**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Data Opt-Out Policy and Guidance**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Introduction**

**Data Opt-Out**

The National Data Opt-Out applies to the disclosure of Confidential Patient Information (“CPI”) for the purposes beyond individual care across health and adult social care systems in England.

National data opt-outs apply to a disclosure when an organisation such as a research body confirms they have obtained an approval from the [Confidentiality Advisory Group](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/) (CAG) for the disclosure of CPI held by another organisation responsible for the data (the data provider) such as an NHS Trust or a Local Authority.

A CAG approval is an approval made under section 251 of the NHS Act 2006 and its current regulations, the Health Service (Control of Patient Information) Regulations 2002, which enable the common law duty of confidentiality to be temporarily lifted so that CPI can be disclosed without the data provider being in breach of the common law duty of confidentiality. In practice, this means that the person responsible for the information (data provider) can, if they wish, disclose the information to the data applicant e.g. research body without being in breach of the common law duty of confidentiality.

It is only when a section 251 is relied on to obtain CPI that national data opt-outs apply. National data opt-outs do not apply where information being disclosed is anonymised in accordance with the Information Commissioner’s Office (ICO) anonymisation code of practice or the individual has given their consent for their information to be used for a particular purpose, for example a specific research study.

Where a patient has set a National Data Opt-Out it does not stop that patient from giving their consent for a specific use of their data. It is important that patients continue to be offered the opportunity to participate in medical research studies, provided this is done in a way that does not breach their confidentiality, i.e. it addresses the Common Law Duty of Confidentiality.

This document provides operational guidance to understand the application of National Data Opt-Out policy for practical purposes.

People who use health and social services can set an Opt-Out via several channels that include online, digitally assisted and non-digitally assisted channels.

Any person who uses health and social services and has an NHS number is able to set a National Data Opt-Out. The Opt-Out is stored in a central repository against their NHS number on the NHS Spine and is not set or visible at practice level. The National Data Opt-Out will also continue after the patient’s death.

Sandwell Council is compliant with the Opt-Out in line with the Council’s Data Security and Protection toolkit.

**What are National Data Opt-Outs**

Sandwell Council follows the Data Opt-Out process implemented by the [National Data Guardian’s Review of Data Security, Consent and Opt-Outs](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/535024/data-security-review.PDF).

The review stipulates that they should be

* consent, and
* an Opt-Out model to allow people to Opt-Out of their confidential and personal date being used for purposes beyond direct care

**The Councils application of the National Data Opt-Out**

Health and social care are required to apply the national data Opt-Outs in line with the NHS National Data Opt-Out Policy. NHS Digital had developed a technical service which enables health and adult social care to check if the people who use their services have Opted-Out in order to enable them to only disclose the CPI of individuals who have either consented or have not elected to Opt Out. . This service will only be sued in the following way:

* Organisations submit a list of NHS numbers that they need to disclose, and the service looks these up against the central repository of national data opt-outs. It returns a cleaned list of those that do not have a national data Opt-Out i.e. it removes the NHS numbers for those with a national data Opt-Out. This is most suitable for one -off and infrequent disclosures of data.

**NHS Data Opt Out Process Map**



**NHS Data Opt Out Process Steps**

|  |  |
| --- | --- |
| **Process Step** | **Responsibility** |
| 1. Decision is made using the guidance that the data will be used for research purposes and the NHS Data Opt Out process needs to be followed | Adults Social Care |
| 1. Call is logged on the Adults ICT Helpdesk using the Category “LAS NHS Data Opt Out” | Adults Social Care |
| 1. Helpdesk System will send automated email to Assistant Director of Adults Social Care to approve the request | Assistant Director of Adults Social Care |
| 1. If request is approved the Systems Team will send Email Notification sent to [Info\_Governance@sandwell.gov.uk](mailto:Info_Governance@sandwell.gov.uk) to allow them to be aware a request has been made. | Systems Team |
| 1. Systems Team will request Data Cohort from Requester | Systems Team |
| 1. Systems will Request Via MESH System Details of Records which are Flagged for NHS Data Opt Out | Systems Team |
| 1. List of Records Flagged for NHS Data Opt Out Supplied to Requester | Systems Team |
| 1. Notification Sent to [Info\_Governance@sandwell.gov.uk](mailto:Info_Governance@sandwell.gov.uk) that NHS Data Opt Out details have been supplied | Systems Team |

**What data falls within the Data Opt-Out?**

The opt-out only applies to Confidential Patient Information (CPI) - data that includes both:

* information that identifies or could be used to identify the service user
* information about their physical or mental health, care or treatment

And is given in circumstances where the individual is owed an obligation of confidence.

The Opt-Out does not apply to data that has been anonymised in line with the ICO guidance.

**Exceptions on data Opt-Out**

**Invoice validation:**

Data Opt-Out does not apply to invoice validation. It specifically does not apply to invoice validation for non-contracted activity. For contracted activity anonymised data should be used.

The Opt-Out does not apply where the person who uses services has given their explicit consent for use of their data for payment and invoice validation.

**Risk Stratification**

* National data Opt-Outs do not apply to risk stratification for case finding where carried out by a provider for individual care as this should be treated an individual care.
* National data Opt-Outs do not apply where the data for risk stratification is anonymised in line with the ICO Code of Practice and Anonymisation.
* National data Opt-Outs do apply to data disclosures for the risk stratification which rely on section 251 support unless the standard condition requiring patient Opt-Outs to be respected is waived.

**What data is not affected?**

**Communicable disease and Risk to Public Health**

The national data Opt-Out does not apply to the disclosure of patient information required for monitoring and control of communicable disease and other risks to public health. This includes any data disclosed where Regulation 3 of The Health Service Regulations 2002 provides the awful basis for common law duty of confidentiality to be lifted. (*Section 251, pg4*)

**Public Interest**

The national data Opt-Out does not apply to the disclosure of confidential information of the person who uses health and social care services where there is an overriding public interest in the disclosure.

**Direct Care**

The national data Opt-Out does not apply to direct care as mentioned earlier in the policy.

**Consent**

The data Opt-Out does not apply where explicit consent has been obtained from the person who uses health and/or social care services, for a specific purpose. This might include a person previously opted out but wishes for the data to be processed for a specific purpose The consent would override the national data Opt-Out and data would be processed for that specific purpose only. Other information that is not covered by the explicit consent would still be subject to the Opt-Out if applied.

**References**

The National Data Opt-Out Policy and Guidance Document

General Data Protection Regulations

Data Protection Act 2018

Freedom of Information Act 2000 (FOIA)

|  |  |
| --- | --- |
| Author: | Sitabile Pswarayi |
| Owner: | Graham Terry |
| Version: | 1 |
| Modified by | Vanessa Mahersmith, Binda Rana |
| Date: | 31.3.22 |
| Review Date: | 1.3.2023 |