evidence of the potential harms arising out of administrative data linkages. The findings from this evidence review will inform a key element of the legal research in examining the likely features of good governance for administrative data.

In sum, the legal research will consider the likely features of good governance of administrative data including:

- The identification of the wide range of public and private interests at stake in the linkage of administrative data.
- Robust risk-assessment, based on the basis of evidence of the potential harms that could arise out of administrative data linkages.
- Asking what proportionate governance looks like in the context of administrative data, based upon consideration of the specific risks and benefits likely to arise.
- Assessing the relative roles of governance tools to help achieve robust yet proportionate governance of administrative data, including the appropriate role to be played by consent, anonymisation, and authorisation.
- Understanding the precise flexibilities and limits under UK data protection law and how this applies to the administrative data context.
- Accounting for the effect of time on changing governance requirements.
- Providing for the familial and privacy impact of historical research.
- Considering whether and how commercial involvement changes approaches to governance and how related concerns can be accounted for within a governance framework.

In line with the research questions set forth within this report, the next stage of research will focus on evidence gathering through systematic literature reviews for the
likely harms to arise out of administrative data linkages. This will serve as a benchmark for assessing the suitability of a principles-based approach to the governance of administrative data, adapted from well-established frameworks in other contexts. These first steps will contribute towards a better understanding of what good governance looks like for the administrative data context and thus the governance of the ADRC-Scotland.
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