Guidance about the appointment of Caldicott Guardians, their role and responsibilities published by the National Data Guardian for Health and Social Care

Guidance version 1.0
National Data Guardian for Health and Social Care
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About this guidance

This is guidance issued by the National Data Guardian for Health and Social Care in England (the “NDG”) under section 1(2) of the Health and Social Care (National Data Guardian) Act 2018 (the “Act”).

Section 1(2) of the Act empowers the NDG to provide guidance about the processing of health and adult social care data in England. The Act requires that certain organisations and persons must have regard to such guidance, to the extent that it is relevant to their functions or activities. (See also section Who is this guidance for?).

The NDG acts as an independent advocate for patients and service users about how health and adult social care data is used. The NDG does not hold any regulatory function or enforcement powers, although it works closely with (and may make referrals to) other relevant bodies with such powers, such as the Care Quality Commission (CQC), in relation to potential breaches of an organisation’s responsibilities which fall within the regulatory scope of those relevant bodies.

This guidance is about the appointment of Caldicott Guardians, their role, responsibilities, competencies, knowledge, training, and continuous professional development. Due to the large variety of organisations that appoint Caldicott Guardians, this document does not stipulate operational details of how the guidance should be implemented.

We expect those organisations who are subject to the statutory duty to have regard to this guidance to comply with it, including by registering the details of their Caldicott Guardian(s) on the Caldicott Guardian Register. Where an organisation completes the Data Security and Protection Toolkit (“DSPT”), the DSPT requires that it should provide details about its Caldicott Guardian(s) as part of their annual submission.

‘Having regard’ to the NDG guidance about the appointment of Caldicott Guardians, their role and responsibilities means that the organisations in scope of the guidance should be able to show that:

• they are aware of the guidance and,
• they have taken it into account when making a decision to which the guidance is relevant and,
• if they have decided to depart from the guidance, they have good reasons for doing so.

Review date

This guidance will be kept under review and updated to reflect any changes to law or policy affecting the role and responsibilities of Caldicott Guardians.
**Who is this guidance for?**

This guidance may assist any organisation that appoints a Caldicott Guardian.

However, it is directed specifically at those organisations that have a statutory duty to have regard to it, namely:

1. Public bodies exercising functions that relate to the health service, adult social care or adult carer support in England only, and that process confidential information about patients or service users; and

2. Other persons or organisations providing (i) services as part of the publicly funded health service, (ii) adult social care, or (iii) adult carer support, pursuant to arrangements with a public body falling within paragraph (1) above, and that process confidential information about patients or service users. For the avoidance of doubt, the duty to have regard to this guidance applies to organisations that are *not* public bodies *only* in relation to work that is publicly funded.

There is nothing within this guidance to prevent organisations or bodies that may not fall within the two categories above from appointing a Caldicott Guardian. For example, these might include police forces, prisons, universities, software or other suppliers, purely private health or social care providers or other organisations processing confidential patient or service user information. It may well be appropriate for organisations which are data processors1 of confidential patient or service user information to appoint a Caldicott Guardian, particularly where they are processing large volumes of data, and such organisations may find this guidance useful.

There may also be other circumstances where an organisation or body not falling within the two categories above will be required to appoint a Caldicott Guardian. For example, this might be because the organisation completes the Data Security and Protection Toolkit2 or enters into a contract that stipulates it should have a Caldicott Guardian. Such organisations and bodies may also find this guidance useful. (See also section 3 Should your organisation appoint a Caldicott Guardian).

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2 https://www.dsp-toolkit.nhs.uk/
Which laws, reports and policies does this guidance refer to?

This guidance refers to the following law, reports and policies:

- The common law duty of confidentiality
- Human Rights Act 1998⁴
- Freedom of Information Act 2000⁵
- Health Service Circular: HSC 1999/012⁶
- Local Authority Circular: LAC (2002)²⁷
- Caldicott review: Information: to share or not to share? The Information Governance Review⁸
- The Health and Social Care (National Data Guardian) Act 2018⁹
- Data Protection Act 2018 (the “DPA”)¹⁰
- Caldicott Principles: A consultation about revising, expanding and upholding the principles (2020)¹¹
- The Caldicott Principles (December 2020)¹²
- EU General Data Protection Regulation as incorporated in English law by the EU (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (the “UK GDPR”)¹³
- National Data Opt-out policy (2021)¹⁴

⁵https://www.legislation.gov.uk/ukpga/2000/36/contents
⁸https://www.gov.uk/government/publications/the-information-governance-review
¹²https://www.gov.uk/government/publications/the-caldicott-principles
Guidance

1. Purpose and structure of this guidance

1.1 This is guidance on the role and responsibilities of Caldicott Guardians in respect of data processing activities undertaken within their organisations. It is published under the NDG’s power to issue guidance contained within the Health and Social Care (National Data Guardian) Act 2018.

