

## **1. Introduction**

1.1 The national data opt-out was introduced on 25<sup>th</sup> May 2018 enabling patients to opt out from the use of their data for research or planning purposes in line with the recommendations of the National Data Guardian in her review of Data Security, Consent and Opt-outs.

The deadline for NHS Trusts to become compliant with the national data opt-out is 31st July 2022. Essentially this means that to comply with the national opt-out policy University Hospitals of Leicester NHS Trust Research and Innovation must put in place procedures to review uses or disclosures of confidential patient information.

1.2 The National data opt-out [operational policy guidance document](#) details when the policy must be applied. It also details exemptions where it does not apply.

1.3 The national data opt-out policy is aligned with the authorisation used for sharing a patient's data in accordance with the common law duty of confidentiality. The national data opt-out applies unless there is overriding public interest for the data to be shared. The opt-out does not apply when the individual has consented to the sharing of their data or where the data is anonymised in line with the Information Commissioner's Office (ICO) Code of Practice on Anonymisation.

1.4 The percentage of patients who have chosen to opt out by region can be seen here: [National Data Opt-Out open data dashboard - NHS Digital](#)

1.5 Additional information is also available via <https://digital.nhs.uk/services/national-data-opt-out>

## **2. Scope**

This SOP applies to all individuals conducting research where the National Data Opt Out applies.

## **3. How Do I Apply Data Opt-Out**

3.0.1 A process to enable 'data opt-out' has been implemented by UHL R&I. The process will be managed by R&I as confirmation that the appropriate governance steps have been taken is required by UHL Information Governance Steering Group (UHL Privacy mailbox: [PrivacyandCompliance@uhl-tr.nhs.uk](mailto:PrivacyandCompliance@uhl-tr.nhs.uk)). The process will be documented using the R&I EDGE Database. A report will be provided to UHL Privacy on a monthly basis detailing studies that have requested a check. The report will also be appended to reports tabled at the monthly R&I Governance meeting.

### **3.1 When Does the Data Opt-Out Policy Apply**

3.1.1 The opt-out policy applies to data that originates within the health and adult social care system and to organisations that subsequently process this data for purposes beyond individual care. Any individual with an NHS number is able to opt-out. The opt-out is stored against their NHS Number on the 'Spine'.

3.1.2 NHS Digital and Public Health England are compliant with this policy.

3.1.3 The data opt-out process must be used in the following circumstances:

- Confidentiality Advisory Group approval is being sought – in cases where Section 251 exemption for consent is sought although there are a few exceptions which can be found on page 11 here: [NationalDataOptOutPolicy\\_v4.0.pdf](#). 'Section 251' is a short-hand term, and refers to section 251 of the National Health Service Act 2006 and its current

Regulations, the Health Service (Control of Patient Information) Regulations 2002. Section 251 enables the common law duty of confidentiality to be temporarily lifted so that confidential patient information can be transferred to an applicant without the discloser being in breach of the common law duty of confidentiality.

- When manually conducting searches on UHL patients to provide data for NHS Digital / Public Health approved research.

### **3.2 Process to comply with opt-out policy**

**3.2.1** In order to comply with the opt-out policy, a ‘NHS Spine’ search must be carried out before the research is carried out. A search on the ‘NHS Spine’ will be done via the MESH system. R&I have access to the MESH system and will carry out the search on your behalf. The list of names and corresponding NHS numbers will be provided from the search done in 3.2.1.

**3.2.2** The researcher must provide a full list of individual names and corresponding NHS Number must be provided in MS EXCEL format to the R&I Office using [RIData@uhl-tr.nhs.uk](mailto:RIData@uhl-tr.nhs.uk). The R&I Office will conduct the MESH search and provide a ‘cleaned’ copy of the data search back to the research team. The ‘cleaned’ copy will have removed all individuals who have exercised their right to ‘opt-out’. A record of the search will be captured on the R&I EDGE Database. A report detailing all MESH searches will be provided via the R&I Governance meeting on a monthly basis, and copied to UHL Information Governance (UHL Privacy mailbox: [PrivacyandCompliance@uhl-tr.nhs.uk](mailto:PrivacyandCompliance@uhl-tr.nhs.uk)) for information.

### **3.3 When the data opt-out policy doesn’t apply**

**3.3.1** The opt-out does not apply when the individual has consented to the sharing of their data, or where data is anonymised in line with the Information Commissioner’s Office (ICO) Code of Practice on Anonymisation.

**3.3.2** In certain scenarios, researchers may need to access confidential patient information to identify people with particular conditions to invite them to take part in clinical trials and other interventional studies. This process is often referred to as seeking ‘consent to contact’. Established mechanisms for identifying potential research subjects have been set out in the [2013 IG Review](#) and the application of the national data opt-out is summarised below:

#### **3.3.3**

Mechanism for identifying the cohort for a research study	National data opt-out applies?
The researcher gains the explicit consent of every patient with a record in the population pool being assessed. (Research databases where patients have previously consented to be approached)	No
The search is conducted by a health or social care professional who has a ‘legitimate relationship’ with the patient, such as a clinician or social worker. This would also include where data is provided to a researcher in fully anonymous form.	No
The search is conducted by a member of the research team who is also part of the immediate clinical team – NB: For the purposes of governance, UHL research staff are considered to be embedded within clinical teams and are therefore regarded as ‘part of the clinical team’.	No
The search makes use of ‘privacy enhancing technologies’ – analytical computer software that can trawl clinical databases, selecting only those patients who are eligible for a specific study, and only reveal the identities of potential participants to someone with a legitimate relationship to the patient e.g. clinician. (UHL Use TriNetX)	No

#### **4. Responsibilities**

	Responsibility	Undertaken by	Activity
1.	R&I Corporate	R&I Office	Advise location of tool links
2.	R&I Corporate	R&I Office	Where necessary provide information on next steps on audit, SE or research processes.

#### **5. Who Guideline Applies To**

All staff within UHL and external to UHL who are delivering research.

#### **6. Guideline Standards and Procedures**

No supporting flowchart is required / provided.

#### **7. Education and Training**

This SOP will be widely circulated and advice will be available from the UHL Privacy Team.

#### **8. Monitoring and Audit Criteria Compliance**

All guidelines should include key performance indicators or audit criteria for auditing compliance,

Key Performance Indicator	Method of Assessment	Frequency	Lead
Research requiring MESH	Recording of MESH requests	Monthly	R&I DCOO

#### **9. Supporting Documents and Key References**

- [NationalDataOptOutPolicy\\_v4.0.pdf](#)
- [2013 IG Review](#)
- <https://digital.nhs.uk/services/national-data-opt-out>

#### **10. Key Words**

National, Opt-out, Privacy, Section 251, CAG, Confidentiality Advisory Group, Research, MESH

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