

# Roll-out of National Data Opt-Out in England

## MRC Regulatory Support Centre Guidance for Researchers

### 1. Key message

From March 2020, all NHS organisations in England, not just NHS Digital, must apply the National Data Opt-Out. This means that releases of Confidential Patient Information for research, which have Section 251 support from the Confidentiality Advisory Group, are likely to be incomplete. This will not affect research where consent has been obtained to share Confidential Patient Information.

### 2. What is the National Data Opt-Out?

In 2016, the National Data Guardian recommended:

*“a new consent/opt-out model to allow people to opt-out of their personal confidential data being used for purposes beyond their direct care”*

To date this has only been possible for data disseminated by NHS Digital. However, from March 2020, all publicly-funded, commissioned or coordinated health and adult social care providers in England must apply the National Data Opt-Out for purposes beyond individual care and treatment (including research).

### 3. What information does the National Data Opt-Out apply to?

The National Data Opt-Out applies only to Confidential Patient Information (CPI) that is disclosed from the health and adult social care sector in England. CPI is information that meets the following requirements:

- a) the individual is identifiable either:
  - (i) directly from the information, or;
  - (ii) from the information and other information which is in the possession of, or is likely to come into the possession of, the person viewing the information,

**and**

- b) the information was obtained or generated by a person who owed an obligation of confidence to that individual.

#### 4. What does this mean for research?

Most research will be unaffected because the National Data Opt-Out **does not apply** when:

- i. consent has been obtained for disclosure of CPI, regardless of whether consent was obtained before or after opt-out. Even when a patient has opted-out it does not stop that patient from being approached to take part in research, provided this is done in a way that does not breach confidentiality
- ii. researchers already have the CPI i.e. when a patient opts-out, the opt-out is only applied from that time onward
- iii. researchers receive only anonymous information, as long as no flows of CPI rely on Section 251 support (it is worth noting that data collection, linkage and anonymising may require Section 251 support)
- iv. the CPI is disclosed from outside the health and adult social care sector
- v. the CPI does not originate from England

**The National Data Opt-Out will only affect research that has Section 251 support.**

If research involves obtaining CPI from NHS Digital with Section 251 support, National Data Opt-Outs are already applied. This will continue to be the case.

**If research involves a Section 251-supported disclosure of CPI from any health or adult social care provider in England there may be an impact on the data received. The current National Data Opt-Out rate is approximately 2.75%.**

#### 5. Impact on research with Section 251 support

When National Data Opt-Outs are applied there will be a potential to introduce bias into some types of research. For example,

- it may not be possible to obtain data from 100% of a research population
- opt-out rates vary by location, age-groups and specific conditions
- it may not be clear which populations have opted-out

Data providers are not required to supply information on the numbers of National Data Opt-Outs applied to a release of CPI. However, this is not prohibited if it is done in a way that maintains confidentiality. For example, NHS Digital provide a [breakdown of National Data Opt-Out rates](#).

Section 251 support for research is conditional on related expressions of dissent being upheld, this includes the National Data Opt-Out. Any justification for opt-outs not to apply should have been made and agreed as part of the Confidentiality Advisory Group application. The roll-out of the National Data Opt-Out is unlikely to provide a reason for existing studies to seek a change to this condition.

## 6. Summary

The roll out of the National Data Opt-Out will have no impact on most research, because most research does not rely on Section 251 support.

If research involves obtaining CPI from NHS Digital with Section 251 support there will be no further impact, since NHS Digital already apply National Data Opt-Outs.

If research requires Section 251 support, even if you, as the researcher, are working with anonymous information, National Data Opt-Outs will apply from March 2020. If you have any questions about whether National Data Opt-Outs will be applied to the CPI in your research, please speak to the organisation that is providing the CPI.

## 7. Further reading

HRA information on [how the National Data Opt-Out applies in health research](#).

NHS Digital provide general information about the [National Data Opt-Out](#)

The latest [National Data Opt-Out rates with a statistical breakdown](#)

Patients can find out more and set their choices at [nhs.uk/your-nhs-data-matters](https://nhs.uk/your-nhs-data-matters)