1.2 The main purposes of this guidance are to: describe which organisations should appoint a Caldicott Guardian; provide advice on how to appoint them; describe the way the role should be supported by organisations; describe the role and responsibilities of a Caldicott Guardian; and describe the competencies and knowledge that will assist a Caldicott Guardian.

1.3 Annex A to this guidance sets out the Caldicott Principles, which the Caldicott Guardian helps their organisation to uphold.

2. History of the Caldicott Guardian role

2.1 The Caldicott Committee’s Report on the Review of Patient-Identifiable Information, published in 1997, recommended six good practice principles to be applied to the use of confidential patient and service user information in the National Health Service (NHS). It also recommended that a senior person, preferably a health professional, should be nominated in each health organisation to act as a guardian responsible for protecting the confidentiality of patient information and ensuring the principles were upheld.

2.2 These principles became known as the Caldicott Principles, and the senior individuals responsible for ensuring the principles were upheld within their organisations became known as Caldicott Guardians.

2.3 The Government has recommended that NHS trusts and local authorities with social services responsibilities should appoint a Caldicott Guardian since 1999 and 2002 respectively. Many other organisations, both within the health and social care sector and outside it, have chosen to appoint a Caldicott Guardian, and to use the Caldicott Principles to help guide the safe use of confidential patient and service user information.

2.4 The United Kingdom Council of Caldicott Guardians was launched in 2005. Since 2015, it has been the UK Caldicott Guardian Council (UKCGC) and has been supported by the NDG. The UKCGC aims to be a point of contact for all Caldicott Guardians and for health and care organisations seeking advice on the Caldicott Principles and matters regarding the Caldicott Guardian role and responsibilities. It offers a range of support including: A Manual for Caldicott...
Guardians, a job description template, regional peer-to-peer networks, a Caldicott Guardian forum and virtual workshops. Caldicott Guardians and organisations may find it helpful to explore the available support and resources on the UKCGC website.15

2.5 In 2020, the National Data Guardian ran a public consultation entitled *Caldicott Principles: a consultation about revising, expanding and upholding the principles.* This guidance is one of the outcomes of that consultation.

2.6 This guidance builds on the Government’s previous recommendations (see paragraph 2.3 above). By issuing this guidance under the Act, the NDG intends that a wider range of organisations should now appoint a Caldicott Guardian.

2.7 At the time of issuing this guidance, there were over 22,0006 Caldicott Guardians in the UK. They are sometimes described as the ‘conscience of the organisation’ when it comes to using information, and they work closely with other information governance and legal colleagues. Caldicott Guardians help their organisations to ensure that confidential information about health and social care service users is used ethically, legally, and appropriately. They help to protect each patient and service user’s right to confidentiality. They also support their welfare by helping to ensure that information about them is shared safely and appropriately among those caring for them, often across organisational boundaries. Caldicott Guardians balance ethical as well as legal considerations when making judgments and providing advice to their organisations. (See also section 5 **Relationship of the Caldicott Guardian to other key organisational roles**).

2.8 The way that Caldicott Guardians operate differs according to their organisational environment. In a large NHS hospital trust, the Caldicott Guardian may be a senior clinician with wide-ranging professional responsibilities, supported by teams with expertise in information management and governance. In a local authority, the Caldicott Guardian may be a senior professional of similar seniority and with similar support, but with different information sharing and confidentiality scenarios to consider. A Caldicott Guardian in a small or medium-sized care home might be a social care professional or registered nurse; they will likely have less infrastructure and resources to support them, and may be dealing with different issues, such as trying to ensure good information sharing between the health and social care sectors. There are Caldicott Guardians in hospices, clinics, prison healthcare teams, GP practices, pharmacies and charities. Whether in the largest or smallest organisations, they all perform a key role in protecting patient and service user confidential information.

