

1. Introduction

1.1 The national data opt-out was introduced on 25th 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.

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

A process to enable 'data opt-out' for research is managed by R&I, ensuring that the appropriate governance steps required by UHL Information Governance Steering Group have been taken (UHL Privacy mailbox: infogov@uhl-tr.nhs.uk).

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 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.

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.

3.2.2 The researcher must provide a full list of NHS Numbers in MS EXCEL format to the R&I Office using RIData@uhl-tr.nhs.uk. The R&I Office will conduct the MESH search and provide a 'clean' copy of the data search back to the research team. The 'clean' 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.

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

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	When requested	R&I

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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