Care Home Data: Governance, Ethics, Access and Readiness
through an Exemplar Demonstration

The GEARED UP project

Final Report

March 2023

Edinburgh Napier University
The University of Edinburgh
health innovation South East Scotland

The Data Lab value from data
Chief Scientist Office
NHS Scotland Central Management Team
DataLoch

Funded by CSO Innovation Catalyst Fund.

Authors

Lucy Johnston, Senior Research Fellow, School of Health and Social Care, Edinburgh Napier University

Irina McLean, NHS Research Scotland Central Management Team (Health and Social Care)

Dr Susan D Shenkin, Reader, Ageing and Health, Usher Institute, University of Edinburgh; Co-Chair of ENRICH Scotland

The GEARED UP Team

Lucy Johnston, Senior Research Fellow, School of Health and Social Care, Edinburgh Napier University

Heidi Koikkalainen, Research Assistant, School of Computing, Engineering and the Built Environment, Edinburgh Napier University

Lynda Anderson, Research Fellow, School of Health and Social Care, Edinburgh Napier University

Alistair Lawson, Associate Professor, School of Computing, Engineering and the Built Environment, Edinburgh Napier University

Contact: l.johnston@napier.ac.uk

Summary

This report sets out learning and recommendations arising from work undertaken to source individual care home resident level data gathered as part of routine care for repurposing/re-use within a Small Business Research Initiative (SBRI) - jointly funded by the Chief Scientist Office (CSO) in Scottish Government and The Data Lab, and hosted by Health Innovation South East Scotland (HISES), an innovation test bed.

GEARed Up: The Care Home Data: Governance, Ethics, Access and Readiness Demonstration was established to identify potential routes and required processes for public sector and commercial company use of care home data, and to explore data sources. It was funded by the CSO innovation catalyst fund and aligned to the SBRI Care Home Data Innovation Foundation Challenge.

Large amounts of individual-level data are collected in care homes. As set out in the Scottish Government's Health and Care Data Strategy, there is great potential to use these data assets to improve services, support research and increase data driven innovation that benefits care home residents and providers.

The issues identified by the GEARed Up project are important for three main reasons. Firstly, it identifies the **Governance** and **Ethical** issues that arise in the vacuum created by the fact that, in Scotland, there is currently no consensus or defined route for the legal, ethical and efficient access to permit reuse/re-purposing of care home data for research, service evaluations and Innovation Challenges/Test Bed work.

Secondly, it highlights additional problems that arise when using the current routes to data acquisition, by highlighting the practical challenges of navigating the **Access** routes and again the issue of data **Readiness.**

Thirdly, it is important because care home residents are important. We must not lose sight of the fact that the data collected about them should first and foremost add value to their lives and the services they use.

Summary of Recommendations

1. Create a realistic and resourced action plan to address the limitations and barriers of the current information and governance systems for care home research and data driven innovation projects
2. Engage with a wide range of stakeholders – with care home residents/families and workers the core – and ensure all are aware of the work across the sector
3. Ensure high-level oversight and responsibility for clear communication and coherence between local and national data initiatives

4. Fund a Scottish extension of the ongoing DACHA study to ensure that findings are relevant and implementable in Scotland

5. Provide adequate financial and staffing resource to support collection and reporting of summary care home statistics and individual resident-level data (care homes, PHS, RDS, Care Inspectorate)

6. Develop a robust national framework to support the review process for social care research and innovation, ensuring appropriate data provider, processor and subject involvement to establish a clear pathway for accessing, and seeking ethical and governance approval for using care home and other social care data

7. Clarify with care home residents (or their legal representatives) and service providers when consent processes are required for the re-use of data (identifiable/anonymised) for research and innovation purposes

8. Resource the completion of the exemplar of data ingestion from care homes to a trusted research environment for research/innovation use

Contents

Summary **3**

Background **6**

Who should read this report? **6**

Approach **7**

Scope **8**

Terminology and definitions used **8**

Introduction **9**

Findings **10**

GDPR compliant but REC and PBPP exempt? 10

Care Home Research and Innovation – 'ethics lite'? 11

Is the devil in the (lack of) detail? 11

Public 'sectorness' of health and social care data – presumed and prioritised? ... 14

Is the data ready for innovation? 15

Is there adequate certainty and coordination? 15

What can be done now to 'GEAR up' care home data? **16**

Conclusion **19**

APPENDIX ONE: Current guidance on information governance and ethical approval **20**

Governance 20

Legally compliant, with a legal basis 20

GDPR and non-identifiable care home data 20

GDPR and consent to data being repurposed 21

Ethics 21

APPENDIX TWO: High-level use case diagram **24**

APPENDIX THREE: ENRICH Scotland Care Home Research Ethics Review Process **27**

APPENDIX FOUR: Considerations for individual resident level data as the foundation for a Care Home Data Platform **28**

References **29**

Background

Work was undertaken to source individual care home resident level data gathered as part of routine care for repurposing/re-use within a Small Business Research Initiative (SBRI), jointly funded by the Chief Scientists Office (CSO) in Scottish Government and The Data Lab and hosted by Health Innovation South East Scotland (HISES) [1].

The aim of data collection was originally for use within Phase 2 of the Care Home Data Platform Innovation Foundation Challenge, to produce a prototype of a holistic digital picture of an individual resident's health, well-being and care needs. Phase 1, completed in 2021, tasked five technology innovation companies to assess existing data collected on residents by care homes.

The Phase 1 technical feasibility findings were positive, determining that:

- It is technically feasible to combine individual-resident-level data from Care homes with other health and social care data
- A holistic digital picture of an individual resident's health, wellbeing and care needs can be created
- A trajectory of changes over time can be shown
- There is the potential to apply risk stratification and decision support

Phase 2 was known to be contingent on the provision of (real or simulated, historic or live) individual resident data. GEARed Up: The Care Home Data: Governance, Ethics, Access and Readiness Demonstration was established to identify potential routes and required processes for public sector and commercial company use of care home data, and to explore data sources. It was funded by the CSO innovation catalyst fund and aligned to the SBRI Care Home Data Innovation Foundation Challenge.

Who should read this report?

