**Public Benefit and Privacy Panel for Health and Social Care**

**Guidance for Applicants**

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# Introduction

This guidance document is for use by applicants in completing application forms for submission to the Public Benefit and Privacy Panel for Health and Social Care, which undertakes information governance scrutiny of requests to access NHSScotland-originated data for a variety of purposes. You should read the Introduction section in full before beginning to complete your application form. You should refer to the Completing the Application Form section whilst filling out your application form.

Your application form (and supporting evidence) are your opportunity to explain your study, project, audit or other piece of work (your ‘proposal’) in detail, to show that it is a carefully considered and well-designed piece of work which will be of demonstrable value to society and will appropriately safeguard the privacy rights of those whose information it seeks to use.

Full information about the panel (for applicants, members of the public, and participants in the panel process) is available from the [**panel website**](http://www.informationgovernance.scot.nhs.uk/).

## When is an application appropriate?

You must complete an application if your proposal requires any of the following in respect of NHSScotland originated data relating to individuals, derived from information relating to individuals, or of an otherwise sensitive nature (for example commercially sensitive organisational data):

* Access to or use of such data from more than one NHSScotland board
* Linkage, matching or mixing of such data with data from other sources (outside of NHSScotland)
* The transfer of such data outside of Scotland
* Access to or use of national datasets held by NHS National Services Scotland (including for linkage, matching or anonymisation)

You may complete an application for:

* Any other use of NHSScotland originated data which you consider to be complex, contentious, having wider national implications, or requiring the scrutiny of the panel (including use of data from a single NHSScotland board)
* Use of data originating from primary care providers, and from beyond NHSScotland, but with a relevant implication for the service (for example social care information use)

The following relevant factors do not remove the requirement to complete an application (and should be fully explained at the relevant point in the application form):

* Consent of data subjects
* Status of data subjects as patients/non-patients
* Whether data subjects are alive or deceased
* Purpose of the proposed work - audit, management, performance, research or other
* Statutory or regulatory requirement for the proposed work

## Application Process

You are strongly advised to seek the input of your eDRIS application coordinator before completing your application form. Contact the eDRIS Team, who will assist you - [Nss.edris@nhs.net](mailto:Nss.edris@nhs.net) or by phone on 0131 275 7333.

You must submit your application via your eDRIS application coordinator, who will be your single point of contact throughout the application process. Applications for review at the next panel must be submitted in an administratively complete form before the corresponding submission deadline. Application submission deadlines are published on the [panel website](http://www.informationgovernance.scot.nhs.uk/).

Once submitted, your application will be passed to information governance (IG) colleagues who will conduct a proportionate IG review of your application. They may approve your application (with or without conditions), seek further information or clarification from you, or refer your application for review by panel members.

If your application is approved, you will be issued with an approval letter. In this scenario, it is the normal expectation is that applications will be concluded within 20 working days of submission.

If further information or clarification is requested, this will be communicated to you by your eDRIS application coordinator, along with a recommended deadline for responding to this request. Your response will be considered by IG colleagues and an outcome determined. Again, if your application is approved, you will be issued with an approval letter. In this scenario, the timescale for the conclusion of an application is dependent upon the timeliness of your response.

If your application is referred for review, it will be passed in the first instance to a small group of panel members (comprised of public representatives and NHSScotland Caldicott Guardians) for their opinion. This group may also approve your application (with or without conditions) or refer your application for review by all members of the panel. Again, if your application is approved, you will be issued with an approval letter. In this scenario, it is the normal expectation is that applications will be concluded within 30 working days of submission, not including any time elapsed whilst awaiting a response from you.

If your application is referred onwards for review by all members of the panel, it will be reviewed at the next full meeting of the panel. In exceptional circumstances the panel may request that you appear in person at a meeting to discuss your application. You will be informed of the outcome shortly after the panel meets in full. In this scenario, your application will take longer to conclude, and your eDRIS application coordinator will discuss likely timescales with you.

## Definitions Used

**‘Proposal’**

The study, project, audit or other piece of work which is the subject of an application for scrutiny. The entirety of what the applicant proposes in their application form.

The panel has a wide remit to consider applications for use of NHSScotland data for a variety of purposes. These purposes but include such uses of data as medical research, healthcare audit, healthcare planning and improvement, medical education, etc. For these reasons neither the word ‘study’ or ‘project’ is wholly appropriate to describe the proposed uses of data for which applicants seek the panel’s approval, and so the word ‘proposal’ is used to describe all such work which the panel is asked to consider.

**‘Identifiable or potentially identifiable data’**

Information which does, or could be used to, identify an individual or individuals.

You should consider this definition to be wide in scope and encompass both data and variables which do identify individuals (for example name) as well as data and variables which, even after controls such as anonymisation have been applied, could potentially be used to identify individuals depending on context (for example postcode). For example, dates of admission and discharge to hospital present a risk of individuals being identified, since a specific date combined with an unusual diagnosis in a defined geographic area and another variable such as 'Sex' or 'Ethnicity' could identify a single individual.

**‘Datasets and data sources’**

Information assets which your proposal seeks to access and use.

You should consider this definition to be wide in scope and include any source of information which you propose to access and use, whether highly structured or less structured in nature, and whether already existing or to be newly collected or gathered. Examples may include national datasets, local data sets, national or local extracts from systems, national or local registries or networks, patient records, or new information to be gathered from patients, families or other cohorts.

**‘Safe Haven’**

Physical and technical environment designed to facilitate the safe processing and secure access to data.

Usually within the context of research activities, several such recognised environments exist within Scotland – these are listed at Appendix A of the a Application Form. Their use for access to and processing of data represents a significant control and provides additional assurance.

# Completing the Application Form

You should refer to the sections below whilst filling out the corresponding parts of your application form. You can direct any questions or queries to your eDRIS application coordinator ([Nss.edris@nhs.net](mailto:Nss.edris@nhs.net) or by phone on 0131 275 7333).

## Section 1: People Involved

### 1.1 Applicant

The applicant is the person filling out the application form and principal contact for the application. Typically this is the person with operational responsibility for the proposal. If you are filling out the application form, this is you. You should not complete the application form on behalf of another applicant – Section 6 of the form requires a declaration and undertakings on your behalf.

