16. Research data sharing

16.1 Introduction

This policy sets out the Trust's position on sharing data gathered for research studies set up within the scope of the UK Policy Framework for Health and Social Care research. That includes any database or registry generated from such studies that are shared either internally with other individuals or groups, or externally with other organisations. The policy defines those organisations with which the Trust is prepared to share such identifiable, pseudo-anonymised and anonymised datasets as it controls. It also defines the type of data the Trust is prepared to share and how we share that data. The policy also states that all such research databases must be reviewed by the JRMO.

The context for this policy is the Trust's commitment to improving patient care through the careful use of data collected for research purposes. The Trust will not share or disclose such data on an exclusive basis, nor will it enter into arrangements that grant third parties (commercial or non-commercial) exclusive access to the raw data that it holds (healthcare, research or operational) or include conditions limiting any benefits relating to that data that belongs to the Trust. The Trust will always endeavour to grant access only to anonymised or pseudo-anonymised data sets. The Trust already shares patient data with a range of external organisations and partners and internally amongst different parts of the organisation, applying a range of managed governance processes and procedures to do so

The Policy should be read in conjunction with the policies referenced above that deal with data protection and the standards all staff must adopt in the handling and management of information (data) about people, to ensure compliance with the General Data Protection Regulation and Data Protection Act, 2018, and in a research context, the UK policy framework for health and social care research 2017. It should also be read in conjunction with the Department of Health & Social Care Guidance, 'Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation', published on 15th July 2019. This guidance can be found on the UK Government website and its Guiding Principles are included at Appendix 1.

For clarity, this policy applies only to data for which Barts Health NHS Trust is the data controller. Where others are the data controller their policies will apply.

16.2. Scope

16.2.1 Data covered by this policy

This policy includes, but is not limited to, personal data in any form, including anonymised or pseudo-anonymised data and special category data (for example, race, health, genetics, ethnic origin, etc), that is collected during a research project, or during an activity that is ancillary to a research project or any associated activity that is conducted with or without ethical approval.

Appendix 2 sets out some examples where research data is already collected and stored in line with a variety of data management processes.

16.2.2 Data Sharing Partners

The Trust is committed to sharing data with external partners and amongst internal groups to provide an increased understanding of the conditions that our patients suffer from, acknowledging the potential benefits that accrue to our care systems from research conducted under required regulatory and security controls.

Specific partners the Trust is prepared to share data with include:

- Internal speciality groups at all Barts Health Sites
- Other NHS Trusts
- Primary Care organisations
- Higher Education Institutions
- Charities
- Government Departments
- Social and Community Services
- Commercial Entities
- Research Funders

Other institutional policies may preclude the sharing of data with several organisations, including, for example, companies engaged in the supply of tobacco products, certain market survey organisations, political lobbyists, etc. It is expected that the Trust's research project approval process, which includes approval at Speciality level and approval from Joint Management Research Office (JRMO), Health Research Authority (HRA) and/ or NHS regulated Ethics Committee, as applicable, will determine whether or not an entity is a suitable partner with which the Trust is prepared to share its patients' data.

16.3 Data Sharing

16.3.1 Data Sharing Modalities

How the Trust shares its data with external research partners will, to a degree, depend on the partner's organisational purpose and the kind of activity they are engaged in. For most research activities, data may only be shared when a clear purpose has been defined for data use and HRA/NHS Ethics approval obtained for the activity. This applies to data collections or registries for which the Trust is data controller, whether this is data collected during a wide range of research activities and held on a database, or data collected specifically for formulating a registry, under a specific NHS Ethics approval, or clinical service data that is collected for identifying new areas of research.

16.3.2 Data Sharing Formats

The Trust maintains the right to share its data either internally or with external organisations in a format that is acceptable to the Trust. It may decide that it is acceptable to share patient identifiable data with some partners but may wish to restrict data sharing arrangements to anonymised or pseudo-anonymised formats with certain categories of partners.

