

## National Data Opt-out SOP

Issue Date	Review Date	Version
November 2019	November 2024	1

### Purpose

To ensure the Trust complies with:

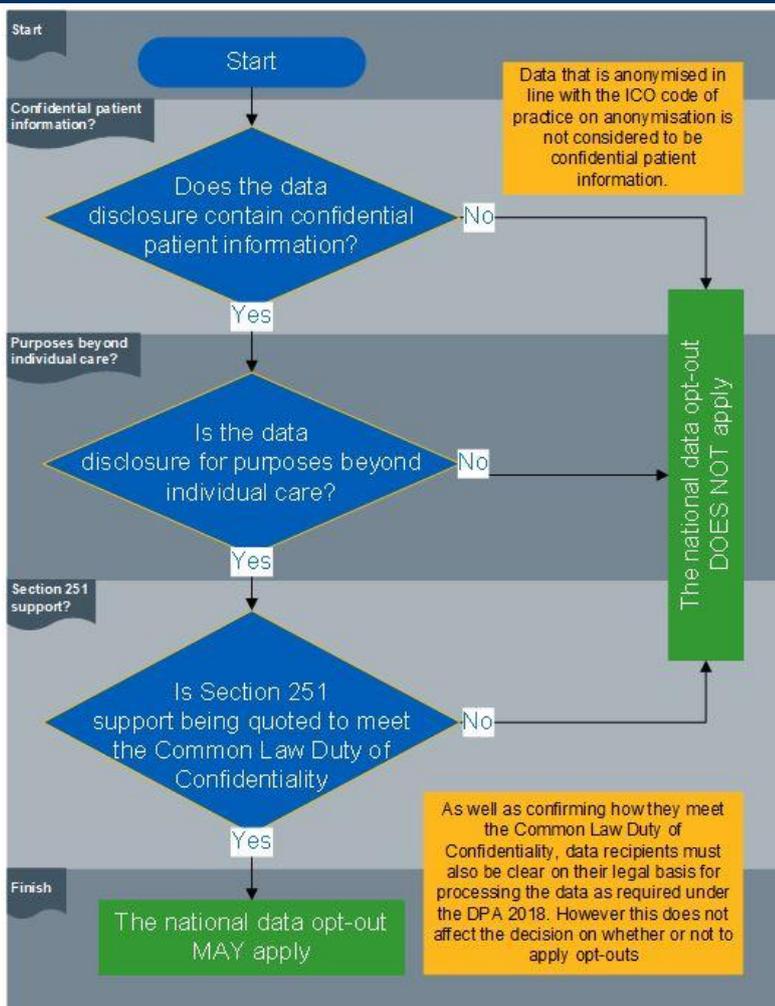
- NHS Digital(X) Information Standard *DCB3058 Compliance with National Data Opt-outs*  
[compliance-with-national-data-Opt-outs](#)
- [Data Security and Protection toolkit](#) for 2019/20.

### Who should read this document?

Staff responsible for Confidential Information Data Flows out of the Trust which;

- Are not for Direct Care
- Rely on Section 251 of the NHS Act 2006 and its current Regulations, the Health Service (Control of Patient Information) Regulations 2002 (Reg 2 or 5)

### Key Messages



Core accountabilities		
Owner	Head of Information Governance/Data Protection Officer	
Review	Caldicott and Information Governance Assurance Committee	
Ratification	Director of Corporate Business/Senior Information Risk Owner	
Dissemination (Raising Awareness)	Head of Information Governance/Data Protection Officer	
Compliance	Head of Information Governance/Data Protection Officer	
Links to other policies and procedures		
Information Governance Policy		
Data Protection SOP		
Confidentiality SOP		
Version History		
1	August 2019	Initial Draft and ratified by Director of Corporate Services

*The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.*

**An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.**

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

<b>Section</b>	<b>Description</b>	<b>Page</b>
1	Introduction	4
2	Definitions	4
3	Background	5
4	Key Duties	6
5 - 8	Procedure to Follow	7
9	Document Ratification Process	8
10	Dissemination and Implementation	8
11	Monitoring and Assurance	9

## Standard Operating Procedure (SOP)

### National Data Opt-out

#### 1 Introduction

This SOP applies to any staff responsible for data flows that go outside of the Trust that may fall under the scope of the National Data Opt-out. The National Data Opt-out is a service that allows patients to Opt-out of their confidential patient information being used beyond their direct care for research and planning.

The SOP also applies to staff responsible for supporting the Trust in complying with the Opt-out.

#### 2 Definitions

##### Section 251

Refers to section 251 of the NHS Act 2006 and its current Regulations, the Health Service (Control of Patient Information) Regulations 2002. The NHS Act 2006 and the Regulations enable 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.

In practice, this means that the Trust can, if they wish, disclose information for the specified purpose without being in breach of the common law duty of confidentiality. They must still comply with all other relevant legal obligations e.g. the Data Protection Act 2018 and GDPR. Approval also provides reassurance that the person(s) receiving the information has undergone an independent review of their purposes and governance arrangements.

##### When Opt-out applies

Data shared for research or planning purposes and being released under section 251 NHS Act 2006 and its current Regulations, the Health Service (Control of Patient Information) Regulations 2002 (regulation 2 or 5) to meet Common Law Duty of Confidentiality unless there is a specific exemption.

##### When Opt-out does not apply;

- Data shared for direct care,
- Legal Requirement such as court order,
- Public interest,
- Explicit consent,
- Data is anonymised.