1.1.01 Please provide your own full name

1.1.02 Please provide your title (for example *Mr, Mrs, Ms, Dr, Professor*)

1.103 Please provide your position – this will be your current professional role or roles relevant to your application (for example ‘*Project Coordinator, Scottish Diabetes Research Network’*)

1.1.04 Please provide your professional registration number if applicable – indicate which type of professional registration (for example ‘*GMC 1234567’, ‘GDC 12345’)*

1.1.05 Please give the full name of the organisation on whose you are making the application or within which you work in your professional capacity as an applicant – this should include a parent organisation, and sub-division or department if appropriate (for example ‘*NHS Tayside, Medical Directorate, ‘University of Edinburgh, Department of Informatics’, ‘Scottish Government, Director General of Health and Social Care’)*

1.1.06 Please provide your own work address where you can be contacted

1.1.07 Please provide your own work postcode

1.1.08 Please provide your own work telephone number/s

1.1.09 Please provide your own work email address – ideally this will be an email address associated with your organisation or institution, and not a personal email address (such as hotmail or gmail)

1.1.10 Please select ‘Yes’ if you have either a standard (NHS employee) or honorary NHS contract (irrespective of hours), or ‘No’ if you do not

1.1.11 Please provide the fullest details you are able regarding the most recent professional training or education you have undertaken on the topic of Information Governance (IG). A non-exhaustive list of training courses is included in Appendix A of the application form. Evidence of IG training is an important aspect of all applications, giving assurances that individuals are aware of the privacy, confidentiality, data protection and Caldicott implications of working with personal data. IG training is typically mandatory in NHSScotland boards and if you have a contract or honorary contract with an NHSScotland board, you should have undertaken IG training. For experienced researchers beyond NHSScotland, there are alternative IG training courses, listed at Appendix A.

Please provide the name of the course/s most recently undertaken (for example ‘*NHSScotland Safe Information Handling eLearning module’*), the name of the institution providing the training ( for example ‘*NHS Tayside via Knowledge Network’*), and the date or approximate date you completed the training. If you have listed IG training which is not included at Appendix A, please also include links to further information regarding the training or directly to the course material.

### 1.2 Clinical Sponsor/Lead

The clinical sponsor or lead is a senior clinician/Head of Department/Principal Investigator with overall clinical responsibility for the proposal. This will usually be a registered clinician or senior member of the team, whether directly involved with the processing of data or simply having clinical oversight of the proposal.

1.2.01 Please provide the full name of the clinical sponsor/lead

1.2.02 Please provide the title (for example *Mr, Mrs, Ms, Dr, Professor*) of the clinical sponsor/lead

1.2.03 Please provide the position of the clinical sponsor/lead – this will be their current professional role or roles relevant to your application (for example ‘*Medical Director, NHS Grampian’; ‘Director of Neonatal Epidemiology Unit , Glasgow University*)

1.2.04 Please provide the professional registration number of the clinical sponsor/lead – indicate which type of professional registration (for example ‘*GMC 1234567’, ‘GDC 12345’)*

1.2.05 Please give the full name of the organisation which the clinical sponsor/lead represents – this should include a parent organisation, and sub-division sub-division or department if appropriate(for example ‘*NHS Tayside, Medical Directorate’, ‘University of Edinburgh, Department of Informatics’, ‘Scottish Government, Director General of Health and Social Care’)*

1.2.06 Please provide the work address where the clinical sponsor/lead can be contacted

1.2.07 Please provide the work postcode of the clinical sponsor/lead

1.2.08 Please provide the work telephone number/s of the clinical sponsor/lead

1.2.09 Please provide the work email address of the clinical sponsor/lead – ideally this will be an email address associated with your organisation or institution, and not a personal email address (such as hotmail or gmail).

1.2.10 Please select ‘Yes’ if the clinical sponsor/lead has either a standard (NHS employee) or honorary NHS contract (irrespective of hours), or ‘No’ if they do not

1.2.11 Please provide the fullest details you are able regarding the most recent professional training or education the clinical sponsor/lead has undertaken on the topic of Information Governance (IG). A non-exhaustive list of training courses is included in Appendix A of the application form. Evidence of IG training is an important aspect of all applications, giving assurances that individuals are aware of the privacy, confidentiality, data protection and Caldicott implications of working with personal data. IG training is typically mandatory in NHSScotland boards and if the clinical sponsor/lead has a contract or honorary contract with an NHSScotland board, they should have undertaken IG training. For experienced researchers beyond NHSScotland, there are alternative IG training courses, listed at Appendix A.

Please provide the name of the course/s most recently undertaken (for example ‘*NHSScotland Safe Information Handling eLearning module’*), the name of the institution providing the training ( for example ‘*NHS Tayside via Knowledge Network’*), and the date or approximate date the clinical sponsor/lead completed the training. If you have listed IG training which is not included at Appendix A, please also include links to further information regarding the training or directly to the course material.

### 1.3 Information/Data Custodian

The information or data custodian is the person with responsibility for safeguarding the confidentiality of data throughout the proposed work and should have training in Information Governance. An information custodian is a senior colleague with a key role in any proposal and is always required to be named in an application. If this is you (the Applicant) or the Clinical Sponsor/Lead, then please simply state this in question 1.3.01 (for example ‘*same as Applicant’, ‘same as Clinical Sponsor/Lead’)*  and do not complete the remaining questions in section 1.3.

1.3.01 Please provide the full name of the information/data custodian

1.3.02 Please provide the title (for example *Mr, Mrs, Ms, Dr, Professor*) of the information/data custodian

1.3.03 Please provide the position of the information/data custodian – this will be their current professional role or roles relevant to your application (for example ‘*Medical Director, NHS Grampian*)

1.3.04 Please provide the professional registration number of the information/data custodian if applicable – indicate which type of professional registration (for example ‘*GMC 1234567’, ‘GDC 12345’)*

1.3.05 Please give the full name of the organisation which the information/data custodian represents – this should include a parent organisation, and sub-division or department if appropriate(for example ‘*NHS Tayside, Medical Directorate’, ‘University of Edinburgh, Department of Informatics’, ‘Scottish Government, Director General of Health and Social Care’)*

1.3.06 Please provide the work address where the information/data custodian can be contacted

1.3.07 Please provide the work postcode of the information/data custodian

1.3.08 Please provide the work telephone number/s of the information/data custodian

1.3.09 Please provide the work email address of the information/data custodian – ideally this will be an email address associated with your organisation or institution, and not a personal email address (such as hotmail or gmail).

1.3.10 Please select ‘Yes’ if the information/data custodian has either a standard (NHS employee) or honorary NHS contract (irrespective of hours), or ‘No’ if they do not

1.3.11 Please provide the fullest details you are able regarding the most recent professional training or education the information/data custodian has undertaken on the topic of Information Governance (IG). A non-exhaustive list of training courses is included in Appendix A of the application form. Evidence of IG training is an important aspect of all applications, giving assurances that individuals are aware of the privacy, confidentiality, data protection and Caldicott implications of working with personal data. IG training is typically mandatory in NHSScotland boards and if the information/data custodian has a contract or honorary contract with an NHSScotland board, they should have undertaken IG training. For experienced researchers beyond NHSScotland, there are alternative IG training courses, listed at Appendix A.

Please provide the name of the course/s most recently undertaken (for example ‘*NHSScotland Safe Information Handling eLearning module’*), the name of the institution providing the training ( for example ‘*NHS Tayside via Knowledge Network’*), and the date or approximate date the information/data custodian completed the training. If you have listed IG training which is not included at Appendix A, please also include links to further information regarding the training or directly to the course material.

### 1.4 Others with access to identifiable or potentially identifiable data

Please provide details of all additional people (if any) who will have access to theidentifiable or potentially identifiable data. This will include those who are processing such data on your behalf (for example in research safe havens or linkage agents). Where the organisation and contact details are the same as for the applicant, please simply indicate this next to each name. For applications where this is a large group or number of people, the required details can be appended separately, for example in a suitable extract from a study protocol, or simply on an additional sheet.