The work and outputs have a broad contribution to make and therefore a broad audience, including Scottish Government policy makers, NHS Research Scotland, Chief Scientist Office, The Care Inspectorate, and those working in research, innovation and service improvement in Health and Social Care Partnerships, and Universities, including Trusted Research Environments, in Scotland. The findings inform and enhance the prospect of the use of routinely collected care home data used to support care decisions, improve services, inform research and increase data driven innovation that benefits care home residents and providers.

Specifically, we envisage value for those working in care home and social care research and innovation, development of technologies, regulatory and policy stakeholders who are currently working to:

- Inform preparations for improved data capture necessary for Scotland's National Care Service [2] which will, once implemented, result in significant strategic and operational changes and the related construction of a National Digital Platform [3].
- Consider how best to enable and support research and innovation which is a key aim of Scotland's Digital Health and Care Strategy [4] and NHS National Services Scotland's Research, Development and Innovation Strategy 2021 - 2024 [5].
- Contribute to the Scottish Government's current review of care home data which aims to ensure a coherent suite of data collections, reduce requests on data providers and more comprehensively understand and meet the existing and emerging needs of data users.
- Inform and support the continued development of a specific social care research infrastructure, that encompasses innovation in care homes and social care settings.
- Populate trusted and secure repurposing environments, such as NHS Lothian's DataLoch [6] and other Safe Havens and repositories with care home data specifically and social care in general.

Approach

The data discovery demonstration involved:

- Consultative meetings and email conversations with a range of stakeholders involved in the provision, use and management of care home data.
- Comprehensive and detailed documentation of the process/paperwork required for access to data from care homes – delineating where necessary that required for innovation, research or evaluation projects and all provider sector differences.
- Review of relevant, current operational policies and procedures, key legislation and the guidance from regulatory bodies to established current systems and frameworks relevant to the repurposing of individual resident data for research, innovation and evaluation.
- Collaboration with two care homes in Lothian to provide insight into their information/data governance structures, issues around the secondary use of

routinely collected care data for research and innovation and work towards agreed data sharing and ingesting into DataLoch.

Ethical approval was given by Edinburgh Napier University School of Health and Social Care Ethics Committee (Reference No. 2748925).

Scope

The focus of GEARed Up was on research and innovation in care homes for older people (people aged 65 or over) and was a 'study limited to working with data', as defined by the NHS Health Research Authority (HRA) [7], meaning that care home residents are data subjects and NOT research participants.

This work is exclusively about anonymous (non-identifiable) individual resident level data and how it can be used in data driven innovation, research and service evaluation. Throughout we therefore use the term 'routinely collected data' to convey individual care home resident level data that is collected in the course of normal care - that is, without the intention to use it for research at the time of collection.

This work does not cover or consider the important but broader data issues of (1) identifiable data (2) data linking or (3) routine national data, such as the Scottish Care Home Census: for a full list please see [8].

Terminology and definitions used

Data-Driven Innovation (DDI): the use of data and analytics to develop or foster new products, processes, organizational methods and markets [9].

Data driven research: using data analysis techniques and interpretation to extract knowledge and insights (e.g. patterns).

Data Repository: a secure computing environment for example a Trusted Research Environment or 'safe haven' that holds data and enables access to it for analysis.

Repurposing (or re-use) of data: the secondary use of data in data driven innovation and research that was collected in the course of normal care (without the intention to use it for research/innovation) at the time of collection.

Introduction

Understanding the challenges in the collection, importantly the subsequent sharing and repurposing of care home data for data driven evidence and digital innovation, are core aspects of the COVID-19 overall NHS recovery plans in Scotland [10]. This includes the healthcare framework for adults living in care homes and is also part of the continued development and adoption of digital solutions to address key health and social care challenges, as outlined by the Scottish Government in the last three years.

The available current guidance relevant to the information governance and ethical approval for research and innovation projects are shown in Appendix One. There are no specific or dedicated processes or routes for those wanting to repurpose data for innovation [11] or use data on care home residents specifically [12].

The process for accessing health data by researchers although well established, is well documented as being difficult and time consuming [13]. The routes for social care data and care home data are less well trodden, viewed as more complicated and time-consuming, with no single acknowledged pathway [12]. The use of both health and social care data for innovation by commercial companies is also acknowledged as less than straightforward and in need of improvement [11, 14, 15, 16] to ensure that innovation is well supported and inclusive, with sound and secure oversight.

Difficulties and challenges in accessing care home data and conducting research with care homes are often presented using metaphors to convey experiences of long, arduous journeys over difficult and at times unmapped terrain (see for example [12] [17, 18]. Within these reports there is an inherent acknowledgement that however difficult the journey, reaching the end point is worthwhile with data being described as having value, as an asset [19, 20, 21].

Excluding small COVID-19 specific data sets on individual care home residents provided to government and academic bodies as part of the pandemic response in 2020, we identified only one small research study that had repurposed routinely collected anonymised data in a research project [22].

In designing and conducting GEAREd UP we knew that the accurate curation, sharing and processing of care home data for innovation is the road less travelled. We began by constructing a high-level Use Case Diagram (see Appendix Two), which illustrates the relationships between data controllers, data processors and data subjects in relation to data flow. The main 'actors' and their interactions with the data and each other when working to establish a route to the reuse of routinely collected care home data are shown.

Below we reflect on the key actors, processes and practicalities that are making all the difference and set out some of the questions that will have to be addressed to improve the processes of governance, ethics, access and readiness of care home data for innovation and research.

Findings

GDPR compliant but REC and PBPP exempt?

Our reading of guidance and application documents is that HRA approval is not necessary for the repurposing of non-identifiable routinely collected care home data. What is required is *"review by another committee operating in accordance with the Economic and Social Research Council's Framework for Research Ethics, (for example, a University REC - UREC)"*.

NHS Health Research Authority – Research data and tissue resources [23]

> There is no formal requirement for databases to apply for ethical review under NHS research governance systems or under Governance Arrangements for Research Ethics Committees (GAfREC) [42]. A "research database" is defined as: A collection of data, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending. Databases established for purposes other than research, where there is now an intention to use that database for research purposes, for example databases originally established to support the delivery of care.

ENRICH (Enabling Research in Care Homes) Scotland has also used this interpretation as part of their care home review process [24, Appendix Three].

