

**Honest Broker Service Research Application Form**

**Project Title:**

|  |  |  |
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| Click here to enter text. |

|  |
| --- |
| HBS Project No. |

 |

**About this application**

The application form is split into 5 sections:

## [*Section A – Safe People*](#_Section_A_–)

## [*Section B – Safe Project*](#_Section_B_–)

## [*Section C – Safe Data*](#_Section_C_–)

## [*Section D – Safe Settings*](#_Section_D_–)

## [*Section E – Safe Outputs*](#_Section_E_–)

Preparation is key to a successful research application. You need to be able to demonstrate how you will ensure safe use of patient data and the potential for public benefit. The steps below are intended to help you get off to a good start.

**Check what approvals you might need**

Before requesting access to health data, you need to demonstrate that everyone involved in the project has appropriate information governance training.

[Becoming an approved researcher through the ONS approved researcher scheme](https://researchaccreditationservice.ons.gov.uk/ons/ONS_registration.ofml)

[ ]  I have completed this step

Please note that as of November 2019, if a project involves linking external datasets to HSC Regional Data Warehouse data, ethical approval will be required.

[Applying to an NHS or HSC Research Ethics Committee](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/applying-research-ethics-committee/)

[ ]  I have completed this step

There should be evidence that an independent peer review has taken place. In larger scale projects this could be evidenced by an external funding grant being secured, however in smaller scale projects, for example, PhD projects, a separate peer review should be sought. This review should be conducted by someone independent of the project that has expertise in the associated field of research.

[ ]  I have completed this step

**Understand what happens after you submit your application**

* The Honest Broker Advice Service (HBAS) will review the form and may ask for additional information to be provided before the application is submitted for approval.
* Please complete the HBS Research Output Planning Document alongside this application form.
* The finalised application will be presented to the HSC Data Access Committee (HSC DAC) who are responsible for the approval of all Northern Ireland health and social care related research applications received by the Honest Broker Service.
* If the application is approved, the project team will be required to sign a Research Data Access Agreement which provides the terms and conditions on which access will be granted to the requested datasets.
* If the application is denied, you will either be asked to make amendments and resubmit, or complete a De Novo application. The HBAS will continue to provide assistance in either case.
* Once you have been granted access to the requested datasets you will have one month to confirm they contain all the necessary information you require, modifications / amendments beyond this point may be subject to additional charges.

# Section A – Safe people

Who is going to be accessing the data?

Safe People should have the right motivations for accessing research data and understand the legal and ethical considerations when using data that may be sensitive or confidential. Safe People should also have sufficient skills, knowledge and experience to work with the data effectively. Researchers will need to undergo specific accreditation before accessing data via the secure safe setting and demonstrate that they are part of a bona fide research organisation.

The purpose of this section is to ensure that:

* details of people who will be accessing the data and the people who are responsible for completing the application are identified
* any individual or organisation that intends to access the data requested is identified
* all identified individuals have the necessary accreditation and/or expertise to work with the data effectively.

Please list all individuals who will have access to the data requested, or are responsible for helping complete this application form. This section should include key contact details for the person who is leading the project; key contact details for the person(s) who is (are) leading the project from other organisations.

The 'Applicant' is the person filling out the application form and principal contact for the application. This is usually the person with operational responsibility for the proposal. Each application must have details for at least one person.

Each project must have a Chief Investigator. Usually the Chief Investigator is the person and organisation that will be signing contracts/agreements, and whose name will be published by the HBS as requesting data. Please ensure the Chief Investigator has signed the relevant section below.

HSCNI also requires applicants to provide an appropriate signature from their organisation to confirm it supports the project and are aware of its responsibility with regards data as research sponsor according to the UK Research Governance Framework:

(<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/>). Please ensure the relevant signature has been provided below.

**1 – Applicant**

Full name

|  |
| --- |
| Click here to enter text. |

Job title

|  |
| --- |
| Click here to enter text. |

Telephone

|  |
| --- |
| Click here to enter text. |

Email address

|  |
| --- |
| Click here to enter text. |

Will you access the data requested?

[ ] Yes

[ ] No

Are you an accredited researcher under the Digital Economy Act 2017?

[ ] Yes

[ ] No

If yes, please provide your accredited researcher number

|  |
| --- |
| Click here to enter text. |

If no, please specify if you are planning to become an accredited researcher

|  |
| --- |
| Click here to enter text. |

Have you undertaken professional training or education on the topic of Information Governance?

