

NATIONAL DATA OPT-OUT **Frequently Asked Questions**

What is the National Data Opt-Out?

The national data opt-out (NDOO) allows a patient to choose if they do not want their confidential, person-identifiable data (PID) to be used for purposes beyond their individual care and treatment – i.e. for research and planning.

What does that mean?

Normally, a patient's permission is required if an NHS Trust intends on sharing their confidential information outside of the team providing their care, for purposes other than delivering care. This is a requirement of complying with the common law duty of confidentiality.

However, this can be prohibitive for wide-scale national studies where large numbers of patients are involved, as it would be difficult to obtain permission from all of them. In some cases, there might be significant public benefit to collecting this information, and it is necessary to collect information in a manner which identifies individual patients.

Where this is the case, it is possible for national project teams, researchers or auditors to apply for approval from the Secretary of State for Health to set aside the common law duty of confidentiality, and therefore remove the need to ask a patient's permission for their information to be shared. This is known as "[Section 251 approval](#)" (referring to S.251 of the NHS Act 2006). This approval is granted by a national Confidentiality Advisory Group (CAG), who review all applications.

When this approval is given, it is considered appropriate for information to be shared outside of NHS Trusts for the purposes set out in the S.251 approval, without individual patient permission being sought.

When does the NDOO apply?

NDOO applies when S.251 is being relied upon by an organisation (such as a research body or national clinical audit provider) to collect confidential PID from another organisation (such as an NHS Trust). It does not apply to the disclosure of anonymous data sets.

It is the responsibility of the NHS Trust that is disclosing confidential PID to carry out checks and make sure that if a patient has opted out, their information is not disclosed for this purpose.

When does the NDOO not apply?

NDOO does not apply where information is being shared within the Trust, nor to the recording of patient information within Trust systems. Patients may not opt out of having medical records. NDOO only applies where the sharing of information outside of the Trust is based on S.251 approval.

NDOO does not apply if a patient has given explicit consent for their data to be used for a certain purpose (e.g. if they have registered an opt-out choice but still wish to participate in a specific research study).

NDOO also does not apply in situations where all data being shared is anonymised, i.e. there is no means of identifying a person from it.

Does this affect local clinical audits?

No, local clinical audits are part of the delivery of individual care and treatment of patients, and therefore are outside of the scope of the NDOO.

Can patients change their mind?

Yes, patients can alter their opt-out choice at any time, via the NHS app, online, or via their GP. It is also possible for patients who have registered an opt-out to give their permission to be involved in specific research studies or clinical audits, if they wish.

Whose data is in scope?

The NDOO relates to patient information only, and includes both living and deceased patients. The NDOO applies to staff to the extent that they are also patients, but not to personnel/HR-related information held by the Trust.

How do I find out if a patient has opted out?

The Business Intelligence department has developed a tool to check whether a patient has registered an opt-out decision. They can be contacted via information.requests@uhd.nhs.uk, or through the eForms Portal. The tool can also be accessed via the [Clinical Audit department intranet page](#).

How do I know if the data I wish to share is subject to NDOO?

If the sharing of data is reliant on S.251, it will be in scope. The Clinical Audit dept or the Research department may be able to advise you, if your use of data is registered with them.

What is the deadline for compliance?

The Trust is required to confirm to NHS Digital by 31st March 2022 that it is compliant with the NDOO.

Is there any information available for patients?

Yes, information is available online at <https://www.nhs.uk/your-nhs-data-matters/>

Is there any further information available for staff?

Yes, information is available online at <https://digital.nhs.uk/services/national-data-opt-out>