As part of the data discovery exercise, we made an application to the Edinburgh Napier University ethics committee. We stated that we would (1) investigate, with key stakeholders, the options for providing challenge solvers and researchers a location/safe place for datasets to be held, including for example Safe Havens, Sand Box or Data Loch environments and (2) as a result of these discussions carry out the work required to transfer data into DataLoch. This received a favourable ethical opinion with the caveat that a new ethics application would have to be made to them before the data could be examined/analysed by the named research team and if third party (private companies) were to be provided with legitimate access to repurpose the data.

Care Home Research and Innovation – ‘ethics lite’?

Given the greater understanding of the role innovation has in the future of health and social care provision and the post pandemic awareness of the critical part care homes have to play within the overall efficiency and effectiveness of publicly funded health and wellbeing services – care home research and data driven innovation will undoubtedly increase.

Currently, the process for social care project approval in Scotland is unclear, and only a small number of social care projects are currently passed to Research Ethics Committees (RECs) for review. In Scotland, many are reviewed by REC A who oversees research with Adults with Incapacities. In England, Wales, and Northern Ireland, this is done by a Social Care Research Ethics Committee [25]. The debate as to how and the extent to which care home research and innovation is exempt from the current HRA ethics framework is not new. The applicability of a primarily NHS/health focussed process has been questioned and reviewed over the last two decades, starting in 2001 when the first Research Governance Framework was published, including in [26, 27, 28].

A short life working group is currently gathering more specific information about existing issues NHS RECs are facing when dealing with social care studies and researchers and innovation teams are being consulted.

Key issues of relevance to the use of NHS REC criteria and procedures to the reuse of care home data for innovation and research include:

- Why is there no equivalent robust framework nationally to support the ethical review process for social care research and innovation?
- Do REC committees have sufficient social care expertise and related knowledge of research and innovation design and methods used in social care research and can the current ethical review accommodate these different methodologies?
- Why is there a reported lack of consistency in outcomes of reviews by different NHS REC?
- How can guidance and signposting be improved to direct social care projects towards particular Ethics Reviewing bodies (RECs, ESRC, Local Authorities etc)?

Is the devil in the (lack of) detail?

Repurposing care home data involves several separate processes designed for NHS data. There is a default to NHS controlled 'health data' within the systems, criteria and current guidance.

The different bodies that play a role in controlling care home data access, include the Integrated Research Application System (IRAS), NHS Scotland's Public Benefit and Privacy Panel for Health and Social Care (NHSS HSC-PBPP), Caldicott Guardian(s), and NHS Boards R&D. Their role and responsibilities in relation to care home data arguably lacks clarity and gives rise to different interpretations.

An important example of this is given below in relation to whether or not individual care home residents have to give consent for data repurposing and in what circumstances.

The GEARed Up team held conversations with data controllers and data processors such as care home providers and care planning/monitoring software companies; and also those involved in the review of studies and read the guidance in great detail. This identified three different views on the need for consent:

1. Explicit individual consent: every resident would have to sign a consent form before any anonymised data was shared for re-use in research or innovation.
2. Existing agreement adequate: consent to the analysis of anonymised data was built into the data sharing and processing agreement between care home and digital care management system provider (see Box 1).
3. Not required: the processing of non-identifiable data outside the care team does not need consent" (see Box 2).

Care providers nationally have consented to the anonymised data being made available with the aim of benefiting health and social care and fellow software users. Individual resident consent for the use of data is given (and a record maintained within the resident's file in the system) by residents or responsible persons; non-consenting residents will be screened out, but to date there are no instances of opting out. All data will be anonymised prior to transfer to secure networked servers. All output will be disclosure checked so no information identifies (or could be used in conjunction with other data to identify) individual residents.

Box 1: Ethics approval, information governance and data management statement of one digital care management system provider

Excerpt From HRA 'Standard Operating Procedures for Research Ethics Committees' (v7.5, March 2021) [29]

"Processing of non-identifiable data outside the care team does not need consent. If processing **identifiable** data outside the care team within a Scottish Study, data will require Caldicott Guardian approval if within single Health Board or Public Benefit and Privacy Panel (PBPP) approval if more than one Health Board or Public Health Scotland."

IRAS Application - Definitions in pop up information boxes

Research limited to secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection) is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research.

Research involving information which has been anonymised by an intermediary (such as NHS Digital) before its onward release to the researchers is excluded from REC review provided that there is a legal basis for the anonymisation.

Organisations responsible for the management of research databases anywhere in the UK may apply for ethical review of their arrangements for collection, storage and use of data, including arrangements of release of data to researchers. There is no formal requirement for databases to apply for ethical review under NHS research governance systems or under Governance Arrangements for Research Ethics Committees (GAfREC).

A "research database" is defined as: A collection of data, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending. Databases established for purposes other than research, where there is now an intention to use that database for research purposes, for example **databases originally established to support the delivery of care**.

Box 2: Governance guidance for repurposing of data for research and innovation

The lack of clarity or consensus around what consent is required is an example of the overall lack of social care specific and care home processes, potential for a lack of scrutiny by topic experts and the need for practical guidance to data controllers and processors.

Public ‘sectorness’ of health and social care data – presumed and prioritised?

To some extent it is the inbuilt presumption of public ‘sectorness’ - i.e. the assumption that health and social care data is collected and managed primarily by public sector organisations within current governance and ethic infrastructures - that is impacting on the efficiency and effectiveness of access routes for data driven innovation and research.

For example, in Scotland, healthcare data repurposed for research use is stored in secured and four regional managed facilities known as Safe Havens/TREs, with access requests administered centrally by Electronic Data Research & Innovation Service (eDRIS). It operates as the single-entry point application for researchers who want to use NHS Scotland data [30]. To gain permission to access Scotland’s Data Safe Havens for research projects approval must be granted by the Public Benefit and Privacy Panel for Health & Social Care.

In contrast, there is no Scotland wide, or even local authority/H&SCP level process for social care/care home data. A researcher or innovator seeking to re-use data on care home residents currently has to negotiate data protection issues, data sharing and third-party processing agreements with each individual care home. The relevant governance oversight and procedures are not tailored sufficiently to support access to useful care home data by legitimate data processors.

The major data curators and access gatekeepers (for example Public Health Scotland and Research Data Scotland) are focused on NHS and public sector data sets. However, data generated by care home providers about the people who live in their care homes cannot be simply encompassed under the definition of ‘public sector data’. In Scotland, only a small percentage of care homes for older people are run and owned by the public sector, with some others run by the voluntary / independent sector and the majority run by private organisations.

