# Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) Application Form

**Instructions:**

***Please fill in all white boxes. Please do not add anything to or change any blue boxes.***

***Please do not reformat the form in any way or change the footer.***

*Instructions are written in black, e.g. Please answer all questions as instructed in the white boxes*

*Detailed guidance notes can be found in the ‘****Guidance for Applicants’*** *on the HSC-PBPP website. Please refer to this document when completing the form.*

[*https://www.informationgovernance.scot.nhs.uk/pbpphsc/home/for-applicants/*](https://www.informationgovernance.scot.nhs.uk/pbpphsc/home/for-applicants/)

*Brief guidance for each question is written in blue: e.g. “this should be the person in charge”.*

***To fill in a tick box****, double-click on it and change “default value” from “checked / unchecked” as required.*

***To ‘choose an item’****, click on the text and choose the appropriate item from the drop-down menu that should appear.*

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| **Application Control***Applicants should not complete the “submitted date” field*  |
| Application Coordinator |  |
| Application Number |  | Submitted Date |  |
| Applicant Name and Title |  |
| Proposal Name |  |
| Proposed End Date |  |
| Which version of the Guidance for Applicants did you read? |  |

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| **Application History and Version Control*****HSC-PBPP use only*** |
| **Application*****YYYY-1234 Surname*** | **Submitted date***dd/mm/yy* | **Approval date***dd/mm/yy* | **Approved version***V1.x* | **PSD\* version***if applicable**V1.x* | **End date***dd/mm/yy* |
|  |  |  |  |  |  |
| **Amendment No.***Amendment 1**Amendment 2* | **Reason***Addition of personnel**Addition of data* | **Submitted date***dd/mm/yy**dd/mm/yy* | **Date of approval***dd/mm/yy**dd/mm/yy* | **Approved version***V2.x**V3.x* | **PSD\* version***if applicable*V1.xV2.x | **End date***dd/mm/yy**dd/mm/yy* |
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Add rows as required for subsequent amendments.

\* PSD is the eDRIS Project Specification Document

*For any amendments, the latest approved version of the application form is that which should be amended and sent to HSC-PBPP.*

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| **Pre-submission checklist *(to be completed by the eDRIS coordinator)****Applicants should not fill out this section* |
| Approved Information Governance Training | [ ]  Approved training complete and certificates received*Application should not be submitted until all training certificates have been received for* ***all*** *people in sections 1.1 – 1.5.* |
| Use of accredited Scottish Safe Haven | [ ]  Yes [ ]  National Safe Haven [ ]  NHS Research Scotland Regional Safe Haven (please specify which): [ ]  Lothian Research Safe Haven (Edinburgh) [ ]  North (DaSH, Aberdeen) [ ]  West (Robertson Centre, Glasgow) [ ]  East (HIC, Dundee) [ ]  NRS SLS (Ladywell House)[ ]  No |
| If applicant is using the National Safe Haven:Is the proposal covered by National Safe Haven generic ethics approval or other ethical opinion? | For this proposal, please confirm that the following statements are true:1. Data held / accessed in National Safe Haven (Q3.4) [ ]  Yes [ ]  No
2. Research in field of Health or Social care (Q3.1.04) [ ]  Yes [ ]  No
3. There will be no contact with participants (Q4.5) [ ]  Yes [ ]  No
4. Study has undergone external scientific peer review (Q3.1.16)

 [ ]  Yes [ ]  No1. Will be carried out by UK-based research team (Q2.1) [ ]  Yes [ ]  No

[ ]  Yes, covered by National Safe Haven generic ethics[ ]  Covered by other ethical opinion or approval[ ]  Ethical opinion is not required |
| NHS Central Register(NHSCR) Involvement | [ ]  Yes Reference number:  [ ]  Email confirmation of approval supplied[ ]  No |
| Has section 7 been signified by all signees? | [ ]  Yes[ ]  No |

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| **Supporting Documents** *Please list only supporting documents which you have* ***clearly referenced in your application****, the* ***brief*** *name of each should clearly indicate the nature and content of the document*  |
| Document no.e.g. SD1 | Document type / description*e.g. protocol, DPIA* | Filename (please use short names)e.g. SD1 protocol YYYY-1234 Surnamee.g. SD2 DPIA YYYY-1234 Surname |
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**Note to Applicants**

Prior to completing your application form you should:

* Contact the eDRIS Team, who will assist you at phs.edris@phs.scot
* Read and understand the Guidance for Applicants

[*https://www.informationgovernance.scot.nhs.uk/pbpphsc/home/for-applicants/*](https://www.informationgovernance.scot.nhs.uk/pbpphsc/home/for-applicants/)

Your application should be typed, not handwritten. Your eDRIS coordinator will inform you of how to submit your application form and any supporting evidence. Before submitting your completed application, you should ensure that:

* All relevant sections of the application are complete
* Relevant supporting evidence is attached
* Individuals named on the form have read and approved its submission, and signed and dated in section 7.

Please note that submitted applications may be circulated to panel members, administrative colleagues, NHSScotland information governance and information security colleagues, Caldicott Guardians, the CHI Advisory Group and, where appropriate, non-NHS Scotland colleagues from a variety of participating partner bodies, in the course of processing. You must make your eDRIS coordinator aware of any confidential or sensitive information contained in your application which you would consider inappropriate for circulation in such a manner. Your application could be subject to disclosure or partial disclosure under the Freedom of Information (Scotland) Act, and will be retained in line with NHSScotland information policy.

