



Caldicott Approval Form
For the use or release of patient identifiable data (please print clearly)

Guidance

All questions on the Caldicott form should be answered as fully as possible, and all relevant documents (research proposals, information sharing protocols, correspondence etc) should be attached. Processing of applications may be delayed if the Caldicott Guardian feels that it is necessary to request further information from the applicant.

If more space is required to complete any questions, please continue on a separate sheet and attach it to the form. You can also use and attach a separate sheet if there is any further information that you wish to add, for which there is no space on the form.

A completed and signed, hard copy of the Caldicott Approval Form must be received before Caldicott approval will be given. However, it will assist the quick processing of the application if a copy of the form (and any supporting documentation) is emailed, at the earliest opportunity, to caldicott@neas.nhs.uk.

Key information about the proposal

Title – The proposal should be given a short and appropriate title, to be used as a reference for correspondence. If the Caldicott application is being made as part of a research project proposal, then the research project title should be recorded here.

Description of proposal – A brief description of what information will be used, who will use it, and for what purpose.

Indicate which identifier information has been requested – Tick the boxes to indicate which information will be used, which will be (or could be) used to identify individual patients. List the other information which will be gathered / used / shared about these individuals – including medical conditions or history of healthcare. Also include here any information that will be compiled about individuals by combining information received from records held by NEAS with information from another source(s) e.g. if you are compiling information from NHS and Police records to create a database of people who have required hospital treatment after being a victim of crime.

Name of organisation(s) receiving data – List all organisations, other than NEAS, who will receive patient identifiable information. Caldicott approval is not required to transfer anonymised *and* aggregated data.

Contact details – These do not have to be the details of the applicant, but can be a nominated person who can be contacted and is authorised to provide any clarification or additional information that may be required.

How will data be transferred? Tick 'hard copy' if data will be transferred by paper records or lists, microfiche etc. Tick 'electronic' if data will be transferred on computer files, including digital images or scanned copies of paper records. If data will be transferred by both means, then tick both boxes.

Who else will have access to the data? This may be a list of individuals, or of groups of people. However, the applicant must show that Caldicott Principle 4 will be met, to restrict access to identifiable information on a strict need to know basis.

How will the service users be contacted? It is a minimum requirement of the Data Protection Act (1998) that each patient should be informed about how the information they give to the NHS is used. Explicit consent is usually required if the patient's information will be used for any purpose other than direct continuing healthcare. Therefore the applicant should demonstrate how they will contact individuals to gain informed consent. Alternatively they should demonstrate by which exemption under the DPA they are not required to obtain consent. For further information, please refer to the NEAS Confidentiality Policy and Code of Conduct (QSSD 1302).

Where will the data be stored? / How will it be protected? If identifiable data is being stored in multiple locations or formats, please include them all. Caldicott approval will only be granted if the Caldicott Guardian is satisfied that appropriate and sufficient security measures will be taken at all times. This includes physical data security (secure premises, locked filing cabinets etc) and appropriate computer security (password protection, antivirus software and firewalls etc).

If the data is on a computer is there access via a network? Networking presents an extra risk of unauthorised access, so it must be demonstrated that all reasonable steps have been taken to protect the data.

How long will the data be stored? Under the Data Protection Act (1998), identifiable data must not be kept for longer than necessary. However, there are minimum retention periods for storing certain types of information i.e. records of inclusion in a clinical trial (please refer to NEAS Records Retention Schedule QSSD 1301). If you are unsure of how long data must be stored, please contact the Information Governance Manager for advice. Please remember that the data must be stored securely throughout this retention period.

At the end of this period how will the data be disposed of? The destruction or other disposal of the data must be performed in an appropriate and secure fashion i.e. shredding or pulping, but never disposal as normal office waste. If a commercial waste disposal company is used to destroy and dispose of data, a confidentiality agreement must be in place.

Who will be responsible for ensuring that the data is disposed of in a confidential manner? If the data will have to be stored for a significant length of time, responsibility for the safe storage and disposal of data should be held within a job role (and written into the job description) rather than held by a specific individual. This will ensure that the responsibility for the data will continue to be met as individuals change jobs / leave organisations.

Compliance with Caldicott Principles

The purpose of this section is to demonstrate that the applicant (and anyone else who will access the data) is aware of their responsibilities. It is also intended to ensure that the applicant has considered their proposal in light of the Caldicott Principles, and can justify all uses of identifiable data.

Principle 1 – Justify the purpose(s)

What benefits will the proposed use of information bring? What will be the implications or risks of not using the information?

Principle 2 – Don't use patient identifiable information unless it is absolutely necessary

Is it necessary to use patient identifiable information to achieve these benefits / avoid these implications / risks? Could the same results be achieved by using anonymised data? Do the benefits of using patient identifiable information outweigh the risk to confidentiality?

Principle 3 – Use the minimum necessary patient identifiable information

Is all of the information that will be used absolutely necessary to achieve the purpose?

Principle 4 – Access to patient identifiable information should be on a strictly need to know basis

Have access controls been arranged so that only authorised persons can access information? Where possible, have role based access controls been arranged, so that each person can only access the information required to carry out their part of the process?

Principle 5 – Everyone with access to patient identifiable information should be aware of their responsibilities

Has everyone who will be accessing information signed a confidentiality agreement that advises them that they must only access the information required to perform their job and that information must only be shared with authorised persons?