The mixed provider landscape gives rise to a further issue of key importance to data repurposing – especially for commercial innovation. The commercial sensitivity of data for private sector providers can impact on their decisions around data-sharing [31]. Care home providers can be reluctant to share data that might compromise their competitive advantage. GEARed Up worked with a third-party intermediary (DataLoch), who could aggregate data from service providers and securely share it with appropriate data users. However, the project was only able to work with a handful of care homes who volunteered to participate due to their interest in this topic, but whose involvement is currently paused due to limited capacity and the complexities around data sharing, and also changes in electronic care planning software being used.

Is the data ready for innovation?

There is no systematic, standardised curation of routinely collected care home data in Scotland or the UK. Previous related works by LJ and SDS [32] identified the effects of this by detailing the information collected at the individual resident level by care homes in the domains of demographics, diagnoses, and detailed care planning information. The rationale for data collection and the reality of how it is collected is undermining the utility of and access to individual resident level data for innovation and research. All stakeholders need to understand better the way in which data about care home residents and services are actually collected on the ground by individual care homes. addressing the initial curation, storage and potential for sharing this data will assist in setting up systems that can benefit care home residents, their families, and the staff who care for them; and also, then repurposed for innovation and research (See Appendix Four).

Is there adequate certainty and coordination?

Multiple stakeholders are now ‘gearing up’ to implement change in data management and collection in social care, with a shared goal to provide better services for the end user, through data driven insights and innovation. Figure 1 illustrates these stakeholders as multiple moving ‘cogs’ in the care home data wheel and suggests that changes made by each of them will, in turn, impact each of the others. Unless coordinated tightly, changes implemented by one of the stakeholders may inadvertently ‘turn the cogs’ of the others with unintended consequences. Furthermore, resistance of lack of activity by any one stakeholder could impede the whole progress of the whole ecosystem.

While this increased interest from a wide range of stakeholders will undoubtedly help drive change, there is a danger that a lack of coordination will result in duplicated efforts or, at worst, in incompatible ideas hindering each other’s progress. During our work we identified that in Scotland, there are over 20 separate organisations, groups/collaborations and projects pursuing new ways to collect and use care home data either for research, innovation or service management purposes.

CMO/CNO: Chief Medical Officer/Chief Nursing Officer; **DACHA**: Developing resources And minimum data set for Care Homes' Adoption study (https://dachastudy.com/) **DHI**: Digital Health & Care Innovation Centre Scotland; **ENRICH**: Enabling Research in Care Homes (https://www.nhsresearchscotland.org.uk/research-in-scotland/facilities/enrich); **ENU**: Edinburgh Napier University; **HISES**: Health Innovation South East Scotland; **NES**: NHS Education for Scotland; **NHS**: National Health Service; **QI**: Quality improvement; **SBRI**: Small Business Research Initiative; **SE**: South East; **SG**: Scottish Government; **TEC**: Technology Enabled Care Scotland; **UoE**: University of Edinburgh

Figure 1. Care home 'cog' diagram of stakeholders.

What can be done now to 'GEAR up' care home data?

Scottish Government's data strategy aspires to empower innovators, industry and researchers who can deliver new technology and data driven insights to improve and inform policy and practice. Calls for improvement to information and governance systems more broadly have been made [33]. However, there is a need now for significant work to make this a reality in social care, and particularly for care home data.

We propose below the priority practical steps needed to strengthen the data foundations and ensure that the currently available care home data can be used, while working to maximise the future potential of this valuable asset.

Overall, we recommend the **creation of a realistic and resourced plan of action** to address the limitations and barriers of the current information and governance systems specifically for care home research and data driven innovation projects. DHI suggest that this may involve agile, short-life groups including representatives from national and local stakeholders to provide expertise and help navigate this complex area[1]. There is also perhaps value in assessing the utility and the applicability of the recommendations of the Goldacre review [34]. Whilst its focus was on the use of health data for research and analysis, work refocussing and applying this detailed and practical thinking to care home data could be a valuable first step. As an example, recommendation 22 is presented below:

> *"Rationalise approvals: create one map of all approval processes; require all relevant organisations to amend it until all agree it is accurate; de-duplicate work by creating a single common application form (or standard components) for all ethics, information governance, and other access permissions; coordinate shared meetings when approval requires multiple organisations; have researchers available to address misunderstandings of their project; build institutions to help users who are blocked; recognise and address the risk of data controllers asserting access monopolies to obstruct competitors; publish data on delays annually; ensure high quality PPIE is done".*

Key Scottish stakeholders required to implement improvement represent a diverse mix, including national policymakers, regulators, charitable organisations, academic researchers, clinicians and commercial innovators, each with different aims and plans for using care home data. Care homes are however the most significant and most central cog. We must therefore ensure the mechanisms for including them in decisions and hearing their views and experiences are prioritised and built in. This input cannot rely as it does currently on the goodwill, enthusiasm and interest of individual managers and staff. **Care home involvement must be resourced and supported** – and we envisage a key role for ENRICH Scotland in this.

Identifying who has **high-level oversight and responsibility for ensuring clear communication and coherence between local and national data initiatives. This should take into account plans for the National Care Service, and the Data Strategy**, as well as wider whole system coordination from the foundations up. This will be essential to ensure the identified wheel of stakeholders all turn in the same direction and at the same time. ENRICH Scotland should be considered a natural partner. It is a multi-disciplinary team of professionals from nursing, medicine, psychology and social care backgrounds with a breadth of knowledge and experience in relation to care home research.

Scotland would benefit from NIHR funded DACHA study [35]. At present, this study does not encompass the Scottish Care Home sector, although one of the co-investigators is based in Scotland and can provide a Scottish perspective. Without direct Scottish involvement, the study will be unable to address in full the specific Scottish laws, regulation and governance and research frameworks. Its potential to shed light on the questions raised by GEARed Up is high if closer links, Scottish based fieldwork and analysis were to be resourced by Scottish Government and dovetailed to the work of this expert study team. There is an acknowledged lack of investment in social care data and data analysis [36]. Funding a proven practical project with shorter timescales is a way forward.