### 1.5 Others

Others without access to identifiable or potentially identifiable data, but with a significant involvement in proposal design, content or outcomes. This might include colleagues who will be accessing aggregated tables, interpreting study findings, or providing strategic direction. Please provide the requested details for such persons. For applications where this is a large group or number of people, the required details can be appended separately, for example in a suitable extract from a study protocol, or simply on a separate sheet.

## Section 2: Organisations & Bodies

### 2.1 Organisation or Body Leading Proposal

This organisation (for example, *Aberdeen University*) or body (for example *Farr Institute* or *Scottish Infection Research Network*) is putting forward the proposal requesting access to data for the purposes specified in the application. The applicant at section 1.1 is acting on this organisation’s behalf. Where multiple organisations are collaborating to produce the proposal, this should be the organisation which has a lead in the operational delivery of the proposal and will therefore be taking responsibility for matters relating to the access and processing of data.

2.1.01 Please provide the full name of the organisation or body. If this is an NHSScotland board, please provide the board name and go directly to question 2.1.04.

2.1.02 Please indicate whether the organisation is a Data Controller, currently registered with the Information Commissioner’s Office (by selecting ‘Yes or ‘No’). Please provide the current ICO Data Protection Registration Number if this is the case. You can find your organisation’s Data Protection Registration Number by using [this tool from the ICO](https://ico.org.uk/esdwebpages/search).

2.1.03 Please indicate if the organisation is commercial in nature (by selecting ‘Yes’ or ‘No’). Where in doubt, please answer ‘Yes’, and qualify this answer at the following question 2.1.03a.

2.1.03a Please provide details of any commercial aspects of the organisations work. This should include details of industry sector, the organisations activities within this sector, and also any previous experience of working with NHSScotland data. Please attach any relevant supporting information you wish to provide.

2.1.04 Please indicate whether the organisation is wholly funding or paying the costs of conducting the proposal (by selecting ‘Yes or ‘No’). If the answer is ‘Yes’, you do not need to complete section 2.2 below.

### 2.2 Organisation or Body Funding Proposal

This organisation or body is providing the financial resource to make the proposal possible, and is different to the organisation detailed in section 2.1 above. You do not need to complete this section if you answered ‘Yes’ to question 2.1.04 above. Examples of funding bodies are *Medical Research Council*, *Chief Scientist’s Office (CSO)*, *Administrative Data Research Network, National Institute for Health Research* etc.

2.2.01 Please provide the full name of the organisation or funding body. If this is an NHSScotland board, please provide the board name and go directly to question 2.3.

2.2.02 Please indicate whether the organisation is a Data Controller, currently registered with the Information Commissioner’s Office (by selecting ‘Yes or ‘No’). Please additionally provide the current ICO Data Protection Registration Number if this is the case. You can find your organisation’s Data Protection Registration Number by using [this tool from the ICO](https://ico.org.uk/esdwebpages/search).

2.2.03 Please indicate if the organisation is commercial in nature (by selecting ‘Yes or ‘No’). Where is doubt, please answer ‘Yes’, and qualify this answer at the following question 2.2.03a.

2.2.03a Please provide details of any commercial aspects of the organisation’s work. This should include details of industry sector, the organisation’s activities within this sector, and also any previous experience of working with NHSScotland data. Please attach any relevant supporting information you wish to provide.

### 2.3 Other Relevant Organisations or Bodies

Organisations or bodies which have a significant involvement or interest in proposal design, content or outcomes. Please provide the requested details for such organisations or bodies. For applications where this is a large number of organisations, the required details can be appended separately, for example in a suitable extract from a study protocol.

## Section 3: Overview

### 3.1 Proposal Essentials

This is a key section which must outline in a clear way the nature of the proposal, the ways in which it proposes to use NHSScotland originated data, and how this will result in benefit for the wider public. It places the proposal in context, and establishes if it has used peer review or lay involvement in the course of its design. Applicants should aim to provide absolute clarity when completing this section, and supporting evidence, specifically referenced, may be useful in achieving this. You should use clear concise language which can be easily understood by colleagues and public partners without a background in epidemiology, health research, statistics or analysis.

3.1.01 Please provide a full name or title for the proposal.

3.1.02 Please indicate whether this proposal seeks to extend, renew or alter an existing proposal (by selecting ‘Yes or ‘No’), If ‘Yes’, additionally describe in what way specifically the existing proposal will be extended, renewed or altered. Please give the reference number, full name and title of any relevant existing proposal.

3.1.03 Please indicate whether this proposal is related to an existing proposal (by selecting ‘Yes or ‘No’), approved or otherwise, and provide details of the proposal and the way in which the two are related. This may be the case, for example, where separate proposals have been submitted for component parts of a wider project.

3.1.04 Please indicate the substantive purpose/s of the proposal – this might include one or more of the purposes listed, and you should select each that applies in a substantive way. These will be further outlined in your answers to sections 3.1.07 and 3.1.08 below. If the purpose/s of the proposal are not listed here, please include these at the foot of this section in the details box.

3.1.05 Please indicate whether the proposal seeks to use information which identifies or potentially identifies individuals (by selecting ‘Yes or ‘No’). This will include the use of such information at any point in the course of the processing which is being proposed, whether by the applicant, another party involved in the study, or an organisation (such as a safe haven) acting on behalf of an applicant/organisation. It will include scenarios where personal identifiers are being collected as part of a new dataset or being used for data linkage purposes.

3.1.06 Please indicate the sources of the data which the proposal seeks to access - this might include one or more of the sources listed, and you should select each that applies. These will be further outlined in your answers to sections 3.1.07 and 3.1.8 below. If the sources of the data it is proposed to access are not listed here, please include these at the foot of this section in the details box.

3.1.07 Please provide a full, clear outline of the proposal background. Describe the purpose of your proposal, its aims and objectives and envisaged benefits to the public and/or patients. This section must outline why the proposal, and the access to data it proposes, is necessary and demonstrate a clear connection between this work, the outcomes that will result, and the benefit to patients or the wider public which will result thereafter. If this is a research proposal you may wish to consider using the PICO principle: Population/Participants, Interventions/Indicators, Comparator/Control and Outcome when responding to this question.

You should use clear concise language which can be easily understood by colleagues and public partners  without a clinical background or extensive knowledge and expertise in epidemiology or health research. Your explanation will probably not extending beyond 400 words of text. If you are using extracts from study protocols or other relevant existing documentation, please ensure that it is relevant to the section.

3.1.08 Please provide a full, clear outline of the proposal design and data sources. It is essential that you use this section to paint a clear picture of the processing of data which you propose to undertake. This is often best achieved by appending or including data flow diagram/s in support of a written explanation, showing what data sources are being accessed and processed by which part at what point in the proposal methodology – such illustration can also include key processes undertaken with respect to data, such as anonymisation or linkage. You should include details of sample size, cohort inclusion or exclusion criteria, ranges of data to be used, and incidences of proposed data access/extract/transfer and linkage/matching/anonymisation, etc.