[ ] Yes

[ ] No

Please provide full details regarding the most recent training

|  |
| --- |
| Click here to enter text. |

Please provide any details of plans to attend training, if applicable

|  |
| --- |
| Click here to enter text. |

CV has been provided

[ ]  I have completed this step

**2 – Organisation**

Your organisation name

|  |
| --- |
| Click here to enter text. |

If the project is linked to a particular Health and Social Care (HSC) Trust service, dataset or resource you should ensure that the appropriate research governance personnel in the HSC Trusts are fully informed of the project and have signed this section i.e. the Trust Research Office. If you are a student or staff member within a university then you should refer this section to your university Research Governance Office.

Sign-off name(s)

|  |
| --- |
| Click here to enter text. |

Organisation

|  |
| --- |
| Click here to enter text. |

Job title

|  |
| --- |
| Click here to enter text. |

Email address

|  |
| --- |
| Click here to enter text. |

Signature

|  |
| --- |
| Click here to enter text. |

Date

|  |
| --- |
| Click here to enter a date. |

**3 – Other individuals**

**(This section should be copied as many times as necessary to ensure all members of the project team have been listed)**

Full name

|  |
| --- |
| Click here to enter text. |

Job title

|  |
| --- |
| Click here to enter text. |

Organisation

|  |
| --- |
| Click here to enter text. |

Email address

|  |
| --- |
| Click here to enter text. |

Role

[ ] Chief investigator

[ ] Collaborator

[ ] Team Member

[ ] Other

Will this person access the data requested?

[ ] Yes

[ ] No

Is this person an accredited researcher under the Digital Economy Act 2017?

[ ] Yes

[ ] No

If yes, please provide details

|  |
| --- |
| Click here to enter text. |

If no, please specify if you are planning to become an accredited researcher

|  |
| --- |
| Click here to enter text. |

Has this person undertaken professional training or education on the topic of Information Governance?

[ ] Yes

[ ] No

Please provide full details regarding the most recent training

|  |
| --- |
| Click here to enter text. |

Please provide any details of plans to attend training, if applicable

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| Click here to enter text. |

CV has been provided

[ ] I have completed this step

**4 – Chief Investigator Signature**

If your application is approved, you will be required to sign a Research Data Access Agreement which will ask that you have read and, where appropriate, signed the following documentation:

* Honest Broker Service Disclosure and Publication Policy.
* HSC & BSO Security Policies (if accessing data on BSO premises).
* Department of Health Northern Ireland Code of Practice on Protecting the Confidentiality of Service User Information (Updated 2019).
* Wellcome Sanger Institute data access agreement for access to the COVID-19 Genomics UK (COG-UK) data (if applicable).

Full name

|  |
| --- |
| Click here to enter text. |

Signature

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| Click here to enter text. |

Date

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| Click here to enter a date. |

# Section B – Safe project

What is the purpose of accessing the data?

Safe projects are those that have a valid research purpose with a defined public benefit. For access to data to be granted the researchers need to demonstrate that their proposal is an appropriate and ethical use of the data, and that it is intended to deliver clear public benefits. The purpose of this section is to ensure that:

* the project rationale is explained in lay terms.
* the research purpose has a defined public benefit. This can be new knowledge, new treatments, improved pathways of care, new techniques of training staff.
* how the data requested will be used to achieve the project objectives is articulated.

**1 – Project details**

Title of project

|  |
| --- |
| Click here to enter text. |

Please provide a lay summary of the project (300 words)

*Please use plain language easily understood by non-specialists*

*This information will be included in the data use register which is a public facing document so should be easily readable for a lay audience.*

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|   |

What is the anticipated project duration?

[ ]  Up to 24 months

[ ]  Over 24 months.

If data access is required for more than 2 years, please provide further information on expected duration and rationale:

|  |
| --- |
|   |

 What are the project aims, objectives and rationale?

|  |
| --- |
| Click here to enter text. |

A copy of the peer review has been provided (if applicable)

[ ] I have completed this step

How will the data requested be used to achieve the project objectives?

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| --- |
| Click here to enter text. |

Is there a HSC Trust resource commitment?

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| Click here to enter text. |

How will your project benefit the public and what is the anticipated impact?

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| Click here to enter text. |

Can you provide an outline of the public and patient involvement and engagement (PPIE) strategies of the study or a brief explanation of why they are not planned?