**Please answer all questions in the form.**

## Section 1: Safe People

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| **1.1** | **Applicant** *This should be the person who is the principal contact for the application and has operational or day-to-day responsibility for the project.* *For more details please read section 1.1 of Guidance for Applicants* |
| **1.1.01** | Full Name |  |
| **1.1.02** | Title |  |
| **1.1.03** | Position |  |
| **1.1.04** | Organisation Name |  |
| **1.1.05** | Address (incl. postcode) |  |
| **1.1.06** | Email |  |
| **1.1.07** | Professional Registration No.(organisation and number) |  |
| **1.1.08** | Do you have an NHS contract? | Choose an item. |
| **1.1.09** | Does this proposal form a part of an academic qualification?(If yes please also complete section 1.2) | Choose an item. |
| **1.1.10** | Please state which HSC-PBPP-approved Information governance (IG) training has been completed within the last 3 years. *Please see Guidance for Applicants (p6) regarding IG training. Please provide evidence of IG training.**A list of the approved IG courses can be found in Table 4 of appendix A of the guidance. Even if the applicant will not personally access the data, IG training is required so they are aware of the standards required for processing the data by those for whom they are responsible. Access to data will not be given until evidence of HSC-PBPP-approved IG training has been provided.* |
| Name and institution of course |  |
| Date completed |  |

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| **1.2** | **Academic Supervisor** (*Do not fill in if you answered ‘No’ to Q1.1.09)**This should be the primary academic supervisor for the applicant undertaking the academic qualification, usually from the same organisation.* *For more details, please read section 1.2 of Guidance for Applicants* |
| **1.2.01** | Full Name  |  |
| **1.2.02** | Title |  |
| **1.2.03** | Position |  |
| **1.2.04** | Organisation Name |  |
| **1.2.05** | Address (incl. postcode) |  |
| **1.2.06** | Email |  |
| **1.2.07** | Professional Registration No.(organisation and number) |  |
| **1.2.08** | Does this person have an NHS contract? | Choose an item. |
| **1.2.09** | Please state which HSC-PBPP-approved Information governance (IG) training has been completed within the last 3 years. *Please see Guidance for Applicants (p6) regarding IG training. Please provide evidence of IG training.**A list of the approved IG courses can be found in Table 4 of appendix A of the guidance. Even if the academic supervisor will not personally access the data, IG training is required so they are aware of the standards required for processing the data.*  |
| Name and institution of course |  |
| Date completed |  |

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| **1.3** | **Clinical Lead** *This should be the person with clinical responsibility for the use of health data. This person cannot be someone also completing an academic qualification.**For more details, please read section 1.3 of Guidance for Applicants*  |
| **1.3.01** | Full Name |  |
| **1.3.02** | Title |  |
| **1.3.03** | Position |  |
| **1.3.04** | Organisation Name |  |
| **1.3.05** | Address (incl. postcode) |  |
| **1.3.06** | Email |  |
| **1.3.07** | Professional Registration No.(organisation and number) |  |
| **1.3.08** | Does this person have an NHS contract? | Choose an item. |
| **1.3.09** | Please state which HSC-PBPP-approved Information governance (IG) training has been completed within the last 3 years. *Please see Guidance for Applicants (p6) regarding IG training. Please provide evidence of IG training.**A list of the approved IG courses can be found in Table 4 of appendix A of the guidance. Even if the clinical lead will not personally access the data, the training is required so they are aware of the standards required for processing the data.* |
| Name and institution of course |  |
| Date completed |  |

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| **1.4** | **Information/Data Custodian** *This should be a senior person responsible for safeguarding the confidentiality and security of the data throughout the application. This person cannot be someone also completing an academic qualification.**For more details, please read section 1.4 of Guidance for Applicants* |
| **1.4.01** | Full Name |  |
| **1.4.02** | Title |  |
| **1.4.03** | Position |  |
| **1.4.04** | Organisation Name |  |
| **1.4.05** | Address (incl. postcode) |  |
| **1.4.06** | Email |  |
| **1.4.07** | Professional Registration No.(organisation and number) |  |
| **1.4.08** | Does this person have an NHS contract? | Choose an item. |
| **1.4.09** | Please state which HSC-PBPP-approved Information governance (IG) training has been completed within the last 3 years. *Please see Guidance for Applicants (p6) regarding IG training. Please provide evidence of IG training.**A list of the approved IG courses can be found in Table 4 of appendix A of the guidance. Even if the information custodian will not personally access the data, the training is required so they are aware of the standards required for processing the data.*  |
| Name and institution of course |  |
| Date completed |  |

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| **1.5 Others with access to identifiable or potentially identifiable data***Please give details of all additional people who will have access to identifiable, potentially identifiable, or pseudonymised individual-level data. Please add lines for each additional person. Please do not use a separate list.**Pseudonymised data is where someone still holds the identifiers and can re-link the data back to the patients and still counts as personal data under data protection law. Combinations of data can make people potentially identifiable.* *All researchers accessing data must have completed IG training within the last three years. Please see Guidance for Applicants (p6) regarding IG training. Please provide evidence of IG training for each researcher.* *For more details, please read section 1.5 of the Guidance for Applicants* |
| **Title and Name** | **Position** | **Organisation** | **Email** | **Professional Registration (organisation and number)** | **Does this person have an NHS contract?** | **Information governance (IG) training** |
| **Name and institution of course** | **Date completed** |
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| **1.6 Others***Please include here all people who are involved in the project (e.g. significant involvement in proposal design, content or outcomes), but who will* ***not*** *access the data for analysis.**Please copy and complete box for each additional person. Please do not use a separate list.**For further information, please read section 1.6 of the guidance.* |
| **Title and Name** | **Organisation** | **Position**  | **Involvement in Proposal** |
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## Section 2: Safe Organisations & Bodies

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| **2.1** | **Organisation or Body Leading Proposal** *The lead organisation is usually the one by which applicant is employed, and which will be responsible for the data and will become the (joint) data controller. 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 take responsibility for matters relating to the access to and processing of personal data.**For more details, please read section 2.1 of the Guidance for Applicants* |
| **2.1.01** | Organisation or Body Name |  |
| **2.1.02** | What type of organisation is this? | Choose an item. |
| **2.1.02a** | If this is a commercial organisation, please provide a full explanation of the organisation or body’s activity and industry sector, including any previous experience of using NHSScotland data. Please append supporting documents as appropriate. |
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| **2.1.03** | Is this organisation or body wholly funding or paying for the costs of conducting the proposal?If wholly funding the proposal, you do not need to fill in Q 2.3. | Choose an item. |

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| **2.2** | **Main Contact for Lead Organisation** *This should be the agreed senior person within the lead organisation who is aware of the proposal and accepts and assures the organisation’s obligations and roles, for compliance with data protection law and GDPR, with respect to any processing of data. This person cannot be anyone who is also mentioned in section 1.* *This is for the lead organisation to comply with the Data Protection Accountability principle.* *For further information, please read section 2.2 of the Guidance for Applicants.* |
| **2.2.01** | Full Name |  |
| **2.2.02** | Title |  |
| **2.2.03** | Position in organisation |  |
| **2.2.04** | Email |  |