Principle 6 – Understand and comply with the law

What training have staff involved in using the information received?

Other supporting documentation

List all other documents which are being submitted with the Caldicott Approval Form, and which make up part of the application. Examples of supporting documents which must be submitted are: research proposal forms and applications for / proof of ethical approval; correspondence which will help in assessing the application (such as the original letter from another organisation, requesting the information); copies of other organisations' policies and procedures which will apply to the information (such as the Confidentiality Policy of a Local Authority), contracts or agreements that relate to the proposal. These documents can be supplied by email, provided that they do not contain any patient identifiable information. If the Caldicott Guardian feels that any further documents will be required in order to process the application, they will be requested; however this may cause a delay.

Title:
Description of proposal:
<p>Proposed date to commence use/release of data :</p> <p>Proposed date to end use/release of data:</p> <p>Please state regularity e.g. monthly:</p>
<p>Indicate which identifier information has been requested:</p> <p>Forename <input type="checkbox"/> Surname <input type="checkbox"/> DOB <input type="checkbox"/> Age <input type="checkbox"/> Sex <input type="checkbox"/></p> <p>Address <input type="checkbox"/> Postcode <input type="checkbox"/> NHS No <input type="checkbox"/> Full patient record <input type="checkbox"/></p> <p>Other (please state):</p>
Name of organisation(s) receiving data:
Person responsible for release of data:
Name: _____ Job title: _____
Person responsible for receipt of data:
Name: _____ Job title: _____
Contact details (person to be contacted if further information is required to process this application):
Name :
Address :
Telephone :
Email :
How will the data be transferred?
Paper records <input type="checkbox"/> Electronic records <input type="checkbox"/>
Other (please state)
Who else will have access to the data?
<i>Note: If data recipients are not employed by the NHS please state whether NHS honorary contracts are in place. If not – detail confidentiality agreements.</i>
How will the service users be contacted?

<p>How will service users consent be obtained?</p> <p>If no consent being obtained, please detail the reason why not e.g. exemption under section 60 Health & Social Care Act 2001</p>
<p>Where will the data be stored?</p>
<p>How will the data be protected? <i>(Please detail security measures to be taken)</i></p>
<p>If the data is on a computer is there access via a network?</p>
<p>How long will the data be stored <i>Note: Applicants must comply with NEAS Records Retention Schedule (QSSD 1301) and the Data Protection Act 1998.</i></p>
<p>At the end of this period, how will the data be disposed of?</p>
<p>Who will be responsible for ensuring that the data is disposed of in a confidential manner?</p>

You must address the 6 Caldicott principles – please give a brief description under each of the following headings

Principle 1 – Justify the purpose(s)

Every proposed use or transfer of patient identifiable information from within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed, by an appropriate guardian.

Principle 2 – Don't use patient-identifiable information unless it is absolutely necessary

Patient identifiable information items should not be included unless it is essential for the specified purpose(s) of that flow. The need for service users to be identified should be considered at each stage of satisfying the purpose(s).

Principle 3 – Use the minimum necessary patient identifiable information

Where use of patient identifiable information is considered to be essential, the inclusion of each individual item of information should be considered and justified so that the minimum amount of identifiable information is transferred or accessible as is necessary for a given function to be carried out.

Principle 4 – Access to patient identifiable information should be on a strictly need to know basis

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

Principle 5 Everyone with access to patient identifiable information should be aware of their responsibilities

Action should be taken to ensure that those handling patient identifiable information (both clinical and non clinical staff) are made fully aware of their responsibilities and obligations to respect patient confidentiality.

Principle 6 Understand and comply with the law

Every use of patient identifiable information must be lawful. Someone in each organisation handling patient information should be responsible for ensuring that the organisation complies with legal requirements.

Other supporting information e.g. Ethics approval, correspondence etc

Declaration

To be completed by the applicant for Caldicott Approval to confirm acceptance of the responsibility to ensure that the data will be processed in accordance with the agreed conditions.

1. The data will be treated as confidential.
2. The data will be used only for the purposes described.
3. In the case of anonymised or confidential aggregated data, no attempt will be made to identify or contact individuals or organisations identified through these data.
4. The data may be disclosed to staff of the above organisation but only for the purposes described.
5. The data may not be disclosed to any third party.
6. The data will be stored in secure condition at all times whether held on computer medium or as a printed copy.
7. The organisation to which the data are released will maintain and comply with a Data Protection Registration which encompasses the data and data usage described.
8. The data will be destroyed when the work is completed: any printed copies will be destroyed, and files deleted from computer systems (including any copies held on backup or archive media) – except where retention is required by the Data Protection Act (1998).
9. If there are any subsequent changes to the proposal (which affect the way in which patient information is collected, stored, processed, used or disposed of) further Caldicott approval will be required.
10. All staff given access to the data will be made aware of these conditions (principle 5).

I confirm that the data will be held and used according to the conditions and information given as described within this approval from.

Name _____ Title _____
Signature _____ Date _____

Please return completed form to :

Information Governance Manager, North East Ambulance Service NHS Trust, Bernicia House, Goldcrest Way, Newburn Riverside, Newcastle NE15 8NY

For Office Use Only

The release and use of data as described above is: **approved / not approved**

Caldicott Guardian / deputy _____ Date _____

Further conditions applied