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15 [https://www.ukcgc.uk/](https://www.ukcgc.uk/)
3. Should your organisation appoint a Caldicott Guardian?

3.1 The NDG recommends that all of the following organisations (who must have regard to this guidance) should appoint a Caldicott Guardian:

1. Public bodies exercising functions that relate to the health service, adult social care or adult carer support in England and that process confidential information about patients and service users; and

2. Other organisations providing services as part of the publicly funded health service, adult social care, or adult carer support pursuant to arrangements with a public body falling within paragraph (1) above, and that process confidential information about patients and service users. For the avoidance of doubt, the duty to have regard to this guidance applies to organisations that are not public bodies only in relation to work that is publicly funded; these organisations should appoint a Caldicott Guardian to assist with processing of confidential data of patients and service users of publicly funded services, and they may well consider it appropriate for the Caldicott Guardian’s remit to cover all processing of confidential patient and service user data (regardless of how services are funded).

3.2 Where an organisation appoints a Caldicott Guardian who is, or will be, a member of its staff, it will need to consider whether the individual will undertake the Caldicott Guardian role in addition to another role or duties, for example as a clinician or social care professional. While it is not an expectation that Caldicott Guardians focus solely on the Caldicott Guardian role, the work required may be time intensive.

3.3 When considering how an individual might balance other responsibilities with their Caldicott Guardian role, an organisation should take into account factors such as: the amount of confidential information about patient and service users that it processes; the extent of its data uses beyond just processing for direct (individual) care; and what resources will be available to support the Caldicott Guardian. (See also section 5 Relationship of the Caldicott Guardian to other key organisational roles and section 6 Accountability and decision making).

3.4 Where an organisation considers that it is not proportionate or feasible to appoint a member of its own staff to the Caldicott Guardian role, it should arrange for the function to be provided in another way. An organisation may choose to share a Caldicott Guardian with one or more other organisations. For example, a group of care homes, a primary care network (PCN) or consortium of GP practices may arrange to share one of their Caldicott Guardians with other members. Very small organisations might agree with an organisation that is commissioning it to provide services that the commissioning organisation’s Caldicott Guardian would be available to provide advice where necessary.
3.5 Where organisations share a Caldicott Guardian, it is up to the organisations to make these arrangements. They will need to consider factors such as the size and type of organisations involved, and the amount of confidential information about patients and service users that is processed. Questions to consider include:

- Will the Caldicott Guardian have sufficient time and resources to take on the workload for the range of organisations involved?
- Will the Caldicott Guardian have sufficient access to the information required to look into and resolve issues?
- How will the Caldicott Guardian raise issues to decision makers in the organisations involved?
- Is the Caldicott Guardian likely to face any conflicts of interest and how will these be resolved or managed?

Where a Caldicott Guardian is to be shared between organisations, those organisations should consider if there should be a deputy Caldicott Guardian from one or more of the organisations to provide support and another perspective.

3.6 When any organisation appoints its Caldicott Guardian, it should also consider appointing a deputy Caldicott Guardian. A deputy can help to ensure that there is another point of call, and that there is continuity of service when the principal Caldicott Guardian is unavailable. Deputies can be particularly useful in large organisations, where the Caldicott Guardian’s workload may need to be shared. Where an organisation appoints a deputy Caldicott Guardian, it should also bear in mind the considerations outlined within sections 4 to 9 of this guidance. Where appointing a deputy is impractical, arrangements should be made for an appropriately experienced individual to provide cover when the Caldicott Guardian is not available, for instance, if they are on annual leave.

3.7 If an organisation with a statutory duty to have regard to this guidance chooses not to appoint a Caldicott Guardian, it should document this decision and the reasons for it, for example in the minutes of a meeting, by e-mail, or in correspondence with other key organisational roles. (See also section 5 Relationship of the Caldicott Guardian to other key organisational roles).

4. Roles and responsibilities of the Caldicott Guardian

4.1 Caldicott Guardians help their organisations to ensure that confidential information about health and social care service users is used ethically, legally, and appropriately.