The following table sets out examples of the parameters within which the Trust is prepared to share data with research partners and the modality that must be employed to secure our patient data:

Partner Organisation	Data Format	Designated Purpose	Transfer/ access requirements
Internal speciality groups at all Barts Health Sites.	Open access to all contemporary patient records accessible on the Electronic Patient Record system or paper files.	Used solely for research purposes for a specific research project with JRMO Sponsorship review and HRA/ NHS ethics approval (as applicable) or transfer to registries with similar approvals in place.	Only the patient's direct care team can access patient records unless there is a Section 251 approval in place.
Other NHS Trusts and Primary Care Organisations	• Patient identifiable data • Pseudo-anonymised data • Anonymised data	Used solely for research purposes for specific research projects with NHS Ethics and/ or HRA approvals or transfer to registries with similar approvals.	Research referrals must be made by the direct care team and must have the written consent of the patient unless there is a Section 251 approval in place. The process is normally covered by the Sponsor's research project protocol or under research site Patient Identification Centre (PIC) arrangements. All data transfers must be covered by appropriate research or data sharing contract.
Higher Education Institutions	• Pseudo-anonymised data • Anonymised data	Patient data must only be used for specific research projects with HRA/ NHS ethics approvals or transfer to registries with appropriate ethics approval, to be used solely for research purposes.	Unless anonymised, the patient must have consented to possible non-specific data transfer taking place. Anonymisation must take place before data is transferred to HEI storage. Data must be kept for the duration of the research project and deleted on completion as set out in n accordance with the Trust's Records Retention and Disposal Policy. Data collected for inclusion in

Partner Organisation	Data Format	Designated Purpose	Transfer/ access requirements
			registries can only be transferred or shared with third-party organisations for research purposes. All data transfers to HEIs must be covered by appropriate research or data sharing contract. All data sharing contracts with Barts Health must be reviewed by the Trust's Information Governance team or the JRMO as applicable.
Charities; Social and Community services; and other non-commercial research Funders	• Pseudonymised/ Anonymised data	Patient data must only be used for specific research projects with HRA/ NHS ethics approvals or transfer to registries with appropriate ethics approval, to be used solely for research purposes.	Unless anonymised, the patient must have consented to possible data transfer taking place (non-specific). Anonymisation or Pseudonymisation must take place before data is transferred to the partner organisation. Data must be kept for the duration of the research project and deleted on completion in accordance with the Trust's Records Retention and Disposal Policy. Data collected for inclusion in registries can only be transferred or shared with third-party organisations for research purposes. All data transfers must be covered by an appropriate research or data-

Partner Organisation	Data Format	Designated Purpose	Transfer/ access requirements
			sharing contract. All data-sharing contracts with Barts Health must be reviewed by the Trust's Information Governance team or the JRMO as applicable.
Commercial Entities including pharmaceutical and devices companies, private research establishments and hospitals, data analyst organisations. (A list of potential commercial research partners is attached at Appendix 3)	• Pseudo-anonymised data • Anonymised data	Patient data must only be used for specific research projects with NHS ethics approvals or transfer to registries with ethics approval, to be used solely for research purposes.	As above for Charities; Social and Community services; and other non-commercial research Funders'. In addition, access to the Trust's patient records must be managed according to the protocols agreed between the Trust and Sponsor, which will be laid down in the research contract between the parties. It is acknowledged that sponsor representatives will be granted access to source data for monitoring and auditing purposes.
Government Departments	• Patient identifiable data • Pseudo-anonymised data • Anonymised data	Patient data must only be used for specific research projects with NHS ethics approvals or transfer to registries with ethics approval, to be used solely for research purposes. Access to patient identifiable records and source documentation is restricted to regulatory authorities with a legal right to access such data.	As above for 'Charities; Social and Community services; and other non-commercial research Funders'. In addition, access to the Trust's patient records must be managed according to the protocols agreed between the Trust and regulators and in accord with the regulator's legal responsibilities in handling such data.

16.3.3 Data Transfer and Storage

Methods for transferring data from Trust systems and locations to other internal or external are covered by the Trust's Information Security policy. All agreements and contracts covering research activities that involve the transfer of data must reference the standards set out in the Trust's data management policies and undergo review by the Trust's Data Protection Officer or the JRMO as applicable.