The role major agencies such as Public Health Scotland and Research Data Scotland play in relation to developing care home data – and other data from social care - must be enhanced. For example, in February 2020, the Office for Statistics regulation stated [37] that *"**More resource is certainly needed to support PHS's social care statistics production function**, and also to support the teams and systems responsible for data collection in local areas".* Whilst our work is supportive of this, any increase in resources must be used to fill the data driven innovation and insight gap – with routinely collected real time data and not just the improvement of national data sets. Again, the work of the DACHA team on the development of a Minimum Data Set should be of interest to Scottish Government and Scottish data agencies. There needs to be clarity in what data should be collected for what purpose, and the process should be made as simple as possible for care home staff who should only be required to enter data once to allow it to be used for multiple purposes (with appropriate consent), both at the aggregate care home level, and the individual resident level.

There is a need for **a clear pathway for accessing, and seeking ethical and governance approval, for care home – and other social care – data**. To a large extent, this can only be produced after a line-by-line review of the mandates, processes and guidance provided by governance bodies is undertaken to ensure that social care in general and care home studies in particular are correctly routed through the infrastructure and supported by accurate detailed advice and signposting. From our experience we suggest this could be started by ensuring that the addition of the words "and social care" within all systems are supported by sound definitions and supplemented by sufficient detailed support to those seeking to use care home data for research and innovation.

The **proof-of-concept data ingestion work** initiated by the GEARed Up team should be continued with an exemplar to establish that it is feasible. It would benefit from being at a larger scale to inform a model for national use. This should be done in collaboration with the Scottish Government's Care Home Data Review Team as it will provide an opportunity for the utility, quality, and functionality of such care home data to be developed, then tested, evaluated and interrogated by researchers and innovators for the first time.

Conclusion

The importance and value of care home data was made very clear by the COVID-19 pandemic. It exposed what has rightly been called out by Burton et al, 2020 as "the data failings that have hindered service development and research in care homes for years" [12]. There is also an acknowledged lack of investment in social care data and data analysis. As a result, data driven research and innovation now have an even more prominent role to play in care home practice development, service and system improvements, and service transformation [38].

There is rightly a lot of interest in trying to foster the best conditions and processes for high quality data driven innovation and research. We hope that the issues raised here will contribute to the debate on how we work to ensure high quality data driven research and innovation at scale for the benefit of care home residents, their families and the staff who care for them. It is essential they are not excluded because of solvable problems with current processes and policies.

APPENDIX ONE: Current guidance on information governance and ethical approval

Governance

Every individual or organisation collecting, sharing or using data (be they controllers or processors) have to comply with **The Data Protection Act 2018** and **UK GDPR**, two key pieces of legislation that govern how data is handled in the UK. For care home data specifically and social care data overall, project data processors must adhere to the principles and responsibilities for health and social care research as set out in the UK Policy Framework for Health & Social Care Research [39].

Legally compliant, with a legal basis

All actors must establish and abide by lawful processing (collecting, using or storing) of personal data and set out how this will be done in key documents including - data flow maps, data protection impact assessments (DPIA), and data processing and data sharing agreements.

The processing of any data must have a legal basis [40]. HRA Technical Guidance on GDPR (NHS Health Research Authority, 2018) is that

- research organisations that are public authorities such as NHS organisations and universities rely on **public interest** and
- commercial research partners should use **legitimate interests** as their legal basis.

GDPR and non-identifiable care home data

GDPR Recital 26 [41] explains that: Anonymous data: data from which no connection to a specific identifiable person can be drawn, based on either the specific data alone or through linking to other datasets.

"…The principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. This Regulation does not therefore concern the processing of such anonymous information, including for statistical or research purposes."

If anonymised data is exempt from GDPR and (re) consent requirements, there is a need to understand how it can be anonymised before providing access to the project data processors.

HRA also give further guidance on anonymised data with their 'Guidance for using patient data':

> "A member of a patient's or service user's care team may render confidential patient information anonymous without breaching the duty of confidentiality. The care team includes registered health and social care professionals and other staff that directly provide or support care to patients. ,…….. a member of the care team does not need to have consent to enter de-identified data into the database."

GDPR and consent to data being repurposed

Within the data protection law and regulations consent in relation to being an anonymous data subject in a data driven research or innovation project is different to consent required from research participants. Consent for taking part in research, under the Research Governance Framework, is different from consent obtained for processing data under GDPR. What is important here is the difference between a data subject giving consent for the PRIMARY purpose (that of providing care) and giving consent to that data having a *secondary* purpose – that of being used anonymously in data driven research or innovation. Therefore, data collected for the primary purpose of research would require informed consent but reuse of anonymised data collected for providing care would not require individual consent.

Ethics

For data driven innovators, 'A guide to good practice for digital and data driven health technologies' was updated in January 2021 by the Department of Health and Social Care [38]. It states that innovators should abide by the principles of the data ethics framework. The HRA confirm this by stating on their website that "There are no specific laws or regulatory approvals that apply to data driven healthcare technologies…. already covered by existing laws and regulatory approvals" and directs readers to conform to the UK Framework for Health and Social Care Research and seek approval from an ethics committee to access patient data.

Research Ethics Committees review studies to determine if being delivered in fair, ethical and appropriate way. They are governed by **Health Research Authority (HRA)** via **Governance Arrangements for Research Ethics Committees (GafREC)**

UK Policy Framework for Health & Social Care Research [39] applies to health and social care research that is within the responsibility of the HRA or Devolved Administrations' Health Departments. This includes care homes.

A directory on HRA website gives details on all RECs in the UK. Submitters choose a committee, and if special category, needs to choose one that is 'flagged' to review that category. Of relevance to GEARed Up are the RECs 'flagged' for social care, and database research

All applications to NHS RECs are made via online system, IRAS (Integrated Research Application Service).

Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health and social care / community care research in the UK.

There are 3 Social Care RECs in England. Social care research funded by the DH or the School for Social Care Research should be reviewed by the SCREC. It should be noted that the Social Care REC operates to a wider interpretation of 'research' than may apply in the NHS. For example, most service evaluations and certain types of audit would be accepted as suitable for review by the Social Care REC, whereas in the health sector such activity would not be considered as research. In Northern Ireland, however, it does if it involves residents or patients (or information about them) in or for the purpose of residential care homes or nursing homes in Northern Ireland. Nursing Homes Regulations (Northern Ireland) 2005.

Universities: If the study is carried out in non-NHS or social care settings, by academic staff or students, the investigator should seek a review from their university REC.

Some research – for example, non DH-funded social care research carried out by researchers not employed by local authorities or universities – has no immediate source of review.

