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National Data Opt-out Guidance for researchers

Document management

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Sami Mansoor	NHS England	1/5/19	V0.1 Draft
Robin Barker	NDOP Business Analyst	1/5/19	V0.1 Draft
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Alex Bailey	Health Research Authority	27/5/19	V0.1
Janet Messer	Health Research Authority	27/5/19	V0.1
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Approved by

This document must be approved by the following people:

Name	Signature	Title	Date	Version
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Document Control:

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Glossary of Terms

Term / Abbreviation	What it stands for
APC	Admitted Patient Care
CAG	Confidentiality Advisory Group
CPI	Confidential Patient Information (originating in the health and social care sector in England)
DARS	Data Access Request Service
ICO	Information Commissioners Office
MRC	Medical Research Council
NDG	National Data Guardian

Table of Contents

1. Introduction

1.1 Document purpose

This document supports researchers to help understand the impact of national data opt-outs on the data they receive for their research studies from health and adult social care providers in England.

1.2 Audience

The intended audience for this document is health and care researchers, such as those undertaking research in universities, NHS Trusts, research institutes, and organisations that fund and support researchers, such as the Medical Research Council (MRC), who have an interest in understanding and managing the impact of the national data opt-out on research.

1.3 Scope of this document

Based on the intended audience, this document will:

- ✓ provide researchers with an understanding of national data opt-outs and when these are applied;
- ✓ provide researchers with an understanding of the types of organisations who will need to comply with national data opt-outs, and the importance of respecting individuals' data sharing preferences;
- ✓ enable researchers to understand how the application of national data opt-outs across the health and adult social care sector will affect their datasets and research studies;
- ✓ set out products and resources available to researchers which will support them to manage the impact of national data opt-outs on their research studies;
- ✓ signpost researchers to other resources and information.

2. Background

The national data opt-out was recommended in the National Data Guardian's (NDG) Review of Data Security, Consent and Opt-Outs, which was published in July 2016. The Government response to the NDG review: Your Data: Better Security, Better Choice, Better Care, published in July 2017 accepted all the recommendations made by the NDG. The NDG recommended that:

"The National Data Guardian recommends a new consent/opt-out model to give people a clear choice about how their personal confidential data is used for purposes beyond their direct care".[1]

The national data opt-out is based on the 8 principles set out in the NDGs report:

1. You are protected by the law
2. Information is essential to good quality care
3. Information is essential for other beneficial purposes
4. You have the right to opt out
5. The opt out will be respected by all organisations that use health and social care information
6. Explicit consent will still be possible
7. The opt-out will not apply to anonymised data (ICO code)
8. The opt out will not apply to exceptional circumstances

One of the key considerations behind the NDG's review was the need to address patient concerns and confusion about how their confidential patient information (CPI) is used, and to ensure that patients are empowered to have a say in how their data is used. An opt-out model was recommended as a mechanism which would enable patients to have a choice to stop their CPI being used for purposes beyond their individual care and treatment, e.g. for research and planning.

The NDG's review also recognised the strong case for sharing CPI including the importance of data sharing for research:

"Information essential for high quality health and care….to improve the safety of care, including through research, to protect public health, and support innovation".[2]

To ensure this message is understood by patients when they set a preference for sharing their data, the national data opt-out is offered within the wider context and message of "Your NHS Data Matters"[3], with supporting patient handouts and more details on-line.

3. What researchers need to know about the national data opt-out

The national data opt-out was introduced for the health and social care system in England on 25 May 2018 and applied by NHS Digital. Since then Public Health England have become compliant with national data opt-out policy and all health and adult social care providers across England are required to comply with national data opt-out policy by March 2020.

[1] National Data Guardian for Health and Care – Review of Data Security, Consent and Opt-Outs, pg. 6,1.25
[2] National Data Guardian for Health and Care – Review of Data Security, Consent and Opt-Outs, pg. 6,1.26
[3] https://www.nhs.uk/your-nhs-data-matters/

This means that national data opt-outs will need to be applied when disclosing CPI which originates in a health and/or adult social care organisation for purposes beyond an individual's care and treatment.

For the purpose of compliance with national data opt-outs health and adult social care organisation are defined as:

- NHS bodies and Local Authorities providing health and adult social care services in England; and
- other organisations or persons who provide health or adult social care services in England under contracts agreed with NHS and Local Authorities.

Broadly this includes (but is not limited to) health service providers (e.g. NHS Trusts, GP practices), private providers who deliver services which are publicly funded and or coordinated by a public body, e.g. Local Authorities, commissioners of health and care services (e.g. Clinical Commissioning Groups and Local Authorities) and Arm's-Length Bodies.

Once an organisation has declared they are compliant, usually through a Privacy Notice made available to the public, then the organisation must continue to comply with the policy from that point in time.