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| **2.3** | **Organisation or Body Funding Proposal** *Complete the following section if you answered ‘partially funding or not funding’ to question 2.1.03. Otherwise please go to Q 2.4.**Please read section 2.3 of the Guidance for Applicants.* |
| **2.3.01** | Who is funding this proposal? *Please give organisation or body name:* |  |
| **2.3.02** | What type of organisation is this? | Choose an item. |
| **2.3.02a** | If this is a commercial organisation, please provide a full explanation of the organisation or body’s activity and industry sector, including any previous experience of using NHSScotland data. *Please append supporting documents as appropriate* |
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| **2.4** | **Research Sponsor** *Please read section 2.4 of the Guidance for Applicants.**Any research that uses health and social care data requires a Research Sponsor according to the UK Policy Framework for Health and Social Care Research (2017).* *The Research Sponsor should be aware of all activity regarding the research study.*  |
| **2.4.01** | Does this proposal require a research sponsor? | [ ]  Yes[ ]  No |
| *If no, please go to Q 2.5.**If yes, please fill details of the Research Sponsor below* |
| **2.4.02** | Full Name |  |
| **2.4.03** | Title |  |
| **2.4.04** | Position |  |
| **2.4.05** | Organisation |  |
| **2.4.06** | Email |  |
| **2.4.07** | Sponsor’s Reference number |  |

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| **2.5**  | **Other Relevant Organisations or Bodies** *These are other organisations or bodies which have a significant involvement or interest in the proposal (design, content or outcomes, provision of services or who host or employ individuals mentioned in section 1). Any organisation mentioned elsewhere in this application should be added below.* *Complete this section if applicable.* *For more details, please read section 2.5 of the guidance* |
| Organisation Name | Nature of Business/Sector | Nature of interest in proposal |
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## Section 3: Safe Proposal Overview