4.2 Caldicott Guardians should provide leadership and informed advice on complex matters involving the use and sharing of patient and service user confidential
information, especially in situations where there may be areas of legal and/or ethical ambiguity.

4.3 The Caldicott Guardian should play a key role in helping to ensure that their organisation(s) satisfy the highest ethical and legal standards for processing patient and service user confidential information. Their main concern is confidential information relating to patients, service users and their care. However, in some circumstances the Caldicott Guardian's judgment may also be needed in relation to the use of information about other individuals, such as staff or relatives of service users.

4.4 Day-to-day activities of a Caldicott Guardian will vary according to organisation type and size. They may include:

- advising on disclosures of confidential information, in particular whether they can be made in line with the common law duty of confidentiality
- involvement with patients’ or service users’ complaints
- reviewing and advising on data protection impact assessments, data sharing agreements, and instructions to data processors (although noting also the specific role that the organisation's DPO may also have in relation to these issues, as considered further in section 5.3 below)
- involvement in audit reporting or recommendations
- involvement in data breach investigations (again noting the role of the DPO in this regard as well).

4.5 The Caldicott Guardian should promote the Caldicott Principles and good information governance throughout their organisation, using the Principles to encourage and facilitate decisions in the best interests of patients, service users and their care. The Caldicott Guardian helps to ensure that information sharing is safe and effective, in line with the seventh Caldicott Principle:

**Principle 7: The duty to share information for individual care is as important as the duty to protect patient confidentiality**

Health and social care professionals should have the confidence to share confidential information in the best interests of patients and service users within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

4.6 By helping their organisation to uphold the Caldicott Principles, the Caldicott Guardian is also helping their organisation to use and share information in line with the common law duty of confidentiality, data protection law, and human rights.
5. Relationship of the Caldicott Guardian to other key organisational roles

5.1 The relationships between the Caldicott Guardian and other information governance (IG) professionals within an organisation and with decision makers are very important.

Senior Information Risk Owner (SIRO)

5.2 Some of the organisations that must have regard to this guidance will also have a Senior Information Risk Owner (SIRO). The SIRO is usually an executive director or member of the senior management board of an organisation with overall ownership of an organisation’s information risk policy. The SIRO is accountable and responsible for the overall information risk across an organisation. The Caldicott Guardian’s role and responsibilities are particularly concerned with upholding the eight Caldicott Principles and the common law duty of confidentiality.

5.3 It would not normally be appropriate for the same person to be both SIRO and Caldicott Guardian, due to the possibility of a conflict of interest and the decision-making role that the SIRO may hold. (See also section 6 Accountability and decision making).

Data Protection Officer (DPO)

5.4 Some organisations within the scope of this guidance will be required by law\(^\text{17}\) to appoint a Data Protection Officer (DPO), who is primarily responsible for providing advice on, and monitoring compliance with, data protection law and other relevant legislation. The DPO may be either an internal or an external appointment.

5.5 The roles of the Caldicott Guardian and the Data Protection Officer will overlap to some extent so it will be necessary for them to work well together. Where a Caldicott Guardian has the necessary experience and knowledge of data protection and relevant legislation it may be possible for them to also be appointed as Data Protection Officer, but care must be taken to ensure that no conflict of interest arises as a result of one individual holding both roles, and that it is clear to all when they are acting as the DPO, and when they are acting as the Caldicott Guardian.

Other information governance roles

5.6 Some organisations have other roles that focus on the processing of information, for instance, Head of Information Governance (who in some organisations may also be the DPO), Chief Clinical Information Officer or Chief Information Security Officer. It is essential that the Caldicott Guardian works in close partnership with these individuals. It is important to stress that all of these roles complement each other, and some may overlap. Where they do, it is important that the points outlined above regarding potential conflicts of interest are borne in mind.

5.7 The Caldicott Guardian should work closely with a range of other relevant internal and external roles or teams. These may include, for example, clinical multi-disciplinary teams, clinical governance teams, information management and technology teams and safeguarding teams, as well as relevant health and social care external agencies and the police.

5.8 The Caldicott Guardian may have other tasks and duties to fulfil outside their role as the Caldicott Guardian, as already noted above. The organisation(s) and Caldicott Guardian should ensure that those additional tasks and duties do not result in a conflict of interests, and that any conflicts that do arise are managed appropriately.