The national data opt-out is a facility via which patients can object to their CPI being used for research and planning. However, it does not apply to CPI when an individual has given their explicit consent for their CPI to be used for a particular purpose. Specifically, it is applied to a use/disclosure of CPI where a section 251 of the NHS Act 2006 is used as the legal gateway for disclosing the data (see section 4). The national data opt-out will always apply were a section 251 is relied on to enable the data to be shared unless Confidential Advisory Group (CAG) agrees to set aside the national data opt-out. More information about section 251 approvals is set out in section 4 below.

The responsibility for complying with national data opt-out policy rests with the data provider (as Data Controller) or processor acting on behalf of the data provider. In practice this means that national data opt-outs are applied by the health and adult social care provider of the data, i.e. disclosing the CPI, (e.g. a hospital trust), not by the recipient of CPI, (e.g. a research body). To be clear national data opt-outs are applied to CPI before it is received by a researcher. Researchers are not required to apply national data opt-outs to the data they receive.

Patients can set their national data opt-out preference via both digital and non-digital services. Their preference will remain in place unless and until such a time that the patient decides to change their opt-out preference. A patient's preference to opt-out will continue to be applied after the person's death.

National data opt-outs are not applied retrospectively. This means that when a patient sets their opt-out preference for their CPI not to be shared for uses beyond their individual care their records will be removed from any disclosure of CPI from that time onwards. However, it should be noted that patients are notified when setting their opt-out preference that there is a potential 21-day fair processing period

from their opt-out being registered with NHS Digital to being fully applied across all disclosures of data. Data providers will not need to recall data which has already been processed prior to this date.

4. Section 251 and the application of national data opt-outs

National data opt-outs apply to a disclosure when an organisation such as a research body confirms they have obtained an approval from CAG for the disclosure of CPI held by another organisation responsible for the data (the data provider) such as an NHS Trust.

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 (see appendix 1), 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.

CAG consider a number of section 251 applications each year, the CAG Registers give details of approvals under section 251 (regulation 2 and 5) which cover both non-research and research applications.

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, e.g. 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.

For more information about CAG and the section 251 approvals process see: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/

5. Consent to recruit people into research studies

In certain scenarios, researchers may need to access CPI to ensure that the individual meets the criteria for clinical trials and interventional studies, e.g. has a particular condition, has received a specific treatment or is on a certain drug regime.

In these scenarios' researchers must establish the legal gateway before they can identify and approach eligible participants in order to contact them to ask for their consent to participate in their research studies.

Where researchers need to identify people to participate in research studies, the national data opt-out may apply if the research is relying on support under section 251 regulations as the legal gateway to identify the potential research participants.

The impact of the introduction of the national data opt-out on the process to recruit people into research studies should be relatively small as the mechanisms for recruiting potential participants for research studies remain the same.

There are a range of mechanisms available to researchers for recruiting potential participants which are set in the IG Report 2013: To Share or Not to Share – Information Governance Review, and summarised in appendix 2.

6. What the national data opt-out means for researchers?

Most researchers will see no impact on their research because they are not relying on section 251 support for obtaining their CPI. For example; the national data opt-out does not apply where the researcher is using data which is:

- obtained by explicit consent from the individuals which make up their cohort, for the use/disclosure of the CPI - consent will override the national data opt-out regardless of whether a preference was registered before or after this consent is given
- anonymised in line with the ICO Code of Practice on Anonymisation
- does not originate from health and adult social care providers located in England

It is the responsibility of the data provider to comply with national data opt-out policy and apply opt-outs if required to data disclosures. The introduction of the national data opt-out does not require researchers to do anything and therefore doesn't change very much for researchers.

6.1 Potential bias as a result of the application of national data opt-outs

When a researcher obtains CPI from a health and adult social care provider in England with section 251 support, they should expect that, once that organisation has stated its compliance with the national data opt-out policy then the records of patients who have registered a national data opt-out will have been removed. This may mean that the dataset provided might not be complete.

When researchers receive data, where national data opt-outs have been applied, there is a potential to introduce bias to their studies which researchers will need to consider. For example, there might be higher levels of opt-out across certain geographical areas, age groups or specific conditions that might impact on the results of studies.

6.1.1 Available products for managing bias

There are several products and resources available to support researchers to manage and understand whether any bias may have been introduced into the data provided to them.

- **National data opt-out statistics – publication**

  NHS Digital produces a statistical publication on the volumes of national data opt-outs. It includes the number of people who have a national data opt-out, broken down by age, gender and a variety of geographical breakdowns.