You should use clear concise language which can be easily understood by colleagues and public partners  without a clinical background or extensive knowledge and expertise in epidemiology or health research. Your explanation will probably not extending beyond 400 words of text. If you are using extracts from study protocols or other relevant existing documentation, please ensure that it is relevant to the section.

3.1.09 Please indicate whether the proposal has implications for (specifically targets or otherwise impacts) sensitive groups or vulnerable populations. A non-exhaustive list of Vulnerable Populations is included at Appendix A of the application form, but you should include any group or cohort which might reasonably be considered as sensitive or vulnerable in nature. Please provide details of which groups and in what way the proposal might target/impact each.

3.1.10 Please indicate whether the proposal seeks to use information exclusivelyabout deceased persons. This will include where the proposal seeks to access and use individual datasets which consist only of information relating to deceased persons. Please provide details of the relevant data sources.

3.1.11 Please indicate whether any members of the public/lay representatives have been involved in the design of the proposal. This would include details of any public engagement or consultation activity which has been undertaken in the course of designing the proposal. If supporting evidence resulting from consultation exists, you may wish to attach this as supporting evidence.

3.1.12 Please indicate if peer review has been part of proposal design. If this is the case, please give details of how this was undertaken, including bodies or organisations involved. If supporting evidence resulting from peer review exists, you may wish to attach this as supporting evidence.

3.1.13 Please indicate if there is *any* commercial aspect or dimension to the proposal or its outcomes. This would include any involvement of commercial organisations at arms-length to the proposal, or likely impact on commercial organisations, individually or collectively, that might result from the outcomes or methodology of the proposal.

### 3.2 Proposal Geography

This section is used to clarify the scope of the proposal, and the outcomes it commits to delivering, in geographical terms – this information can help identify statutory and regulatory considerations in respect of the proposal. Please indicate the geographical scope of the proposal in the context of the outcomes it seeks to deliver, by selecting one of the available options (for example, a proposal might be part of a larger, Europe-wide initiative, such as the European Medicines Consortium).

### 3.3 Proposal Duration and Frequency

This section is used to clarify the duration and frequency of the access and use of data which is proposed. If longitudinal study or follow up is intended, this should be indicated here. When providing details, it can be helpful to make reference back to the wider proposal methodology.

3.3.01 Please indicate what the intended duration of the proposal is – this would include a complete timeframe to cover all activities in the proposal, and if appropriate, the duration of key phases within the proposal, from commencement to completion.

3.3.02 Please indicate if the proposal seeks access or transfer of data at regular intervals. For example, daily, weekly or monthly, quarterly, annual extracts throughout a proposed period, or at pre-determined trigger events (for example a monthly feed from a hospital system to a disease register). Please provide details of what these intervals are.

3.3.03 Please indicate if the proposal requires another iteration of the whole methodology to be undertaken at regular intervals. For example, where the proposal methodology would be undertaken in its entirety, but thereafter repeated at one or more intervals in the future (for example a research cohort to be linked every two years). Please provide details of what these intervals are.

### 3.4 Statutory and Regulatory Context

This section explores the statute and regulation relevant to the proposal, and ensures that confidentiality, Data Protection and Caldicott obligations have been accounted for. It identifies key controls in place to help reduce risks to individual privacy. It is necessary to reference Schedule 2 and Schedule 3 conditions of the Data Protection Act, and to understand how these apply to your proposal – these conditions are listed at Appendix B, Part 3 of the application form.

3.4.01 Please indicate if your proposal is substantively in response to, or calls upon, a statutory or regulatory requirement placed upon your organisation. This might include the exercise of a statutory power, or a regulatory requirement to carry out audit or monitoring. Please provide details of any statutory or regulatory basis to support the proposal.

3.4.02 Please indicate one condition from Schedule 2 and one condition from Schedule 3 of the Data Protection Act (Schedules and conditions are included at Appendix B, Part 3 of the application form) as the legal basis for the access and use of data proposed. It is important that you make clear reference to one condition from each Schedule, demonstrating that you understand how this aspect of the Data Protection Act provides the legal basis for you to access and use data.

Schedule 2 conditions which are most likely to be relevant are listed below, although each condition should be carefully considered within the context of the proposal:

* condition 1, the data subject has given consent to the processing
* condition 4, the processing is necessary in order to protect the vital interests of the data subject
* condition 6 (1), the processing is necessary for the purposes of legitimate interests pursued by the data controller or by the third parties to whom the data are disclosed, except where the processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms of legitimate interests of the data subject

Schedule 3 conditions which are most likely to be relevant are listed below, although each condition should be carefully considered within the context of the proposal:

* condition 1, the data subject has given explicit consent to the processing of the personal data
* condition 3, the processing is necessary (a) in order to protect the vital interests of the data subject or another person, in a case where – (i) consent cannot be given by or on behalf of the data subject, or (ii) the data controller cannot reasonably be expected to obtain the consent of the data subject
* condition 8, (1) the processing is necessary for medical purposes and is undertaken by – (a) a health professional, or (b) a person who in the circumstances owes a duty of confidence which is equivalent to that which would arise if that person were a health professional (2) In this paragraph “medical purposes” includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services

3.4.03 Please indicate any relevant information sharing agreements, protocols or contracts which are in place which support your proposal. This can include any formal documented procedures or agreements which facilitate the exchange or sharing of information in ways or between parties or organisations relevant to your application. Such procedures can indicate both a basis for access, sharing or transfer of information, and also the existence of controls in place to ensure that risk is minimised where data is processed in this way. You should give details and also append any relevant supporting documentation, providing references to the relevant sections if appropriate.

3.4.04 Please indicate if a Privacy Impact Assessment (PIA) has been carried out in relation to, or relevant to, your proposal. A PIA is a recognised control for identifying and assessing risk where data is being processed, and is good practice when new proposals for the processing of personal data are being considered. A PIA should ideally be commenced in the early stages of planning a project. [ICO guidance on conducting a PIA can be found here](https://ico.org.uk/media/for-organisations/documents/1595/pia-code-of-practice.pdf) . Although a PIA is not required for approval of a proposal, it’s existence will indicate that applicants have made best efforts to identify and control risks around the processing of data.

3.4.05 Please indicate if local Caldicott Guardian approval has been given for your proposal in one or more organisations (this will usually be an NHSScotland Board but could be another organisation). Please indicate which organisation’s Caldicott Guardians have given approval in respect of the proposal – you should provide names of organisations and individual Caldicott Guardians, and append any relevant documentation associated with these approvals.

This national application process alleviates the need for applicants requiring access to data from multiple NHSScotland boards to consult each board’s Caldicott Guardian individually in respect of the same proposal. This question is intended simply to capture where any existing local scrutiny may have already taken place, but should not be read as implying that this is required. Applicants in any doubt should consult their eDRIS application coordinator.

3.4.06 Please indicate if you have sought Caldicott Guardian approval in relation to your proposal from any organisations outside of Scotland, whether received or pending. You should provide names of organisations and/or Caldicott Guardians, and append any relevant documentation associated with these approvals.