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| **3.1** | **Proposal Essentials** *This section must outline the need and nature of the proposal, how it will benefit the public, how it will use NHSS data and justify the data requests and data processing from patient to outputs.* *For more details for each question, please read section 3.1 of the Guidance for Applicants.*  |
| **3.1.01** | Please specify the proposal end date.*Please note that requests for data from NHS Central Register (NHSCR) will be capped at five years.**To reduce the need for amendment requests for time extensions, this end date should reflect the* ***entire duration*** *of the proposal, including time for obtaining the data, data analysis and preparation of manuscripts or reports based on the outcomes.*  |  |
| **3.1.02** | Please indicate whether this application is:  |
|  | [ ]  A new application *Please go to Q 3.1.03*[ ]  An extension of an existing application (e.g. in terms of scope)[ ]  A renewal of an existing approval (e.g. for NHSCR)[ ]  Related to a previous application (approved or not) |
| **3.1.02a** | If this is an extension, renewal or related to a previous or existing application, please provide details, including the HSC-PBPP reference number and a copy of the previous or existing application, and summarise the changes requested. Please explain how this updated application relates to any associated, currently ongoing application.  |
|  |  |
| **3.1.03** | Does this proposal require updates of health information or to be repeated at regular intervals?  |
|  | Choose an item. |
| **3.1.03a** | If no, please go to 3.1.04If yes, please advise of the frequency of these updates. |
|  |  |
| **3.1.04** | What is the **substantive purpose** of the proposal? *Please choose* ***one*** *option from below that best matches your proposal.* *Please be clear and consistent about the purpose of this application, as this will affect the answers to other questions within this application form: e.g. the legal basis for processing data under data protection law (Q 3.2.02) should match the purpose of the application.* |
|  | [ ]  Audit / Clinical Audit [ ]  Service Planning / Improvement[ ]  Research [ ]  Research Resource[ ]  Performance Monitoring / Management[ ]  Health / Social Care Administration [ ]  Systems Implementation / Testing[ ]  Training/Education[ ]  Other (please specify below) |
|  | If ‘other’ clearly defined purpose, please give details: |
|  |  |
| **3.1.05** | Access is requested to data from which sources, covered by HSC-PBPP? *Please tick all that are relevant* |
|  | [ ]  NHS National Services Scotland (NHS NSS)[ ]  Public Health Scotland (PHS)[ ]  A single NHS Scotland Board (excluding NHS NSS or PHS) including any system / database[ ]  More than one NHS Scotland Board including any system / database[ ]  NRS births *Please tick, even if getting data from PHS*[ ]  NRS deaths *Please tick, even if getting data from PHS*[ ]  NHS Central Register (NHSCR) *Please complete section 4.4. Please ensure NHSCR are aware of the request for their data.* [ ]  Community Health Index (CHI) database  *Please complete section 4.6. This refers to specific access to the CHI database, not the use of CHI numbers for data linkage.* [ ]  Other (*please specify below*) |
|  | If other, please give details: |
|  |  |
| **3.1.05a** | For this proposal, are you requesting access to data from any other sources, not covered by HSC-PBPP?*This is to give an idea of the full scope of the combined datasets and variables for this proposal, and the requirement for approvals from other data controllers.*  |
|  | Choose an item. |
| **3.1.05b** | If no, please go to Q 3.1.06If yes, please tick all that are relevant |
|  | [ ]  GP data via Albasoft[ ]  Scottish Government (e.g. Education, Census) via Stats PBPP[ ]  Local Authority[ ]  Other (please specify): |
|  | Please give details of the requested data.*Please provide evidence of the data controller approval, as a supporting document.*  |
|  |  |
| **3.1.06** | Provide a clear and concise ***lay*** outline of the proposal (max. 250 words). This will be published on the HSC-PBPP website.*This is a* ***stand-alone*** *lay summary of the whole proposal, from participants to outputs, to* ***inform the public*** *of the use of their confidential health data. This should include why this is required and how the outcomes will benefit them, and should be written in clear and concise language that the public will understand. All abbreviations should be explained.*  |
|  |  |
| **3.1.07** | Provide the specific aims and objectives of the proposal outlined in this application.*This should be the bullet points of the goals of the proposal.* |
|  |  |
| **3.1.08** | Provide a description of the envisaged **benefits** of this specific proposal to the public and / or patients.*This section must outline why the proposal and its access to data is necessary, and to demonstrate a clear connection between this work, its expected outcomes and the benefit to patients or the wider public which will result from it. The benefit to patients and public of the use of NHS Scotland data must be clear.*  |
|  |  |
| **3.1.09** | Provide concise details of the proposal: background and reason for requesting data, sample size, inclusion and exclusion criteria, time period; data collection; data processing or other means required to achieve the aims of your proposal. Please justify the use of all the datasets requested.*This should describe why and how you will carry out this work, for the whole proposal, from patient to outcomes. The prompt questions below have been provided for the relevant information required by the reviewers. Please ensure all relevant questions are covered.* *Please do not include academic literature references in the application form. A separate protocol can be provided as a supporting document.* *Please be as clear and concise as possible as this will help the review process. Please use language that will be understood by reviewers who will not have the same background or extensive knowledge of your area of work.*  |
|  | * Why is this proposal needed?
* What is the background, design and methodology of your proposal?
* How will the datasets and variables requested be able to answer the questions posed in your proposal?
* How many individuals will be required for this proposal (approximation)? Why is this number required?
* What criteria will be used to define your cohort or population of interest?
* Are there any datasets that will only be used for the cohort creation and or linkage and therefore needs to be identified in the project but won’t be released to the researcher?
* Will you contact the individuals for this work?
* Please define and justify the time-period of the data required?
* How will the data be obtained and processed?
* Will you require any data linkage to take place? If so, who will carry out the linkage?
* Will you be linking datasets from different sources?
* Do you require matched controls for your subjects?
 |
| **3.1.10** | Provide a clear and concise outline of any statistical methods that will be used in the proposal. Is there a formal statistical plan in place? *This should be a brief and non-technical description of the statistical analysis, for people who may not have a background in statistics.*  |
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| **3.1.11** | Provide a diagram to illustrate the data flow or data linkage process envisaged.*This data flow diagram should show the data sources where the data is accessed and stored at each point in the process from patient to outcomes, and by whom, so that roles and responsibilities are clear for data controller and / or processors and for transfers of data.* *If the data flow diagram is in a supporting document, please state where it can be found.*  |
|  |  |
| **3.1.12** | Does the proposal focus on or include information from people who might be considered vulnerable?*Definitions of vulnerable people are given in Table 5 of Appendix A of the Guidance for Applicants.* |
|  | Choose an item. |
| **3.1.12a** | If vulnerable people are the focus of, or included in, your proposal, please give details. |
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| **3.1.13** | Does the proposal seek access to data that could be considered to be highly sensitive or request other (non-health) special category data in addition to health data? *Under GDPR, all health data is classed as special category data. However, some variables are considered highly sensitive health data. In addition, some commonly requested variables are also special category data but not health data (e.g. ethnicity). Classes of special category data and highly sensitive data are given in section 6 of Appendix A of the Guidance for Applicants.*  |
|  | Choose an item. |
| **3.1.13a** | If highly sensitive data or non-health special category data are requested, please give details of the variables and why they are required.  |
|  |  |
| **3.1.14** | Does the proposal seek to use information exclusively about deceased persons? Please give details.*Please note that while deceased people are not subject to data protection law, they are still subject to the Common Law Duty of Confidentiality and legislation governing access to their health records.*  |
|  |  |
| **3.1.15** | Describe how you have included input from the public / lay representatives / patient groups in the design or any other aspect of your proposal.  |
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| **3.1.15a** | How did the public / lay / patient input change your proposal? |
|  |  |
| **3.1.15b** | How will you keep these patients and the public informed about the ongoing use of their health data for this application and its outcomes? |
|  |  |
| **3.1.16** | Describe any scientific peer review undertaken, with details (e.g. formal external scientific review by a peer organisation or funding body, informal internal review, or review by a third party). If no formal external review has been carried out, please explain why not.  |
|  |  |
| **3.1.17** | *The Information Commissioner’s Office (ICO) recommends that a Data Protection Impact Assessment (DPIA) should be carried out at the beginning of any proposal to assess the privacy risks raised by processing people’s personal and special category (e.g. health) data. It is also good practice.* *The ICO has information and screening questions as to whether a DPIA is legally required here (*[*https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/accountability-and-governance/data-protection-impact-assessments/*](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/accountability-and-governance/data-protection-impact-assessments/)*. If any of these screening questions are answered with a* ***Yes****, then a DPIA is mandatory as a* ***legal requirement*** *by the ICO and a DPIA* ***must*** *be provided, which should be signed off by a suitable senior person.* *Some organisations provide their own screening questions and / or require a DPIA anyway.* *If your organisation does not sign off DPIAs, please provide evidence that your organisation has seen and accepts the risks associated with this processing of personal data.*  ***Please read the guidance for 3.1.17.*** Has a Data Protection Impact Assessment (DPIA) been carried out for this proposal and the risks accepted by your organisation?  |
|  | Choose an item. |
| **3.1.17a** | If Yes, please provide the DPIA as a supporting document and go to Q 3.1.18. If No, a DPIA has not been done, have the ICO screening questions been answered and agreed by your organisation? |
|  | Choose an item. |
| **3.1.17b**  | If Yes, please provide the screening questions and your reasoning for the answers as a supporting document and go to Q 3.1.18. If neither a DPIA nor the ICO screening questions have been carried out, please justify your reasoning and explain how your proposal has undergone a suitable privacy risk assessment.  |
|  |  |
| **3.1.18** | Is there *any* commercial aspect or commercial dimension to the proposal or its outcomes? *This could include involvement of a commercial organisation, commercialisation of the product or outcome for which the data is required, commercial access to data, outsourced services provided by a commercial company. This needs to be explained carefully. If the commercial organisation is based outside the European Economic Area (EEA), then special consideration has to be made as GDPR does not allow personal data to be transferred outside the EEA.* |
|  | Choose an item. |
| **3.1.18a** | If no, please go to section 3.2. If yes, please justify the requirement for the involvement of this commercial aspect, how it is necessary for the success of the proposal and what the company will gain from their involvement in this proposal. *Please read 3.1.18 of the Guidance for Applicants.*  |
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| **3.1.18b** | Please list the partners involved in the commercialisation of this application, and particularly those from NHSScotland. How will NHSS directly benefit from such use of NHSS data?*Please provide the formal agreement between these partners so the panel can be assured that suitable arrangements are in place for the commercialisation of outcomes from the use of NHSS data.*  |
|  |  |
| **3.1.18c** | How will the commercialisation of any product or outcome and its associated intellectual property be handled, and by whom? Please give details.  |
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| **3.2** | **Statutory and Regulatory Context** ***Please read section 3.2 of the Guidance for Applicants.*** |
| **3.2.01** | Does your proposal have a statutory or regulatory justification? i.e. is the proposal responding to a statutory or regulatory instruction, duty or order? *This should relate to* ***specific*** *statutory or regulatory obligations that are detailed in specific legislation.*  |
| Choose an item. |
| **3.2.01a** | If No, please go to Q 3.2.02If yes, please give details and citation of the specific statutory or regulatory basis involved.  |
|  |
| **3.2.02** | Will both personal and special category data be processed (either by you or on your behalf) as part of this proposal? *Definitions of personal and special category data are given in section 3.2.of the Guidance for Applicants.* |
| Choose an item. |
| **3.2.02a** | Please tick which legal basis you will use to process **personal data**, under Article 6(1) of GDPR. The most appropriate and commonly ones used for health and social care data are listed below. *Please indicate the lawful basis under current data protection law for processing personal data. If you are unsure which lawful basis is applicable to your proposal, then you may wish to consult your organisation’s Information Governance team or Data Protection officer or lead for advice.* ***Please read the information on legal bases provided in 3.2.02 of the Guidance for Applicants, including the issues concerning using consent as a legal basis for processing data.***  |
| [ ]  6(1)(c) processing is necessary for compliance with a legal obligation to which the controller is subject. Please cite the specific legislation that applies: |
| [ ]  6(1)(e) processing is necessary for the performance of a task carried out in the public interest. |
| [ ]  Other: if using another legal basis under article 6(1) please cite specific basis: |
| **3.2.02b** | Please tick which legal basis you will use to process **special category data**, under Article 9(2) of GDPR. The most commonly used appropriate bases for health and social care data are listed. A further condition from the Data Protection Act (DPA) 2018 Schedule 1 Part 1 is also required for some legal bases and must be provided. ***Please see the table 5 in Appendix B of the Guidance for Applicants for details, the link below, or get advice from your local data protection team.***[*https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/special-category-data/what-are-the-conditions-for-processing/*](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/special-category-data/what-are-the-conditions-for-processing/) |
|  [ ]  9(2)(h) processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services. |
| Please cite the appropriate condition from the DPA 2018 Schedule 1 Part 1 Paragraph 2 |
|  |
|  [ ]  9(2)(i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care, and of medicinal products or medical devices. |
| Please cite the appropriate condition from the DPA 2018 Schedule 1 Part 1 Paragraph 3 |
|  |
|  [ ]  9(2)(j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1). |
| Please cite the appropriate condition from the DPA 2018 Schedule 1 Part 1 paragraph 4 |
|  |
| If you are using another legal basis under GDPR article 9.2, please cite the specific basis and additional DPIA Schedule 1 part 1 conditions, if required.  |
| [ ]  Other: |
| Schedule 1 part 1 condition (if required): |
| **3.2.02c** | Please specify who will process the personal and / or special category data? e.g. eDRIS, trusted third party (CHILi /NRS), local analysts, you, research team, other (please specify)? |
|  |
| **3.2.03** | Are there any existing information sharing agreements or contracts in place which support your proposal? *Please give details and provide as supporting documents**This would include any contracts or agreements with other parties involved in your proposal, which can inform the panel about the bases for access, sharing and / or transfer of data or information, and reassure of the controls in place to reduce any privacy risks arising from these processes.*  |
|  |
| **3.2.04** | Are other regulatory approvals pending or received, from within or outside Scotland? *Please give details and provide as supporting documents.**This would include approvals from other regulatory bodies e.g. Confidentiality Advisory Group (CAG) of the Health Research Authority (HRA).* |
|  |