- **National data opt-out - Hospital Episode Statistics analysis**

  NHS Digital has produced analysis showing the impact of removing opt-outs on Hospital Episode Statistics (HES). This provides counts on hospital episodes before and after national data opt-outs are applied to the following datasets:

  - ✓ Admitted Patient Care (APC)
  - ✓ Outpatients
  - ✓ Accident & Emergency

  Further comparative analysis provides counts by gender, age bands, broad ethnicity, and Clinical Commissioning Groups. In addition, for the APC data, analysis will be provided on primary procedure and diagnosis groups.

- **Information from the data provider**

  There is no requirement on the data provider to supply any information on the numbers of records removed from their disclosures of data; however, this is also not prohibited, provided this is done in a way that maintains confidentiality.

  - **Numbers of records removed**

    When NHS Digital discloses data through its Data Access Request Service (DARS) the data recipient is provided with additional information to help them understand the impact of the application of national data opt-outs on the data provided. This includes the number of records removed and the number of unique patient records removed (as data releases can contain more than one set of data records for the same patient).

Other organisations may similarly provide details of the number of records and/or unique patient records removed but are not obliged to.

- **Bespoke Analysis provided by data providers**

  Health and adult social care providers may wish to undertake more bespoke or specific analysis to help researchers understand the potential impact of national data opt-outs on the data that they receive.

6.2 Potential broader impact

While compliance with national data opt-out policy is the responsibility of the data provider there may be potential broader repercussions if national data opt-outs have not been applied when they should have been. Where CPI has been received under section 251 approval and the need to apply national data opt-outs has not been waived by CAG, then it is recommended that researchers check whether the data provider has applied the national data opt-out. Researchers can request the data provider to verify that they have applied the opt-out and/or in some cases the data provider might provide information which evidences compliance. Health and adult social care providers must be able to demonstrate in their Data Security and Protection Toolkit submissions that they are compliant with national data opt-out policy.

If a data provider does not apply the national data opt-out where required and a case was raised with the ICO they have confirmed they would look at it under the data processing principle of lawfulness, fairness and transparency. Any such case, if it became high profile, could lead to patient and public mistrust in the handling of their data which might lead to a possible increase in the volume of people registering an opt-out and/or a decrease in the number of patients consenting to take part in research studies, both of which would impact negatively on research. Equally, patients who identified that their data may have been disclosed against their expressed wishes may choose to go to those organisations, such as a research body, that have received their data to demand that the data be destroyed, creating more work for those organisations.

7. Further information and support

National Data Opt-out Operational Policy Guidance

8. Useful links and reference document

NHS Digital Website DARS webpage: How national data opt-out affects data released by NHS Digital

National Data Guardian Review of Data Security, Consent and Opt-outs

National data opt-out statistical publication

Appendix 1: Section 251 of the National Health Service Act 2006

Section 251 of the National Health Service Act 2006 and its current Regulations, the Health Service (Control of Patient Information) Regulations 2002 allows the Secretary of State for Health to make regulations to set aside the common law duty of confidence for defined medical purposes. In practice, this means the person responsible for the information can disclose confidential patient information without consent to an applicant without being in breach of the common law duty of confidence, if the requirements of the regulations are met. The person responsible for the information must still comply with all other relevant legal obligations such as the Data Protection Act 2018 and the Human Rights Act 1998

Regulation 2 permits confidential patient information relating to patients referred for the diagnosis or treatment of cancer to be processed for the medical purposes set out in the regulation.

Regulation 3 provides specific support for identifiable patient information to be processed to diagnose, control or prevent, or recognise trends in, communicable diseases and other risks to public health. Regulation 3 applications are managed by Public Health England.

Regulation 5 can be used to permit processing for a range of medical purposes, broadly defined to include ‘preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of health and adult social care services.

Appendix 2

1. **Obtaining consent via a person with a "legitimate relationship" with the subject**

   Where an individual has registered a preference to opt out from their CPI being shared it is still possible for a person with a "legitimate relationship" with the subject to contact this individual either through correspondence or in person (e.g. during a clinic) as a potential participant, to obtain their consent to participate in a specific research study, or to ask them if they would like to be put forward for such a study.

   A person with a "legitimate relationship" with the subject would be for example a member of their direct clinical or care team like a GP, practice nurse, social worker or hospital consultant. In some cases a researcher might have a "legitimate relationship" with the potential participant, for example, they might be part of the subjects clinical or care team, but for many researchers this will not be the case and they will need to approach the clinical or care team to do this on their behalf.

2. **Through a person identifying themselves as a potential participant**

   Potential participants can also identify themselves, for example, via a web portal giving their consent to be contacted by the research team. Potential participants are usually asked to complete a consent form setting out clearly what they are consenting to, e.g. permission to access their medical information.

3. **Using privacy enhancing search tools**

   Computer software is available which can search clinical databases, selecting patient who are eligible for a specific research study, and will only reveal the identities of these potential participants to someone with a "legitimate relationship" to the patient (clinician/social worker), who can then contact the patient to obtain consent for them to be approached by a research team.