6. Accountability

6.1 The Caldicott Guardian role is primarily advisory but in practice, Caldicott Guardians may legitimately make judgments or decisions on matters of confidentiality, sharing and disclosure. Those undertaking the role must be afforded the freedom to exercise their judgment and advise or decide in the best interests of patients and service users, and help their organisations ensure that confidential information is used ethically, legally and appropriately.

6.2 The relationship between the Caldicott Guardians and their organisations’ senior management is of critical importance. Caldicott Guardians must be free to raise concerns at senior management or board level. It may be appropriate and helpful for them to attend senior management or board meetings in an advisory capacity when there are matters under discussion involving the use or sharing of patient or service user confidential information.

6.3 Some Caldicott Guardians may also have senior management responsibilities, for example as a member of an organisation’s board. If so, it is important that they are free to advise in the best interests of patients and service users even if this conflicts with the views of other senior management colleagues. The line between their advice as a Caldicott Guardian and their corporate view must be very clear to all.
6.4 It will also be important that Caldicott Guardians are allocated sufficient, dedicated time to fulfil their Caldicott Guardian duties, alongside other demands on their time, for example as a clinician, senior manager or board member.

6.5 Caldicott Guardians should take care to document any advice offered, judgments or decisions made and the reasoning behind them in the interests of transparency and accountability. For example often emails and written communications are preferable to verbal conversations as they provide Caldicott Guardians with a clear, documented history including details such as the request received, how the Caldicott Principles have been considered, any advice given, how much information has been shared, and with whom.

7. The competencies and knowledge a Caldicott Guardian needs

7.1 It is essential that the Caldicott Guardian should be a person with the ability to apply the Caldicott Principles wisely, and the ability and courage to speak openly and with authority to the highest level of decision maker in the organisation. They should be able to act with compassion, integrity, objectivity, honesty and in the best interests of the organisation’s patients or service users, recognising their advice will affect people. All Caldicott Guardians need a strong commitment to the role. They need the inquisitiveness to question, analyse and challenge decision-makers. They need to be able to apply wise judgment to the precise circumstances of each case. They need good interpersonal and communication skills.

7.2 The Caldicott Guardian should have a good understanding of the common law duty of confidentiality. They should also have knowledge and awareness of the wider legal frameworks relevant to information governance, for example, the UK General Data Protection Regulation, the Data Protection Act 2018, the Human Rights Act 1998, the Freedom of Information Act 2000, the National Data Opt Out policy and the law and national guidance around use of patient information in clinical research. (See also section What law and reports does this guidance refer to?).

7.3 It is preferable for a Caldicott Guardian to be a health or social care professional who has experience and knowledge of working with patients or service users and managing the complexities of frontline care. For example, this will often be a regulated or registered professional such as a doctor, social worker, or nurse.

7.4 Organisations may make their own judgment on any additional competencies and knowledge required by their Caldicott Guardian, with reference to their organisational needs and the needs of their patients and service users. These may include skills, personal attributes, and qualities and capabilities such as the ability and willingness to learn and develop new skills.
8. **How organisations should involve and support their Caldicott Guardian**

8.1 Organisations should ensure that the Caldicott Guardian is involved appropriately in issues that relate to the use of patient and service user confidential information so that they can help to ensure it is used legally, ethically and appropriately, including adherence to the common law duty of confidentiality.

8.2 Organisations should support the Caldicott Guardian to perform their role by providing the resources required to carry out the role and responsibilities. For example, permitting appropriate access to patient and service user confidential information in order to resolve issues, and providing opportunities to maintain expert knowledge.

8.3 The Caldicott Guardian should not be dismissed or penalised by the organisation for performing their role and responsibilities to the required standard.

8.4 Organisations should enable their Caldicott Guardians to have meaningful and effective engagement with patients and service users on issues that relate to the use of confidential information about those who use services, to help ensure it is used ethically, legally (including adherence to the common law duty of confidentiality) and appropriately. (See also section 9 *Relationship of the Caldicott Guardian to patients, service users, the public and other staff*).

