9. Use of participant information for research

9.1 Background

The UK General Data Protection Regulation (GDPR)[1], Data Protection Act 2018[2], Caldicott Report[3], UK policy framework for health and social care research, 2017[4], ICH-GCP[5], funding and professional bodies[6] have all issued guidance on how patient information for research should be gathered, handled, stored and disclosed.

The purpose of this policy is to ensure that Barts Health and Queen Mary staff undertaking research that uses research participant information are aware of their responsibilities concerning the use of existing medical records, as well as the creation of a new hard copy or electronic patient records for research.

9.2 The Policy

This policy covers the following areas:

(i) Use of existing records to identify or enrol participants in a study.

(ii) Obtaining and storing participant data for research, or retrospective note-based studies.

(iii) The compilation, handling, audit and storage of research documentation utilised for research.

(iv) New or existing electronic files of research participant information for research.

General Guidelines

- Data must be kept and shared in keeping with the details supplied in the original ethics application.

- Organisations outside Barts Health, including Queen Mary, wishing to access personally identifiable data for research must comply with Barts Health Information Governance, confidentiality and information security policies.

- Only members of the patient's care team should have access to patient records and make first contact with patients before any consent being taken (except for section 251 exemption).

---

[1] UK GDPR

[2] Data protection laws.

[3] Caldicott Committee (2013) Report on the Review of Patient - Identifiable Information

[4] Department of Health (2004) Research Governance Framework for Health & Social Care, 2017 and The Department of Health (2003) Code of Confidentiality.

[5] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996.

[6] MRC Guidelines for Good Clinical Practice in Clinical Trials, 1998. Safeguarding Good Scientific Practice (1998) Joint Statement by the Director General of the Research.

- Participant information used for research whether it is existing records or records created purely for research must conform to accepted standards laid out by the Health Research Authority (HRA), EU and UK law, professional bodies and funding organisations regulations. All staff must make sure that they are aware of these standards before commencing a research project.

- Costs of providing a Medical Records and Archiving Service must be included in the research project costing for externally funded research.

- The confidentiality of records that could identify individual participants should be protected. Where data is needed for research investigators should comply with data protection principles, specifically the principles of:

    - Lawfulness, fairness and transparency.
    - Purpose limitation.
    - Data minimisation.
    - Accuracy.
    - Storage limitation.
    - Integrity and confidentiality (security)
    - Accountability.

- Records made for one purpose, such as the provision of care, should not usually be disclosed for another purpose without the patient's consent. Investigators asked to supply participant information for research should assure themselves that the patient has given explicit consent wherever this is practicable.

- Where it is not practical for the person that holds the records to obtain consent or to de-identify records, data may be supplied for research. However, participants must be informed that:

    - Their records may be disclosed to persons outside the team which provided their care.
    - The purpose and extent of the disclosure.
    - That the person given access to the records is bound by confidentiality.
    - That they have a right to object and their objection will be respected unless there is a significant public interest to be served.
    - They can opt-out from the use of their data for research or planning purposes, in line with the recommendations of the National Data Guardian. They can view or change their national data opt-out choice at any time.

- Where the intention is to access confidential patient information without consent or by staff who are not members of the patient's care team in England and Wales, Confidentiality Advisory Group (CAG) approval must be in place before records are accessed. CAG application forms will also require Caldicott authorisation.

- Where a clinician or an academic controls access to personal information on research participants they must not allow access to any staff member unless they are members of the patient's care team and:

    - The person has been properly trained.
    - Appropriate ethical and Barts Health/ Queen Mary approval has been obtained.

- The person is subject to a duty of confidentiality Records used for research are NOT the property of the Investigator or researcher but the property of the sponsor or institution. They must, therefore, be stored, handled and reported in a way that means they are accessible to:

    - Other clinicians responsible for the care of the patient.
    - Monitors from approved regulatory, funding and sponsor organisations.
    - Other academics or academic organisations who, under funding body rules, have a use for the base data collated by Queen Mary or Barts Health researchers for future research projects[7].

- All records used for research must conform to The National Health Service Litigation Agency (NHSLA) Risk Management Standards[8], Barts Health and Queen Mary Information Security and Management Policies.

- All research projects submitted to JRMO will be reviewed to ensure consistency with data protection laws and local policy requirements[9]. They will also receive a review by the Health Research Authority who check for compliance against all data protection laws.

- Researchers must conform to Barts Health and Queen Mary data protection policies and should seek guidance, when required, from the JRMO and Barts Health and Queen Mary Information Governance teams.

Patient's care team

- For the purposes of this policy, the definition of "care team" is that used by the Health and Research Authority and come from The Information Governance Review in 2013 by the National Data Guardian which stated that 'direct care is provided by health and social care staff working in 'care teams', which may include doctors, nurses and a wide range of staff on regulated professional registers, including social workers, care teams may also contain members of staff, who are not registered with a regulatory authority, but who may need access to a proportion of someone's personal data to provide care safely'.

---

[7] UK Research Councils (UKRC) policy on Research data-sharing – information can be found at https://www.ukri.org/funding/information-for-award-holders/data-policy/ . An example of a specific policy is the MRC policy on Data Sharing September 2011

[8] NHSLA Risk Management Standards 2012-13, Organisational Policies and Procedures.

[9] Barts Health NHS Trust Data Protection Policy Queen Mary Data Protection Policy

- To ensure compliance with this definition, individuals may be required to evidence all the following criteria:
  - Staff members must have a contract (which could be honorary) with Barts Health;
  - Line manager determines the level of Barts Health statutory and mandatory training that must be completed commensurate to the type of access required
  - Oversight by a line manager, who holds a contract with Barts Health, to ensure all appropriate training/supervision is in place to deliver the role;
  - An appropriate level of competency in their role as determined by line manager; and
  - Line manager's confirmation that the individual meets the above criteria.
- For clarity, the line manager has the ultimate responsibility for ensuring staff members fall within a patiet's care team. The line manager ideally should be substantively employed by Barts Health but a clinical honorary contract will suffice.
- If the above criteria cannot be met then CAG Approval must be sought before any patient approach is made or patient data is accessed.
- A DPIA for this approach to the role of the patient's direct care team in research (outlining the above) have been approved by the Information Governance Committee and Trust Data Protection Officer in December 2020.

Use of Barts Health Medical Records Service

- Medical Records will only be supplied for research that has appropriate ethical and Barts Health/ Queen Mary approval, following completion of the Request for Access to Patient records form.

- All research that uses Barts Health patient records or includes volunteers must be formally registered with the JRMO for internal review and the subsequent approvals process.

- All requests for records for research should supply the name and contact details of a person who will be responsible for their safekeeping.

- Research staff must give adequate notice of the need for records to be traced and pulled, particularly where large numbers of records are involved. Records should then be viewed in a secure area.

- Where a large number of records are required, they should be requested in batches to avoid compromising access to patient data for the purposes of service or audit.

- Records must be returned to the Health Records Department as soon as possible and NOT passed onto other staff or departments without appropriate documentation being completed which will allow onward tracing.

- Patients have the right to expect that staff will adhere to approved standards for maintaining confidentiality. Records must be stored securely during their use in research and not left in areas where there is public access.

This policy applies to both Barts Health and Queen Mary.