Please refer to the [PPIE guidance](https://bso.hscni.net/directorates/digital/honest-broker-service/honest-broker-service-researcher-access/patient-and-public-involvement-and-engagement/) provided on the HBS website.

Please note PPIE should be considered in all areas of research including planning and design, it does not just relate to dissemination of findings.

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| Click here to enter text. |

**2 – Funder information**

**(This section should be copied as many times as necessary to ensure all funders have been listed)**

A funder is the organisation or body providing the financial resource to make the project possible, and may be different to the organisation detailed in the Safe people section. Please provide details of the main funder organisations supporting this project.

Does your project have a funder?

[ ] Yes

[ ] No

If yes, please provide the organisation name

|  |
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| Click here to enter text. |

If no, please provide details of how you intend to fund the study

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| Click here to enter text. |

**3 – Sponsor information**

**(This section should be copied as many times as necessary to ensure all sponsors have been listed)**

The sponsor is usually, but does not have to be, the main funder of the research. The sponsor takes primary responsibility for ensuring that the design of the project meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting.

Does your project have a sponsor?

[ ] Yes

[ ] No

Organisation name

|  |
| --- |
| Click here to enter text. |

Registered address (line 1)

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| --- |
| Click here to enter text. |

Registered address (line 2)

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| Click here to enter text. |

City

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Postcode

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Country

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Sector

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| Click here to enter text. |

Additional details

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| Click here to enter text. |

Contact email address

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| Click here to enter text. |

**4 – Declaration of interest**

All interests that might unduly influence an individual’s judgement and objectivity in the use of the data being requested are of relevance, particularly if it involves payment or financial inducement.

These might include any involvement of commercial organisations at arm’s-length to the project, or likely impact on commercial organisations, individually or collectively, that might result from the outcomes or methodology of the project.

All individuals named in this application who have such an interest in this application must declare it.

Is there a commercial interest in this project?

[ ] Yes

[ ] No

Organisation name

|  |
| --- |
| Click here to enter text. |

Registered address (line 1)

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| Click here to enter text. |

Registered address (line 2)

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| Click here to enter text. |

City

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| Click here to enter text. |

Postcode

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| Click here to enter text. |

Country

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| Click here to enter text. |

Describe the nature of the interest

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| Click here to enter text. |

**5 – Intellectual property**

All interests that might unduly influence an individual’s judgement and objectivity in the use of the data being requested are of relevance, particularly if it involves payment or financial inducement.

These might include any involvement of commercial organisations at arm’s-length to the project, or likely impact on commercial organisations, individually or collectively, that might result from the outcomes or methodology of the project.

All individuals named in this application who have such an interest in this application must declare it.

Please indicate if the research could lead to the development of a new product/process or the generation of intellectual property.

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| Click here to enter text. |

# Section C – Safe data

Safe data ensure that researchers have a clear legal basis for accessing the data and do not inadvertently learn something about the data subjects during the course of their analysis, minimising the risks of re-identification. The minimisation of this risk could be achieved by removing direct identifiers, aggregating values, banding variables, or other statistical techniques that may make re-identification more difficult. Sensitive or confidential data could not be considered to be completely safe because of the residual risk to a data subject’s confidentiality. Hence other limitations on access will need to be applied.

The purpose of this section is to ensure that:

* there is a clear legal basis for accessing the requested data
* the data requested is proportionate to the requirement of the project
* all data requested is necessary in order to achieve the public benefit declared
* data subjects cannot be identified by your team by cross-referencing data sets from anywhere else.

**1 – Data fields**

These are the 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. The data may be highly structured or less structured in nature, already existing or to be newly collected or gathered.

Examples may include national datasets, local datasets, 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.

“New data” should only include data that is being specifically gathered for the first time for the purposes of this proposal. i.e. data already held in case notes and transferred to a form is not “new” data, but a survey filled out by clinicians in order to gather information not recorded anywhere else is “new”.

Please indicate the data necessary to conduct the study, the data fields required and the justifications for each field, using the [HBS Variable Request Form](https://bso.hscni.net/directorates/digital/honest-broker-service/honest-broker-service-researcher-access/metadata/), available on the website.

[ ]  I confirm I have completed a copy of the HBS variable request form including details of the patient cohort, and a list of datasets, fields and variables required for the study as well as justification for each field.

Will you require periodic refreshes of the data?