16.3.4 Approved use under this policy

Each data sharing agreement or research contract will determine, on a case-by-case basis, the use to which patient data can be put. The assumption shall be that, unless a Section 251 approval is in place, a patient is fully informed, explicit consent will be required to participate in the proposed research project and before data is accessed and transferred to partner organisations. This means that the patient should be made aware of the purpose, nature and scope of the research, including the partner organisations with whom the data will be shared. Given consent should be formally recorded. Patients should also be informed that they have the right to withdraw their consent for any further research participation should they wish to do so. Both the Trust and its research partners should have sufficient arrangements in place to facilitate the withdrawal of consent if required, and where appropriate, delete the data held. There are instances where right of erasure does not apply if processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority. This means that less reliance should be placed on consent as the lawful bases for processing.

For information on the NHS National opt our please refer to JRMO policy on consent.

Anything that falls within the scope of the UK policy framework for health and social care is a permitted use, which includes:

- Clinical trials
- Research registries, Trust managed and registries to which our data has been transferred.
- Non-commercial tissue banking activities.
- Genome and other "omic" databases.
- Basic science research studies that include the collection of data for analysis that supports the examination of tissue or other human materials.
- Prospective or retrospective research surveys.

16.3.5 Management of Data

In all cases, the Trust will ensure that suitable arrangements are in place for the transfer, storage and ongoing management of shared research data. Internal registries, databases and data collections in any form that contain patient information in identifiable, anonymised or pseudo-anonymised formats must be notified to the Trust's Information Governance Team who will maintain a register of all data stores and their permitted uses.

In entering agreements with external organisations, the Trust will ensure that research contracts or data sharing agreements comply with the permitted uses set out in this policy and the Trust's rules on transferring and storing personal data.

The Trust will not enter into arrangements that grant third parties (commercial or non-commercial) exclusive access to the raw data that it holds (healthcare, research or operational) or include conditions limiting any benefits relating to that data that accrue to the Trust.

16.4. Definitions

Anonymised data: Data that is unrecognisable, even to the data owner. It cannot be re-identified by referring to the study ID or by processing it together with other information which is available or likely to be available. (See Recital 26, GDPR)

Direct Care Team: Those health and social care professionals who provide direct care to the patient, and others, such as administrative staff, who directly support that care. (See Policy 9)

Pseudonymised data: Identifiable data that has been replaced with alternative identifiers that bear no overt relationship to the true values. Re-identification of data can only be achieved with knowledge of the de-identification key. (See Article 4, GDPR)

Registry: A collection of information about individuals usually focused on a specific diagnosis or condition. Many registries collect information about people who have a specific disease or condition, while others seek participants of varying health status who may be willing to participate in research about a particular disease. Individuals provide information about themselves to these registries voluntarily. Registries can be sponsored by a government agency, HEIs or a non-commercial organisation, a healthcare facility, or a private company (United States National Institute for Health).

Research sponsor(s): An individual, company, institution, organisation or group of organisations that takes on responsibility for initiation, management and financing (or arranging the financing) of the research (NHS Health Research Authority).

Section 251 approvals: Section 251 of the NHS Act 2006 (originally Section 60 of the Health and Social Care Act 2001) provides the statutory power to ensure that NHS patient identifiable information needed to support essential NHS activity can be used without the consent of patients. The power can be used only to support medical purposes that are in the interests of patients or the wider public, where consent is not a practicable alternative and where anonymised information will not suffice. Separate arrangements are in place in Scotland and Northern Ireland, see Central NHS and other data approvals for further information. In England and Wales, Section 251 approval provides a reliable basis in law to permit the disclosure and temporary use of identifiable NHS patient information for those either wishing to obtain identifiable NHS patient information without consent, or data controllers who are asked to supply identifiable patient information without consent.