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| **3.3** | **ResearchEthics Governance** *If you answered No to Q 2.4, please go to Q 3.4.**Please read section 3.3 of the Guidance for Applicants and consult your Research Sponsor.* *All research projects potentially need an ethical review, whether by NHS REC or by another ethics body. It is the responsibility of the applicant and research sponsor to ensure that suitable ethical review has taken place.*  |
| **3.3.01** | Has your proposal sought NHS or university research / ethics approval? | Choose an item. |
| **3.3.01a** | If yes, provide committee details, status of approval (i.e. pending, approved) and reference number, as supporting documents and go to Q 3.4 |
|  |
| **3.3.01b** | If no, is your application covered by the National Safe Haven generic ethical approval? *This only applies for applications that will use the National Safe Haven, if the specific conditions outlined in the pre-submission checklist are met.*  |
| Choose an item. |
| If no, explain why NHS or university research ethics approval is not sought |
|  |

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| **3.4** | **Safe Havens** *Please read section 3.4 of the Guidance for Applicants.* |
| **3.4.01** | Do you intend to access the data requested exclusively through any Scottish Government-accredited safe haven? *The Scottish Safe Havens are listed in Table 3 of Appendix A of the Guidance for Applicants.* |
| Choose an item. |
| **3.4.02** | If yes, please go to Q 3.4.03.If No, please answer this question and then go to section 4.If you are applying to use national data from Public Health Scotland (PHS) or NHS National Services Scotland (NHS NSS) and you do not intend to access these data through the National Safe Haven, please explain why.*If you are not obtaining national data, then that should be stated.*  |
|  |
| **3.4.03** | Is this the National Safe Haven or a regional safe haven? *If you are using the National Safe Haven you do not need to complete sections 5.1 or 5.2.* |
| Choose an item. |
| **3.4.03a** | If you are using a Regional Safe Haven, please specify which one.*If you are using a regional Safe Haven you do not need to complete sections 5.1 or 5.2.,* ***unless*** *you wish to include NHSCR data. Please see section 3.4 of the guidance.* |
|  |
| **3.4.03b** | If you are applying to use national data from Public Health Scotland (PHS) or NHS National Services Scotland (NHS NSS) and you do not intend to access this through the National Safe Haven, please explain why.*If you are not obtaining national data, then that should be stated.*  |
|  |
| **3.4.04** | How and from what location will you access the safe haven specified above? *E.g. remotely from on a university-provided laptop from a university office.**E.g. using a safe setting from… (specify location)* |
|  |
| **3.4.05** | Will the safe haven be accessed by anyone working from home?  |
| Choose an item. |
| **3.4.05a** | If no, please go to section 4.If yes, please provide your organisation’s home working policy and / or outline any mitigation measures in place to ensure that the access to the safe haven will be secure.  |
|  |