[ ]  Yes

[ ]  No

Please provide justification for periodic refreshes of the data

|  |
| --- |
| Click here to enter text. |

How often will the data refreshes be needed?

[ ]  Every month

[ ]  Every 3 months

[ ]  Every 6 months

[ ]  Every 12 months

[ ]  Other

If other, please specify

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| --- |
| Click here to enter text. |

Do you require aggregated or record level data?

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| --- |
| Click here to enter text. |

**2 – Other datasets - Intention to link data**

This section should include information on the planned use of datasets not readily available via the BSO Regional Data Warehouse/BSO. The following information is required:

* A descriptive name so that it is clear what the dataset is.
* Sufficient information to explain the content of the dataset.
* Details of the data controller responsible for the dataset and whether the relevant data access agreements are in place for the data to be transferred to the Honest Broker Service for the proposed linkage.
* Evidence that the relevant ethical approval has been sought.

Do you intend for external datasets to be linked to HSC Regional Data Warehouse data?

[ ]  Yes

[ ]  No

If yes, specify all datasets, details of the organisation responsible for the data and how the data will be securely transferred to the Honest Broker Service.

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| Click here to enter text. |

**3 – Ethics approval**

This section details the research and ethics approval which you have obtained or sought for your project, or otherwise provides evidence as to why such approval is not necessary.

Where such approval is not in place, it is important that you demonstrate why this is the case or provide assurances if approval is pending.

Please note that as of November 2019, if a project involves linking external datasets to HSC Regional Data Warehouse data, ethical approval will be required.

[Applying to an NHS or HSC Research Ethics Committee](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/applying-research-ethics-committee/)

Has ethics approval been obtained?

[ ]  Yes

[ ]  No

[ ]  Approval pending

[ ]  Not required

If yes, please enclose a copy of the final approval letter and letters documenting any approved amendments

[ ]  I have completed this step

If ethics approval hasn’t been obtained, is pending approval or is not required, please provide details

|  |
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| Click here to enter text. |

# Section D – Safe settings

Safe settings are analytics environments where researchers can access and analyse the requested datasets in a safe and ethical way. Safe settings encompass the physical environment and procedural arrangements such as the supervision and auditing regimes. For safe settings, the likelihood of both deliberate and accidental disclosure needs to be explicitly considered.

The purpose of this section is to ensure that:

* researchers access requested data in a secure and controlled setting such as a Trusted Research Environment (TRE) that limits the unauthorised use of the data

**1 – Method of Access**

How will the data be accessed?

[ ]  Honest Broker Service ‘Safe Haven’

[ ]  UK Secure e-Research Platform (UK SeRP)

If you wish to access data via the UK SeRP and require external datasets for your project, has the relevant data controller agreed the anonymised data can be uploaded to this platform within the Data Access Agreement?

[ ]  Yes

[ ]  No

If no, please provide alternative evidence to support this requirement

[ ]  I have completed this step

# Section E – Safe outputs

Safe outputs ensure that all research outputs cannot be used to identity data subjects. They typically include ‘descriptive statistics’ that have been sufficiently aggregated such that identification is near enough impossible, and modelled outputs which are inherently non-confidential. The purpose of this section is to ensure that:

* controls are in place to minimise risks associated with planned outputs and publications
* the researchers aim to openly publish their results to enable use, scrutiny and further research.

**1 – Outputs dissemination plans**

Please include any plans for dissemination and publication of the data and results arising from your proposal. Please also specify any controls in place to minimise risks associated with publication. Dissemination can take place in a variety of ways and through many mechanisms, including through electronic media, print media or word of mouth.

How will proposal findings be disseminated, to what audience and in what format?

|  |
| --- |
| Click here to enter text. |

Please include any milestones for outputs dissemination.

|  |
| --- |
| Click here to enter text. |

What steps will be taken to ensure that individuals cannot be identified? Please describe what disclosure control policy will be applied.

|  |
| --- |
| Click here to enter text. |

Please complete the [HBS Research Output Planning Document](https://bso.hscni.net/wp-content/uploads/2024/11/HBS_Research_Output_Planning_Document_Oct24.docx), available on the HBS website, outlining intermediate and final outputs planned for the duration of the project. Please detail the statistical tests you plan to use throughout the project so the HBS team are aware of the associated disclosure risk ahead of submission.

[ ]  I confirm I have completed a copy of the HBS Research Output Planning Document