- There is an exemption, examples in;  
<https://digital.nhs.uk/binaries/content/assets/website-assets/services/national-data-Opt-out/compliance/national-data-Opt-out-data-uses-release-compendium-v1.2.pdf>

### 3 Background

The National Data Opt-out was introduced on 25 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. Patients are able to Opt-out once through NHS Digital who stores this choice. Information for patients on how to Opt-out can be found at; <https://www.nhs.uk/your-nhs-data-matters/>

By March 2020 the Trust is required to be applying the Opt-out to any data flows that fall under the scope of the programme.

In general, where section 251 is being relied upon as the lawful basis (under the Common Law Duty of Confidentiality) to process confidential patient information then the National Data OptOut will apply. In some circumstances the Confidentiality Advisory Group (CAG), which provides independent expert advice on section 251 applications, may recommend that the National Data OptOut does not need to be applied. The Trust will need to be satisfied that such an exemption has been given, for example, they could request sight of the CAG approval letter which should clearly indicate that Opt-outs do not apply, before they provide any data.

Key NHS Digital documentation sets out what is required of public bodies to adhere to the data Opt-out;

- 1) National Data Opt-out operational policy to explain what is expected;  
<https://digital.nhs.uk/services/national-data-Opt-out-programme/operational-policy-guidance-document>
- 2) Compliance Implementation Guide;  
<https://digital.nhs.uk/services/national-data-Opt-out-programme/compliance-with-the-national-data-Opt-out/compliance-implementation-guide>
- 3) A licence agreement that the Trust must adhere to in order to access NHS Digital's stored Opt-out choices. A key point is that the Trust cannot store the opt\_out choice on its Patient Administration System. It is acceptable to store it in the Data Warehouse;  
<https://digital.nhs.uk/services/national-data-Opt-out-programme/compliance-with-the-national-data-Opt-out/check-for-national-data-Opt-outs-service/licence>
- 4) NHS Digital(X) Information Standard *DCB3058 Compliance with National Data Opt-outs*; [compliance-with-national-data-Opt-outs](#)
- 5) [Data Security and Protection Toolkit](#) for 2019/20.

### **SIRO**

The Executive Director who takes ownership of the Trust's information risk policy and acts as advocate for information risk on the Trust Board. This role is undertaken by the Director of Corporate Business.

### **Caldicott Guardian**

The senior clinician who has advisory responsibility for safeguarding and governing patient information.

### **Data Protection Officer (DPO)**

Has overall managerial responsibility for operational Information Governance in the Trust. As part of the Records of Processing Activities (ROPA) required by Data Protection Legislation the DPO is responsible for ensuring all data flows are recorded. The DPO will ensure that these records indicate if the national Opt-out applies.

### **IG Team**

Continually update the ROPA records ensuring those data flows that are in scope are recorded accurately.

### **Business Intelligence Manager**

Manages the performance information team who process the majority of data flows from the Trust and ensures these are documented in the data flow template which indicates if the Opt-out applies.

Responsible for implementing a technical solution to exclude Opted-out patients from relevant data flows.

### **Enterprise Solutions Architect**

Provides the IM&T link to the Opt-out programme and ensures that new initiatives are cognisant of the Opt-out. Provides an app for Trust staff who submit direct data flows.

### **Information Asset Owners and Information Asset Administrators**

Ensure data flows are accurately recorded either in SLSPs or dedicated information flow documents as directed by the IG team. Assist the IG team with deciding if data flows are in scope.

## 5 IG team Procedures to Follow

### Document any relevant Data Flows

IG Team identify any data flows that may fall under the scope of the Opt-out by reviewing each data flow on the ROPA data flow templates;

- Does the Data Flow contain patient confidential data?
- Ascertain if the flow relies on section 251 (reg 2 or 5)?
  - Consult the IAO and/or IAA
  - Refer to documentation relevant to the data flow, eg contracts, directives
  - Refer to the Health Research Authority (HRA) CAG registers <https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/confidentiality-advisory-group-registers/>
  - Ask the receiving body if section 251 applies.

### Record if each section 251 data flow is not subject to the Opt-out

- Refer to the NHS Digital's [compendium of common data disclosures](#) to see if the data flow has an exemption to Opt-out
- Ask the receiving body and ask for the CAG letter to confirm and file

### If data flow is subject to Opt-out then

- Ensure that this recorded.
- Ensure that the team responsible for the data flow/entry are able to remove Opted-out patients.

## 6 Performance Information team Procedure to Follow

Responsible for implementing a technical solution to submit a list of NHS Numbers for the Trust's entire cohort of patients to NHS Digital on a weekly basis and store the resulting 'cleaned list' on the Trust's Data Warehouse. This information is used to filter opted out patients from data flows processed by the Performance Information team.

## 7 Other teams responsible for Data Flows/Entry

To liaise with the IG team for guidance on whether the Opt-out applies and how it can be implemented in their area.

## 8 IM&T

Create and maintain an Opt-out App to enable Trust staff who enter S251 data flows directly to screen the opted-out patients.

## 9 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Caldicott and Information Governance Assurance Committee and ratified by the Director of Corporate Business.

Non-significant amendments to this document may be made, under delegated authority from the Director of Corporate Business, by the nominated author. These must be ratified by the Director of Corporate Business and should be reported, retrospectively, to the Caldicott and Information Governance Assurance Committee.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

## 10 Dissemination and Implementation

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Director of Corporate Business and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

## 11 Monitoring and Assurance

The effectiveness of this SOP is reported to the Caldicott and Information Governance Assurance Committee as set out in the Forward Work Programme.

The metrics in the table below provide the programme of compliance monitoring in the form of formal reports to the committee:

Measure	Metric
DSPT compliance	Compliant 31 <sup>st</sup> March 2020

Non-compliance with any IG component set out in this SOP will be treated as an IG risk and added to the Trust Register and highlighted to the committee. Serious risks will be escalated to the Trust Board.