


TITLE: National Data Opt-out for Clinical Audits and Research

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Lead Specialty:	Clinical Audit, Information Governance and Research and Innovation		
Lead Author:	Craig Short, Alison Steel and Terri-Ann Sewell		
Sponsor:	Ceri Feltbower		
<i>Name the documents here or record not applicable</i>			
Associated Policy	Clinical Audit Policy November 2019		
Associated Guideline(s)			
Associated Pathway(s)			
Associated Standard Operating Procedure(s)			
Other associated documents e.g. documentation/ forms	NHS England National Data Opt-out policy		
Consultation Undertaken:	Information Governance Working Group Information Governance Committee Medical Director Chief Nurse		
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1 INTRODUCTION/ 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.

By 30th September 2021 all health and care organisations are required to be compliant with the national data opt-out policy.

2 AIMS/ OBJECTIVES/ PURPOSE (including Related Trust Documents)

This procedure has been designed to detail the processes at the Trust which have been set up to ensure our compliance with national data opt-out for both local and national clinical audits and research.

Related Trust Documents

- Opting out of information sharing leaflet.

3 ROLES AND RESPONSIBILITIES

Whoever submits data externally to the national clinical audits or national/international audits/surveys must check if the project requires compliance with national data opt-outs. It is the responsibility of whoever submits the data to check the NHS number via the web based tool designed by the Information team and to not submit patient's data who have opted out.

All projects must be registered by the project lead on Audit Management and Tracking system (AMaT) and approved by the Quality Improvement (QI) officer.

For research it is the responsibility of the sponsor who may delegate this to the Chief/Principal investigator who must liaise with the research and innovation department if a national data opt-out check is required.

4 PROCEDURE DETAILS (including Flowcharts)

4.1 In the Trust's Clinical Audit Policy November 2019, all clinical audit projects and service evaluations need to be registered with the Clinical Audit team to ensure compliance with our audit process.

We currently use the Audit Management and Tracking (AMaT) system for the registration of projects. There are three common types of project that we see:

1. -Local audits (including internal Trust wide audits)
2. -National audits included in the Quality Accounts (QA) and mandated by NHSE/I.
3. -Nationally done audits not included in the Quality Accounts but performed nationally or internationally where each Specialty can volunteer to participate.

4.2 Local audits including Trust wide audits

The data is used internally and analysed by our employees, therefore the national data opt-out does not apply. NHS Digital provides the following direction:

There are other elements of patient care which rely on the wider processing of data, but that should also be treated as individual care, and so not within scope of national data opt-out policy. These include:

- Population screening programmes - for conditions such as cervical and bowel cancer, which the UK National Screening Committee (UK NSC) has advised that the NHS should offer
- Risk stratification used for case-finding - when carried out by a provider involved in an individual's care
- Local audit of the safety and quality of care - when carried out by the professionals and team responsible for the care of the patient.

4.3 National audits included in Quality Accounts

National data opt-outs apply to a number of national clinical audits. Several national audit providers have added relevant information to their websites and these should be checked by the audit lead to see if the national data opt-out applies to the audit.

Annually the Trust participates in approximately 60 [National audits](#)¹. These are mandatory and each one has an audit lead from the Trust that manages the project and submits data and/or oversees data submission.

All national audits must be registered on our Audit Management and Tracking (AMaT) system either by the audit lead or Quality Improvement officer. Data is captured internally and submitted/uploaded and analysed externally.

The deadline for health and care organisations to comply with national data opt-out policy was 31 July 2022. Therefore each of the Trust's audit leads will need to check the individual national audit provider's website before submitting **any** data to a project.

If the national audit provider confirms the project needs to comply with the national data opt-out, the following steps **MUST** be taken by the Trust's audit lead before data is submitted:

All NHS numbers **MUST** be checked using the Trusts 'National data opt-out checker' (https://sfhinformationhub.notts-his.nhs.uk/MESH/import_check). The national data opt-out

¹ <https://www.hqip.org.uk/a-z-of-nca/#.YAluAjlxdPY>

checker requires you to input the name of the audit you are checking data for and then you will be required to enter the NHS numbers you wish to use for the audit.