Box 3: Ethical infrastructure and instructions for care home 'research' and 'innovation'

Under paragraph 2.3.9 of GAfREC [42], social care research **does not require review by a REC** within the UK Health Departments' Research Ethics Service **if it is reviewed by another committee operating in accordance with the Economic and Social Research Council's Framework for Research Ethics,** (for example, a University REC - UREC) unless the research involves deviating from standard social care or involves NHS patients or service users as research participants. Moreover, in Scotland, GAfREC does not normally require REC review of research in the social care settings. For care home research, NHS permissions will be required:

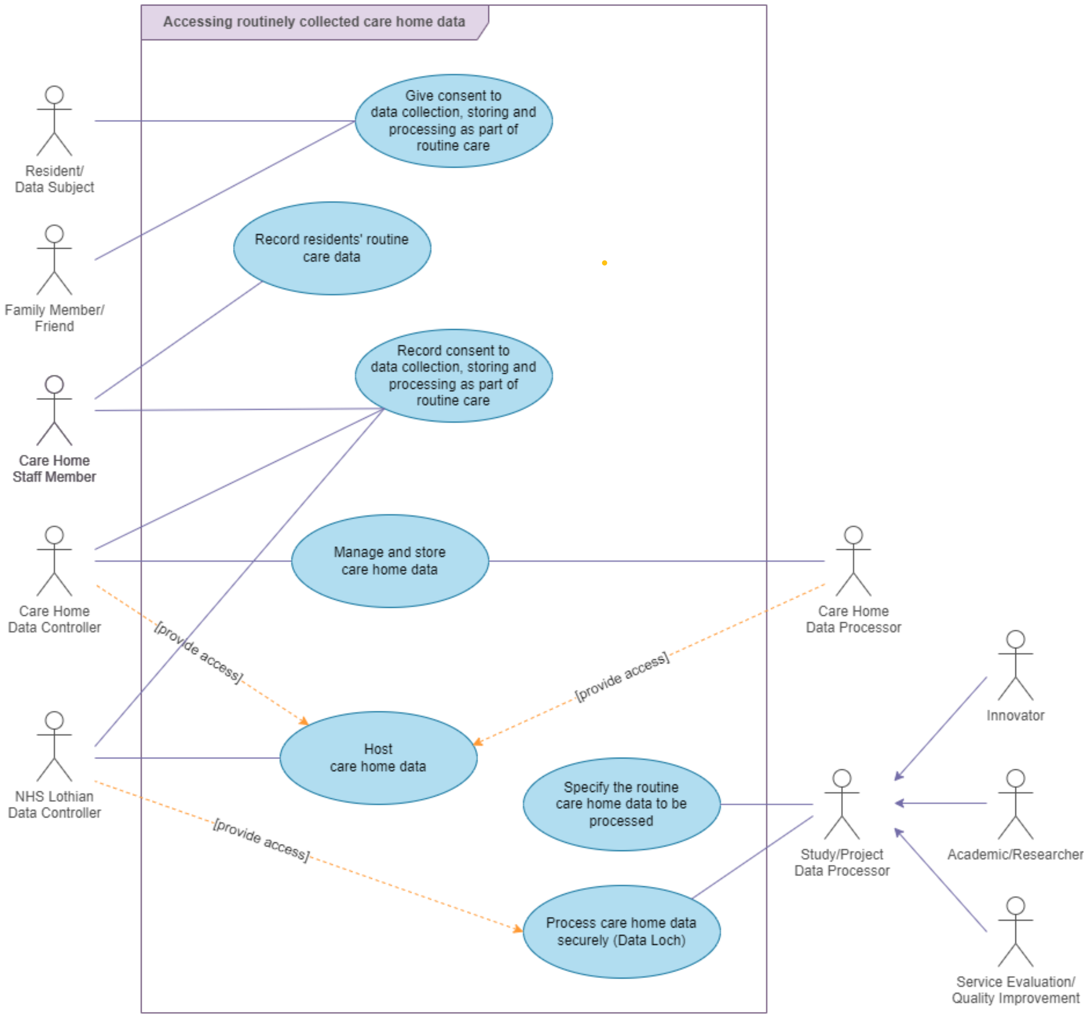
- if the care home residents are identified via the NHS, i.e. via their GP records or their secondary care records.
- if the care home study involved the delivery of an NHS intervention to a care home population.

Box 4: Governance arrangements for social care research and 'innovation'

APPENDIX TWO: High-level use case diagram

The notation follows the Unified Modelling Language (UML) standard, which is a common way of gathering and communicating user requirements in software development and has the following main components [43].

- **System boundary**: Represented as a rectangle, the system boundary depicts the scope of the system.
- **Use cases:** Visualised as horizontal ellipses, use cases describe high-level functionalities of the proposed system. Each use case represents a discrete unit of interaction between a user and the system.
- **Actors:** Visualised as stick men, actors represent stakeholder groups or entities (e.g. an organisation or another system) that use or interact with the system to perform a piece of meaningful work to achieve a goal.
- **Associations:** Visualised as solid lines, associations represent interactions between actors and use cases.



This Use Case Diagram sets out the data ownership, and data controller(s), when collecting data gathered in the provision of routine care, storing or hosting it within e.g. DataLoch (as an example TRE/Safe Haven) and how and when the end user (data processor being a researcher, innovator or NHS service evaluator/practitioner) is permitted to use the specified data.

Actor descriptions

Actor	Description
Resident/Data Subject	A resident of a care home whose data is collected and processed. The resident gives consent for their data to be recorded, accessed and shared by the Care Home Data Controller and/or the NHS Lothian Data Controller.
Family Member/Carer	A family member or carer who acts as a resident's legal representative if the resident lacks mental capacity to make their own decisions. The family member or carer may give consent for the resident's data to be recorded, accessed and shared by the Care Home Data Controller and/or the NHS Lothian Data Controller.
Care Home Staff Member	An employee of a care home who records and uses residents' data for the provision of the care home services. The employee may be a care home manager, support worker, nurse, or administrator. They may seek a resident's, or their legal representative's, consent for their data to be recorded, accessed and shared for the provision of the care home services.
Care Home Data Controller	The person or organisation responsible for ensuring that the collection and processing of data within a care home complies with the data protection law. They make sure that data is managed, stored and shared appropriately for the provision of the care home services. The Data Controller seeks a residents, or their legal representative's, consent for their data to be recorded, accessed and shared by the care home staff. They may also provide the NHS Lothian

	Data Controller access to the care home data.
Care Home Data Processor	A third-party person or organisation who processes the care home data on behalf of the Care Home Data Controller. For example, a care management software provider.
NHS Lothian Data Controller	The NHS Lothian data governance team, who acts as the Data Controller in the GEARed Up project. They are responsible for gaining access to the data from care homes and ensuring that it is stored and shared securely and in line with the data protection law. The NHS Lothian Data Controller provides the Data Processors access to the care home data.
Study/Project Data Processor	A third-party person or organisation who processes the care home data on behalf of the NHS Lothian Data Controller.
Innovator	A commercial company interested in using the care home data for innovation purposes.
Academic/Researcher	An academic team or researcher interested in using the care home data for research purposes.
Service Evaluation/Quality Improvement	A team or organisation interested in using the care home data for service evaluation or quality improvement purposes.