## Section 4: Safe Data, Data Subjects and Methodology

|  |  |
| --- | --- |
| **4.1**  | **New Data yet to be collected for this proposal***Please read section 4.1 of Guidance for Applicants*If no new data is to be collected please go to Q 4.2 |
| Dataset/source Name | Collection by whom? *This is the organisation or individuals referenced within the proposal.*  |
|  |  |
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| --- | --- |
| **4.2** | **All Other Existing Datasets or Sources***Please use a separate line for each dataset.* *Please read section 4.2 of the Guidance for Applicants.* *Contact should be established as early in the process as possible with NHS Scotland boards / data providers to discuss data provisioning requirements for any of the applicable sources listed below.*  |
| Dataset or source Name | Data Controller (Organisation)**For existing dataset/sources for which the data controller is not an NHSScotland board, please append evidence of the data controllers permission to use the data** |
|  |  |
|  |  |
|  |  |

Add rows as required.

|  |  |
| --- | --- |
| **4.2.01** | How were individuals originally informed of the use of their data? Please ensure that you include an appropriate explanation for each of the data sources which you have listed above.*Please see Guidance for Applicants on the use of privacy notices relevant to each dataset, which should be transparent about how people’s data will be used and comply with current data protection legislation.*  |
|  |
| **4.2.02** | Please explain and justify how the principle of data minimisation has been applied to this application, and what measures have been followed to comply with it? *Data protection law requires that the use of potentially identifiable data is* ***minimised*** *to those variables, people and time-frame which are necessary and sufficient to achieve the stated purpose. This is known as the ‘data minimisation’ principle.(GDPR Article 5)* |
|  |

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| **4.3** | **Data Variables** *Please justify the need for* ***all*** *of the variables included in your proposal.**Please read section 4.3 of the guidance, especially regarding the processing only variables.* *While a variable may not seem identifiable on its own, combinations of variables can make people identifiable, particularly for small populations or rare conditions.*  |
| Dataset Name | Variable | Dates required  | Justification (i.e. why variable is required) | Please tick to show this item is for processing only and will not be part of the dataset used for analysis |
|  |  |  |  | [ ]  |
|  |  |  |  | [ ]  |
|  |  |  |  | [ ]  |

Add rows as required or provide the eDRIS Project Specification Document (including version number).

|  |  |
| --- | --- |
| **4.4** | **National Records of Scotland (NRS) / NHS Central Register (NHSCR) Data** *Please read section 4.4 of the Guidance for Applicants**This is for access to NHSCR data and any access to NRS data, apart from the NRS births, stillbirths and deaths records (copies of which are held by PHS).* |
| **4.4.01** | Do you require access to NHSCR or any NRS involvement? |
| Choose an item. |
| **4.4.02** | If No, please go to Q 4.5.If Yes, please provide the NHSCR Reference Number |  |
| **4.4.03** | Does the proposal require access to NHSCR as a sampling frame for cohorts? | Choose an item. |
| Does the proposal involve flagging of individuals on the NHSCR for long term follow up? | Choose an item. |
| **4.4.04** | If flagging is requested, please give reason below |
| [ ]  To contact individuals in Scotland[ ]  To be informed of fact and cause of death[ ]  To be informed of the incidence of on-going anonymised cancers registrations[ ]  To be informed of emigrations prospectively and retrospectively |
| **4.4.05** | Is any other NRS / NHSCR involvement required? Please provide details |
|  |

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| --- | --- |
| **4.5** | **Making Contact with Individuals** *Please read section 4.5 of the Guidance for Applicants.**This question is about contacting any people in relation to data collection or recruitment of participants.* |
| **4.5.01** | Is any direct contact with any group of individuals required as part of this proposal?  |
|  | Choose an item. |
| **4.5.01a** | If no, please go to Q 4.6.If Yes, please provide details below.Contact Group and Method of contact.*Please note if communications are being sent electronically (via text or email) you need to ensure that they comply with Privacy and Electronic Communications Regulations (PECR). Please see Guidance for Applicants for further details.*  | Contact by whom |
|  | [ ]  Hospital Consultants  | [ ]  Letter / email | [ ]  Phone / text message | [ ] Other (specify): |  |
|  | [ ]  Other NHSS Staff | [ ]  Letter / email | [ ] Phone / text message | [ ] Other (specify): |  |
|  | [ ]  General Practitioners | [ ]  Letter / email | [ ] Phone / text message | [ ] Other (specify): |  |
|  | [ ]  Patients / Public | [ ]  Letter / email | [ ] Phone / text message | [ ] Other (specify): |  |
|  | [ ]  Relatives of participants | [ ]  Letter / email | [ ] Phone / text message | [ ] Other (specify): |  |
|  | [ ]  Others (please specify): | [ ]  Letter / email | [ ] Phone / text message | [ ] Other (specify): |  |
| **4.5.02** | Please justify and explain why contact is being made and append copies of any relevant correspondence as supporting evidence |
|  |  |

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| **4.6** | **Community Health Index (CHI) Database** *Please read section 4.7 of the Guidance for Applicants.**This section does not apply to routine use of CHI for data linkage nor for obtaining matched controls.* |
| **4.6.01** | Do you require access to data from the live CHI database? |
| Choose an item. |
| **4.6.02** | If No, please go to Section 5.If Yes, what monitoring and audit of the use of CHI is planned? Please provide details. |
|  |
| **4.6.03** | What technical method will be used to access CHI (online read-only, download, other extract, anonymised extract)? Please provide details |
|  |
| **4.6.04** | Have any risks been identified in the proposal which relate specifically to CHI? |
|  |