Once you click “Run check” you will see a list of NHS numbers along with a ‘Yes’ or ‘No’ in the next column “Patient opted-out”. This indicates the information that NHS Digital holds in terms of national data opt-out for that patient. If there is a ‘Yes’ against an NHS number then that patient **MUST NOT** be used for the purposes of the audit. This list is updated daily and you should see a time stamp for when the last update occurred.

4.4 National and International studies not on Quality accounts that the Trust might participate in during the year

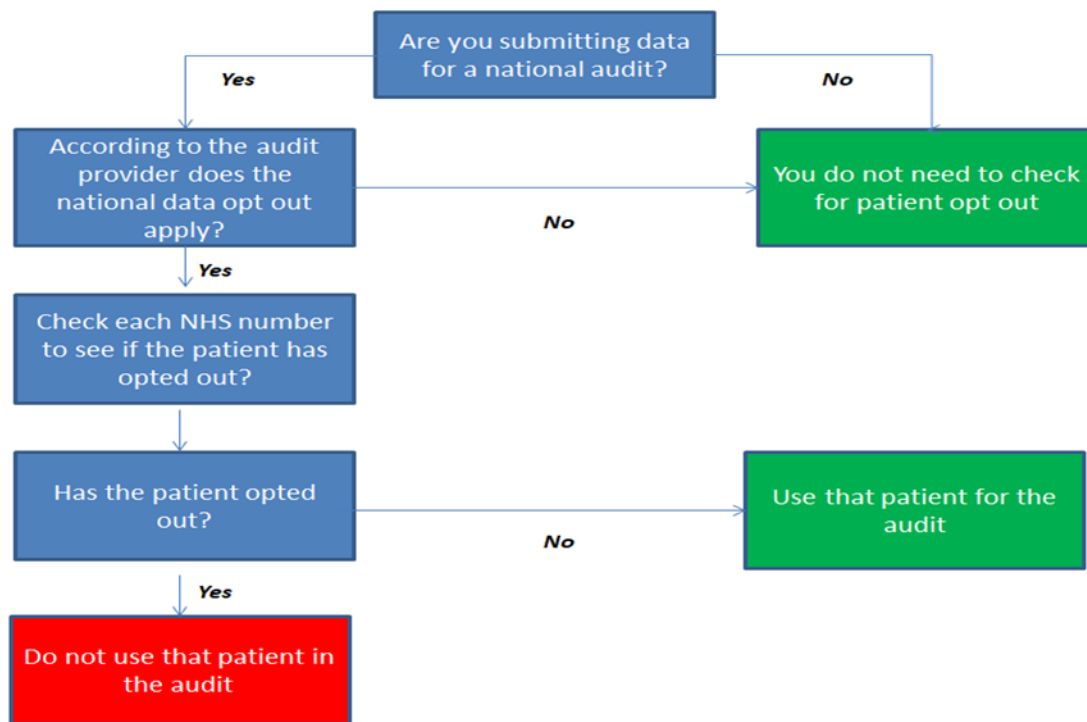
Annually there are number of national and international projects the Trust can volunteer to participate in. Each nationally/internationally done project must be registered on Audit Management and Tracking (AMaT) system by the audit lead who would like to take part in the project. All projects must have a protocol attached which is written and issued by the organiser of the project. The protocol outlines the aims and objectives of a project, timescales, scope of patients included in the study and requirement to register on Audit Management and Tracking (AMaT) system before submission of **any** data.

Some of these projects may need to comply with the national data opt-out which needs to be clearly outlined in the protocol. If the protocol does not clearly indicate the requirement for national data opt-out compliance, then it will be rejected by the Quality Improvement team member until clarification is obtained by the member of staff wanting to participate in the project.