16.5. Duties and responsibilities

All staff working in the Trust	All staff working in the Trust are expected to comply with this policy.
Managers	Clinical Board Directors of Research, Joint Research Management Office Managers and Clinical Leads managing research groups must ensure that their staff comply with this policy.
Other posts	All staff involved in the delivery of research, including medical

	personnel, research nurses, data managers and processing staff will have specific duties under the protocols that govern the conduct of each research project, which will include sharing information with external sponsors of research.
Committees	The Trust Research Board will monitor the implementation of this policy and its regular review, in line with its remit to oversee all research in the Trust, following the UK policy framework for health and social care research 2018, GCP regulations and all other statutes and regulations that pertain to research.
Research staff working at Queen Mary University of London	All staff working in the University who have access to Barts Health patient data of some form must adhere to this policy and ensure they are compliant with it.

APPENDICES

Appendix 1: Guiding Principles

These are taken from the Department of Health & Social Care Guidance, 'Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation', published 15 July 2019.

Principle 1

Any use of NHS data, including operational data, not available in the public domain must have an explicit aim to improve the health, welfare and/or care of patients in the NHS, or the operation of the NHS. This may include the discovery of new treatments, diagnostics, and other scientific breakthroughs, as well as additional wider benefits. Where possible, the terms of any arrangements should include quantifiable and explicit benefits for patients which will be realised as part of the arrangement.

Principle 2

NHS data is an important resource and NHS organisations entering into arrangements involving their data, individually or as a consortium, should ensure they agree to fair terms for their organisation and the NHS as a whole. In particular, the boards of NHS organisations should consider themselves ultimately responsible for ensuring that any arrangements entered into by their organisation are fair, including recognising and safeguarding the value of the data that is shared and the resources which are generated as a result of the arrangement.

Principle 3

Any arrangements agreed by NHS organisations should not undermine, inhibit or impact the ability of the NHS, at a national level, to maximise the value or use of NHS data. NHS organisations should not enter into exclusive arrangements for raw data held by the NHS, nor include conditions limiting any benefits from being applied at a national level, nor undermine the wider NHS digital architecture, including the free flow of data within health and care, open standards and interoperability.

Principle 4

Any arrangements agreed by NHS organisations should be transparent and communicated clearly to support public trust and confidence in the NHS and wider government data policies.

Principle 5

Any arrangements agreed by NHS organisations should fully adhere to all applicable national-level legal, regulatory, privacy and security obligations, including in respect of the

National Data Guardian's Data Security Standards, the Data Protection Act, 2018, the General Data Protection Regulation (GDPR) and the Common Law Duty of Confidentiality.

Appendix 2: Examples of where research data is already collected

- The collection and storage of samples in national or local biobanks with associated anonymised data, for example the 100k Genome project.
- The collection of data for externally sponsored commercial or non-commercial clinical trials where data is collected and stored via sponsors electronic case report forms and stored in accordance with MHRA or other regulatory bodies' rules and regulations.
- A wide variety of organisations collect patient data via Barts Health participation in ethically approved national data collection projects, with data stored in managed registries. These include government organisations such as NHS Digital (via is ODS), The National Cancer Registration and Analysis Service, charities such as the National Irritable Bowel Registry, several Royal Colleges and a range of other not for profit organisations.
- The Picture Archiving and Communication Systems (PACS). This is a system based on the universal (Digital Imaging and Communications in Medicine) standard, which uses a server to store and allow facile access to high-quality radiologic images, including conventional films, …

Appendix 3: Potential commercial research partners

Companies that sponsor clinical trials of medicinal products and devices.

1. Companies involved in the collection of data for sale or distribution to pharmaceutical and device companies or other organisations for purposes that include the development of software applications that create clinician and patient benefits.
2. Application development companies that work with our clinicians to build patient-based apps for diagnostic or treatment purposes.
3. Companies that work on the development of new diagnostics.
4. Commercial entities involved in the use of artificial intelligence to develop new treatment modalities.
5. Companies involved in the development of research registries or other data stores that are accessible for a fee.
6. Providers of Internet-related services and products, which include online advertising technologies, search engines, cloud computing, software, and hardware.
7. Companies providing interactive computer-mediated technologies that facilitate the creation and sharing of information, ideas and other forms of expression, via virtual communities and networks.

This policy applies only to Barts Health.