### 3.5 Research and Ethics Governance

This section details the research and ethics approval which you have obtained or sought for your proposal, or otherwise provides evidence as to why such approval is not appropriate. Where such approval is not in place, it is important that you adequately evidence why this is the case and provide assurances if approval is pending.

If you need advice on whether ethics approval is necessary you should approach your local ethics services in the first instance. Information about UK research ethics committees and approval can be found on the [Health Research Authority website.](http://www.hra.nhs.uk/)

3.5.01 Please indicate whether you have sought research and ethics approval (by selecting ‘Yes or ‘No’). If you answer ‘No’, please proceed directly to question 3.5.01b below.

3.5.01a If you have answered ‘Yes’ to question 3.5.01 above, please provide details of the relevant research and ethics committee, and status of the approval (whether approved or pending). You should append relevant documentation in relation to the applications for or approval of your proposal. If you have answered ‘No’ to question 3.5.01 above, you do not need to complete this question.

3.5.01b If you have answered ‘No’ to question 3.5.01 above, please provide a full explanation of why research and ethics approval has not been sought or is not appropriate for your proposal. Where this has been indicated by relevant colleagues with research and ethics expertise, you should provide an explanation and details of the colleague or committee which has advised you. Wherever relevant supporting evidence for this decision is available, it should be appended. If you have answered ‘Yes’ to question 3.5.01 above, you do not need to complete this question.

### 3.6 Safe Havens

This section indicates if your proposal intends to use the services of a research Safe Haven – a list of recognised safe havens is included at Appendix A of the application form. Safe Havens provide a physical and technical environment designed to facilitate the safe processing of data - their use represents a significant control and provides additional assurance. The use of the national safe haven (see below) is normally expected where processing national datasets or data sources accessed from NHS National Services Scotland. If you are proposing to access data exclusively through a recognised safe haven, then you will not need to complete sections 5.2 or 5.3 of the form. Please note that you may be asked to use a safe haven as a condition of your approval if the panel feel it is appropriate

National Safe Haven - As part of the eData Research and Innovation Service (eDRIS), National Services Scotland (NSS) host secure access points to the National Safe Haven at the Farr Institute Scotland. The National Safe Haven is a secure workspace environment where your data will be stored and can be accessed and analysed using statistical analysis software packages. Microsoft Office packages are also available for use. The National Safe Haven can also be accessed remotely by approved researchers from approved institutions.

3.6.01 Please indicate if you do intend to access data exclusively through a recognised safe haven – this would be the case only where data (existing or newly created) is being accessed and processed exclusively within the confines of the safe haven environment, and would not be transferred beyond this environment. Please provide details of which safe haven you intend to use. If you have answered ‘Yes’ to this question, you do not need to complete sections 5.2 or 5.3 of the form.

3.6.02 If you are requesting access to data for which NHS National Services Scotland (NSS) is the Data Controller, and you do not intend to do this through the National Safe Haven , please explain why. NHS NSS data is typically processed from within the National Safe Haven – if your proposal seeks to process NSS data out-with this environment, you should provide a full explanation as to why this is the most appropriate way of processing the data.

## Section 4: Data & Data Subjects

### 4.1 Data yet to be collected

This section should indicate which data sets are being newly collected for the purpose of this proposal, and how the consent of individuals is being sought for their data to be collected and used for the purposes outlined in the proposal. If no such collection of new data is proposed, please proceed directly to question 4.2 below. The emphasis here is on the *collection* of new data, as distinct from the creation of new data from existing data (for example by linkage) or data collected prior to application.

For each such source of new data, you should clearly identify which party (organisation or individual referenced within the proposal) will be collecting the new data, and whether explicit consent for the collection and subsequent use of this data for the purpose outlined in the proposal, has been sought from individuals (data subjects). If you do propose to seek explicit consent from individuals (answering ‘Yes’), please describe the method by which this will take place and by which consent will be captured – append copies of relevant participant consent/registration forms. If you do not propose to seek explicit consent from individuals (answering ‘No’), please illustrate why this approach is appropriate, giving details of the consideration which you have given to seeking consent in proposal design – please give full explanation here if this is the case.

### 4.2 All Other Datasets / sources

This section should indicate data sources or data sets that are already in existence, and are not being newly collected for the purposes of the proposal. This will include each existing local or national data set or source which your proposal seeks to access, and could include extracts from hospital systems, or research databases. It establishes the purposes for which these datasets exist, and that these purposes are compatible with the expectations of those individuals to whom they relate. It establishes that appropriate permission has been received for the data to be accessed and used in the manner proposed.

Please list each such data set or data source. Provide the name of the dataset or source, and the name of the current data controller of the data. If the data controller is not an NHSScotland board, you should append documentation or details to illustrate your permission to use this data, to your application.

Indicate whether you consider the original purpose for which this data was created (for example, for the purpose of administering direct care) to be compatible with the purposes outlined in your proposal (for example, health research, healthcare planning, statutory or regulatory audit, etc). If this is not obvious, please include a brief description of the dataset or data source which will give an indication as to its original purpose (for example, a survey undertaken to examine the health of the population of over 65 year olds living in deprived areas over a 5 year period).

Include any explanation you are able to give of how individuals who are the subject of the data were originally informed that their data would be used (for example, participants were asked to consent to the collection of their data and asked for consent to access their medical records for the purpose of diabetes research).

If data sources which are controlled by the same organisation and collected for the same purpose, you do not repeat the purpose for each individual one. For example: Scottish Morbidity Records (SMR) 00, 01, 02, 04, 06, Birth, Stillbirth and Death Registrations.

Please ensure that if you are using the Community Health Index (CHI) number or any other information from the CHI database that this should be listed as a data source. This may be for the use of attaching CHI to your new data system or for use of matched controls in a research study.

### 4.3 Data Variables

This section should provide a full, clear account of all the data variables included within your proposal, regardless of whether they are used only in processing of the data on your behalf (for example in linkage, or prior to anonymisation) or whether your proposal will make direct use of the data. Examples of your proposal making direct use of the data may include linked data extracts, IT front end of a database or results of case file audit. Please include any derived variables, for example those included in an output file.

Please list the data set or data source within which each variable is contained, and list each variable by name. Please indicate the time period or range over which the variable required extends.

Please indicate for each variable whether it is required only for use in processing of data on your behalf (for example by a linkage agent or third part to whom identifiable variables are disclosed so that anonymisation can be effected prior to release of anonymised data to you) by answering ‘Yes’, or alternatively choose ‘No’ for each variable which you will make direct use of (will be disclosed to you and which you will have access directly).

If you are requesting identifiable or potentially identifiable variables please ensure you justify your requirement for this level of detail so that the appropriateness, proportionality and risk associated with their disclosure can be carefully considered.

### 4.4 NRS/NHSCR Data Sources

This section establishes if the proposal seeks to use data originating from National Records of Scotland (including the NHS Central Register) , and if so, in what way. If no such data is required by the proposal, please proceed directly to question 4.6 below. Please note that this **excludes** births, stillbirths and death registration data held by NSS as part of a long standing agreement with National Records Scotland (NRS). These should be listed in 4.2.