8.5 Organisations should provide their Caldicott Guardian with access to training and continuous professional development that is appropriate to the individual and the organisation. The organisation should, where necessary, set aside time and resource for this purpose. The peer-to-peer support and other resources available through the UKCGC may be helpful in supporting this.

9. **Relationship of the Caldicott Guardian to patients, service users, the public and other staff**

9.1 The introductory section to the Caldicott Principles (see Annex A) reminds Caldicott Guardians, organisations, and their staff that patients, service users and their representatives should be included as active partners in the use of confidential information.

9.2 Caldicott Guardians should be available and accessible for patients and service users to enable meaningful and effective engagement about the use of their confidential information.
9.3 Caldicott Guardians can play an important role in helping patients and service users to understand how information is used, for what purposes, and the choices they have. This is in line with the eighth Caldicott Principle:

**Principle 8: Inform patients and service users about how their confidential information is used**

A range of steps should be taken to ensure no surprises for patients and service users, so they can have clear expectations about how and why their confidential information is used, and what choices they have about this. These steps will vary depending on the use: as a minimum, this should include providing accessible, relevant and appropriate information - in some cases, greater engagement will be required.

9.4 The experience or knowledge that many Caldicott Guardians have of interacting with patients or service users can be particularly helpful in this regard.

9.5 Contact details for the Caldicott Guardian should be publicly accessible to patients and service users. This may be via websites, notice boards and other information provided to the public.

9.6 It is also important for other members of staff to be aware of the Caldicott Guardian, their role and responsibilities and how they can be contacted, so that they can be involved in novel or difficult judgments or decisions about the use of patient and service user confidential information.

**10. Caldicott Guardian Register**

10.1 Organisations are responsible for including their Caldicott Guardian’s contact details on the Caldicott Guardian register, which is maintained by NHS Digital.18

Annex A
The Caldicott Principles

Good information sharing is essential for providing safe and effective care. There are also important uses of information for purposes other than individual care, which contribute to the overall delivery of health and social care or serve wider public interests.

These principles apply to the use of confidential information within health and social care organisations and when such information is shared with other organisations and between individuals, both for individual care and for other purposes.

The principles are intended to apply to all data collected for the provision of health and social care services where patients and service users can be identified and would expect that it will be kept private. This may include for instance, details about symptoms, diagnosis, treatment, names and addresses. In some instances, the principles should also be applied to the processing of staff information.

They are primarily intended to guide organisations and their staff, but it should be remembered that patients, service users and/or their representatives should be included as active partners in the use of confidential information.

Where a novel and/or difficult judgment or decision is required, it is advisable to involve a Caldicott Guardian.

Principle 1: Justify the purpose(s) for using confidential information

Every proposed use or transfer of confidential information should be clearly defined, scrutinised and documented, with continuing uses regularly reviewed by an appropriate guardian.

Principle 2: Use confidential information only when it is necessary

Confidential information should not be included unless it is necessary for the specified purpose(s) for which the information is used or accessed. The need to identify individuals should be considered at each stage of satisfying the purpose(s) and alternatives used where possible.
Principle 3: Use the minimum necessary confidential information

Where use of confidential information is considered to be necessary, each item of information must be justified so that only the minimum amount of confidential information is included as necessary for a given function.

Principle 4: Access to confidential information should be on a strict need-to-know basis

Only those who need access to confidential information should have access to it, and then only to the items that they need to see. This may mean introducing access controls or splitting information flows where one flow is used for several purposes.

Principle 5: Everyone with access to confidential information should be aware of their responsibilities

Action should be taken to ensure that all those handling confidential information understand their responsibilities and obligations to respect the confidentiality of patient and service users.

Principle 6: Comply with the law

Every use of confidential information must be lawful. All those handling confidential information are responsible for ensuring that their use of and access to that information complies with legal requirements set out in statute and under the common law.

Principle 7: The duty to share information for individual care is as important as the duty to protect patient confidentiality

Health and social care professionals should have the confidence to share confidential information in the best interests of patients and service users within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

Principle 8: Inform patients and service users about how their confidential information is used

A range of steps should be taken to ensure no surprises for patients and service users, so they can have clear expectations about how and why their confidential information is used, and what choices they have about this. These steps will vary depending on the use: as a minimum, this should include providing accessible, relevant and appropriate information - in some cases, greater engagement will be required.