If the external audit provider confirms the project needs to comply with the national data opt-out the following steps **MUST** be taken by the audit lead before the data is submitted:

All NHS numbers **MUST** be checked using the trusts ‘National Data Opt-out checker’ (https://sfhinformationhub.notts-his.nhs.uk/MESH/import_check). The checker requires you to input the name of the audit you are checking data for and then you will be required to enter the NHS numbers you wish to use for the audit.

Once you click “Run check” you will see a list of NHS numbers along with a ‘Yes’ or ‘No’ in the next column “Patient opted out”. If there is a “YES” against an NHS number then that patient **MUST not** be used for the purposes of the audit. This list is updated daily and you should see a time stamp for when the last update occurred.



4.5 Clinical Research

For the research community the national data opt-out has no impact where a patient has consented to participate in a research study and has agreed for their data to be used in that study. Nor will it affect studies that use anonymised data.

However, for researchers intending to access confidential patient information without consent in England and making an application through the [Confidentiality Advisory Group \(CAG\)](#), the standard condition of Confidentiality Advisory Group's advice is that the wishes of people who have withheld or withdrawn their consent (i.e. opted out) are respected and therefore the national data opt-out checker should be used. It has taken the position that it will advise that it is not in the public interest to override any national data opt-out's in anything other than the most exceptional circumstances, e.g. serious public safety concerns.

All NHS numbers MUST be checked using the trusts 'National Data Opt-out checker' (https://sfhinformationhub.notts-his.nhs.uk/MESH/import_check). The checker requires you to input the research and innovation project reference number you are checking data for and then you will be required to enter the NHS numbers you wish to use for the research.

For projects using more than 50 NHS numbers please use the following link: <https://sfhinformationhub.nnotts.nhs.uk/ADHOCS/Request>.

5 EDUCATION AND TRAINING

Information around the process and a user guide are located on the Clinical Audit Intranet page (<https://sfhnet.notts.nhs.uk/admin/webpages/default.aspx?RecID=4055>) under the sub heading National Data Opt-out for Clinical Audits.

6 MONITORING COMPLIANCE AND EFFECTIVENESS

On a quarterly basis the Quality Improvement team will request a report from the Information team detailing which audits have been checked using the 'National Data Opt-out checker' to see if it's being utilised.

On a quarterly basis the research and innovation team will inform Information Governance of any research projects being undertaken and those that have made a Confidentiality Advisory Group application.

7 EQUALITY IMPACT ASSESSMENT (please complete all sections)

Name of service/policy/procedure being reviewed: National Data Opt-out for Clinical Audits and Research			
New or existing service/policy/procedure: Existing			
Date of Assessment: 25 th January 2021			
<i>For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)</i>			
Protected Characteristic	a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?	b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?	c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality
The area of policy or its implementation being assessed: n/a			
Race and Ethnicity:	None	Not applicable	None
Gender:	None	Not applicable	None
Age:	None	Not applicable	None
Religion:	None	Not applicable	None
Disability:	Visual accessibility of this policy	Already in Arial font size 12. Use of technology by end user. This policy can be made available in alternative formats, such as	None

		easy read or large print, and may be available in alternative languages, upon request	
Sexuality:	None	Not applicable	None
Pregnancy and Maternity:	None	Not applicable	None
Gender Reassignment:	None	Not applicable	None
Marriage and Civil Partnership:	None	Not applicable	None
Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation):	None	Not applicable	None

What consultation with protected characteristic groups including patient groups have you carried out?

- None

What data or information did you use in support of this EqIA?

- Trust guidance for completion of the Equality Impact Assessments

As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?

- No

Level of impact

Low Level of Impact (*Delete as appropriate*)

Name of Responsible Person undertaking this assessment: Craig Short

Signature:



Date: 25th January 2021