4.4.01 Please indicate if the proposal requires access to the NHS Central Registry as a sampling frame for cohorts identified in the proposal.

4.4.02 Please indicate if the proposal involves the flagging of individuals on the NHSCR for the purpose of long-term follow up. If you answer ‘No’ to this question, please proceed directly to question 4.5.04 below.

4.4.03 If you have answered ‘Yes’ to question 4.5.02 above, please select the specific purpose for which flagging of individuals against the NHSCR will be undertaken, selecting each relevant specific purpose listed.

4.4.04 Please indicate if the proposal requires any further involvement of National Records of Scotland (NRS), its data, infrastructure or staff, providing details where this is the case.

### 4.5 Making Contact with Individuals

This section outlines in detail any proposed contact with individuals, who are the subject of data or who are to be involved in a proposal as part of a cohort or sample, and how this will be controlled. It is considered best practice in most cases that contact with patients, patient’s relatives and families in particular will be undertaken by clinicians or other professionals already known to them. Proposed contact with individuals by those not already known to them should be supported by detailed evidence as to the reasons that contact in this way is appropriate.

4.5.01 Please indicate if any direct contact with any group of individuals is proposed. If you answer ‘No’ to this question, please proceed directly to section 4.7 below. If you answer ‘Yes’ to this question, please use the section below to indicate which group will be contacted, what method of contact will be used, and who will make contact – please include these details in respect of each group to be contacted.

4.5.02 If you answered ‘Yes’ to question 4.5.1 above, please provide an explanation of why contact is necessary within the context of the proposal methodology. You should attach as supporting evidence any relevant documentation detailing the methodology proposed for making contact, and in particular contact forms, information leaflets, letters or other communications being used when making contact with individuals.

### 4.6 Community Health Index (CHI) Database

This section details any proposed use of the Community Health Index (CHI) number and/or other information held within the CHI database. This includes the use of details such as current and previous address, current GP Practice, NHS Number, where accessed via the CHI database. If no use of information from the CHI Database is proposed, please proceed directly to section 5.1 below.

4.6.01 Please provide details of how the use of the CHI number will be monitored and audited. This would include any controls which specifically govern access to, and use of, CHI data, outlined in the proposal. Examples might include additional controls around how and when CHI data is to be accessed, or regular checks on access to CHI data throughout the proposal.

4.6.02 Please provide details of the technical method which will be used to access the CHI number – you should explain how any extract or access to CHI will be facilitated technically such as electronic direct feed or provision of data from the CHI database by NSS or NHSCR. Please make reference to anonymisation or other controls which will be used to minimise risks of re-identification associated with the use of the CHI number.

4.6.03 Please provide any further details regarding risks which have been identified as arising specifically from the use of the CHI number – these may have been identified in a PIA or other information risk assessment, or have arisen from the proposal methodology.

## Section 5: Methodology & Data Processing

### 5.1 Methodology

This section identifies if processes such as linkage, matching or anonymisation of data are intended as part of the proposal methodology. It establishes clearly any linkage between data sources or datasets listed at section 4.1 & 4.2, where this is taking place, and which variables within these data will be used for the purpose of linkage. If the proposal requires no matching or linkage of data, and does not require the use of matched controls or the extraction of anonymised data within a safe haven other environment, then please proceed directly to section 5.2 below.

5.1.01 Please indicate whether the proposal requires matching or linkage of data, the use of matched controls, or the extraction of anonymised data, by selecting each of these processes which is required.

5.1.02 Please indicate which organisation or body is undertaking these processes, and in what environment they will take place (this would typically be a recognised safe haven or other similar appropriate environment). For example, the linkage of Tayside data may take place in the TASC Safe Haven, or if the proposal involves national data requiring to be linked and anonymised then the indexing team at National Records Scotland may act as a third party linker. See the [eDRIS website](http://www.isdscotland.org/Products-and-Services/eDRIS/) for further information on linkage processes.

5.1.03 Please indicate which of the data sources listed in section 4.1 or 4.2 will be linked together. If all please just state all those listed in 4.1 & 4.2. If a subset of these please specify which ones.

5.1.04 Please indicate which variables from the data sources listed in question 5.1.03 above will be used to achieve the proposed linkage - please select each of the variables listed which applies, or specify alternative variables not listed. To achieve the best possible linkage rates it is preferable to be provide all available personal identifiers.

### 5.2 Access

This section details in what way the proposal aims to provide access to data, and controls in place to minimise risks associated with this. If you have answered ‘Yes’ to question 3.6.01 above (that your proposal seeks access to data exclusively through a recognised safe haven), then you do not need to complete this section or section 5.3 below, and should proceed directly to section 5.4 below.

The section asks you to provide details of relevant policies and procedures which are in place to govern access to data as outlined in the proposal – wherever you make reference to these you should include a specific reference to the part, section, point or paragraph of the relevant document which corresponds to the question being asked and specifically acts as evidence in response to it. General and repeated references to a whole policy (unless of a sufficiently narrow scope) should be avoided.

This section requires to be repeated (on separate sheets if necessary) for each of the environments where data is to be accessed. Where the answers to each of the questions asked is identical for more than one environment (for example a network of physical or technical environments governed by the same policies and procedures and with identical controls in operation), then it is sufficient to state this at question 5.2.01 below.

5.2.01 Please provide details of the organisation and environment in which the proposal seeks to access data - if these details have been provided in previous sections, then you can provide a reference to the relevant section and question above. You may list multiple environments (for example a network of physical or technical environments) provided that these are governed by the same policies and procedures and with identical controls in operation. If you propose to use multiple environments not governed by the same policies and procedures and with identical controls in operation, then you should complete the whole of section 5.2 for each environment.

5.2.02 Please provide details (organisation and policy/procedure name as a minimum) of the relevant policy or procedure governing the proposed access to data within the physical and technical environment listed in question 5.2.01. This policy/procedure will make reference to information security, and may exist within its own right, as part of a wider policy/procedure, or in more than one policy/procedure. Please make specific reference to the part, section, point or paragraph of the relevant supporting documents which act as evidence in response to the question.

5.2.03 Please confirm that the relevant policy/procedure detailed at question 5.2.02 above accounts for the implementation of robust password policy as a control to access of data. Please make specific reference to the part, section, point or paragraph of the relevant supporting documents which act as evidence in response to the question.

5.2.04 Please confirm that the relevant policy/procedure detailed at question 5.2.02 above accounts for the management of user accounts, including the removal of access to sensitive personal data. Please make specific reference to the part, section, point or paragraph of the relevant supporting documents which act as evidence in response to the question.

5.2.05 Please confirm whether access controls are associated with individual users accessing data, or whether shared/pooled user accounts or other access mechanisms are in use, and the controls in place to govern and manage the use of these. Please provide details of account management, including any specific reference to the part, section, point or paragraph of any relevant supporting documents which act as evidence in response to the question.