APPENDIX THREE: ENRICH Scotland Care Home Research Ethics Review Process

CARE HOME RESEARCH ETHICS REVIEW PROCESS

This guide has been developed to help researchers and students identify what type of ethics review is required when planning research in care homes.
Review by a Research Ethics Committee (REC) is necessary for projects that meet the definition of research outlined in the UK Policy Framework for health and social care research.

Social care research is research carried

NHS RECs accept applications for:

- Clinical trials testing devices, interventions and medicinal products.
- Analysis of previously collected data or tissue that could be identifiable.
- Studies involving unpaid carers that might identify care-dependent people through their use of health and social care services.
- Exceptional circumstances where staff participants could disclose identifiable and sensitive information that breaches confidentiality would require REC review.

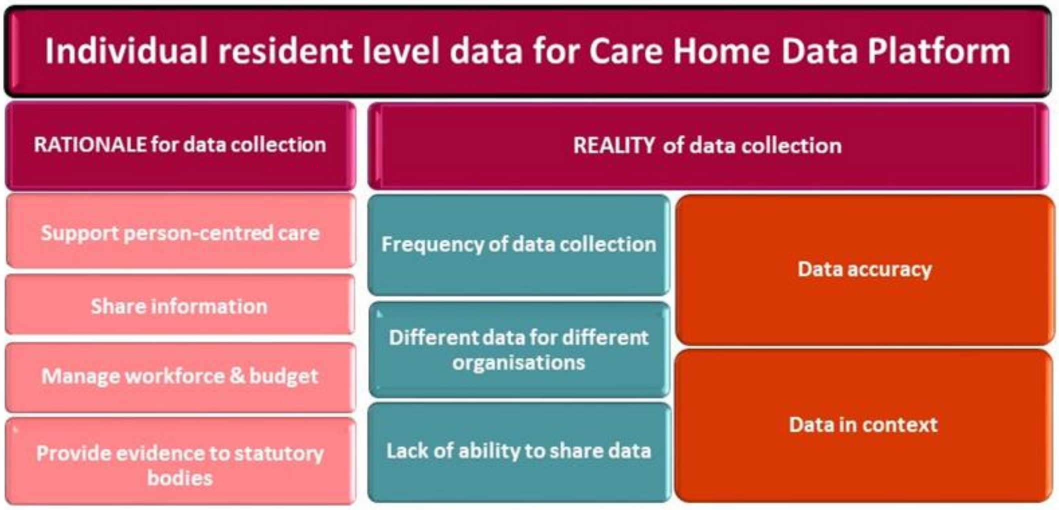
*NHS REC will review social care research that cannot be reviewed by a University or other suitable Research Ethics Committee, or social care research that involves deviating from usual care.

What about Patient and Public Involvement?

Preparatory Patient and Public Involvement (PPI) does not require a REC review. However, any PPI activities should be described fully to support the ethics review of a study.

ENRICH Scotland advise that all research studies involving care home staff, residents and/or their families be reviewed by a research ethics committee. The MRC REC Check is a useful tool for all health and social care researchers.

APPENDIX FOUR: Considerations for individual resident level data as the foundation for a Care Home Data Platform



References

[1] HISES Website: Care Home Data Platform Innovation Foundation Challenge. Available at: https://hises.edinburghbioquarter.com/care-home-innovation-challenge

[2] Scottish Government website: National Care Service. Available at: https://www.gov.scot/policies/social-care/national-care-service

[3] NHS Education for Scotland. National Digital Platform. Available at: https://www.nationaldigitalplatform.scot/

[4] Scottish Government. Digital Health and Care Strategy. Available at https://www.gov.scot/publications/scotlands-digital-health-care-strategy/documents/

[5] NHS National Services Scotland. Research, Development and Innovation Strategy 2021 – 2024. Available at: https://www.nss.nhs.scot/media/2465/rdi-report_final_06012022.pdf

[6] DataLoch website. Available at: https://dataloch.org/

[7] NHS Health Research Authority website. Available at: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/

[8] Scottish Government (2022). Mapping National Adult Social Care and Care Home Data Sources in Scotland. Available at: https://www.gov.scot/publications/mapping-national-adult-social-care-care-home-data-sources-scotland-baseline-understanding-future-potential-september-2022/documents/

[9] Gartner Glossary. Available at: https://www.gartner.com/en/information-technology/glossary/data-driven-innovation-ddi-

[10] NHS Scotland. NHS Recovery Plan 2021 – 2026. Available at: https://www.gov.scot/binaries/content/documents/govscot/publications/strategy-plan/2021/08/nhs-recovery-plan/documents/nhs-recovery-plan-2021-2026/nhs-recovery-plan-2021-2026/govscot%3Adocument/nhs-recovery-plan-2021-2026.pdf

[11] NHS Health Research Authority. How we're supporting data-driven technology. Available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/how-were-supporting-data-driven-technology/

[12] Burton, JK, Goodman, C, Guthrie, B, Gordon L, Hanratty B and Quinn, TJ (2020). Closing the UK care home data gap – methodological challenges and solutions. International Journal of Population Data Science, 5(4). Available at: https://doi.org/10.23889/ijpds.v5i4.1391.

