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| 1. **Proposal Title :** |  |

1. **Sponsor Details and Declaration**

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| Name: |  | | Address: |  |
| Position: |  | |  |  |
| Organisation: |  | |  |  |
| Email: |  | |  |  |
| Telephone: |  | |  |  |
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| **Sponsor’s Declaration [[1]](#footnote-1)**: | | I declare that the named Data User is engaged in a reputable research/audit project and that the data requested can be entrusted to this person in the knowledge that they will discharge their obligations in regard to the confidentiality of the data. | | |
| **Sponsor’s Dated Signature** | |  | | |

1. **Data User Details and Declaration**

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| --- | --- | --- | --- | --- |
| Name: |  | | Address: |  |
| Position: |  | |  |  |
| Organisation: |  | |  |  |
| Email: |  | |  |  |
| Telephone: |  | |  |  |
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| **Data User’s Declaration** : | | I declare that I understand and undertake to abide by the rules of confidentiality and security in the use of patient identifiable information received from NHS Tayside. | | |
| **Data User’s Dated Signature** | |  | | |

1. **Caldicott Approval**

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| **Approval is given for the release and use of patient identifiable information as specified in this application** | | |
|  |  | **Caldicott Guardian, NHS Tayside** |

1. **Name and Data Protection Registration Number of the organisation requesting the information, if not NHS Tayside**

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1. **Data Co-user(s) –** please list all personnel who will have access to the patient identifiable information released to the Data User

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| **Title & Name** | **Organisation** | **Role e.g., Consultant etc.** | **Email Address** |
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1. **What Information do you require and what is the Intended Use**

In the following sections provide, in straightforward language, and **in sufficient detail to understand the proposal**, a brief description of the proposal including **aims**, **objectives** and **methods**. In particular, it should be clear whether the proposal relates to audit and service improvement or research.

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**Consent** – If appropriate, please describe whether consent is to be sought from the people whose personal data you wish to access or where there are barriers to gaining consent please describe those barriers.

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**A separate Data Processing Specification (Section 14-18 of this form) must be completed for each source of data** e.g. if your study requires the linking of data from different sources by way of using the CHI then it should be clear what data is collected from each source and how that data will be linked and at what stage and how any anonymisation of the collated data will take place.

1. **Caldicott Principle 1 – Justify the Purpose(s).** Every proposed use or transfer of patient-identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed by an appropriate guardian.

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1. **Caldicott Principle 2 – Why is Patient Identifiable Information required?** Patient identifiable information items should not be used unless there is no alternative.

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**Contacting Patients** - if you intend to make **contact with patients** identified through the processing of this data, indicate how this will be done and how you will ensure that it is appropriate to contact them. It is recommended that contact with patients is through correspondence signed by the patient’s GP/Clinician or Head of Clinical Service.

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1. **Caldicott Principle 4 – Is access to the data on a 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.

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1. **Caldicott Principle 5 – How will you ensure that everyone with access to the data is aware of their data protection and confidentiality responsibilities?**

**Have all data users completed their mandatory online data protection training and is it still valid?** - Action should be taken to ensure that those handling patient-identifiable information – both clinical and non-clinical staff – are aware of their responsibilities and obligations to respect patient confidentiality.

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1. **Caldicott Principle 6 – How will legal requirements for the use of the data be met? -** Every use of patient-identifiable information must be have a lawful basis under the relevant legislation e.g. Article 9(2)(j) of the GDPR. Someone in each organisation processing personal data should be responsible for ensuring that the organisation complies with legal requirements.

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1. **Caldicott Principle 7 – The need to lawfully and securely share personal data can be just as important as the responsibility to maintain confidentiality.** Please fully complete the Data Processing Specification (Sections 14 to 19 below) to justify the use of every item of personal data being accessed or used in the proposed study.

Unless patient identifiers are required to meet the purpose of the request, only anonymised or pseudonymised data should be requested (in pseudonymised data identifiers are replaced by e.g. a unique study number).

As patients may be identified from a combination of variables in anonymous data, such as date of birth, date of admission, treating hospital, area of residence, please request only the minimum detail required to meet the purpose of the study.

1. **Caldicott Principle 3 – Why is each data item required?**

Where the use of patient‑identifiable information is considered to be essential, each individual item of information should be justified with the aim of reducing identification and the possibility of a breach of confidentiality.

For **each separate** Data Source (casenotes, system, database) of patient identifiable information that you intend to access in support of your study, please provide the following information (additional blank Data Processing Specifications are available on the [Caldicott section of the Information Governance Staffnet pages](http://staffnet.tayside.scot.nhs.uk/OurWebsites/InformationGovernanceandCyberAssurance/PROD_295481) otherwise email TAY.informationgovernance@nhs.scot)

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| Data Source: |

You must approach the person who you will rely on to provide you with the data that you are requesting. You must agree with the Data Source Contact that it is feasible to provide you with what you are requesting.

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| NHS Tayside Data Source Contact Details: | |
| Name: | Designation: |
| Location: | Tel No: |
| Email address: |  |

Please indicate **all** potentially identifying **demographic** data items to which you are requesting access.

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| **Data Item** | **Required** | **Reason Required** |
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| CHI number |  |  |
| Forename |  |  |
| Surname |  |  |
| Initials |  |  |
| Date of birth |  |  |
| Age |  |  |
| Gender |  |  |
| Address |  |  |
| Post code |  |  |

Please indicate all **clinical** data items to which you require access.

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| **Data Item** | **Reason Required** |
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1. **Data Transfer**

Give details of how the requested information will be transferred to you from the Data Source e.g. encrypted USB device, password protected file, paper, NHSmail email attachment, etc.

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1. **Safeguards**

Describe the measures in place to protect and use the data securely and confidentially.

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| Physical Location (NHS Tayside, University, etc.): |
| Device to be held on (desktop, laptop, network storage, etc.): |
| Access Controls (how will the data be protected from unauthorised access?): |
| Encryption (what encryption will be used to protect the data?): |
| Format (spreadsheet, database, etc.): |
| Anonymisation (how will the identity of individuals be protected) : |

1. **Data Transfer Regularity**

How often do you intend the requested data to be provided to you?

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1. **Data Retention**

How long do you intend to retain the information that you will rely on for your study and how will you dispose of the information at that time?

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1. **Application Checklist**

Have you included:

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| Ethics Committee correspondence |  |
| the proposed study protocol |  |
| information provided to patients where appropriate |  |
| relevant draft correspondence templates |  |
| relevant Information Governance procedures |  |
| full Sponsor and Data User contact details |  |
| and have both the Sponsor and Data User signed the application? |  |

**Submitting the Caldicott Application**

Once the Caldicott application has been completed and all supporting documentation gathered then the application should be submitted to:

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| **By Post**  Information Governance  Maryfield House South  Mains Loan  Dundee  DD4 7BT | **By email**  TAY.informationgovernance@nhs.scot  subject line to be:  Caldicott Application: *Study Name* |

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| **NHS Tayside Information Governance & Cyber Assurance Team must be notified immediately on discovering that there has been a breach of confidentiality, loss, or theft of the provided data.** |

1. the details of the NHS Tayside person who is supporting the provision of the information in question, usually to be signed by a consultant if patient data is requested and the applicant is not of that status or is not medically qualified [↑](#footnote-ref-1)