5.2.06 Please confirm whether access to data is possible from mobile devices of from out-with the physical environment where it is primarily accessed. This would include, for example, the capability to access data from mobile devices, through cloud solutions, web-based systems or networks which can be accessed remotely, home or flexible working, etc. This type of access will be detailed in your answer to question 3.1.08 above. If you answer ‘No’ then you should proceed directly to question 5.2.07 below.

5.2.06b Please provide details of the relevant policy or procedure in place to facilitate, monitor remote access. Please provide any specific reference to the part, section, point or paragraph of any relevant supporting documents which act as evidence in response to the question. You do not need to complete this question if you have answered ‘No’ to question 5.2.06 above.

5.2.07 Please provide any further additional detail which provides assurances regarding the control of access to data which is proposed.

### 5.3 Storage & Use

This section details in what way the proposal aims to store and use data, and controls in place to minimise risks associated with this storage and use. If you have answered ‘Yes’ to question 3.6.01 above (that your proposal seeks to store and use data exclusively through a recognised safe haven), then you do not need to complete this section or section, and should proceed directly to section 5.4 below.

The section asks you to provide details of relevant policies and procedures which are in place to govern storage and use of data as outlined in the proposal – wherever you make reference to these you should include a specific reference to the part, section, point or paragraph of the relevant document which corresponds to the question being asked and specifically acts as evidence in response to it. General and repeated references to a whole policy (unless of a sufficiently narrow scope) should be avoided.

This section requires to be repeated (on separate sheets if necessary) for each of the environments where data is to be stored or used. Where the answers to each of the questions asked is identical for more than one environment (for example a network of physical or technical environments governed by the same policies and procedures and with identical controls in operation), then it is sufficient to state this at question 5.3.01 below**.**

5.3.01 Please provide details of the organisation and environment in which the proposal seeks to store and use data - if these details have been provided in previous sections, then you can provide a reference to the relevant section and question above. You may list multiple environments (for example a network of physical or technical environments) provided that these are governed by the same policies and procedures and with identical controls in operation. If you propose to use multiple environments not governed by the same policies and procedures and with identical controls in operation, then you should complete the whole of section 5.3 for each environment.

5.3.02 Please provide the current ICO registration (Data Controller) number for the organisation listed in question 5.3.01 above - if these details have been provided in previous sections, then you can provide a reference to the relevant section and question above. If the organisation listed in question 5.3.01 above is not a registered Data Controller, please indicate this.

5.3.03 Please provide the ISO27001 Certificate Number for the organisation listed in question 5.3.01 above, if available. This is not a requirement for approval of the proposal - ISO certification, where it exists, indicates the presence of specific controls and provides additional assurance in respect of storage and use of data.

5.3.04 Please provide details (organisation and policy/procedure name as a minimum) of the relevant policy or procedure governing the proposed storage and use of data within the physical and technical environment listed in question 5.3.01. This policy/procedure will make reference to information security, and may exist within its own right, as part of a wider policy/procedure, or in more than one policy/procedure. Please make specific reference to the part, section, point or paragraph of the relevant supporting documents which act as evidence in response to the question.

5.3.05 Please confirm that the relevant policy/procedure detailed at question 5.3.05 above accounts for the implementation of up-to-date controls for the detection and prevention of malware within this environment. Please make specific reference to the part, section, point or paragraph of the relevant supporting documents which act as evidence in response to the question.

5.3.06 Please confirm that the relevant policy/procedure detailed at question 5.3.05 above accounts for user and administrator access control, and for the auditing of user and administrator activity within this environment. Please make specific reference to the part, section, point or paragraph of the relevant supporting documents which act as evidence in response to the question.

5.3.07 Please confirm that the relevant policy/procedure detailed at question 5.3.05 above accounts for the production of backups, and controls in place around these, within this environment. Please make specific reference to the part, section, point or paragraph of the relevant supporting documents which act as evidence in response to the question.

5.3.08 Please confirm that the relevant policy/procedure detailed at question 5.3.05 above accounts for controls to prohibit unauthorised copying of data within this environment. Please make specific reference to the part, section, point or paragraph of the relevant supporting documents which act as evidence in response to the question.

5.3.09 Please confirm that the relevant policy/procedure detailed at question 5.3.05 above accounts for controls present to manage the physical security of each of the environment/site where data is being stored and used. Please make specific reference to the part, section, point or paragraph of the relevant supporting documents which act as evidence in response to the question.

5.3.10 Please confirm that the relevant policy/procedure detailed at question 5.3.05 above accounts for hardwear (technical equipment) repair, replacement or disposal, and the protection of inappropriate access to data where these processes are taking place in respect of this environment. Please make specific reference to the part, section, point or paragraph of the relevant supporting documents which act as evidence in response to the question.

5.3.11 Please provide a full description of the systems, software and security involved in the storage and use of data which is proposed. This is your opportunity to provide a clear picture of how data is being stored and used, over and above the specific questions identified above. Your answer to this should be proportionate to the complexity of the storage and use of data proposed – where this is straightforward, this question will require less detail, with more detail necessary where more complex storage and use is proposed. It may be useful to append a data flow diagram illustrating the systems and tools which will be used to store and process data.

5.3.12 Please confirm whether the use of outsourced IT is proposed. The definition of outsourced IT should be considered to be very wide in scope, and could include any use of IT infrastructure or systems which are beyond the control of the organisation listed in section 2.1 above, and the originators of the data. You should mention by name organisations or bodies such as safe havens, third party suppliers or arms-length organisations processing data on your behalf.

### 5.4 Transfer

This section details in what way the proposal aims to transfer data, and controls in place to minimise risks associated with this transfer. Transfer can include from person to person, system to system, between organisations or across logical divisions within the same organisation. It includes the movement, for example, of data from one storage media to another, whether for subsequent use, storage, or temporarily for transit.

The section asks you to provide details of relevant policies and procedures which are in place to govern transfer of data as outlined in the proposal – wherever you make reference to these you should include a specific reference to the part, section, point or paragraph of the relevant document which corresponds to the question being asked and specifically acts as evidence in response to it. General and repeated references to a whole policy (unless of a sufficiently narrow scope) should be avoided.

5.4.01 Please provide details (organisation and policy/procedure name as a minimum) of the relevant policy or procedure governing the proposed transfer of data between physical and technical environments which ensures that data is transferred in such a way that it is protected from unauthorised access. This policy/procedure may make reference to such controls as email encryption, secure file transfer protocols, device encryption, or physical controls. It may exist within its own right, as part of a wider policy/procedure, or in more than one policy/procedure. Please make specific reference to the part, section, point or paragraph of the relevant supporting documents which act as evidence in response to the question.

5.4.02 Please describe any proposed triggers which will initiate the transfer of data – these may be detailed at question 3.3.02 above, as they relate to the transfer of data.

5.4.03 Please indicate if any data which could identify individuals will be transferred beyond the UK (Scotland, England, Wales and Northern Ireland). If you answer ‘Yes’, you should provide details in question 5.4.03b below. If you answer ‘No’, proceed directly to question 5.4.04 below.