[13] Williamson K, Nimegeer A, Lean M (2022). Navigating data governance approvals to use routine health and social care data to evidence the hidden population with severe obesity: a case study from a clinical academic's perspective. Journal of Research in Nursing. 27(7):623-636. Available at: https://doi.org/10.1177/17449871221122040

---

[14] NHS England – Transformation Directorate. A sea change in understanding the value of data. Available at: https://transform.england.nhs.uk/key-tools-and-info/data-saves-lives/improving-health-and-care-services-for-everyone/a-sea-change-in-understanding-the-value-of-data/

[15] Scottish Government (2018). Technology and innovation in health and social care. Available at: https://sp-bpr-en-prod-cdnep.azureedge.net/published/HS/2018/2/1/Technology-and-innovation-in-health-and-social-care/HSS052018R01.pdf

[16] Digital Health & Care Innovation Centre. Care Homes Assessment Tool Proof Of Concept Stage 2 Report – Executive Summary. Available at: https://strathprints.strath.ac.uk/81988/1/MacKenzie_etal_DHI_2022_Care_homes_assessment_tool_proof_of_concept_stage_2_report.pdf

[17] Ritchie LA, Gordon AL, Penson PE, Lane DA, Akpan A (2023). Stop and Go: Barriers and Facilitators to Care Home Research. J Frailty Aging. 12(1):63-66. Available at: https://doi.org/10.14283/jfa.2022.51

[18] Guthrie, B. Navigating blindfold in a blizzard: the invisibility of social care in routine data. The University of Edinburgh – Advanced Care Research Centre. Available at: https://www.ed.ac.uk/files/atoms/files/acrc_briefing_1_social_care_data.pdf

[19] Scottish Government. Data Strategy for Health and Social Care: Consultation Paper. Available at: https://www.gov.scot/binaries/content/documents/govscot/publications/consultation-paper/2022/05/data-strategy-health-social-care/documents/data-strategy-health-social-care-consultation-paper/data-strategy-health-social-care-consultation-paper/govscot%3Adocument/data-strategy-health-social-care-consultation-paper.pdf

[20] Scottish Care (2021). Seeing the diamond in social care data. Available at: https://scottishcare.org/wp-content/uploads/2021/06/Data-Report-Seeing-the-diamond-in-social-care-data.pdf

[21]. Future Care Capital. Taking Next Steps to Harness the Value of Health and Care Data. Available at: https://futurecarecapital.org.uk/research/22nd-may-2019-taking-next-steps-to-harness-the-value-of-health-and-care-data/

[22] Dvir, O, Wolfson, P, Lovat, L, Moskovitch, R (2020). Falls Prediction in Care Homes Using Mobile App Data Collection. In: Michalowski, M, Moskovitch, R (eds) Artificial Intelligence in Medicine. AIME 2020. Lecture Notes in Computer Science, vol 12299. Springer, Cham. Available at: https://doi.org/10.1007/978-3-030-59137-3_36

[23] NHS Health Research Authority. Research data and tissue resources. Available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-data-and-tissue-resources/

[24] NHS Research Scotland – information on ENRICH. Available at: https://www.nhsresearchscotland.org.uk/research-in-scotland/facilities/enrich

[25] NHS Health Research Authority. Social care research. https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/social-care-research/

[26] Woolham, J (2011). Research governance and ethics for adult social care research: procedures, practices and challenges. NIHR School for Social Care Research. Available at: https://www.sscr.nihr.ac.uk/wp-content/uploads/SSCR-methods-review_MR004.pdf

[27] Priscilla Alderson & Virginia Morrow (2006). Multidisciplinary research ethics review: is it feasible?, International Journal of Social Research Methodology, 9:5, 405-417. Available at: https://doi.org/10.1080/13645570500435207

[28] Dyer, S, & Demeritt, D (2009). Un-ethical review? Why it is wrong to apply the medical model of research governance to human geography. Progress in Human Geography, 33(1), 46–64. https://doi.org/10.1177/0309132508090475

[29] HRA Standard Operating Procedures for Research Ethics Committees v 7.5 March 2021. Available at: https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/RES_Standard_Operating_Procedures_Version_7.5_March_2021_Exported_from_pdf.pdf

[30] NHS Research Scotland. Data Safe Havens. Available at: https://www.nhsresearchscotland.org.uk/research-in-scotland/data/safe-havens

[31] Johnston L, Koikkalainen H, Anderson L, Lapok P, Lawson A, Shenkin SD (2022). Foundation Level Barriers to the Widespread Adoption of Digital Solutions by Care Homes: Insights from Three Scottish Studies. Int J Environ Res Public Health. 2022;19(12):7407. Available at: https://doi.org/10.3390/ijerph19127407

[32] Shenkin SD, Johnston L, Hockley J, Henderson DAG (2022). Developing a care home data platform in Scotland: a mixed methods study of data routinely collected in care homes. Age Ageing. 51(12):afac265. Available at: https://doi.org/10.1093/ageing/afac265

[33] Scottish Government. Information Governance Review – Executive Summary. Available at: https://www.gov.scot/publications/information-governance-review-executive-summary/

[34] Goldacre, B (2022). Better, Broader, Safer: Using Health Data for Research and Analysis. UK Government Department of Health & Social Care. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1067053/goldacre-review-using-health-data-for-research-and-analysis.pdf

[35] DACHA study website. Available at: http://dachastudy.com/

[36] Office for Statistics Regulation. Glimmers of light for adult social care statistics. Available at: https://osr.statisticsauthority.gov.uk/blog/glimmers-of-light-for-adult-social-care-statistics/

[37] Office of Statistics Regulation. Adult Social Care statistics in Scotland. Available at: https://osr.statisticsauthority.gov.uk/wp-content/uploads/2020/07/ASC_Scotland-1.pdf

[38] UK Government Department of Health & Social Care. A guide to good practice for digital and data-driven health technologies. Available at: https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology

[39] UK policy framework for health and social care research. Available at: https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/Final_Accessibility_uk-policy-framework-health-social-care-research_.pdf

[40] Data Protection Act 2018. Available at: https://www.gov.uk/data-protection

[41] GDPR Recital 26. Available at: https://gdpr.eu/recital-26-not-applicable-to-anonymous-data/

[42] Governance arrangements for research ethics committees: 2020 edition Available at: https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/GAfREC_Final_v2.1_July_2021_Final.pdf

[43] Britton, C. and Doake, J. (2005) A Student Guide to Object-Oriented Development. Butterworth-Heinemann, 1-9. https://doi.org/10.1016/B978-075066123-2/50001-3