## Section 5: Safe Data Processing and Security

|  |  |
| --- | --- |
| **5.1** | **Access to data***Please read section 5.1 of the Guidance for Applicants. If data will be accessed from more than one environment during the proposal, this section must be completed for each one.**If you will access data exclusively via the National Safe Haven, or you are using a Regional Safe Haven and do not need to access NHSCR data, please go to* ***section 5.3.*** *Complete this section if you answered ‘No’ to question 3.4.01 i.e. data will not exclusively be accessed via a Safe Haven.* *If you need to access NHSCR data through a regional Safe Haven, this section must be completed.* *Please provide concise answers from the relevant policies.* |
| **5.1.01** | From what location will identifiable, pseudonymised, or potentially identifiable data be accessed?*Potentially identifiable data includes the combinations of variables in such a way as to make individuals identifiable.* |
|  |
| **5.1.02** | Please provide details of the security policy and procedures governing access to this physical and technical environment. *Please append supporting documents, referencing appropriate sections: e.g. Document no. / page no. / section no / excerpt.* |
|  |
| **5.1.03** | Please provide details of the policy and procedures that cover the use of passwords.*Please provide details and append supporting documents referencing appropriate sections.* |
|  |
| **5.1.04** | Please provide information on the processes for providing and removing user access to the data. Will access to the data be limited to the individual user accounts that require access, or will all users in the environment be able to access the data, even if they do not require to do so? *This question is to try to understand how the principle of least privilege (PoLP) is applied in this system, whereby users can only access the information and resources that are necessary.**Please provide details and append supporting documents, referencing appropriate sections* |
|  |
| **5.1.05** | Will individuals with access to data have individual or shared accounts? |
|  |
| **5.1.06** | Will the data be accessed by staff working off-site (e.g. staff working from home) at any time during the duration of the proposal?  | Choose an item.  |
| **5.1.06a** | If No, please go to Q 5.1.07If Yes, what device will be used to access these data externally? Will this be an organisation-owned device or a personal device? If a personal device, is there a Bring Your Own Device (BYOD) policy, which complies with the organisations policies? *Please provide details and append copies of the relevant policies as supporting documents, referencing appropriate sections* |
|  |
| **5.1.06b** | For off-site working, will data be held in the same host environment, or taken off-site? |
| [ ]  Data remain in the on-site host environment [ ]  Data will be taken off-site |
| If the data remain on-site, will a VPN connection, or similar remote access technology be used to provide secure access to the data? Please give details. |
|  |
| If the data are taken off-site, what measures are in place to maintain the security of the device and data (e.g. encryption of device and data?) |
|  |
| **5.1.07** | Will any moveable devices (e.g. laptops, iPads, USB drives) be used at any time as part of this application?  |
| Choose an item. |
| **5.1.07a** | If No, please go to Q 5.1.08If yes, is there a mobile device management (MDM) solution in place to manage such moveable devices?Does the MDM solution have a remote wipe capability to erase data in the event of theft or the device is lost?  |
|  |
| **5.1.08** | Does your organisation have a clear desk and / or clear screen policy when accessing data? *Please provide details and append copies of the relevant policies as supporting documents, referencing appropriate sections.* |
|  |
| **5.1.09** | Provide any additional detail of any mechanisms by which data will be protected from unauthorised access.  |
|  |

|  |  |
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| **5.2** | **Storage & Use** *Please read section 5.2 of the Guidance for Applicants**Please complete the following section if you answered ‘No’ to question 3.4.01.**If you need to access NHSCR data through a regional Safe Haven, this section must be completed.*  |
| **5.2.01** | Where will the data be stored and used? *(Location, organisation, address. Refer to addresses in previous sections if appropriate)* |
|  |
| **5.2.01a** | If the data will be stored in a cloud, please state who will provide that cloud storage and in what country that cloud server is physically situated. Please provide the security information that covers such cloud storage and what access the provider will have to the data stored therein. |
|  |
| **5.2.02** | To what Cybersecurity standards does your organisation work (e.g. ISO 27001, Cyber Essentials, Cyber Essentials Plus, other of equivalent standard)? *Please give details and expiry dates, and provide certificates as supporting documents.* |
|  |
| **5.2.03** | Please provide details of policies and procedures governing storage and use of data within this physical and technical environment*Please provide details and append supporting documents, referencing appropriate sections.* |
|  |
| **5.2.04** | What policies and procedures are in place to cover the implementation of up-to-date controls for the detection and prevention of malware? *Please provide details and append supporting documents, referencing appropriate sections* |
|  |
| **5.2.05** | What policies and procedures are in place to cover access control and auditing of user and / or system administrator activity? *Please provide details and append supporting documents, referencing appropriate sections* |
|  |
| **5.2.06** | What policies and procedures are in place to cover the production and control of backup copies of the data? *Please provide details and append supporting documents, referencing appropriate sections.* |
|  |
| **5.2.07** | What policies and procedures are in place to ensure business continuity, contingency planning and system restoration in the event of a critical system failure? *Please provide details and append supporting documents, referencing appropriate sections.* |
|  |
| **5.2.08** | What policies and procedures describe the controls in place to prohibit unauthorised copying of data? *Please provide details and append supporting documents, referencing appropriate sections* |
|  |
| **5.2.09** | What policies and procedure describe physical and site controls?*Please provide details and append supporting documents, referencing appropriate sections.* |
|  |
| **5.2.10** | What policies and procedures cover hardware repair, replacement or disposal of data, and protection of data from inappropriate access during such procedures? *Please provide details and append supporting documents, referencing appropriate sections.* |
|  |
| **5.2.11** | Describe the systems, software and security used to store and use data. *Please provide details and append supporting documents, referencing appropriate sections.**Some examples of what information is required:**Is the host environment infrastructure actively vulnerability scanned and penetration tested? If so, is there a policy that covers this?**Is the data suitably encrypted, where possible?**Does the policy describe the organisations patch management policy? Are security updates installed within a suitable timeframe? This is applicable to both server environment hosting the data, as well as the device used to access the data.*  |
|  |
| **5.2.12** | Is outsourced IT in use? If yes, please give details of the provider and the IT security measures in place.  |
|  |
| ***Please repeat section 5.2 above for each relevant location in the proposal – see guidance*** |

|  |  |
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| **5.3** | **Transfer** *Please read section 5.3 of the Guidance for Applicants.* |
| **5.3.01** | Please provide details of the security policies and procedures to ensure that data will be transferred in such a way that it is protected from inappropriate or unauthorised access (e.g. email encryption, secure file transfer protocols SFTP, device encryption, physical controls.)*Please provide details and append supporting documents, referencing appropriate sections.**This should reflect what is in the data flow diagram for Q 3.1.11 and describe the transfer processes in the data flow from the patient to its final destination, including any intermediary stages.*  |
|  |
| **5.3.02** | At what intervals/ trigger points will data transfer take place? E.g. one off transfer, monthly intervals.  |
|  |
| **5.3.03** | Will any personal (identifiable, pseudonymised or potentially identifiable) data be shared with or transferred to any organisation within or outside of the UK? | Choose an item. |
| **5.3.03a** | If no, please go to Q 5.3.04If yes,please specify the organisation and country of destination, and provide details of the method of transfer, the proposed location and method of storage at the destination, and details of the purpose of the data sharing and how the data will be handled and kept secure.  |
|  |
| **5.3.04** | Other than initial transfers from source systems, is there any copying of data required within the proposal? If no, please go to section 6 If yes, please give details.  | Choose an item. |
|  |