5.4.03b Please provide details of the country or countries where you propose to transfer data, the method you wish to use for transfer, the proposed method of storage and location beyond the UK, and the details of any further onward transfer from this location. You should provide full details of such transfers of data. You do not need to complete this question if you have answered ‘No’ to question 5.4.03 above.

5.4.04 Please provide details of any copying of data proposed, other than initial transfers/extracts from source systems. If copying of data sources or datasets is an aspect of your proposal, you should indicate the reason that this copying is necessary, the method of copying, and the extent to which copied data will proliferate (multiple copies, dissemination, etc). Processing of this nature should be detailed in your answers to question 3.1.08 above.

### 5.5 Dissemination

This section details in what way the proposal aims to publish data, and controls in place to minimise risks associated with publication. Publication includes any dissemination or disclosure of any of the data identified in the proposal and in the earlier questions above, to any person not already specifically identified in earlier questions above, or who is not themselves the data subject of the information being disclosed to them. This includes the dissemination or disclosure of any of the data sources or datasets, parts or components thereof, detailed in the proposal, and of any results or findings, detailed, summarised, anonymised or otherwise, resulting from proposed processing of data. Dissemination or disclosure can take place in a variety of ways and through many mechanisms, including through electronic media, print media, or by word of mouth.

5.5.01a Please confirm whetherany of the data identified in the proposal will be disseminated or disclosed to any person not already specifically identified in earlier questions above, or who is not themselves the data subject of the information being disclosed to them. If you answer ‘No’ you should proceed directly to section 5.6 below.

5.5.01b Please describe the steps you will take to ensure the confidentiality of the data when disseminating or publishing your findings. This may include the application of disclosure control procedures, aggregation of data or other approaches.

5.5.01c Please detail any circumstances where a living or dead individual may be cited in the dissemination of results/outputs from your proposal

5.5.01d Please confirm if you have sought any permission from data controller or other bodies to publish any findings / outputs. If you have then please provide details of who has and what they have given permission to publish. Append any approval correspondence.

### 5.6 Retention/Disposal

This section details how the proposal will treat data being processed after it has been used for the purpose of the proposal outlined – including governance in place to determine how long it will be retained, and controls to manage its subsequent disposal. This section should show that your proposal has thoroughly considered these aspects of processing, and that you are able to commit to appropriate retention and disposal of data. A comprehensive records management and/or retention policy will cover each of the aspects explored in this section – you should append this and make specific reference to the part, section, point or paragraph of the relevant supporting documents.

The section asks you to provide details of relevant policies and procedures which are in place to govern retention and disposal of data as outlined in the proposal – wherever you make reference to these you should include a specific reference to the part, section, point or paragraph of the relevant document which corresponds to the question being asked and specifically acts as evidence in response to it. General and repeated references to a whole policy (unless of a sufficiently narrow scope) should be avoided.

5.6.01 Please provide details (organisation and policy/procedure name as a minimum) of the relevant policy or procedure governing the retention of information/data/records relating to this proposal.

5.6.02 Please confirm how long you intend to retain the individual level data relating to your proposal. Remember to include the period of time you intend to retain the data in an archive or back up copy

5.6.03 Please provide details of which organisation and where the data will be held for the specified period. If this is 2 different locations provide details for both

5.6.04 Please provide reason(s) as to why the data should be held for this length of time for example, stipulation by the Medical Research Council. Provide evidence of any stipulations by appending documents or providing the URL to the relevant document.

5.6.05 Please provide details of who the data / files will be disposed of at the end of the period specified above. You may refer to any relevant disposal/destruction policies your organisation have by summarising the relevant section from the policy or including a URL and indicating which section is relevant,

5.6.06 Please confirm what evidence will be obtained following that destruction, if appropriate. This may include certificates of IT hardware destruction or completion of a data destruction certificate locally.

### 5.7 Review

This section describes how the policies and procedures, and the controls described within them, described in sections 5.1-5.6 above, will be operated effectively over time, during both routine and adverse events.

5.7.01Please provide details on the checks to monitor and audit the mechanisms for the safe guarding of the data . You can make reference to the relevant parts of policies and procedures listed in sections 5.1-5.6 above (for example dates of policy review or review intervals, statements about accountability for compliance, or details of regular testing and audit of systems or environments).

5.7.02 Please provide details of any aspect of the provision of physical or technical security of data, described in your answers to sections 5.1-5.6 above, where the resource implications of provision remain unresolved. This might include such examples as encryption of devices which you intend to have in place, but which is not yet fulfilled, training which you intend to complete but which is not yet undertaken, secure email accounts you propose to use which have not yet been created, etc. You should provide assurances as to how you intend to resolve these issues.

5.7.03 Please provide details of how you will report any breaches if inappropriate access to the data occurs. Details can be summarised from any security documents that may be relevant. Please ensure that this includes details of how you will notify the data controllers.

## Section 6: Declaration

Please read this section carefully. It requires to be read and understood by both the Applicant identified at section 1.1 above, and the Information Custodian identified at section 1.3 above.

For the Applicant - You should provide your full name and date the declaration. By doing so you are signifying that you commit to the declarations, undertakings and understandings contained within the declaration.

For the Information Custodian (where this is not the same person as the applicant) – You should provide your full name and date the declaration. By doing so you are signifying that you commit to the declarations, undertakings and understandings contained within the declaration.

## Section 7: Supporting Evidence

Additional information of a relevant nature can be included in support of your application. This is indicated at specific points throughout the application form. The value of supporting evidence will be commensurate with the novelty, complexity, sensitivity, volume and level of risk associated with the proposal. More complex, sensitive or risky proposals will benefit more from additional supporting information. Where available, links to openly accessible web resources can be used instead of attachments.

Please list each of the individual pieces of supporting evidence you have submitted alongside your application form. Please list each with a name which clearly indicates what the document/file submitted is about.

Examples of documents/files which might be submitted in support of an application include:

* Business case
* Data flow diagram/s
* Diagram/s illustrating systems in use
* Previous application (of which this is an extension, renewal, re-application)
* Research/ethics approval or evidence to support its absence
* Example existing local NHS Board (data access/Caldicott) approval
* Caldicott Guardian approval form beyond Scotland
* Approval/permission to use data from non-NHSS data controllers
* Peer review outcomes
* Privacy Impact Assessment
* Information Sharing Protocol/Data Sharing Agreement/Data Processor Contract (between relevant parties)
* Risk Assessment/Register/Log
* Information leaflet (participants/public)
* Participant consent/registration form
* Contact form/letter
* Information Governance training resources (if not available online)
* Relevant Information governance/information security policies and procedures
* Retention and disposal (records management) policies/procedures

# Contacts

You should contact your eDRIS application coordinator in the first instance with any questions or queries relating to any aspect of your proposal, or your application form ([Nss.edris@nhs.net](mailto:Nss.edris@nhs.net) or by phone on 0131 275 7333).

Full information about the panel (for applicants, members of the public, and participants in the panel process) is available from the [panel website](http://www.informationgovernance.scot.nhs.uk/).