## Section 6: Safe Outputs and Review

|  |  |
| --- | --- |
| **6.1** | **Outputs and Dissemination** *Please read section 6.1 of the Guidance for Applicants.* |
| **6.1.01** | What procedures will be used for disclosure control for the outcomes of the proposal? *Please outline or attach the policy that will be used.* *This is to ensure that tables and information from the findings does not include outputs from which any person could potentially be identified, e.g. through small numbers in specific groups.*  |
|  |
| **6.1.02** | Will proposal outcomes be published or disseminated beyond those listed in Section 1? *If ‘No’, please go to Section 6.2**If Yes, please answer questions below* | Choose an item. |
| **6.1.03** | How will outcomes from the proposal be published or disseminated, to what audience and in what format, including to patients and the general public? *Please give details.**How the outcomes from the use of their health data will be fed back to the patients and public needs to be described, as they do not read scientific literature nor attend conferences.*  |
|  |
| **6.1.04** | What steps will be taken to ensure that persons cannot be identified in any outputs? *Please give details.* |
|  |
| **6.1.05** | Are there any circumstances where a living or dead individual would be cited? (E.g. where a person consented to their data being used as a case study)? *Please give details.* |
|  |
| **6.1.06** | Were any permissions to publish data required or sought (e.g. from data controllers)? *Please provide details* |
|  |

|  |  |
| --- | --- |
| **6.2** | **Retention and Disposal of Data***Please read section 6.2 of the Guidance for Applicants.**Under data protection law, potentially identifiable, identifiable or pseudonymised data should only be retained for a limited time. Once it is no longer needed it should be fully anonymised or securely destroyed. This is known as the principle of storage limitation (GDPR Article 5).*  |
| **6.2.01** | Which information / data / records retention policy will you apply to the data obtained and used in this proposal?*Please provide details and append supporting documents, referencing appropriate sections.* |
|  |
| **6.2.02** | For how long do you intend to retain identifiable or potentially identifiable data after the conclusion of the proposal (including archive/backup copies)? |
|  |
| **6.2.03** | Who will retain the data and where? |
|  |
| **6.2.04** | What is the purpose for retaining the data for the specified time? |
|  |
| **6.2.05** | What method of disposal or destruction will be used when this period has expired (including archive and backup copies)? |
|  |
| **6.2.06** | What evidence will be obtained that destruction has occurred (e.g. IT supplier certificate of destruction)? |
|  |

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| **6.3** | **Review** *Please read section 6.3 of the Guidance for Applicants.* |
| **6.3.01** | Describe how the mechanisms which safeguard data security will be audited and reviewed at regular intervals to ensure their continued efficacy. |
|  |
| **6.3.02** | Describe any resource implications to any of the proposed measures for the protection of physical or technical security of information which are unresolved at the time of this application (e.g. encryption of devices is an intention not yet fulfilled, IT training is not yet undertaken etc.) |
|  |
| **6.3.03** | Describe the breach reporting mechanisms to be invoked in the event of any inappropriate access to data or other information security incident |
|  |

##

## Section 7: Declaration

* I DECLARE THAT this application is accurate, and that, should it be successful, any health data made accessible will be used for no other purpose, and in no other way than that described above.
* I UNDERTAKE TO notify the Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) of any future changes to the purpose or manner in which data is processed in accordance with this application.
* I UNDERSTAND THAT any future applications by me, or my employing or sponsoring organisation, may be refused should any health data made accessible be used for any other purpose or in any other way than that described above.
* I AGREE TO abide by any conditions attached to the application by the HSC-PBPP during the approval process. I understand that failure to comply with these conditions may result in any future applications by me, or my employing or sponsoring organisation, may be refused.
* I CERTIFY THAT all those who have access to health data in this proposal are aware of the requirements of confidentiality and understand that any breach (e.g. disclosure of confidential information to a person not authorised to receive it) will be reported to the data controller.
* I CERTIFY THAT that only the persons named in the HSC-PBPP form (1.1-1.6) as requiring access to the data will be given access and that the data will not be transferred to anyone else.
* I GUARANTEE THAT no publication will appear in any form in which an individual may be identified without the written permission of that individual, and that I will apply appropriate disclosure control when planning publications involving the data requested.
* I UNDERSTAND THAT the Data Controller, and agents acting on its behalf, reserves the right to inspect the data on the sites where it is being processed.

To be signified by the APPLICANT

|  |  |
| --- | --- |
| Name (in Capitals): | Date: |

To be signified by the ACADEMIC SUPERVISOR (if applicable)

|  |  |
| --- | --- |
| Name (in Capitals): | Date: |

* I DECLARE THAT (the applicant named above) is a *bona fide* worker engaged in a reputable project and that the data they ask for can be entrusted to them in the knowledge that they will conscientiously discharge their obligations, including in regard to confidentiality of the data, as stated in the declaration above.

To be signified by the INFORMATION CUSTODIAN named in Section 1.4 above (where the Information Custodian is not the applicant).

|  |  |
| --- | --- |
| Name (in Capitals): | Date: |

* I ACCEPT the organisation’s obligations and roles with respect to the processing of data for the purposes outlined in this application.

To be signified by the Main Contact for the Lead Organisation named in Section 2.2 above

|  |  |
| --- | --- |
| Name (in Capitals): | Date: |

To be signified by the Research Sponsor, if named in Section 2.4 above

|  |  |
| --- | --- |
| Name (in Capitals): | Date: |